



Medical Devices Data Bank

User Manual Medical Device Manufacturer Profile

Version 9.1
01/07/2021



Document history

Version	Date	Changes from previous version
5.0	09/02/2010	The new registration procedures for medical devices provided for by D. L. of the 21 th of December 2009, replacing D. L. of the 20th of February 2007, have been acknowledged and envisage the following changes: 1) information about the type of device ("Device" / "System" or "Kit") and the possible composition of systems or kits under Art.12, c. 3 of D.L. No. 46/1997 are no longer registered. The declarants who wish to notify systems or kits (D.L. No.46/1997, Art.12, c. 3) must enter the same information provided for those class devices that are not systems nor kits. The compositions that have been previously notified can no longer be displayed. 2) the role of Marketing Responsible is no longer envisaged. The declarant can no longer enter this role when registering a new device nor when changing an existing one. For all existing devices, all information that has been previously notified can be viewed in the details page. Such change applies to both Class DMs and assembled devices (Art.12, c. 2). 3) the following data (requested in the Class DM data sheet) are optional: ▪ DM materials in direct contact with the patient - Disposal special conditions ▪ DM packaging materials ▪ The DM primary packaging main materials - Disposal special conditions ▪ Sterilization methods - Maximum period of use ▪ Methods of sterilization - Method validated according to harmonized standards ▪ Risterilization methods - Number of sterilizations ▪ Biological tissues or (not vital) animal substances data - State of origin (required in the Class DM documentation) ▪ DM technical information ▪ scientific bibliography supporting the clinical evidence of the DM effectiveness and safety



Version	Date	Changes from previous version
5.1	26/03/2010	Modification of the latex free fields for the data sheet. Extension of the management for the DM notified in minimal form within the make-up of Systems or Assembled Kits (Art. 12 c.3).
5.2	December 2010	The software has been adjusted to EC Directive 2007/47 which amended point 5 of attachment VII of EC Directive 93/42. The feature used to update the documentation after publishing has been reviewed. Many features used to download data – in xml format – pertaining to Medical Devices in batch mode have been added.
6.0	17/10/2011	Impacts of the new management of EC Certificates by the Italian Notified Bodies. Changes apply to the following chapters/paragraphs: 1 Introduction; - DM details for registration/editing 2.4.1.3.1 (specifically, “Page: Certificates”); 2.4.1.17.1.1 General data (specifically, “DM General data fields detail – Details of Community harmonized standards and EC Directive –”); “EC Certificates 2.4.4 (the whole paragraph, sub paragraphs included)
6.1	02/04/2012	Management of the new registration procedures of Medical Devices in the Repertoire in compliance with DL no. 1 of the 24 th of January, 2012. Urgent measures for competition, developing facilities and competitiveness. Updated chapters/paragraphs: - Glossary of terms; 1 Introduction - Functional Area of "Class I, II a/b and III Medical Devices" 2.2.2; 2.4.1.2 Searched DMs list; 2.4.1.14 DM registration in the Medical Device Repertoire Adjustment of the “List of the manufacturers represented by the user” feature to include the field indicating if the data of a given company have been signed or not. The



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		user needs this information when validating one or more DMs; in fact, the validation cannot proceed if there is even one represented company whose data has not been signed. Updated chapters/paragraphs: - 2.3.1.5 List of the manufacturers represented by the user.
6.2	10/09/2012	Adjustment of the interactive functions (Web) of Repertoire registration to allow multiple registrations of medical devices that cannot be configured as a 'similar DM' group. Updated chapters/paragraphs: ▪ 2.4.1.14 DM registration in the Medical Device Repertoire.
6.3	27/03/2013	Added "Multiple notifications of similar DMs" feature. Updated paragraph 2.4.8 and related subparagraphs Adjustment of the interactive (web) "off-trade" statement feature for medical devices of class, in order to extend it to a group of DM not necessarily similar between each other. Updated chapters/paragraphs: - 2.4.7 Menu Item "Multiple Notifications of similar DMs" Notifications to complete (To-do List) – "In progress" medical devices (class DM / Assembled device) registered in the database for which user is required to complete the notification process entered data by using qualified electronic signature (Validation). Updated chapters/paragraphs: - 2.2 Functional areas of the System, - 2.4.1.1 DMs search, - 2.4.2.1 Assembled device search
6.4	16/07/2013	Adjustments regarding the compulsoriness of the expiry date of the certificates notified by Declarants (the expiry date of the certificates notified by Declarants has been made always mandatory, except in the case when the annex according to which the DM was certified is the annex IV/4). Updated chapters/paragraphs:



Version	Date	Changes from previous version
		- 2.4.4.3 New EC certificate registration; - 2.4.4.4 EC certificate detail; - 2.4.4.8 ; - 2.4.4.6 Extension/expansion registration for an existing EC certificate. Adjustments regarding the checks performed by the system on the certificates. Updated chapters/paragraphs: - Errore: sorgente del riferimento non trovata Errore: sorgente del riferimento non trovata; - 2.4.4.8 Replacing certificates within the DM notification; 2.4.4.8.1 Search look up of the new certificate replacing the previous one; - 2.4.1.3.1.1 General Data (New DM registration - Certificates); - 2.4.1.8 DM data consolidation; - Errore: sorgente del riferimento non trovata Errore: sorgente del riferimento non trovata. Adjustments regarding the non-compulsoriness of the date of expiry notified by Italian OONNs in the presence of: - o Directive on implantable medical devices (90/385/EEC) - Annex 4 - o Directive concerning medical devices (93/42/EEC) - Annex IV Updated chapters/paragraphs: - 2.4.1.3.1.1 General Data; - 2.4.4.1 EC certificates search; - 2.4.4.2 List of searched EC certificates; - 2.4.4.8.1 Search look up of the new certificate replacing the previous one. Updates related only to those certificates notified by the Declarant and relative "ONLY to EC Directive 2003/32" Updated chapters/paragraphs: - 2.4.4.3 New EC certificate registration; - 2.4.4.4 EC certificate detail; - 2.4.4.8 ;



Version	Date	Changes from previous version
		– 2.4.4.6 Extension/expansion registration for an existing EC certificate; – Errore: sorgente del riferimento non trovata Errore: sorgente del riferimento non trovata; – 2.4.4.8 Replacing certificates within the DM notification; – 2.4.4.8.1 Search look up of the new certificate replacing the previous one; – 2.4.1.8 DM data consolidation; – 2.4.1.3.1.1 General Data ("EC Reference" added to DM notification); – 2.4.1.17.1.1 General Data (DM details visualisation).
7.0	05/06/2014	Integrating database of in vitro diagnostic medical devices; Chapters/paragraphs inserted: - 2.2.3 Functional Area "In Vitro Diagnostic Medical Devices"; - 2.5 Detailed description of the "In Vitro diagnostic medical Device" Functional area Adjustments related to the processing of sensitive data in the function "Company Data → General Registrant Data". Updated chapters/paragraphs: – 2.3.1.1 Registration of Company Data owned by the user; Adjustments related to the award of mandates by manufacturers, authorised representatives and assembler to registrants: Updated chapters/paragraphs: – 2.3.1.5 List of associated companies; – 2.3.1.7 Company data entry and user association to Company – 2.3.1.8 Edit company data; – 2.3.1.9 Company Data Information; Chapters/paragraphs inserted: 2.3.1.10 Mandates awarded (by manufacturers, Authorised Representatives and Assemblers to Registrants)



Version	Date	Changes from previous version
8.0	11/12/2014	Updates relating to the replacement of mandate files uploaded previously (due to updates or error corrections). Updated chapters/ paragraphs: - 1.1.3 Recurrent use cases; - 2.3.1.5 List of associated companies; - 2.3.1.10 Mandates awarded (by manufacturers, Authorised Representatives and Assemblers to Registrants);
8.1	03/04/2015	Correct typographical error
8.2	20/11/2015	Integrating database of IVDs for Performance Evaluation (IVD - PE) Updated chapters/ paragraphs: - 1 Introduction; - 1.1.1 Stakeholder - roles scheme in the Data Bank of Medical Device system - 2.2.1 Functional Area "Company Data" - 2.2.3 Functional Area "In Vitro Diagnostic Medical Devices" - 2.2.5 Other significant areas of the Home page - 2.2.5.1 To-do List (only for CE Marked class devices and IVDs) Chapters/ paragraphs inserted - 1.2 IVDs for Performance Evaluation; - 1.2.1 Stakeholder - roles scheme in the Data Bank of Medical Device system - 1.2.2 Casi d'uso ricorrenti per la gestione dei dispositivi in vitro destinati alla valutazione delle prestazioni; - 2.2.3.1 Subarea "IVDs for Performance Evaluation"; Updated chapters/ paragraphs: - 2.6 Detailed description of the "IVDs PE" Functional area.
8.3	16/02/2016	Correct typographical error
8.4	13/04/2016	Additional specifications for mandatory uploading of



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Version	Date	Changes from previous version
		Instruction for Use file for class DM. Updated chapters/paragraphs:: - 2.4.1.3.1.3 Documentation - 2.4.1.5 Similar DM Insertion - 2.4.1.6 Similar DM Insertion - 2.4.1.13 DM enclosed documentation update - 2.4.1.18 Manufacturing putback of a DM in the "Published" status - 2.4.8 Menu Item "Multiple Notifications of similar DMs"
9.0	01/05/2017	Updates relating to On-Line signature elimination.
9.1	01/07/2021	Update relating to non-renewal of agreements with Switzerland.

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Glossary of terms

Terms	Definitions
Agent	Individual or legal entity within the European Union territory (Authorised Representatives) who, after having been expressly assigned by the manufacturer, acts on behalf of the Manufacturer and can thus be consulted by the national authority concerned and by Community bodies in place of the Manufacturer.
Consolidating	This operation checks registered data regarding a classified medical devices and active implantable devices (DM) as well as in Vitro diagnostic medical devices (IVD)
Marketing Responsible	Individual or legal entity who, in the case that the Manufacturer is not appointed within the Community, is obliged to keep the relative documentation available for the authorities of the merchandise.
Other person delegated by the Manufacturer	Individual or legal entity who is delegated by the Manufacturer in order to register the medical devices in to the system (e.g. The distributor/Wholesaler)
Publication	The publication of data is the way in which the Ministry of Health makes medical devices, previously passed over from the Manufacturer, available for a subsequent publication on the data portal.
Repertoire Subscription	Operation needed to declare a medical device that will be distributed to the National Health Service and, as a consequence, registered in the Repertoire.
Validation	A key action in which the user, who has registered the medical device data, signs for the data inserted into the system and makes them visible to the Ministry for Health.

Acronyms¹

Italian Acronyms	Definitions
CND	National Classification of Medical Devices
DGFDM	General Management of Medicines and Medical Devices
DM	Medical Device
FAB	Manufacturer
GMDN	Global Medical Device Nomenclature
MdS	Ministry of Health
NSIS	New Health Information System

¹ The Acronyms will be kept in Italian throughout the paper to avoid misunderstandings.

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Italian Acronyms	Definitions
ON	Notified Body
OONN	Notified Bodies
SSN	National Health System



1 Introduction

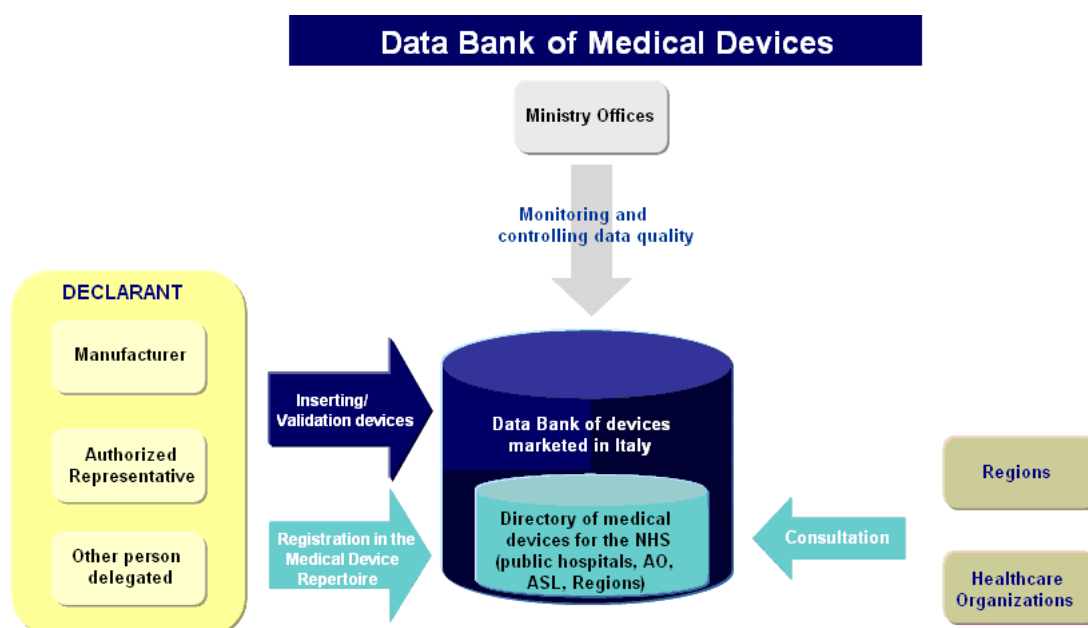
In accordance with what was established by the current legislation relating to medical devices, the "Data Bank of Medical Devices" system provides functions useful for the purposes of:

- registration and enrollment in the Repertoire of the devices in the class of Active Implantable and In Vitro Diagnostic Medical Devices by Manufacturers, Authorised Representatives and other entities validly delegated by them,
- device data updating and editing by the aforementioned entities,
- data consultation of the by key stakeholders in the National Health Service within the scope of their objectives and jurisdiction.
- data registration and modification of IVDs for pre-marketing performance evaluation .

1.1 CE Marked Devices (Class and IVD)

1.1.1 Stakeholder - roles scheme in the Data Bank of Medical Device system

The following figure provides an overview of the system in terms of the different stakeholders involved with their respective roles and objectives and refers only to CE marked devices (Class and IVD).





1.1.2 Registration status of CE Marked device data

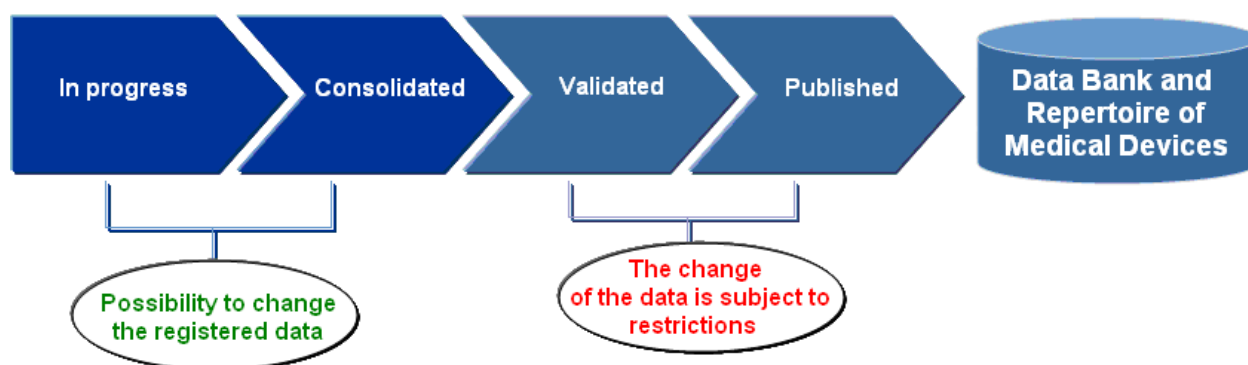
The purpose of this document is to provide a detailed description of the individual functions provided by the system for the "Manufacturer" application profile, i.e. for Manufacturers, Authorised Representatives and other validly delegated entities.

To understand these better, it is useful to know that device data registering entails a series of states:

- "In progress", this state applies to device data when it is first entered and when it is modified,
- "Consolidated", this state applies when the consolidation operation was successful (please refer to Glossary),
- "Validated", this state applies to the data when it has been validly entered (please refer to Glossary). This is the last state directly connected to the activity of the Registrant,
- "Published", this state is assigned to the data by the system upon data Publication.

It should be noted that every state is associated with a data modifiability characteristic/procedure.

Registration status of Medical Devices





1.1.3 Recurrent use cases for CE Marked devices registration

The following table provides users of the Manufacturer profile a potentially simplified and guided course of interpretation of the user manual.

Some recurring purposes of the device registration process are associated with the support functions provided by the system. Most notably the column:

- **"Purposes"** reports recurring cases for users in the process of device registration,
- **"What to do"** for each case, this describes for any multiple/subsequent steps what the user must do to the system,
- **"Function"** for each step this displays the name of the function and the paragraph of the manual that describes it.

Please refer to the glossary and acronyms at the beginning of the document for some recurring terms.

Purpose	What to do	Function	
		DM class Area	IVD Area
Performing preliminary operations	Register and electronically sign the data of the registrant who intends to carry out the notification of medical devices. <i>Note: this is to be performed only once, upon first access to the system.</i>	Registration of Company Data owned by the user (par. 2.3.1.1)	
	Register and electronically sign the data of device Manufacturers and/or Authorised Representatives other than the reporting Authorised Representative. <i>Note: insert the pdf file that contains a copy of the mandate granted to the registrant by the manufacturer or by the authorised representative.</i> <i>Note: to be performed only once for each manufacturer/authorised representative of devices to be notified.</i>	Add association to Company (par. 2.3.1.6)	



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Purpose	What to do	Function	
		DM class Area	IVD Area
	Insert certificates related to devices, if any. <i>(Note: to be performed only once for each certificate)</i>	New EC certificate registration (par. 2.4.4.3)	New EC certificate registration (par. 2.5.3.3)
Perform the user's first device notification.	Enter the device data in the system.	New DM registration (par. 2.4.1.3)	New IVD registration (par. 2.5.1.3)
	Complete device data entry or correct entry errors/inaccuracies entered upon inserting.	DM Editing (par. 2.4.1.4)	IVD Editing (par. 2.5.1.4)
	Verify that the data entered complies with system controls.	DM data consolidation (par. 2.4.1.8) List of the activities in progress (par. 2.4.3)	IVD data consolidation (par. 2.5.1.8) Menu option "Activities in progress" (par. 2.5.2)
	Sign data electronically.	Download file for off line DM signature (par. 2.4.1.9)	Download file for off line IVD signature (par. 2.5.1.9)
Register a device in the Repertoire	Declare willingness to register in Repertoire.	DM registration in the Medical Device Repertoire (par. 2.4.1.14)	IVD registration in the Medical Device Repertoire (par. 2.5.1.12)
Perform the first notification of multiple devices which differ at most by: - Manufacturer code, - Trade name and model, - Measurement, - label.	Enter complete data into the system for only one of the devices. <i>Note: alternatively the user can use a previously entered device, whatever state it is in.</i>	New DM registration (par. 2.4.1.3)	New IVD registration (par. 2.5.1.3)
	Complete device data entry or correct entry errors/inaccuracies entered upon first insertion.	DM Editing (par. 2.4.1.4)	IVD Editing (par. 2.5.1.4)
	Enter only distinctive data for the remaining devices in the system	Similar DM Insertion (par. 2.4.1.5)	Similar IVD Insertion (par. 2.5.1.5)



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Purpose	What to do	Function	
		DM class Area	IVD Area
	Possibly correct errors/inaccuracies perpetrated upon admission.	Similar DM Editing (par. 2.4.1.6)	Similar IVD Editing (par. 2.5.1.6)
	Verify that the data entered complies with system controls.	DM data consolidation (par. 2.4.1.8) List of the activities in progress (par. 2.4.3)	IVD data consolidation (par. 2.5.1.8) Menu option “Activities in progress” (par. 2.5.2)
	Sign data electronically.	Download file for off line DM signature (par. 2.4.1.9)	Download file for off line IVD signature (par. 2.5.1.9)
Perform the first notification of multiple devices which, with respect to a completed previously, differ at most by: - Manufacturer code, - Trade name and model	In an electronically signed file provide the system with the designation of the device already notified and only the code manufacturer and trade name and model.	Menu Item “Multiple Notifications of similar DMs” (par. 2.4.7)	Menu Item “Multiple Notifications of similar IVDs” (par. 2.5.4)
Perform the first notification of a device that has many of the same/similar data to one already notified previously	Enter only distinctive data of the device in the system.	DMs search (par. 2.4.1.1) DM copy	IVDs search (par. 2.5.1.1) IVD copy
	Complete device data entry or correct entry errors/inaccuracies registered upon copying.	DM Editing (par. 2.4.1.4)	IVD Editing (par. 2.5.1.4)
	Verify that the data entered complies with system controls.	DM data consolidation (par. 2.4.1.8) List of the activities in progress (par. 2.4.3)	IVD data consolidation (par. 2.5.1.8) Menu option “Activities in progress” (par. 2.5.2)



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Purpose	What to do	Function	
		DM class Area	IVD Area
	Sign data electronically.	Download file for off line DM signature (par. 2.4.1.9)	Download file for off line IVD signature (par. 2.5.1.9)
Correct or clarify a previous notification. Replace a mandate file uploaded previously (due to updates or error corrections)	Contact RDMSupport (supportoRDM@sanita.fvg.it) to submit a Mandate file unblocking request.	Mandates awarded (by manufacturers, Authorised Representatives and Assemblers to Registrants) [par. 2.3.1.10]; List of associated companies [par. 2.3.1.5];	Mandates awarded (by manufacturers, Authorised Representatives and Assemblers to Registrants) [par. 2.3.1.10]; List of associated companies [par. 2.3.1.5];
Correct or clarify a previous notification. Edit the data from a previous notification if there are no grounds for a new notification.	Make the data from a previous notification editable and specify the reasons.	Manufacturing putback of a DM in the "Published" status (par. 2.4.1.16)	Manufacturing putback of a IVD in the "Published" status (par. 2.5.1.14)
	Change the data to be corrected or specified more accurately.	DM Editing (par. 2.4.1.4)	IVD Editing (par. 2.5.1.4)
	Verify that the data entered complies with system controls.	DM data consolidation (par. 2.4.1.8) List of the activities in progress (par. 2.4.3)	IVD data consolidation (par. 2.5.1.8) Menu option "Activities in progress" (par. 2.5.2)
	Sign data electronically.	Download file for off line DM signature (par. 2.4.1.9)	Download file for off line IVD signature (par. 2.5.1.9)
Update the documentation, the Agent (authorised representative), the devices needed for a previous	Enter and electronically sign the updated data. <i>Note: the electronic signature is not required to update the devices necessary for operation.</i>	DM enclosed documentation update (par. 2.4.1.11) Update of the list of	IVD enclosed documentation update (par. 2.5.1.10) Agent update

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Purpose	What to do	Function	
		DM class Area	IVD Area
notification submitted to work.		(par. 2.4.1.12) Update Agent (Authorized Representative) (par. 2.4.1.13)	(Authorized Representative) (par. 2.5.1.11)
Notify a change of contacts or supervisory officer (if any) of a company	Register the company data changed.	Edit company data (par. 2.3.1.8)	Edit company data (par. 2.3.1.8)
Notify other "company" events: - company data changes other than contacts or supervisory officer, - registrant replacements, - sale of business unit, - merger / acquisition, - ...	- Contact the SupportoRDM (supportoRDM@sanita.fvg.it) - Fill out the appropriate forms indicated by the support service, - Follow the instructions provided by the SupportoRDM	n.a.	n.a.
	In the following cases, proceed with a new device notification: - Change in manufacturer's name - Change manufacturer's Vat Number - Sale of manufacturer's business unit - Merger/acquisition of manufacturing company	New notification of a DM in the "Published" status (par. 2.4.1.7)	New notification of a IVD in the "Published" status (par. 2.5.1.7)
Notify the extension of validity periods for a certificate referring to previously notified devices.	Enter and electronically sign the new expiry date and the updated pdf file for the certificate in the system.	Extension/expansion registration for an existing EC certificate (par. 2.4.4.6)	Extension/expansion registration for an existing EC certificate (par. 2.5.3.6)
Notify the expansion of the	Enter in the system and electronically sign the updated pdf	Extension/expansion registration for an	Extension/expansion registration for an



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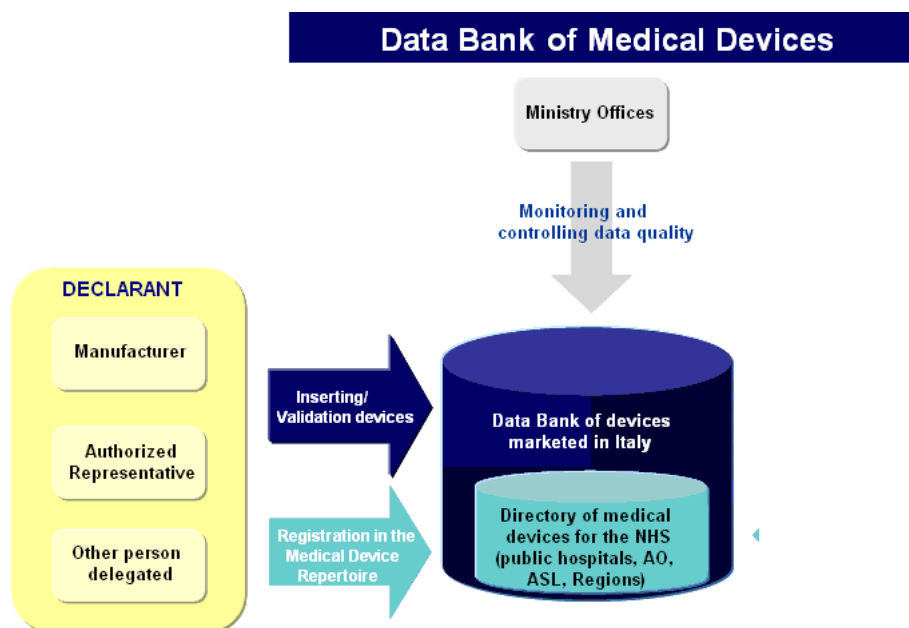
Purpose	What to do	Function	
		DM class Area	IVD Area
set of medical devices covered by the certificate.	file of the certificate. <i>Note: check the requirement for the notification/update of devices covered by the extension.</i>	(par. 2.4.4.6)	(par. 2.5.3.6)
Notify data correction of a certificate for one or more devices previously notified.	Request authorisation by contacting the Ministry of Health's MEDICAL DEVICE REGISTRATION SUPPORT SERVICE (please refer to website)	n.a.	n.a.
	Register correct certificate data.	Editing of EC certificate (par. 2.4.4.5)	Editing of EC certificate (par. 2.5.3.5)
Notify the end of production for a device	Register the end date of production in the system.	End of placing DM on the market (par. 2.4.1.15)	End of placing IVD on the market (par. 2.5.1.13)
Notify the a change of "Legal Representative - Reference for communications - Supervisory officer data on devices" of the user's company	Change "Legal Representative - Reference for communications - Supervisory officer data on devices" of the user's company	Change "Legal Representative - Reference for communications - Supervisory officer data on devices" of the user's company (par. 2.3.1.4)	Change "Legal Representative - Reference for communications - Supervisory officer data on devices" of the user's company (par. 2.3.1.4)



1.2 IVDs for Performance Evaluation

1.2.1 Stakeholder - roles scheme in the Data Bank of Medical Device system

La figura seguente offre una panoramica sul sistema in termini dei diversi attori coinvolti con rispettivi ruoli e obiettivi and refers only to IVDs for Performance Evaluation.



1.2.2 Recurrent use cases for IVDs PE registration

The following table provides users of the Manufacturer profile a potentially simplified and guided course of interpretation of the user manual, in a limited manner for IVDs PE.

Some recurring purposes of the above-mentioned device registration process are associated with the support functions provided by the system. Most notably the column:

- **"Purposes"** reports recurring cases for users in the process of registration of the aforementioned device,
- **"What to do"** for each case, this describes for any multiple/subsequent steps what the user must do to the system,
- **"Function"** for each step this displays the name of the function and the paragraph of the manual that describes it.



Please refer to the glossary and acronyms at the beginning of the document for some recurring terms.

		Funzione
Finalità	Cosa fare	Area “IVD – PE”
Performing preliminary operations	Register and electronically sign the data of the registrant who intends to carry out the notification of medical devices. <i>Note: this is to be performed only once, upon first access to the system.</i>	Registration of Company Data owned by the user (par. 2.3.1.1)
	Register and electronically sign the data of device Manufacturers and/or Authorised Representatives other than the reporting Authorised Representative. <i>Note: insert the pdf file that contains a copy of the mandate granted to the registrant by the manufacturer or by the authorised representative.</i> <i>Note: to be performed only once for each manufacturer/authorised representative of devices to be notified.</i>	Add association to Company (Par. 2.3.1.6)
Perform first device notification.	Enter the device data in the system.	Notification of an IVD-PE device (par. 2.6.1.1)
	Sign data electronically.	Signing IVD-PE device data offline (par. 2.6.1.2)
Correct or clarify a previous notification. Replace a mandate file uploaded previously (due to updates or error corrections)	Contact RDMSupport (supportoRDM@sanita.fvg.it) to submit a Mandate file unblocking request.	Mandates awarded (by manufacturers, Authorised Representatives and Assemblers to Registrants) [par. 2.3.1.10]; List of associated companies [par. 2.3.1.5];
Correct or clarify a previous notification.	Make the data from a previous notification editable and specify the reasons.	Modification to an IVD-PE device (par. 2.6.1.6)



		Funzione
Finalità	Cosa fare	Area "IVD – PE"
Edit the data from a previous notification if there are no	Sign data electronically.	Signing IVD-PE device data offline (par. 2.6.1.2)
Notify a change of contacts or supervisory officer (if any) of a company	Register the company data changed.	Edit company data (par. 2.3.1.8)
Notify other "company" events: - company data changes other than contacts or supervisory officer, - registrant replacements, - sale of business unit, - merger / acquisition, - ...	- Contact the SupportoRDM (supportoRDM@sanita.fvg.it) - Fill out the appropriate forms indicated by the support service, - Follow the instructions provided by the SupportoRDM	n.a.
	In the following cases, proceed with a new device notification: - Change in manufacturer's name - Change manufacturer's Vat Number - Sale of manufacturer's business unit - Merger/acquisition of manufacturing company	Notification of an IVD-PE device (par. 2.6.1.1)



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Please read paragraph 1 "Introduction" before reading on in order to better understand what is reported subsequently.

2.1 Access to the System

To Access the system please refer to what is published on the website of the Ministry of Health www.ministerosalute.it.

2.1.1 Data signing

The Medical Device system requires that the information notified is signed by the user.

Starting from **01/05/2017** in Medical Device system it will not be possible data signing in "On-Line" mode. Data signing will be possible only in "Off-Line" mode.

Signing in off-line mode entails the following steps:

1. download the data file to be signed
2. sign the file saved on the user's workstation
3. upload the signed file

For more information, please refer to the paragraphs describing specific functions in this document.

2.2 Functional areas of the System

When entering the system the user is directed to the home page which displays the following structure:



At the top of the page there are four distinct functional areas:

1. Class I, IIa/b, III medical devices
2. In Vitro diagnostic medical devices
3. Company data
4. Off-line signature



Within In Vitro diagnostic medical devices area it's possible to access IVD – PE subarea.

Through these areas the registrants can notify CE marked class, active implantable and in vitro devices, as well as IVDs for performance evaluation pre-marketing. Custom-made medical devices are not subject to notification in this Database (for information about custom-made devices please refer to the appropriate area on the Ministry of Health website).

2.2.1 Functional Area "Company Data"

This area provides access to functions that provide for company declarations on which the user is empowered to operate for the purposes of notification of data of Ministry both for medical devices and active implantable devices (DM) and for in Vitro diagnostic medical devices (IVD and IVD-PE).

In this area the user can:

- register and electronically sign the Declaration of the entity who logs on to the system for the notification of medical devices. Excluding any changes to company data, this operation is to be performed only once upon first access to the system;
- register and electronically sign the Declaration of other manufacturing companies and/or Authorised Representatives of devices other than the registrant. Excluding any changes to company data, this operation is to be performed only once before starting device data registration. In particular, the system expects the inclusion of the pdf file containing a copy of the mandate granted to the registrant by the manufacturer or authorised representative.

The company data is unique in the system and shared, therefore in the event of company data already present the compilation of these declarations is easier.

During device data notification:

- the registrant can specify previously registered companies,
- the registrant is required to specify the role of a company (Manufacturer, or Authorised Representative).

In the case of companies not yet present in the database there is a mechanism to simplify the registration of company data consisting of the automatic upload of data from the Register of Companies.



2.2.2 Functional Area of "Class I, II a/b and III Medical Devices"

Functionality. This area allows the registrant to notify the Ministry of data for classified medical device and active implantable devices (DM) and assembled devices (Legislative Decree number 46/97 article 12 paragraph 2).

Specifically, the following functions are provided in this area:

- perform the first notification of a device and an assembly,
- register a device in the Repertoire,
- edit a previous notification,
- update a previous device notification with regards to documentation, entity designated as the authorised representative (if any), devices necessary for operation,
- notify the end of production of devices and assembled devices.

Responsibility. The registrant is responsible for performing operations only for mandates granted by manufacturers or their authorised representatives.

Time limits. In general, a data notification can be completed only after the registrant has provided the electronic signature. Notices must also be completed within fixed time limits (30 days for the first notification, 7 days for subsequent notifications).

The registrant is responsible for the data provided in the notifications. The publication thereof in compliance with the regulation does not require any form of endorsement by the Ministry of Health which reserves the right to carry out checks at any time on the statements declared.

Data visibility. The data notified by the registrant is visible only to the registrant and the manufacturer, if these are different, as well as to the Ministry and to the National Health Service stakeholders in accordance with the law.

N.B. Finally, registration in the Repertoire requires that in tenders for the purchase of devices and, more generally in commercial relations, facilities directly managed by the National Health Service abstain from requesting from suppliers any information declared by the suppliers themselves, available and updated in the Repertoire.



2.2.3 Functional Area "In Vitro Diagnostic Medical Devices"

Functionality. This area allows the registrant to notify the Ministry of data for in vitro diagnostic medical devices (IVD).

Specifically, the following functions are provided in this area:

- perform the first notification of a device,
- register a device in the Medical Device Data Bank,
- register only CE Marked IVDs in Repertoire
- edit and update a previous notification,
- for only CE Marked IVDs, update a previous device notification with regards to documentation, entity designated as the authorised representative (if any),
- for only CE Marked IVDs, notify the end of production of devices.

Responsibility. The registrant is responsible for performing operations only for mandates granted by manufacturers or their authorised representatives.

Time limits. In general, a data notification can be completed only after the registrant has provided the electronic signature. Notices must also be completed within fixed time limits (30 days for the first notification, 7 days for subsequent notifications).

The registrant is responsible for the data provided in the notifications. The publication thereof in compliance with the regulation does not require any form of endorsement by the Ministry of Health which reserves the right to carry out checks at any time on the statements declared.

Data visibility. The data notified by the registrant is visible only to the registrant and the manufacturer, if these are different, as well as to the Ministry and to the National Health Service stakeholders in accordance with the law. Data of IVDs for performance evaluation is visible only to Ministry.

N.B. Finally, for only IVD CE marked, registration in the Repertoire requires that in tenders for the purchase of devices and, more generally in commercial relations, facilities directly managed by the National Health Service abstain from requesting from suppliers any information declared by the suppliers themselves, available and updated in the Repertoire.

2.2.3.1 Subarea "IVDs for Performance Evaluation"

This subarea allows the registrant to notify the Ministry of data for in vitro diagnostic medical devices for performance evaluation pre - marketing (IVD - PE).

Specifically, the following functions are provided in this area:



- perform the first notification of a IVD - PE,
- modify/update a previous notification.

The registrant is responsible for performing operations only for mandates granted by manufacturers or their authorised representatives.

The data notified by the registrant is visible only to the registrant and the manufacturer, if these are different, as well as to the Ministry

2.2.4 Offline Signature” Functional area

The “Offline signature” functional area contains a function that allows the user to complete the data off line signature process.

The off line signature allows the signing of the data stored in the “Data Bank and Repertoire of Medical Devices” using any electronic signature certificate issued by one of the certification providers, according to Directive 1999/93/CE and consists of three steps:

1. The user downloads the file in txt format on his computer (**download**); this file, automatically generated by the system, contains all the information previously entered.
2. the user then proceeds to sign the above mentioned files by using the software he already owns in order to use his/her signature device (smart card or other device). For the realization of this step it is not necessary to be connected to the “Data Bank and Repertoire of Medical Devices” system.
3. the user uploads the signed file on “Data Bank and Repertoire of Medical Devices” system through the browse button of this **upload function**.

2.2.5 Other significant areas of the Home page

2.2.5.1 “To-do List” for CE Marked class and in vitro devices (Not for PE)

If the system detects the presence of unfinished notifications in the database, these will be listed in the relevant section: **Notifications to be completed (to-do List)**.

For each medical device the following information will be provided:

- *First notification (Yes/No)*, provides information on whether the medical device being processed is related to a prior notification (YES) or, otherwise, to a reprocessing of a previous publication (No);
- *Device type*: classified/assembled/IVD medical device;
- *Progressive system identification number* assigned to the medical device;
- name of *Manufacturer/Assembler* of the device;



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- Description of the device (trade name and model);
- Code assigned to the medical device (catalogue code);
- Start working date

IN PROGRESS DMs TO VALIDATE OR DELETE						
First notify	Device Type	Progressive	Manufacturer / Assembler	Description	Code assigned to device	Start working date
No	DM di Classe	1153067	Manufacturer DM	Name and model	code 01	23/05/2014
No	DM di Classe	1153068	Manufacturer DM	Name and model ...	code 02	26/05/2014
No	DM di Classe	1153069	Manufacturer DM	Name and model ..	code 03	26/05/2014
Si	DM di Classe	1159609	Manufacturer DM	Name and model ..	code 04	30/05/2014
Si	DM di Classe	1159608	Manufacturer DM	Name and model ..	code 05	30/05/2014
Si	DM di Classe	1153089	Manufacturer DM	Name and model ..	code 06	30/05/2014
Si	DM di Classe	1159607	Manufacturer DM	Name and model ..	code 07	30/05/2014
Si	IVD	1159618	Manufacturer IVD	Name ad model ..	code 08	30/05/2014
Si	IVD	1153088	Manufacturer IVD	Name and model ..	code 09	30/05/2014

Total number of devices: 9 of which first notification 6 manufacturing put back 3

Go to IVD To-do list Go to DM To-do list Go to Assembled To-do list

The list is sorted by processing start date (from the oldest); however, it is possible to order by another column by clicking on its header

The user is required to complete the notification process by using qualified electronic signature the inserted data; the only exceptions are medical devices inserted incorrectly into the system for which deletion is requested. Note, however, that in general it is not possible to delete medical devices in process in case they were previously published (First notification: No). To access the aforementioned list of medical devices (classified / Assembled / IVD), for the purpose of their validation or deletion, use the function: "Go to DM to-do list "/"go to Assembled to-do list "/"go to IVD to-do list".

2.2.5.2 "Highlighted" section

At the top of the page, (see example image, particularly at the red text box), the system can from time to time direct the user to important information for the purposes of using the system (system evolutions, deadlines, etc.).

DATA BANK OF MEDICAL DEVICES
Change in the effective date of entry into force of the time limits for completion of data notification: date changes from 01/09/2013 to 01/01/2014. We invite users to consult the message below updated according to the new date.



2.3 Detailed description of the "Company data" functional area

Following access to the functional area "Company Data", on the left side of the page, there is a menu of functions available in that area.

This area provides access to functions that allow the user to carry out company declarations on which the registrant is empowered to operate for the purposes of notification to the Ministry of both medical device and active implantable device (DM) data and of in Vitro diagnostic medical devices (IVD).

-GENERAL REGISTRANT INFORMATION

This function allows the user register and electronically sign the Declaration of the entity logging on to the system for the notification of medical devices. Excluding any changes to the personal data of the entity, this operation is to be performed only once upon first access to the system;

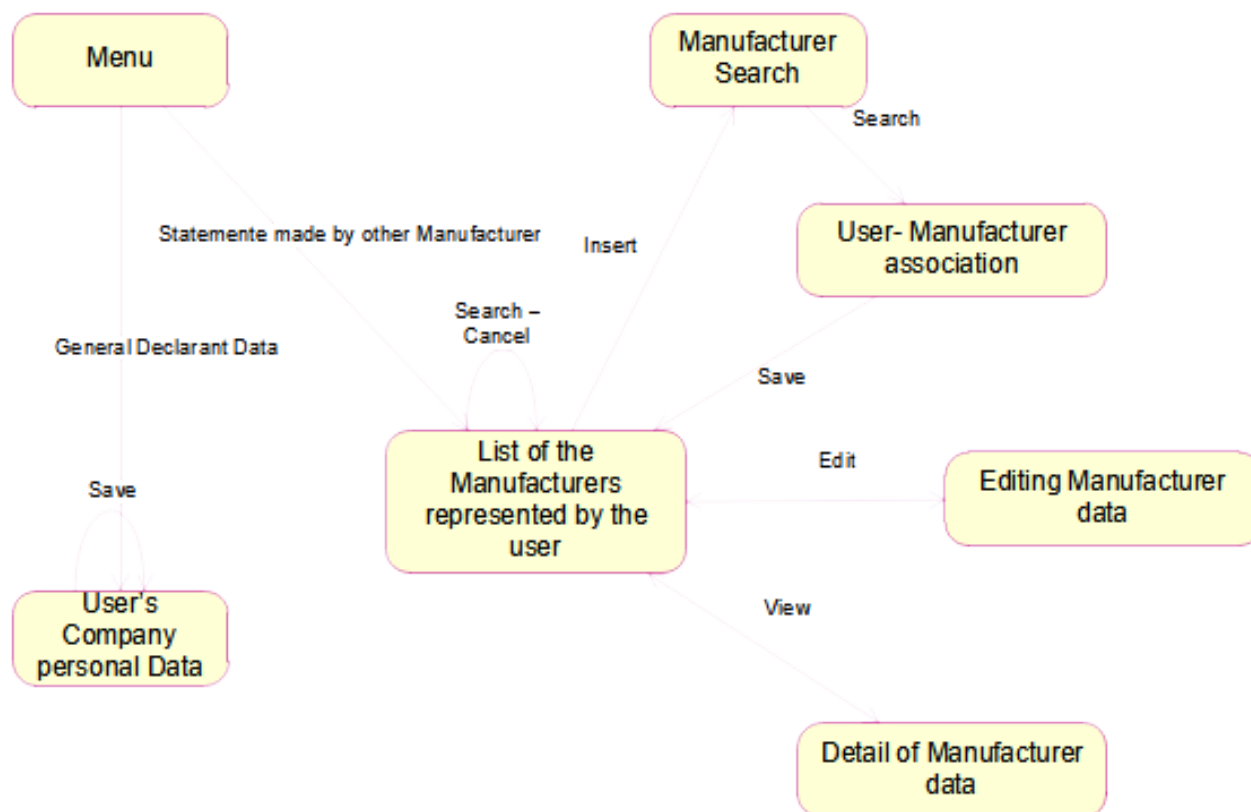
- OTHER COMPANIES' DECLARATIONS

This function allows the user to register and electronically sign the Declarations of other manufacturing companies and/or Authorised Representatives of devices other than the registrant. Excluding any changes to company data, this operation is to be performed only once before starting device data registration. In particular, the system expects the inclusion of the pdf file containing a copy of the mandate granted to the registrant by the manufacturer or authorised representative.



2.3.1 “Company Data Management” Menu option

Screen flowchart:





2.3.1.1 Registration of Company Data owned by the user

Clicking on the menu item "Company Data → General Registrant Information" leads to the page that allows the user to manage their own company's data which plays the role of registrant in the notice of the devices and/or assembled devices. **The registration process provided for must be completed, with the off-line electronic signature before all the other functions of the system can be accessed.**

The page displays personal data in the foreground, where available, in non-editable mode. Most notably the following are specified:

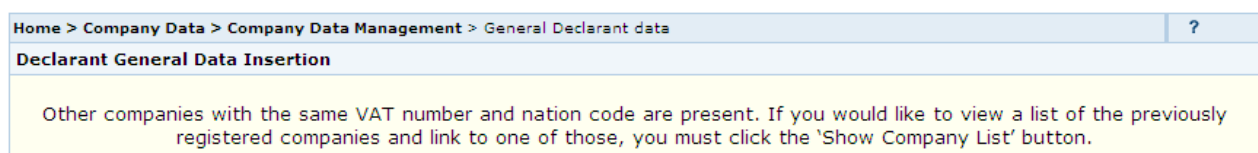
- First name, surname and social security number of the delegated person

In general, the user is required to provide their own company data depending on the user's Nationality and with reference to:

- Name, tax code and Vat Number of the company
- Registered office (mandatory)
- Legal representative (mandatory)
- Reference for notifications (partly mandatory)
- Supervisory officer data on the DM (optional)

If the user's company is an Italian company the system automatically detects whether it already exists in the database, in this case the company data is reused. If that company is not already registered in the database and is present in the register of companies, its data will be automatically reported in the page directly from the register of companies, thus simplifying user operations. In both cases the user will be required only to integrated automatically collected data, where this is allowed/required.

Similarly, if the user's company is not Italian the system provides for viewing the list of companies, if any, with the same Vat Number (EU companies) or with the same post code (non-EU companies) and to reuse any of these (see section 2.3.1.3).



The first time the company data is saved, the user is redirected to the signing page, or alternatively, the user may decide to use the off-line signature function that allows the user to sign data locally on the user's own computer, using any electronic signature recognised at European level.

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Returning to the page after first saving the data, if the user's company is not Italian, the user may also indicate any additional operating offices ("More Operating Locations", optional data).

Declarant General Data Insertion

Registration Data of the person delegated

Fiscal Code: //
Surname: Muhl
Name: Christian

For medical device notification purposes, the statement of the subject logging on to the system is required to be registered and electronically signed. Proceed by validly entering the data requested on the page, saving, and electronically signing according to the appropriate (online/offline) procedures

Company General Data

* Denomination: Test
Tax identification number:
VAT /VAT number: 664743216

Legal office
* Nation: REGNO UNITO
City:
Province:
Foreign city: REGNO UNITO
* ZIP code: HG5 8QB
* Address: ST JAMES BUSINESS PARK, GRIMBALD CRAG COURT
Telephone: 01423888
P.E.C. / e-mail: leonie.gilsenan@test.com

More Operating Locations
Add

Legal representative
* Surname: GILLIAN
* Name: A. DAVID

Reference for communications
* Surname: GILSENAN
* Name: LEONIE
* Office: CORPORATION
* Telephone: 01423888
Fax: 01423888
* e-mail: leonie.gilsenan@test.com

Data of the person responsible for devices supervising

Surname: RENATO
Name: MAURI
Telephone: 7567567
Fax: 087897
e-mail:

*Field detail*

Field Name	Description
Registration data of the delegated person	
Tax Code	Tax code of the delegated person. This field is not editable.
Surname	Last name of the delegated person. This field is not editable.
Name	Name of the delegated person. This field is not editable.
General data of the company	
Name	The company's name. Mandatory non-editable field, other than on first access.
Tax Code	Company tax code. Non-editable field, other than on first access. This information is required in the case of companies for which the Country of the registered office is specified as Italy.
VAT Number	VAT Number of the company. Non-editable field, other than on first access. This information is required in the case of companies for which the Country of the registered office is a country other than Italy.
General data of the company – registered office	
Registered Office - Country	Country of the company's registered office. Mandatory non-editable field, other than on first access.
Registered Office – Municipality	Municipality of the company's registered office. Non-editable field, other than on first access. To select the municipality of the registered office, click on the "Search" link; a look-up opens where the user can search for the municipality. If the registered office country is "Italy", the "Municipality" and "Province" or "Foreign Location" must be specified.
Registered Office – Province	Province of the company's registered office. Non-editable field, other than on first access. To select the province of the registered office, click on the "search" link; a look up opens where the user can search for the province. If the registered office country is "Italy", the "Municipality" and "Province" or "Foreign Location" must be specified.
Registered office - Foreign Location	Foreign location where the company has its registered office. Non-editable field, other than on first access. Optional.
Registered office - Zip/Post Code	Zip/Post Code of the company's registered office. Mandatory non-editable field, other than on first access.
Registered Office – Address	Address of the company's registered office. Mandatory non-editable field, other than on first access.
Registered Office – Telephone	Phone number of the company's registered office. Optional.
Registered office –	P.E.C. certified e-mail address / e-mail of the company's registered office. Optional.



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P.E.C. certified e-mail address / e-mail	
General company data – other operating offices	
Location	Location of additional operating offices. This field is not editable. Only present if the company is not Italian, where this data was previously entered.
Address	Address of additional operating office. This field is not editable. Only present if the company is not Italian, where this data was previously entered.
General company data – legal representative	
Legal representative – name	Name of the legal representative of the company. Mandatory field.
Legal representative – Surname	Surname of the legal representative of the company. Mandatory field.
General company data – reference for notifications	
Reference for notifications – Name	Name of contact person for notifications. Mandatory field.
Reference for notifications – Surname	Last name of the contact person for notifications. Mandatory field.
Reference for notifications – Office	Reference Office for notifications. Mandatory field.
Reference for notifications - Telephone	The s office phone or contact person for notifications. Mandatory field.
Reference for notifications Fax	Fax of the office or contact person for notifications. Optional.
Reference for notifications - E-mail	E-mail of the contact person or the office for notifications. Mandatory field.
Supervisory officer data on devices²	
Supervisory officer – Surname	Name of the supervisory officer or Name of the competent unit. Optional.
Supervisory officer – Name	Name of the supervisory officer (Surname if available). Optional.
Supervisory officer - Phone	Phone number of the supervisory officer or the competent unit. Optional.
Supervisory officer – Fax	Fax number of the supervisory officer or the competent unit. Optional.
Supervisory officer	E-mail of the supervisory officer or the competent unit.

² [1] Compilation of data for the “supervisory officer” must be done for companies that are part of the device's marketing chain. Companies which are exclusively responsible for administrative tasks vis-a-vis relations with the Ministry of Health (service firms, consultants), and for which identification is not required, are excluded..



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– e-mail	Optional.

Implementable operations:

Action Name	Description	Page Called
Check	Only visible at the first access. For Italian companies, this allows for checking prior to "Saving" the existing tax code entered in the Tax Code field and, if it is present in the database, this automatically populates the fields in the page with the existing data.	If it is the same.
Add	This function is available only if the company is not Italian and only after first saving data. This function opens a new window where the user can specify an additional operating office.	Page for entering operating offices.
Off-line signature	This function Allows the user to save the information entered and directs the user to the page for downloading the txt file that contains the company data to be signed locally.	Download signature file page
View company list	Only available if there is at least one database company with the same Country and VAT Number/Post Code fields. This function allows the user to view the list of companies already entered in the data base, with the same VAT Number/Post Code – Country compared to the data entered.	Ddisplay page of the list of companies with same Vat Number/Post Code.



2.3.1.2 Enter more operating offices

This page presents itself as a look up and allows the user to insert the other operating offices of the non-Italian company that the user is declaring as their own company. This function is activated by clicking the button "Add" in the Registrant and other manufacturers data entry pages.

Insert operating locations of the company : MEDIMARK EUROPE

Location: Address:

More Operating Locations		
Location	Address	Select
loca	address	☐

Field Detail

Field Name	Description
Location	Location of another operating office of the foreign company.
Address	Address of another operating office of the foreign company.

Implementable operations:

Action Name	Description	Page Called
Add	This function enters the specified data in the database and updates the list of additional operating offices below.	If it is the same
Close	This function closes the window without saving and returns to the page from which it was called.	
Delete	This function removes the selected operating offices and updates the list of additional operating offices below.	If it is the same
Save	This function closes the window, goes back to the page from which it was called, and updates the list of additional operating offices.	



2.3.1.3 List of companies registered with the same Vat Number/Post Code

This page is activated from the page for entering the general data of the registrant, by clicking the button "Show list of companies".

If the user, upon first access to the system (see paragraph 2.3.1.1 Registration of Company Data owned by the user) enters the data of a non-Italian company with the same "VAT Number/Post Code" and "Country" as another company already registered in the system for other companies, upon saving the following message will be displayed:

Home > Dati Azienda > Gestione Dati Azienda > Dati Generali Dichiarante		?
Inserimento Dati Generali Dichiarante		
Sono presenti altre aziende con la stessa Partita IVA e codice nazione. Se si vuole prendere visione dell'elenco delle aziende già registrate per poi eventualmente collegarsi a una di queste è necessario cliccare sul bottone 'Visualizza Lista Aziende'		
Dati di registrazione della persona delegata		
Codice fiscale: RNTMRA70A01H150I Cognome: Weisenborn Nome: Peter		
Dati Generali dell'Azienda		

By clicking the button "Display Company List", the page displayed below opens, which allows the user to reuse one of the companies already present in the DATA BANK OF MEDICAL DEVICE (thus declaring it the user's own company) or enter a new company, different from previous ones, still with the same "VAT Number/Post Code" and "Country", with the data previously entered on the page.



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Other Company Insertion

Manufacturer	VAT number	Nation	Select
CAVENDISH SCOTT LTD.	GB0000000	GB	☐
ADVENA LIMITED	GB0000000	GB	☐

If you want to view the data of every single company on this list and then possibly connect to one of these you must select it. To restore the data entered manually click on 'Restore'

Registration Data of the person delegated

Fiscal Code: TEST DATA
Surname: TEST DATA
Name: TEST DATA

Company General Data

Denomination: PROVA
Tax identification number:
VAT / VAT number: GB0000000
Legal office
Nation: REGNO UNITO
City:
Province:
Foreign city: TEST DATA
* ZIP code: 00019
* Address: TEST DATA
* ZIP code: 00019
* Address: TEST DATA
Telephone:
P.E.C. / e-mail:
Legal representative
* Surname: TEST DATA
* Name: TEST DATA
Reference for communications
* Surname: TEST DATA
* Name: TEST DATA
* Office: TEST DATA
* Telephone: 908977564
Fax:
* e-mail: test-data@yahoo.com

Data of the person responsible for devices supervising

Surname:
Name:
Telephone:
Fax:
e-mail:

The Ministry of Health ensures that the data conforms to the provisions of the legislation regarding the protection of personal data (Legislative Decree number 196/2003).
The Ministry of Health may use the e-mail addresses indicated above to disseminate useful information in the medical device sector.

Back Sign Off line



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Implementable operations:

Action Name	Description	Page Called
Back	This function returns to the previous general registrant data page.	Declaration of the Company Data owned by the user;
Off-line signature	If the user has not selected any company on the list, this function allows the user to enter a new company in the Data Bank of Medical Device database with data entered on the previous screen, associating it to the user as their own company. If the user has selected a company on the list, by clicking "Save", the system creates an association between the user and the company selected. In both cases, the user is directed to the download page of the txt file that contains the data to be signed locally. Upon downloading the file, in the first case both the company and the report are created on the database, but the data signature will be affixed only upon uploading the signed file. In the second case, only the association between the user and the company is created on the DB, which will be signed only upon uploading the file.	Download signature file page



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2.3.1.4 Change “Legal Representative - Reference for communications - Supervisory officer data on devices” of the user's company

Clicking on the menu item "Company Data → General Registrant Information" leads to the page that allows the user to manage their own company's data which plays the role of registrant in the notice of the devices and/or assembled devices.

The update process must be completed with the off-line electronic signature.

Home > Company Data > Company Data Management > General Declarant data
7

Declarant General Data Insertion

Registration Data of the person delegated
Fiscal Code: 1234567890123456
Surname: Cognome
Name: Nome

For medical device notification purposes, the statement of the subject logging on to the system is required to be registered and electronically signed. Proceed by validly entering the data requested on the page, saving, and electronically signing according to the appropriate (online/offline) procedures

Company General Data

* Denomination:
Tax identification number:
VAT /VAT number:
Legal office
* Nation:
City:
Province:
Foreign city:
* ZIP code:
* Address:
Telephone:
P.E.C. / e-mail:
Legal representative
* Surname:
* Name:
Reference for communications
* Surname:
* Name:
* Office:
* Telephone:
Fax:
* e-mail:
Data of the person responsible for devices supervising
Surname:
Name:
Telephone:
Fax:
e-mail:

* required field

The completion of the field "responsible for vigilance" must be made for companies that, for various reasons, are part of trade of the device. The company responsible solely for the administration in dealings with the Ministry of Health (service companies, consultants) for which the individualisation of each figure is not provided, are excluded.

The Ministry of Health ensures that the data conforms to the provisions of the legislation regarding the protection of personal data (Legislative Decree number 196/2003).
The Ministry of Health may use the e-mail addresses indicated above to disseminate useful information in the medical device sector.

Show / Hide

Field detail

Field Name	Description
General company data – legal representative	
Legal representative – name	Name of the legal representative of the company. Mandatory field.



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Legal representative – Surname	Surname of the legal representative of the company. Mandatory field.
General company data – reference for notifications	
Reference for notifications – Name	Name of contact person for notifications. Mandatory field.
Reference for notifications – Surname	Last name of the contact person for notifications. Mandatory field.
Reference for notifications – Office	Reference Office for notifications. Mandatory field.
Reference for notifications – Telephone	The s office phone or contact person for notifications. Mandatory field.
Reference for notifications – Fax	Fax of the office or contact person for notifications. Optional.
Reference for notifications – E-mail	E-mail of the contact person or the office for notifications. Mandatory field.
Supervisory officer data on devices³	
Supervisory officer – Surname	Name of the supervisory officer or Name of the competent unit. Optional.
Supervisory officer – Name	Name of the supervisory officer (Surname if available). Optional.
Supervisory officer – Phone	Phone number of the supervisory officer or the competent unit. Optional.
Supervisory officer – Fax	Fax number of the supervisory officer or the competent unit. Optional.
Supervisory officer – e-mail	E-mail of the supervisory officer or the competent unit. Optional.

Implementable operations:

Action Name	Description	Page Called
Off-line signature	By clicking "SIGN OFF LINE" the user is directed to the download page of the txt file that contains the data to be signed locally. Upon downloading the file the information on the DB is changed, but the data signature will be affixed only upon uploading the signed file.	Download signature file page

³ [1] Compilation of data for the “supervisory officer” must be done for companies that are part of the device's marketing chain. Companies which are exclusively responsible for administrative tasks vis-a-vis relations with the Ministry of Health (service firms, consultants), and for which identification is not required, are excluded..



2.3.1.5 List of associated companies

Clicking on the menu item "Company Data → Statement made by other Companies" accesses the page that allows the user to view the list of companies associated with him, with the option of filtering by setting one or more search criteria. Associated companies are those, other than the registrant, reported in the notification of the devices and/or assembled devices as Manufacturers/Assemblers/Representatives. It is necessary to proceed to the association before notifying device and assembly data.

The list also shows whether the data for a specific company were signed or not. Please note that during validation of a device, all the data of the represented companies shall be signed, regardless of those referenced in the device that the user is validating. The validation of the device is blocked if even just one associated company is not signed.

Home > Company Data > Company Data Management > Statement made by other companies

Companies List

The statement of other manufacturing companies and/or authorised representatives of the device different from the reporting agent is required to be registered and electronically signed. Proceed by researching the company to be registered, enter the data if it is not found, upload the pdf mandate file of the manufacturer/authorised representative where applicable, save, and electronically sign according to the appropriate (online/offline) procedures

Companies List

Denomination:

Tax identification number:

VAT /VAT number :

Nation:

Data signed:

Mandate file added:

Denomination	Fiscal Code	VAT number	Nation	Mandate	Signed	Select
SEDA SPA	01681100150	01681100150	ITALIA	-----	S	☐

Page 1 of 1

Select: Click on one of the squares beside the component(s) in the list depending on operations.



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Search Field Information

Field Name	Description
Denomination	The user can indicate the name (or the initial part thereof) of the company.
Tax identification number	The user can specify the company's tax code.
VAT Number	The user can indicate the VAT Number of the company.
Nation	The user can choose the company's country from the single selection list.
Signed Data	It is possible to filter companies whose data is signed or companies whose data is not yet signed with this single selection list.
Mandate file added	With this single selection list the user can filter all companies associated with the user with a mandate file or otherwise.

Associated Manufacturers List Field Information

Field Name	Description
Denomination	Company name already associated with the user.
Fiscal Code	Tax code of the company already associated with the user.
VAT Number	VAT Number of the company already associated with the user.
Nation	Country of the company already associated with the user.
Mandate	Mandate file name upon notification of the Manufacturer's, authorised representative's or Assembler's own devices to the Registrant. If the file is not entered in the system, in the field will display the string "-----".
Signed	Flag specifying whether the data of the company they relate to are signed or not. Possible values: S = data are signed; N = data are not signed.

Implementable operations:

Action Name	Description	Page Called
Search	This function start the user's search with the criteria and presents the list of related (i.e. associated) companies to the user consistently with these criteria.	If it is the same.
New search	This function cleans up the previously set search parameters.	If it is the same.
Enter	This function allows the user to access the page by entering a new Association to a company in the system.	Insert association to Company.
Edit	This function provides access to the information page of the company selected to edit its data.	Edit company data.
Clear	This function removes the link (association) with the selected company.	If it is the same.

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Action Name	Description	Page Called
View	This function provides access to the information page of the company selected in non-editable mode.	Company Data Information.
Add Mandate	This function provides the user with access to the page that allows the user to upload the mandate file (in pdf format) issued by the selected company – Manufacturer, Authorised Representative or Assembler - to the registrant that is using the function. The button is enabled in two different cases: - by selecting companies with which the user is already associated, but for which this file has not been uploaded. - by selecting companies for which the mandate file has already been uploaded in the system, but has been unblocked by the Administration to allow the Registrant to make updates or correct errors.	Acquisition of mandates.



2.3.1.6 Add association to Company

Before creating a new association the system preliminarily verifies whether the company is already present in the Data Bank of Medical Device, as it has already been registered by another user. For this reason, the "Insert" function opens a page that prompts the user to search for the company to associate to.

In addition to the country, the following search parameters should be set:

- the tax code for Italian companies;
- the Vat Number for EU companies;
- the Post Code for non-EU companies.

Home > Company Data > Company Data Management > Statement made by other companies

Other Company Insertion

*Prior to registering a new company please check that it is not already present in the database.
To look up a company, it is necessary to select its nation and one of the following fields*

- "Tax identification number" (for ITALY)
- "VAT number" (for EU country)
- "ZIP code" (for non-EU country)

Search for Insertion

Tax identification number:

VAT /VAT number:

ZIP code:

*Nation:

Search

List

Search Field Information

Field Name	Description
Tax Code	The user can specify the company's tax code.
VAT Number	The user can indicate the VAT Number of the company.
Zip/Post Code	Company Zip/Post Code. For foreign Countries not belonging to the EU this field is mandatory; in case the user does not have this information the user must enter the value NA (not applicable). This value must be entered with no spaces and no punctuation marks.
Country	The user can choose the company's country from the single selection list. This is preset to the value "Italy".

**Implementable operations:**

Action Name	Description	Page Called
Search	Start the user's search with the criteria set providing for checking the existence of the company which the user intends to be associated with in the Data Bank of Medical Device.	If it is the same.

2.3.1.7 Company data entry and user association to Company

In the event that the search for the company the user wants to associate (see Par. 2.3.1.5) does not provide the results page, this allows the user to enter data for the new company. The operation is simplified if the company to be associated is either an Italian company in the register of companies, in which case the user's personal data will be uploaded automatically on the page, making it easy to operate. The latter will only be required to supplement the data automatically reported as required. Upon saving, the company's data and the association with the user are placed in the database.

In any case if necessary, the user can acquire the Manufacturer's Representative's or assembler's mandate granted to the registrant. This field is not mandatory, since during the consolidation phase, the system checks that the mandate is present for at least one Manufacturer or Authorised Representative where present.



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Search for Insertion

Tax identification number:
VAT /VAT number:
ZIP code:
*Nation:

Search

No company found

Company data

* Denomination:
Tax identification number:
VAT /VAT number:
* Nation:
City:
Province:
Foreign city:
* Address:
* ZIP code:
Telephone:
P.E.C. / e-mail:
Supervision responsible surname:
Supervision responsible name:
Supervision responsible telephone number:
Supervision responsible fax number:
Supervision responsible e-mail address:
Specify the mandate file received from the Manufacturer /
Authorized Representative:

* required field

By saving, both the company and its relationship with the user are recorded.

The user can save the association with the company and sign it at a later time, using the function "Off-line signature". By clicking the button of the same name, the user will be redirected to the page for downloading the txt file to be signed locally, containing data related to this Association.

In the event that the Italian company to be associated is already present in the database, the user's personal information will be automatically included on the page, making it easy to operate. The latter will only be required to supplement the data automatically reported as required/allowed. By saving, the company's data and the association with the user are placed in the database.

If the company to be associated is not Italian downstream of the search (see Par. 2.3.1.5) the system gives the user the option to view the list of companies, if any, with the same group Vat Number (EU companies) or with the same Post Code (non-EU companies) and starting from it:

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- view the cards of companies found and save - by saving off line - association with one of the companies in the list;
- proceed with the entry of a new company, different from those found in the database (with a different name than those found);

During both steps, the user will be able to upload the mandate file of the manufacturer/assembler/authorised representative related to the Registrant.

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Other Company Insertion

Prior to registering a new company please check that it is not already present in the database.
To look up a company, it is necessary to select its nation and one of the following fields

- "Tax identification number" (for ITALY)
- "VAT number" (for EU country)
- "ZIP code" (for non-EU country)

Search for Insertion

Tax identification number: VAT / VAT number: ZIP code: *Nation:

Denomination	VAT number	Nation	Select
CAVENDISH SCOTT LTD.	GB0000000	REGNO UNITO	☐
ADVENA LIMITED	GB0000000	REGNO UNITO	☐

Any companies present in the grid are those currently registered in the BD / RDM, which meet the chosen search criteria. To join in any of these companies please select it and subsequently press the Save button or the button to sign off line. In case one or more companies in the grid could not be selected, this means that they are already bound (associated) to their users.

User authorized to make a link to the manufacturer but with no edit option.

Company data

* Denomination: CAVENDISH SCOTT LTD.

Tax identification number:

VAT / VAT number: GB0000000

* Nation: REGNO UNITO

City:

Province:

Foreign city: * Address: * ZIP code: Telephone: P.E.C. / e-mail: Supervision responsible surname: Supervision responsible name: Supervision responsible telephone number: Supervision responsible fax number: Supervision responsible e-mail address: Specify the mandate file received from the Manufacturer /
Authorised Representative:

* required field

By saving, the relationship between the company and the User is recorded.

**Search Detail Fields**

Field Name	Description
Tax Code	The user can specify the company's tax code.
VAT Number	The user can indicate the VAT Number of the company.
Zip/Post Code	Company Zip/Post Code. For foreign Countries not belonging to the EU this field is mandatory; in case the user does not have this information the user must enter the value NA (not applicable). This value must be entered with no spaces and no punctuation marks.
Country	The user can choose the company's country from the single selection list. This is preset to the value "Italy".

Field Name	Description
General data of the company	
Name	The company's name. Mandatory non-editable field, other than on first access.
Tax Code	Company tax code. Non-editable field, other than on first access. This information is required in the case of companies for which the Country of the registered office is specified as Italy.
VAT Number	VAT Number of the company. Non-editable field, other than on first access. This information is required in the case of companies for which the Country of the registered office is a country other than Italy.
General data of the company – registered office	
Registered Office - Country	Country of the company's registered office. Mandatory non-editable field, other than on first access.
Registered Office – Municipality	Municipality of the company's registered office. Non-editable field, other than on first access. To select the municipality of the registered office, click on the "Search" link; a look-up opens where the user can search for the municipality. If the registered office country is "Italy", the "Municipality" and "Province" or "Foreign Location" must be specified.
Registered Office – Province	Province of the company's registered office. Non-editable field, other than on first access. To select the province of the registered office, click on the "search" link; a look up opens where the user can search for the province. If the registered office country is "Italy", the "Municipality" and "Province" or "Foreign Location" must be specified.
Registered office - Foreign Location	Foreign location where the company has its registered office. Non-editable field, other than on first access. Optional.
Registered office - Zip/Post Code	Zip/Post Code of the company's registered office. Mandatory non-editable field, other than on first access.
Registered Office – Address	Address of the company's registered office. Mandatory non-editable field, other than on first access.



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Field Name	Description
Registered Office – Telephone	Phone number of the company's registered office. Optional.
Registered office – P.E.C. certified e-mail address / e-mail	P.E.C. certified e-mail address / e-mail of the company's registered office. Optional.
General company data – reference for notifications	
Reference for notifications – Name	Name of contact person for notifications. Mandatory field.
Reference for notifications – Surname	Last name of the contact person for notifications. Mandatory field.
Reference for notifications – Office	Reference Office for notifications. Mandatory field.
Reference for notifications - Telephone	The s office phone or contact person for notifications. Mandatory field.
Reference for notifications Fax	Fax of the office or contact person for notifications. Optional.
Reference for notifications - E-mail	E-mail of the contact person or the office for notifications. Mandatory field.
Supervisory officer data on devices⁴	
Supervisory officer – Surname	Name of the supervisory officer or Name of the competent unit. Optional.
Supervisory officer – Name	Name of the supervisory officer (Surname if available). Optional.
Supervisory officer - Phone	Phone number of the supervisory officer or the competent unit. Optional.
Supervisory officer – Fax	Fax number of the supervisory officer or the competent unit. Optional.
Supervisory officer – e-mail	E-mail of the supervisory officer or the competent unit. Optional.

Operations available:

⁴ [1] Compilation of data for the “supervisory officer” must be done for companies that are part of the device's marketing chain. Companies which are exclusively responsible for administrative tasks vis-a-vis relations with the Ministry of Health (service firms, consultants), and for which identification is not required, are excluded..



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Action	Description	Page Name
Search	Runs a search with criteria entered allowing the existence of the manufacturer with whom the user wishes to be linked, to be verified.	Same
Off line sign	Allows the user to save the information inserted and brings him/her to sign off line page	Off line signature pag
List	Allows the user to return to the list of manufacturers linked to the user	Correlation User Manufacturer List.
View	Allows to view the detail of selected company.	Detail company data
New entry	Allows to insert data for a new company with same vat number and Country	Same

2.3.1.8 Edit company data

This page allows the user to change some data of the companies actually inserted in the database. The data from those companies, previously submitted by other Registrants, which the user is associated with, cannot therefore be changed. The data for these companies can be modified only by Registrants who submitted it first.



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Home > Company Data > Company Data Management> Statement made by other companies ?

Edit company data

Company data

* Denomination: SEDA SPA

Tax identification number: 01681100150

VAT /VAT number: 01681100150

* Nation: ITALIA

City: MILANO

Province: MI

Foreign city:

* Address: VIA CARDUCCI 8

* ZIP code: 20123

Telephone: 02484241

P.E.C. / e-mail: sd@sedaitaly.it

Supervision responsible surname:

Supervision responsible name:

Supervision responsible telephone number:

Supervision responsible fax number:

Supervision responsible e-mail address:

Pdf mandate file received from the Manufacturer /
Authorised Representative:

Save List

Detail Fields

Field Name	Description
General data of the company	
Name	The company's name. Mandatory non-editable field, other than on first access.
Tax Code	Company tax code. Non-editable field, other than on first access. This information is required in the case of companies for which the Country of the registered office is specified as Italy.
VAT Number	VAT Number of the company. Non-editable field, other than on first access. This information is required in the case of companies for which the Country of the registered office is a country other than Italy.
General data of the company – registered office	



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Registered Office - Country	Country of the company's registered office. Mandatory non-editable field, other than on first access.
Registered Office – Municipality	Municipality of the company's registered office. Non-editable field, other than on first access. To select the municipality of the registered office, click on the "Search" link; a look-up opens where the user can search for the municipality. If the registered office country is "Italy", the "Municipality" and "Province" or "Foreign Location" must be specified.
Registered Office – Province	Province of the company's registered office. Non-editable field, other than on first access. To select the province of the registered office, click on the "search" link; a look up opens where the user can search for the province. If the registered office country is "Italy", the "Municipality" and "Province" or "Foreign Location" must be specified.
Registered office - Foreign Location	Foreign location where the company has its registered office. Non-editable field, other than on first access. Optional.
Registered office - Zip/Post Code	Zip/Post Code of the company's registered office. Mandatory non-editable field, other than on first access.
Registered Office – Address	Address of the company's registered office. Mandatory non-editable field, other than on first access.
Registered Office – Telephone	Phone number of the company's registered office. Optional.
Registered office – P.E.C. certified e-mail address / e-mail	P.E.C. certified e-mail address / e-mail of the company's registered office. Optional.
General company data – reference for notifications	
Reference for notifications – Name	Name of contact person for notifications. Mandatory field.
Reference for notifications – Surname	Last name of the contact person for notifications. Mandatory field.
Reference for notifications – Office	Reference Office for notifications. Mandatory field.
Reference for notifications - Telephone	The s office phone or contact person for notifications. Mandatory field.
Reference for notifications Fax	Fax of the office or contact person for notifications. Optional.



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Reference for notifications - E-mail	E-mail of the contact person or the office for notifications. Mandatory field.
Supervisory officer data on devices⁵	
Supervisory officer – Surname	Name of the supervisory officer or Name of the competent unit. Optional.
Supervisory officer – Name	Name of the supervisory officer (Surname if available). Optional.
Supervisory officer - Phone	Phone number of the supervisory officer or the competent unit. Optional.
Supervisory officer – Fax	Fax number of the supervisory officer or the competent unit. Optional.
Supervisory officer – e-mail	E-mail of the supervisory officer or the competent unit. Optional.

Implementable operations:

Action Name	Description	Page Called
Save	This function is present only if the user has permission to edit company information selected. This function saves the changes made by the user.	List of Companies represented by the user.
List	This function allows the user to return to the list of user-related manufacturers.	List of Companies represented by the user.
Add	This function opens a new window where the user can specify additional operating offices. The button is only available if the user is authorised to change the company information selected, and if the company is not Italian.	Page for entering operating offices

⁵ [1] Compilation of data for the “supervisory officer” must be done for companies that are part of the device's marketing chain. Companies which are exclusively responsible for administrative tasks vis-a-vis relations with the Ministry of Health (service firms, consultants), and for which identification is not required, are excluded..



2.3.1.9 Company Data Information

This page allows the user to access the information of the company selected in consultation only mode.

Company general data

Company data	
Denomination:	SEDA SPA
Tax identification number:	01681100150
VAT /VAT number:	01681100150
Nation:	ITALIA
City:	MILANO
Province:	MI
Foreign city:	
Address:	VIA CARDUCCI 8
ZIP code:	20123
Telephone:	02484241
P.E.C. / e-mail:	sd@sedaitaly.it
Supervision responsible surname:	
Supervision responsible name:	
Supervision responsible telephone number:	
Supervision responsible fax number:	
Supervision responsible e-mail address:	
Pdf mandate file received from the Manufacturer /	
Authorised Representative:	

[List](#) [Sign Off line](#)

Detail Fields

Field Name	Description
General data of the company	
Name	The company's name. Mandatory non-editable field, other than on first access.
Tax Code	Company tax code. Non-editable field, other than on first access. This information is required in the case of companies for which the Country of the registered office is specified as Italy.
VAT Number	VAT Number of the company. Non-editable field, other than on first access. This information is required in the case of companies for which the Country of the registered office is a country other than Italy.
General data of the company – registered office	
Registered Office - Country	Country of the company's registered office. Mandatory non-editable field, other than on first access.
Registered Office – Municipality	Municipality of the company's registered office. Non-editable field, other than on first access. To select the municipality of the registered office, click on the "Search" link; a look-up opens where the user can search for the municipality. If the registered office country is "Italy", the "Municipality" and "Province" or "Foreign



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Field Name	Description
	Location" must be specified.
Registered Office – Province	Province of the company's registered office. Non-editable field, other than on first access. To select the province of the registered office, click on the "search" link; a look up opens where the user can search for the province. If the registered office country is "Italy", the "Municipality" and "Province" or "Foreign Location" must be specified.
Registered office - Foreign Location	Foreign location where the company has its registered office. Non-editable field, other than on first access. Optional.
Registered office - Zip/Post Code	Zip/Post Code of the company's registered office. Mandatory non-editable field, other than on first access.
Registered Office – Address	Address of the company's registered office. Mandatory non-editable field, other than on first access.
Registered Office – Telephone	Phone number of the company's registered office. Optional.
Registered office – P.E.C. certified e-mail address / e-mail	P.E.C. certified e-mail address / e-mail of the company's registered office. Optional.
General company data – reference for notifications	
Reference for notifications – Name	Name of contact person for notifications. Mandatory field.
Reference for notifications – Surname	Last name of the contact person for notifications. Mandatory field.
Reference for notifications – Office	Reference Office for notifications. Mandatory field.
Reference for notifications - Telephone	The s office phone or contact person for notifications. Mandatory field.
Reference for notifications Fax	Fax of the office or contact person for notifications. Optional.
Reference for notifications - E-mail	E-mail of the contact person or the office for notifications. Mandatory field.
Supervisory officer data on devices⁶	
Supervisory officer – Surname	Name of the supervisory officer or Name of the competent unit. Optional.
Supervisory officer	Name of the supervisory officer (Surname if available).

⁶ [1] Compilation of data for the “supervisory officer” must be done for companies that are part of the device's marketing chain. Companies which are exclusively responsible for administrative tasks vis-a-vis relations with the Ministry of Health (service firms, consultants), and for which identification is not required, are excluded..



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Field Name	Description
– Name	Optional.
Supervisory officer - Phone	Phone number of the supervisory officer or the competent unit. Optional.
Supervisory officer – Fax	Fax number of the supervisory officer or the competent unit. Optional.
Supervisory officer – e-mail	E-mail of the supervisory officer or the competent unit. Optional.

Implementable operations:

Action Name	Description	Page Called
List	This function allows the user to return to the list of user-related manufacturers.	List of Companies represented by the user
Off-line Signature	This function directs the user to the download page of the txt file that contains the data to be signed locally. This function allows the user to sign company data again if, at the request of the Administration, the SD edited these (TK handling of company data or correction of mistyping during first data entry).	Download signature file.



2.3.1.10 Mandates awarded (by manufacturers, Authorised Representatives and Assemblers to Registrants)

This page allows the user :

- to upload pdf mandate files, issued by Manufacturers, Assemblers and Authorised Representatives to Registrants, for companies that are already associated to their own users (regardless of whether the data is signed or not) but for which the pdf file is not yet uploaded.
- to confirm the acquisition of a new (updated or corrected) mandate file that will replace the previous one. This second operation may be carried out only if the previous mandate file has been “unblocked” by the Administration, which the Registrant must request in advance.

Both of the operations described are completed by signing the data offline.

The first scenario is the standard way of using the function, and is illustrated in the figure below:

Figure 1: Adding the mandate file received from the Manufacturer/Assembler or Authorised Representative, already associated with the user.

Implementable operations:

Action Name	Description	Page Called
Off-line signature	This function allows the user to save the information entered and directs the user to the download page of the txt	Download signature file page



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Action Name	Description	Page Called
	file that contains the data to be signed locally.	

The second scenario applies in cases in which the user has previously uploaded an incorrect file in the system, the content of which does not refer to the mandate received from the Manufacturer/ Assembler or applicable Authorised Representative.

When this occurs, the user must contact RDMSupport (email: supportoRDM@sanita.fvg.it) to request that the incorrect file that has been uploaded be “unblocked”. The communication must provide:

- the identifying data of the Registrant company (which appears in the function “Company Data → General Registrant Data” when connected to the system);
- the identifying data of the Manufacturer, Assembler or Authorised Representative with which the incorrect file has been associated;
- the name of the incorrect file that has been uploaded;
- the new, corrected file in pdf format, which contains the actual mandate.

After carrying out the appropriate checks, RDMSupport may “unblock” the incorrect file uploaded previously, which again enables the “Add Mandate” function for that file. When the file has been “unblocked” and the user clicks on that function, a page similar to the one shown below will appear:

Add Mandate

WARNING: this operation will upload a new PDF file containing the mandate of company CITIEFFE S.R.L. in the system, which will replace the file uploaded previously (due to evident errors or document updates/modifications).

Company data

Previously mandate file added: [Certificato Ce scadenza 2017.pdf](#)

*New mandate file to replace the previous one: [Correct_Mandate.pdf](#)

Denomination: CITIEFFE S.R.L.
Tax identification number: 00574250379
VAT /VAT number: 00516271202
Nation: ITALIA
City: CALDERARA DI RENO
Province: BO
Foreign city:
Address: VIA ARMAROLI, 21
ZIP code: 40012
Telephone: 051721850
P.E.C. / e-mail: citiefte@citiefte.com
Supervision responsible surname: MINGOZZI
Supervision responsible name: FRANCO
Supervision responsible telephone number: 051721850
Supervision responsible fax number: 051721870
Supervision responsible e-mail address: pullega@citiefte.com

Sign Off line

Figure 2: Confirmation of the acquisition of a new mandate file to replace the previous one (due to updates or error corrections)

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The page will provide the data of the company selected, the old mandate file initially uploaded by the user and the new mandate file, which will already be in the system after RDMSupport “unblocks” this function. The user must confirm the replacement by signing the data offline. If necessary, this second scenario may be applied to update the content of a correct mandate file previously uploaded in the system.

Implementable operations:

Action Name	Description	Page Called
Off-line signature	This function directs the user to the download page of the txt file that contains the data to be signed locally, including the new mandate file which replaces the previous one. The replacement takes place only when the signed file is uploaded.	Download signature file page



2.4 Detailed description of the “Class I, II a/b and III Medical Device” Functional area

Following access to the functional area "class I, II a/b and III medical devices", the menu of functions available in that area is displayed on the left side of the page.

Before inserting the devices not yet present in the Repertoire it is important to make sure that preliminary activities have been completed, especially the declarations of the entities for which the user is empowered to operate (see 'Company Data' application area) and the inclusion of EC certificates, if any, issued by non-Italian Notified Bodies (see 'Certificate Management' function of this application area).

- MEDICAL DEVICE (DM)

This menu item allows the user to enter a medical device does not yet exist in the Repertoire or to search for existing devices.

- ASSEMBLED KITS OR SYSTEMS (paragraph 2, article 12)

This menu item allows the user to enter an assembled device not yet registered in the Repertoire or search for existing assembled devices.

- ACTIVITY IN PROGRESS

This menu item displays all messages from the system or from the Ministry relating to:

- device consolidation errors (missing data, ...) reported by the system,
- request for modification of a device validated/published by the Ministry,
- completed publication of a device.

- EC CERTIFICATES

The user can use this menu item to insert a certificate not yet present in the repertoire or search EC certificates already entered.

The user can enter a the data for a certificate issued by a non-Italian Notified Body because Italian Notified Bodies enter the data relating to the certificates issued by them directly.

The user can refer to the user manual and online help for the rules applicable to editing and updating certificates.

- USER DOCUMENTATION

This item allows the user to download supporting documents for the use of the Medical Device system.

- PAYMENTS (HISTORY)

This menu item is kept in the system, basically, just for displaying payments needed to register medical devices in the Repertoire.



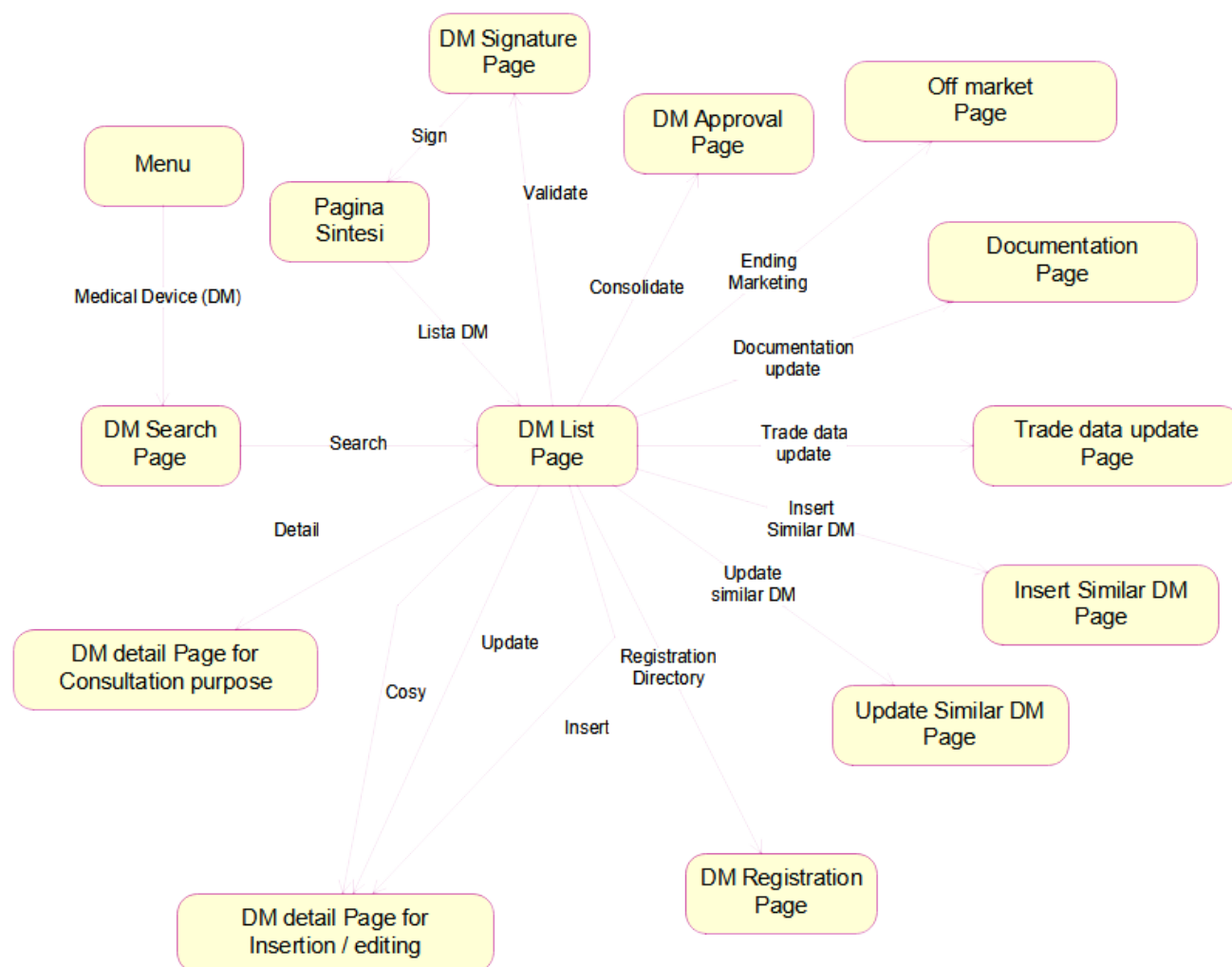
- MULTIPLE NOTIFICATION OF SIMILAR DM

The function capturing multiple similar DM is an operational simplification that allows the user to issue a bulk notification of multiple devices having the same information except for the catalogue code and description (trade name and model).



2.4.1 “Medical Device (DM)” Menu option

Screen flowcharts





2.4.1.1 DMs search

Having clicked on “Medical Device (DM)” on the menu, a page appears which allows the user to define the search criteria of the DM registered on the system

Home > Class I, II a /b, III Medical Devices > Medical Device (DM) ?

DM Search

Research criteria

Search on all DMs ☐ Search in DM To-do list ☒

WARNING: system detected the presence of 'In progress' DMs in the database, which refer to first notifications / manufacturing putback. Select 'Search in DM To-do list' option to find the DMs in order to complete the notification process (Validation by signing). User is required to delete data entered by mistake into the system which only refer to first notifications. It's not possible to delete 'In progress' DMs which come from 'manufacturing putback'

System progressive attributed to DM:

Manufacturer:

Code assigned by the manufacturer from:
(catalogue identifier): to:

Trade name and model:

CND classifications: [Search](#)

First notify Yes ☐ No ☐ All ☒

DM status:

User role as to the DM:

Start working date : from:
to:

[Search](#) [New search](#) [Insert](#)

The user could extend the search to all DMs registered in the system (*Search on all DMs*) whose owner is the user or, otherwise, restrict to the only DMs with status in progress (*Search in DM To-do list*) which refers both to first notification and manufacturing put back. Also “Consolidated” DMs are generally considered in progress.

Select “*Search in DM To-do list*” to complete the notification process of a DM using qualified electronic signature the entered data (Validation) or, otherwise, delete data that were entered by mistake into the system. It's not possible to delete “In progress” DMs which come from “manufacturing putback”

Set the criteria, start the search.

From this page, the user may also access to the insert page of the general data of a DM (Insert button)

Details of DM search Fields



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Field Name	Description
Search on all DMs	allows the extended search of all DMs registered in the system whose owner is the user;
Search in DM To-do list	allows the restricted search of DMs in status in progress;
System Progressive attributed to DM	Option to search a Medical Device by its identification number assigned by the system during registration into the database.
Manufacturer	Option to specify the name (or the beginning) of the Manufacturer of the DM
Code assigned by the manufacturer(identifier catalogue) from/to	Option to indicate the range of codes which includes the product code assigned to the DM by the Manufacturer.
Trade Name and Model	Option to specify the commercial name (or beginning) of the DM
CND Classification	Option to run a search using the National classification of the DM. This field cannot be edited. To select a classified CND and click on the “Search” link. A look-up will then open where the user has the option to search a CND by code or by description or part thereof.
First Notification (Yes/No/All) (Applicable only if “Search in DM To-do list” selected)	allows the restricted search of DMs in first notification (Yes), the restricted search of DMs in manufacturing put back (No), or extended search of all the DMs in progress which refers both to first notification and manufacturing put back;
DM state	Option to search a Medical Device by its current status into the system (“In progress”, “Consolidated”, “Validated”, “Published”).
User role as to the DM	Option to search a Medical Device by the role carried out by the user with respect to that Medical Device (“Manufacturer”, “Agent”, “Marketing Responsible”, “Other person delegated by the Manufacturer”)
Notification Start date (from / to) (Applicable only if “Search in DM To-do list” selected)	allows to filter DMs by specifying the range of date (from – to) for the start of notification of DM. If not used, the search is extended to all DMs present in To-do List whose owner is the user;
Marketing	Option to search a Medical Device by the end trade date. There are three types: “Still on the market”, are sought for the DM whose end date marketing is not valued or is next to the search “No longer marketed”, the DM are searched for which the end date for placing on the market earlier than research
Registered on the index	Option to search a Medical Device by the registration on the index (registered, not registered)

*Operations available*

Action	Description	Page Name
Insert	Allows access to the DM general data entry page	DM detail pages in editable procedures
Search	Activates a search on the basis of the criteria inserted	DM List Page
New search	Clears the search criteria previously defined	Same

2.4.1.2 Searched DMs list

When at least one of the search criteria has been entered, and the user has clicked the “Search” button, the search is activated and a list of DM corresponding to the criteria specified comes up on screen.

For every DM, the following information is displayed:

- Consecutive identification number assigned to the DM by the system
- The manufacturer
- The product code assigned to the DM by the manufacturer
- The Commercial name of the DM
- The CND classification
- The status of the DM
- The end trade date

If /R appears next to the consecutive number assigned to the DM by the system, it means that the DM has been registered on the index.

All systems/kits (art. 12, c. 3) that have been previously entered as “System or kit” DM type and with details of their composition will remain in the data base and will keep their progressive numbers, though they will appear as “Device” DM type.

The DMs list changes, not only on the basis of the criteria set, but also depending on the user connected:

the Manufacturer/Agent/Marketing Responsible will see only those DMs coming from the company he/she represents, regardless of their status in the database; from this page, he/she may set a new search, or:

- a. within the scope of the DMs notifications:
 - insert a new DM
 - insert a new DM by copying an existing DM
 - edit a DM with an “In Progress” status
 - delete a DM with an “In Progress” that has never been published

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- insert quickly one or more DM similar to the selected one indicating only some characteristic data
 - edit the characteristic data of DM in processing inserted by means of the quick insertion functionality
 - notify again a DM in the “Published” status keeping the connection with the same original source device;
- b. within the scope of the validation of the notification that has already been made
- consolidate one or more DM in "In progress" status
 - validate one or more DM in "Consolidated" status
 - quickly validate one or more in "In progress" status
 - activate the off line signature process for one or more DM in “Consolidated” status
- c. within the scope of the update of data after their publication:
- update the commercial data for the DM in “Validated” or “Published” status
 - update the documentation (label and usage instructions) for the DM in ‘Validated’ or ‘Published’ status
 - update the list of DMs needed for the functioning, for those DMs in the “Published” status for which connections to other devices have been stated
 - update the Agent for the DMs in the “Published” status
 - register on the index one or more DMs in the “Validated” or “Published” status declaring they will be distributed to the facilities of the National Health Service,
 - insert the issue date of the placement of a DM on the market marked “Validated” or “Published”
 - set a DM in the “Published” status back to “in progress”;
- d. benefiting of some consultation features or utilities:
- consult the details of a DM
 - consult the history of the versions of a DM reported as “in progress” at least once
 - unload the data of the notified DM in XML format
 - visualize the editable version - in pdf form - of the signature page of a DM in ‘Validated’ or ‘Published’ status



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Home > Class I, II a /b, III Medical Devices > Medical Device (DM) ?

Medical Device (DM)

Research criteria

Search on all DMs ☐ Search in DM To-do list ☒

WARNING: system detected the presence of 'In progress' DMs in the database, which refer to first notifications / manufacturing putback. Select 'Search in DM To-do list' option to find the DMs in order to complete the notification process (Validation by signing). User is required to delete data entered by mistake into the system which only refer to first notifications. It's not possible to delete 'In progress' DMs which come from 'manufacturing putback'

System progressive attributed to DM:

Manufacturer:

Code assigned by the manufacturer (catalogue identifier): from: to:

Trade name and model:

CND classifications: [Search](#)

First notify Yes ☐ No ☐ All ☒

DM status:

User role as to the DM:

Start working date : from: to:

System progressive attributed to DM	Manufacturer	Code assigned by the manufacturer (catalogue identifier)	Trade name and model	CND classifications	Device status	End Trade Date	Select
291879/R	XXXXXXXXXXXX	1050066	HISTOACRYL INTERNAL#	H90010102 - COLLE SINTETICHE	L		☐
463572	XXXXXXXXXXXX	1064345	PREMILENE MESH PRESAGOMATO 4,5X10 CM	P900202 - RETI IN POLIPROPILENE	C		☐
304003	XXXXXXXXXXXX	5518105	CUTFIX STAINLESS BISTURI #12	V0101 - BISTURI MONOUSO	L		☐
74293	XXXXXXXXXXXX	992992	TENDOFIL ACCESSORI	H900399 - DISPOSITIVI DI RINFORZO O SUPPORTO PER SUTURA - ALTRI	L		☐

Device status: L=IN LAVORAZIONE C=CONSOLIDATO V=VALIDATO P=PUBBLICATO U=CANCELLATO D'UFFICIO

If the System progressive attributed to the DM is followed by the symbol (*), this means that in the database there are links with other notifications. If more pages match the search results, by checking 'Select All', only the records in the current page will be selected, leaving out those in the following pages. To select the records in the remaining pages, use the 'previous / next' links and activate the corresponding check ('Select All') for each page.

Select: Click on one of the squares beside the component(s) in the list depending on operations.

Activable operations:

- Insert:** Allows the user to enter a new DM.
- Copy:** Allows the user to make a copy of the selected DM, in order to simplify the entry of another DM reusing the information already entered.
- Edit:** Allows the user to modify the selected DM to change the data previously entered. The user can modify all DMs that are in the "In progress" or "Consolidated" status.
- Delete:** Allows the user to delete the selected DM from the database.



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- **Enter similar DMs:** Allows the user to "quickly" enter the Medical Devices similar to the selected DM having the same features with the following exceptions: Code assigned by the manufacturer, trade name, size and label. The functionality differs from that of the "Copy" since the so entered DMs form a "group" of medical devices having a core of information in common, and on which it is possible to act simultaneously activating the same processes ("Consolidation" and "Validation") or using the same functions (data "Editing" and "Off-trade").
- **Update similar DMs:** Allows the user to access the editing page of the sole specific data of a Medical Device entered through the quick entry feature (Code assigned by the manufacturer, trade name, size and label).
- **New notification:** If the Manufacturer's data have varied significantly, it allows the user to make simplified notifications for a published medical device, ensuring the link to the previous notification.
- **Consolidate:** Allows the user to consolidate the data of one or more Medical Devices that are in the "In progress" status.
- **Validates:** Allows the user to digitally sign all selected DMs. The user can modify all DMs that are in the "Consolidated" status.
- **Validation Fast:** Allows to validate Medical Devices that are in the "In progress" status, without having to switch from the "Consolidated" status, speeding the process of applying for publication while keeping all the checks for the validity of data entered.
- **Off line validation:** Allows to digitally sign-off all selected DMs. The user can modify all DMs that are in the "Consolidated" status.
- **Commercial data:** Allows the user to access the commercial data entry page of a Medical Device.
- **Documentation:** Allows the user to edit the label "pdf" files, the instructions for use of the selected DM and to edit the data sheet. The feature can be activated on the Medical Devices in the "Published" status present in the database.
- **Needed DMs:** Allows to change the list of DMs needed for the functioning of the selected DM in the "Published" status
- **Agent:** Allows to change the Agent for the selected DM in the "Published" status
- **Repertoire registration:** Allows the user to enroll the Medical Device in the selected Repertoire.
- **Off-trade:** Allows the user to state the selected DM off-trade date.
- **Manufacturing putback:** Allows to gain access to the manufacturing putback page for the selected DM.
- **Detail:** Allows the user to view the data detail of the selected DM.
- **Version history:** Allows to view the history of the different versions of the DM put back to manufacturing at least once.
- **Print:** Allows the user to print (in pdf format) a return receipt as evidence of the notification made. Said receipt will report all data signed in the validation stage.
- **Download xml:** Allows the user to download data about the selected medical devices, in the xml format, on the compressed file. The user may only download 10 Medical devices at a time.

Medical Devices notification

Insert Copy Edit Delete Insert Similar DM Update Similar DM New notification

Notification validation (change of the manufacturing status)

Consolidate Validate Validation Fast Off line validation

Post publication update

Trade Data Documentation Needed DMs Agent Repertoire registration Off trade
Manufacturing putback

Consultation and Utilities

Detail Version history Print Download XML

DM Search Detail Fields

Field Name	Description
Search on all DMs	allows the extended search of all DMs registered in the system whose owner is the user;
Search in DM To-do list	allows the restricted search of DMs in status in progress;
System Progressive attributed to DM	Option to search a Medical Device by its identification number assigned during registration into the database.
Manufacturer	Option to specify the name (or the beginning) of the Manufacturer of the DM
Code assigned by the manufacturer(identifier catalogue) from/to	Option to indicate the range of codes which includes the product code assigned to the DM by the Manufacturer.
Trade Name and Model	Option to specify the commercial name (or beginning) of the DM



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Field Name	Description
CND Classification	Option to run a search using the National classification of the DM. This field cannot be edited. To select a classified CND and click on the “Search” link. A look-up will then open where the user has the option to search a CND by code or by description or part thereof.
First Notification (Yes/No/All) (Applicable only if “Search in DM To-do list” selected)	allows the restricted search of DMs in first notification (Yes), the restricted search of DMs in manufacturing put back (No), or extended search of all the DMs in progress which refers both to first notification and manufacturing put back;
DM state	Option to search a Medical Device by its current status into the system (“In Progress”, “Consolidated”, “Validated”, “Published”).
User role as to the DM	Option to search a Medical Device by the role carried out by the user with respect to that Medical Device (“Manufacturer”, “Agent”, “Marketing Responsible”, “Other person delegated by Manufacturer”)
Notification Start date (from / to) (Applicable only if “Search in DM To-do list” selected)	allows to filter DMs by specifying the range of date (from – to) for the start of notification of DM. If not used, the search is extended to all DMs present in To-do List whose owner is the user;
Marketing	Option to search a Medical Device by the end trade date. There are three types: ➤ “Still on the market”, are sought for the DM whose end date marketing is not valued or is next to the search ➤ “No longer marketed”, the DM are searched for which the end date for placing on the market earlier than research
Registered on the index	Option to search a Medical Device by the registration on the index (registered, not registered)

DM List Detail Fields

Field Name	Description
System Progressive attributed to DM	Unique identification number assigned to each DM in the database . If /R appears next to the consecutive number assigned to the DM by the system, it means that the DM has been registered on the index.
Manufacturer	Corporate name of the DM Manufacturing Company
Code assigned by the manufacturer(identifier catalogue) from/to	Code attributed to the DM by the manufacturing company (better known as the identification catalogue)
Trade Name and Model	Commercial name or model of the DM
CND Classification	CND Classification assigned to the DM



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Field Name	Description
State in database	The status of the DM in the database. It can change status in the following order: L: Processing V: Valid P: Published C: Confirmed
End trade date	End trade date

Operations available

Action	Description	Page Name
Search	Activates a search based on the criteria inserted	Same
newSearch	Clears the search criteria previously defined	Same
DMs notification actions		
Insert	Allows access to the DM general data entry page	DM detail pages in editable procedures
Copy	Allows the user to copy a DM in order to insert a new DM which has the same characteristics as the copied DM	DM detail pages in editable procedures
Edit	Allows the user to access the pages containing details of the DM selected and to edit those details (only visible to "MANUFACTURER" users)	DM detail pages in editable procedures
Delete	Allows the user to delete the DM selected (only visible to "MANUFACTURER" users)	Same
Insert Similar Dm	Allows the user to access the page of quick insertion of a DM similar to the selected ones (with the same characteristics except some characteristic data)	Insert similar DM page
Update Similar Dm	Allows the user to access the editing page only for the characteristic data of a DM inserted through the quick insertion functionality	Update similar DM page
New notification	Allows to notify again a DM in the "Published" status keeping the connection with the original source DM	New notification page
Notification validation actions (change of the manufacturing status)		
Consolidate	Allows the approval of a DM in "In Progress" status. The "Consolidate" action brings up the page with the list of DM in the approval phase; specifying whether the process has been activated or not. The outcome of the process, if negative, will be marked on the activity list or will change its status to C, that is "Consolidated"	Detail page about the Starting process status
Validate	Activates the signature page through which Option to validate one or more DM with "Consolidated" status. Changing the status of the DM does not occur simultaneously with the "Validate" action.	Firm page
Validation fast	Activate the check integrity and completeness of the information notified and, if successful, can validate the	Detail page about the process status



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Action	Description	Page Name
	data reported.	
Off line signature	Allows the user to access the page of download of txt file containing DM data	Sign file download page
Post publication update actions		
Commercial data	Grants access to the modification of the page for the commercial data for the published DM selected	DM Commercial data update
Documentation	Grants access to the modification of the page for the label and usage instructions documentation files for the published DM selected	Documentation update
Needed DMs	Allows to change the list of DMs needed for the functioning of the selected DM in the “Published” status	Needed DMs update
Agent	Allows to change the Agent for the selected DM in the “Published” status	Agent update
Off trade	Grants access to the off trade data entry page of the DM selected	Off trade DM page
Repertoire registration	Allows the user to access the repertoire registration page for the DMs devices he/she selected.	Registration on the index
Manufacturing putback	Allows to gain access to the manufacturing putback page for the selected DM.	Manufacturing putback
Consultation actions and utilities		
Detail	Allows the user to enter the details of the DM selected onto the detail page in read-only form	DM detail pages in uneditable procedures
Version history	Allows to view the history of the different versions of the DM put back to manufacturing at least once.	Version history
Print	Makes the pdf file containing the editable version of the signature page of a DM validated or published available	Same
Download xml	Allows the user to unload the detail– in xml format – of a selected DM in a compressed file.	Same



2.4.1.3 New DM registration

In order to insert a new DM, the user must proceed as follows:

1. Run the DM search (from the "Medical Device (DM)" option in the menu, specifying the search parameters and then clicking on "Search") after having verified the DM you wish to insert is not already on the index
2. Click on the "Insert" button
3. Insert the information relative to "General data" and confirm the action by clicking on the "Save" button
4. Insert the specific information that corresponds to the menu options that will then be accessible after the "General data" has been saved using the "Save" button

2.4.1.3.1 DM details for registration/editing

The detail pages of a DM are only accessible by "MANUFACTURER" users and allow them to insert new DMs and also to edit a DM selected from the "DM List page".

The detail pages are:

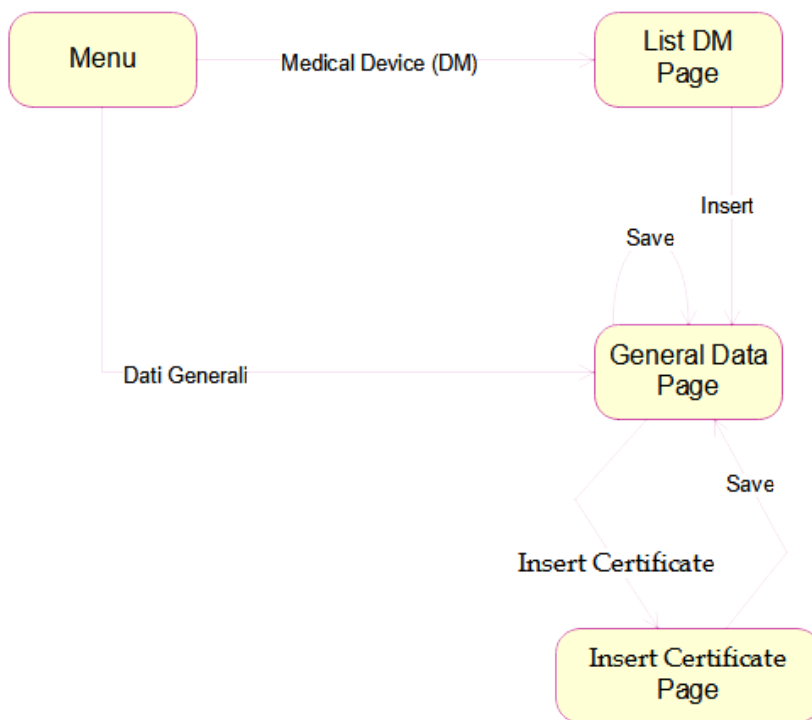
1. General Data
2. Specifications
3. Documentation
4. Commercial Data
5. Any other DM necessary for its function

In particular if it's in insertion mode, the General Data page will become active once the user clicks on the "Insert" button on the list page and only after the data has been saved on the "General data page" will the options on the menu become available and allow the user access to other pages. If it is in edit mode, the General Data page will become available following the selection of a DM from the list and the menu option will become visible simultaneously to allow access to other pages.

Of the five pages "General data", "Technical" and "Documentation" must be completed, the "Commercial data" is to be considered optional, while the "Any other DM necessary for its function" is mandatory only if in "General data" has been declared that the device needs other DM.



2.4.1.3.1.1 General Data



In order to insert a new DM, the manufacturer/mandate holder/marketing director must first specify general data of the DM, in order to then go on to register other information (specifications, commercial data, documentation, any other DM necessary for its function, system or kit components in the case of a system or kit) from the relative page accessible through the corresponding menu options.

The General Data page allows the user to insert general data regarding a DM. The general data of a DM is subdivided in four areas:

- General data
- Classification data
- Certification data
- Links with other DM

In addition to these areas the characteristic data of the DM similar to this one can also be visualized, but only in case if they are present.

It will be necessary to consult the General Data page of a DM in the following cases:



- In the insertion phase of the DM
- In the editing phase of the DM
- In the insertion phase of the DM, by coping a DM that already exists

The user can also connect different DM on this page which are interdependent for operational purposes by clicking on the “Other eventual DM needed for the operation”, after having saved the “General data” by clicking on the “Save” button.

Page Name: General Data Page



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Insertion General data

General data

*Trade name and model:

To indicate the additional trade names, it is necessary to proceed as follows:

1) click on "Add"

2) type the additional trade name

3) any further trade name on the database will be saved along with any other information by clicking on "Save".

More DM trade names

Add

Delete

*Code assigned by the manufacturer (catalogue identifier):

Regulation on prosthetic assistance payable under the National Health Service: Payment conditions and rates:

Search

*User role as to the DM:

Company that entered the DM: MINISTERO DELLA SALUTE

Detail

*Manufacturer:

Search

Detail

Agent:

Search

Detail

Marketing Responsible:

Detail

Was it ever notified to the M.D.S.as provided for by the procedure prescribed before the enforcement of D.M.20/02/07 or under the present procedure?

yes

no

Classification

If the declarant does not have the GMDN code can choose the option 'ND' that means GMDN not declared, and proceed with the compilation of next data. Indication of the GMDN code is essential in order to send the information to the European database EUDAMED.

*Complete GMDN repertoire:

Search

*CND classifications:

Search

Certifications

*EC Classification (D.L.46/97 implementation Dir.CE 93/42, D.L.vo 507/92 implementation Dir.CE 90/385) :

Annex according to which the device was marked:

Annex II/2

Annex III/3

Annex IV/4

Annex V/5

Annex VI

Annex VII

No.of certificate of the EC marking	Certificate Expiration Date	Notified Body Code-Name	Details of Community harmonized standards and of national transposing rules that may be applied	EC Directive 2003/32	File containing the certificate	Select

Clear Reference EC

Insert Reference EC

Link with other DMs

Fields detail General data DM

Field Name	Description
General Data	

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Field Name	Description
DM Type	Indication of the type of classified Medical Device. The following types of DM exist: Device System or kit
Trade Name and Model	Denomination of the DM, as given by the Manufacturer
More DM trade names	List of commercial names subsequently assigned to the DM
Code assigned by the manufacturer (identifier catalogue)	Specific code attributed to the DM by the manufacturer.
Regulation on prosthetic assistance payable under the National Health Service: Payment conditions and rates	Name of DM according to the nomenclature charges in force
User role as to the DM	Indicates the role carried out by the user with respect to the DM. The user can adopt the following roles: - Manufacturer - Mandate Holder - Marketing Director - Other individual delegated by the Manufacturer In respect of D.L. of 21/12/2009, both when registering a new device and changing an existing one, as to the DM, it will no longer be possible to identify the user with the role of Marketing Responsible; this value will however continue to be present amongst the options available to allow the display of all pre-existing data.
Manuf./Agent./Marketing Resp./Other person deleg. By Manuf.	Indicates the Manufacturing company / Mandate Holder / Marketing Director / Other individual from the Manufacturer of the DM
Manufacturer	Name of the Manufacturer of the DM. If the user has selected the role of Manufacturer of the DM, the system therefore selects the Manufacturer that has been previously stipulated by the user in the "Company Data Management" feature. If the user has selected a role other than Manufacturer, he can select the Manufacturer clicking on the "Search" link; a look-up will open where Option to search for and select a Manufacturer.



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Field Name	Description
Agent	Name of Mandate Holder of DM (Authorised Representatives). If the user has selected the role of Mandate holder regarding the DM, the system will automatically display the user's company, as Mandate holder in the "Company Data Management" feature. He can select the Mandate holder by clicking on the "Search" link; a look-up will open where the user has the option to search for and select a Mandate holder. The mandate holder is required if the Manufacturer is registered in a non EU country and it is optional if the manufacturer is registered in a SEE country.
Marketing Responsible	Name of Marketing Director. If the user has selected the role of Marketing Director of the DM, the system therefore selects the Marketing Director that has been previously stipulated by the user in the "Company Data Management" feature. In respect of D.L. of 21/12/2009, both when registering a new device and changing an existing one, it will no longer be possible to indicate the Marketing Responsible; this field will however continue to be present in the page to allow the display of all pre-existing data.
System Progressive attributed to DM	Unique identification number assigned to each DM by the system. This field is not editable and is visible only when editing the DM.
Already Registered	State that the registration has already been carried out in accordance with Legislative Decree 46/1997
Classifications	
Complete Repertoire GMDN	Indicates the classification according to the GMDN(Global Medical Device Nomenclature) of the DM. This field cannot be edited. To select classification according to the GMDN, it is necessary to click on the "Search" link; a look-up will open with which the user can search such a classification by code and description (or part there of). The system will automatically indicate whether the GMDN chosen is linked to only one unique CND code or multiple codes.
CND Classification	Indication of the National classification of the DM. This field is not editable. The system automatically completes the field, following the choice of a GMDN associated with one unique CND. Alternatively it is also possible to specify a CND code unconnected with the GMDN code, selecting a specific check in the same look-up



Field Name	Description
Certifications	
CE classification (D.L.vo 46/97 attuazione Dir. CE 93/42; D.L.vo 517/92; attuazione Dir. CE 90/385	Indication of the EC classification of the DM. The EC classification can adopt the following principals: - Class I with measurement functions - Class I non sterile and or measurement functions - Class I sterile - Class I sterile with measurement functions - Class IIa - Class IIb - Class III - Active implant devices
Annex according to which the Device was marked	Indication of the Annexes according to which the device has been marked. The following inspections are initiated: - in the case of Class I sterile DMs, I with measurement functions DMs or I sterile with measurement functions DMs, annex II or annex VII and IV or annex VII and V or annex VII and VI must be selected. - in the case of Class I DM, annex VII must be selected - in the case of Class IIa, annex II or annex VII and IV or annex VII and V or annex VII and VI must be selected - in the case of Class IIb, annex II or annex III and IV or annex III and V or annex III and VI must be selected - in the case of Class III, annex II or annex III and IV or annex III and V must be selected - in the case of a Active implant device, annex II or annex III and IV or annex III and V must be selected
Links to other DM	
The DM is dependent on other DM in order to operate	Indication of whether or not the DM is dependant on other DM in order to operate

Operations available:

Action	Description	Page Name
Save	Saves inserted information	Same
Clear Reference EC	Deletes the association with the EC Certificate selected	Same
Insert Reference EC	Allows access to the page of the EC Certificates association	Certificate Insertion page
Add	Allows user to add a field which the user can insert an additional commercial name	Same
Delete	Allows the removal of additional commercial name selected	Same

Page Name: Certificates ("Insert Reference EC")



This page is displayed in look-up format and allows the user to search and associate the EC certificates with the DM. This feature is activated by clicking on the “Insert Reference EC” button found on the “General data” page.

The associable certificates can be of two types:

- Certificates entered by the Declarant on behalf of the Manufacturer;
- Certificates entered by the Italian OONNs.

In the first case, the system allows the user to associate certificates that have been issued only by the same manufacturer indicated on the DM that is being notified (as declared on the general data page). In the second case, this check is not performed, as the database of the companies managed by the Declarants does not coincide with the database of Customers of the Italian OONNs. The user may associate the certificates entered directly by the Italian OONNs to their own DMs **only if they know their number, issuing notified body and issue date.**

The expiry date won't be mandatorily required during the search phase as it's no more mandatory in the presence of the Directive on implantable medical devices (90/385/EEC) – Annex 4 or Directive concerning medical devices (93/42/EEC) – Annex IV.

In the case where the user looks for a certificate entered by an Italian ON, the search results will only view a reduced number of information (Certificate number, Certificate Expiration Date and Issuing Notified body). The list will contain all predictable data only in the case where the certificate is already connected to other DMs in the Validated/Published status (namely, after the user has officially associated a given certificate to a DM).

In correspondence to every DM – with the exception of those belonging to Class I non sterile and without measurement functions – it is necessary to associate at least one certificate.



?

EC marking certification

No. of certificate of the EC marking:

Data Emissione: / /

Certificate Expiration Date : / /

Notified Body: [Search](#)

[Reset](#)

Run a search on all Certificates that have been BD/RDM notified by the Italian Notified Bodies: ☐

Search
New search
Confirmation
Cancel

In order to associate the Certificate(s) to DM

- search a certificate, already exist, in the section "Certificates CE" (enter at least one search criteria and click on "Search")
- Select a certificate from the list and click on "Confirm".

If a searched certificate selected as 'EC reference' is expired, it won't be possible to confirm it in the DM notification, whether it was notified by its Declarant or an Italian ON⁷.

Also, if the searched certificate selected as 'EC reference' is at the same time

- Entered in the system by a Declarant,
- without a date of expiry, even though the annex according to which the device was certified is different from the IV/4⁸,

it won't be possible to confirm it in the DM notification⁹.

⁷ Specifically, the halting check on the expiry date of the certificate starts when the expiry date has a value which is less than the current date, but **is not performed** if the certificate's annex is the IV/4 (or if it's equal to the values of the 'Directive 93/42/EEC Annex IV' and 'Directive 90/385/EEC Annex 4' for certificates notified by Italian OONNs) even if a date of expiry is specified.

⁸ The new rules allow an empty date of expiry for the certificates only if the field 'Annex according to which the device was certified' has the value 'Annex IV/4'.

⁹ The case of certificates notified by Italian OONNs isn't discussed because, in the past, the date of expiry of such certificates has always been mandatorily required upon their notification. Only from now on, it will be possible to omit this date if the ON selects one of the following voices from the field 'Annex according to which the device was certified'

- Directive 93/42/EEC Annex IV
- Directive 90/385/EEC Annex 4



Finally, it won't be possible to associate those certificates notified by Declarants with the option "The certificate only concerns the EC Directive 2003/32" to DMs, as this option is no longer available.

In all these cases a message will notify the user of the impossibility to complete the operation.

Certificates with EC stamp Detail Fields

Field Name	Description
No. EC certificate	Identification number of the EC stamp. . This field is mandatory only in the case where the individual that has performed the notification of the certificate in Data Bank of Medical Device is an Italian ON.
Certificate issue date	Certificate issue date. This field is mandatory only in the case where the individual that has performed the notification of the certificate in Data Bank of Medical Device is an Italian ON. If the "Run a search on all Certificates that have been Data Bank of Medical Device notified by the Italian Notified Bodies" check box is not selected, the date cannot be entered.
Certificate expiration date	Expiry date of Certificate.
Reference Notified Body -Code - Name	Indication of the code and name of the organisation notified. This field cannot be edited. To select the code of the organisation notified it is necessary to click on the "Search" link; a look-up will open which will allow the user to search for the notified Organisation by name and code. This field is mandatory only in the case where the individual that has performed the notification of the certificate in Data Bank of Medical Device is an Italian ON.
Run a search on all Certificates that have been notified by the Italian Notified Bodies in Data Bank of Medical Device	By selecting this check box, the user can look for a certificate amongst those notified in the Data Bank of Medical Device directly by the Italian OONNs. In that case, all input fields of the page, with the exception of the expiry date of the certificate, will be mandatory, which means that in order to enter the reference of a certificate that was notified directly by an Italian ON in one of their own DM, the user will have to mandatorily know its name, issue date and the Italian ON that issued that certificate. If this check box is not selected, the search will be performed on the EC Certificates that have been notified in the Data Bank of Medical Device directly by the user.

Operations available:

Action	Description	Page Name
Search	Starts the certificates search, entered by the Declarant on behalf of the Manufacturer and the Italian ON, that are consistent with the parameters that have been set.	Same
New search	Clears the search criteria previously defined.	Same
Confirmation	Closes the look-up, inserts the certificate or the	General data page

in the same way as what happens for the certificates notified by Declarants.



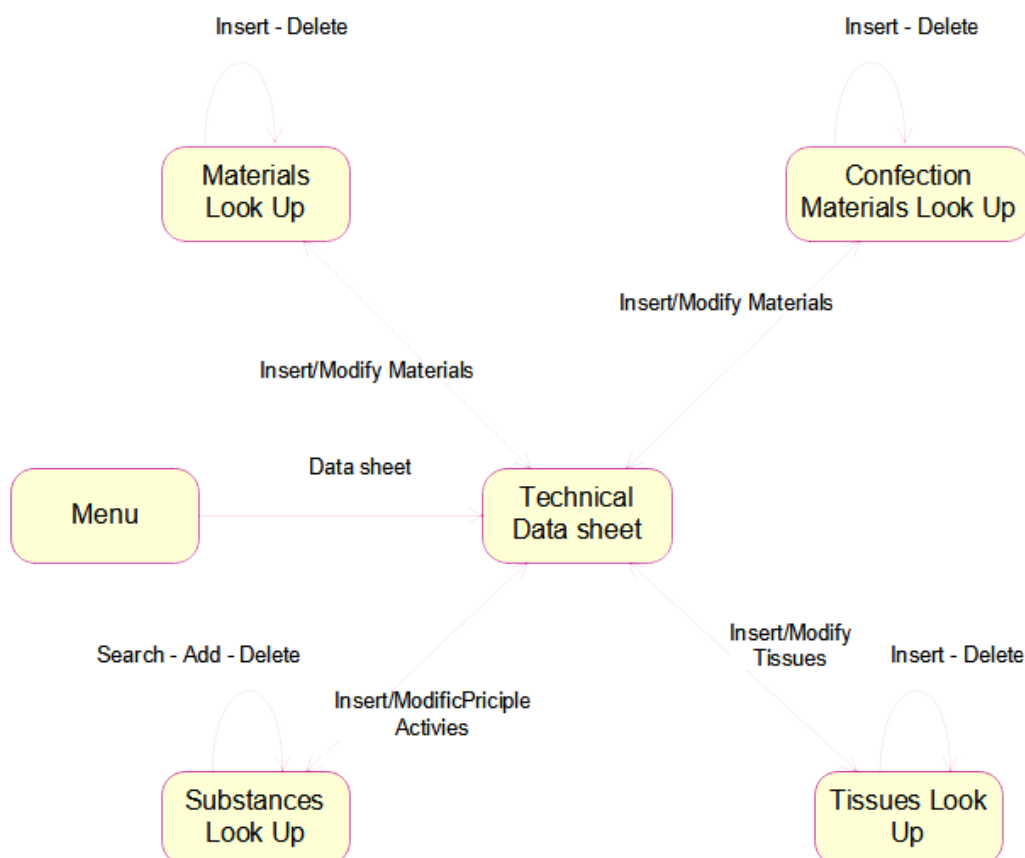
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	certificates selected adjourning the list of the certificates on general DM data page. Verifies that: ○ the selected certificate isn't expired. If it's expired, the procedure will be stopped; ○ if entered by a Declarant, the selected certificate has an expiry date, when the annex according to which was notified is different from the IV/4. If it has no expiry date, the procedure will be stopped; ○ the selected certificate is not relative <u>only</u> to the EC Directive 32/2003. If it is, the procedure will be stopped.	
Cancel	Closes the look-up without saving the work done by user.	General data page



2.4.1.3.1.2 Specifications



Page Name: Specifications

The “Technical Data Sheet” page allows the user to insert/edit information on the technical data of a DM. The data of the specifications data sheet of a DM are subdivided in the following areas:

- General technical characteristics
- Date of sterilisation
- DM material that comes in direct contact with the patient (see related paragraph)
- Medicinal products present patient (see related paragraph)
- Primary packaging of DM patient (see related paragraph)
- Directions for use

The “Technical Data Sheet” page is accessible to users in the following cases:

- During the insertion phase of the DM after the registration of the data

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- During the editing phase of the DM
- During the insertion phase of the DM by coping one that already exists in the system

While saving the data of the specifications data sheet, at least one material contained in the DM that comes in direct contact with the patient and can be pointed out as material contained in the primary packaging of the DM must be indicated only if the label "Sterile" corresponds; and will be marked "Yes"

In the upper part of the page the principal data of the DM are displayed; as well as the "Medical Device General data" link, which allows the user to see the general data of the DM.



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Home > Medical Devices of class I,IIa/b,III > Medical Device (DM) > ?

Edit Data sheet

Trade name and model: ASSO
 Code assigned by the manufacturer (catalogue identifier): ASSO1
 Manufacturer: BAYER_MOD
 System progressive attributed to DM: 10544
[Medical Device general data](#)

General Technology Characteristics

Description:

Intended use according to D.Lgs.46/97 :

Measure (where applicable):

Indicate measurable parameters presently used in commercial catalogs in the relative measurement unit

Medical device materials in direct contact with patient

Material class	Material	Special conditions of disposal
Insert/Modify Materials		

*Latex: both the product and its primary package are latex free

*Latex: during manufacturing, the product came in contact with latex molecules

Biological tissues or substances of animal origins (non-living) data

*Tissue/Substance Presence

Family	State of origin	Tissue used part - Substance	Documents presence
Insert/Modify Tissues			

Medicinal Presences

*Medicinal Presences:

☐ medicines (except those derived from human blood or plasma) ☐ medicines or medicinal components derived from human blood ☐ medicines or medicinal components derived from human plasma

Active substance code	Active substances	Active substance name
Insert/Modify Principal Actives		

For the medical device's medicinal contents, select the principle active

Primary Medical Device Confection

*The prevalent materials of the primary medical device confection require special disposal provisions:

Only for sterile medical devices, or those to sterilize, indicate the prevalent confection materials:

Materials
Insert/Modify Materials

Sterilization Data

*Sterile:

Methods of sterilization	Maximum period of use (months)	Methods of sterilization validated according to harmonized standards	Other sterilization method description
Insert/Modify Sterilization Methods			

Information on the possibility of re-use

*Single:

Method of cleaning/disinfection:

Resterilisation methods	Number of sterilizations	Other sterilization method description
Insert/Modify Resterilization Methods		

[Save](#)



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Field details

Field Name	Description
General technical characteristics	
Description	Description of the general technical characteristics of the DM
Intended use according to D.Lgs.46/97	Intended use In accordance with the D.Lgs.46/97
Measure (where applicable)	Indication of the measurable criteria actually used and present in commercial catalogues with the corresponding unit of measurement of the DM
Material contained in the DM that comes in direct contact with the Patient	
Latex: both the product and its primary package are latex free	Indication as to whether or not the product and its primary package are latex free. This field is required
Latex: during manufacturing, the product came in contact with latex molecules	Indication as to whether or not the the product came in contact with latex molecules during manufacturing. This field is required
Data of biological tissue or substances of animal origin (not vital)	
Tissue/Substance Presence	Indication of whether or not the DM contains Biological tissue/animal substances
Medicinal products Present	
Medicinal Presences	Indication as to whether or not the DM contains medicinal products
medicines (except those derived from human blood or plasma)	Indicates if there are medicines present in the DM (except for those derived from blood or human plasma). This field can be ticked only if it was marked "Yes" in the "Medicinal Presences" field
medicines or medicinal components derived from human blood	Indicates if there are medicines present in the DM derived from human blood). This field can be ticked only if it was marked "Yes" in the "Medicinal Presences" field
medicines or medicinal components derived from human plasma	Indicates if there are medicines present in the DM derived from human plasma). This field can be ticked only if it was marked "Yes" in the "Medicinal Presences" field
Primary packaging of the DM	
The prevalent materials of the primary medical device confection require special disposal provisions	Indicates if the primary packaging of the DM must be disposed of in a specific manner
Sterilization data	



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Field Name	Description
Sterile	Indication of whether or not the DM is sterile
Methods of sterilization	Method used to sterilise the DM. This field is required if the “Sterile” field is marked “Yes”
Other sterilization method description	Description of the sterilisation method if it is not already present on the loaded list previously. This field is required if the “Sterilization method” field is marked “Other”
Methods of sterilization validated according to harmonized standards	The method of sterilisation can be validated: - according to the harmonised norms - other.
Maximum period of use	Maximum length of use of the DM.
Directions for use	
Single	Indicates whether or not the DM is disposable
Method of cleaning/disinfection	Method used to re-sterilise the DM. This field is required if in the “Single” field it was marked “No”
Other sterilization method description	Description of method of re-sterilisation if it is not found on the previously loaded list. This field is required if in the “Other sterilization method description” field it was marked “Other”
Method of cleaning/disinfection	Method used to clean/disinfect the DM. This field is required if in the “Single” field it was marked “No”
Number of sterilizations	Maximum number of times it is permitted to sterilise a DM.

Operations available:

Action	Description	Page Name
Insert/Modify Materials	Allows the user access to the administrative window of the Material contained in the DM	Materials Look Up
Insert/Modify Tissues	Allows the user access to the administrative window of the biological tissues/animal substances contained in the DM	Tissues Look Up
Insert/ModificPrinciple Activies	Allows the user access to the administrative window of the Active ingredients contained in the DM	Substances Look Up
Insert/Modify Materials	Allows the user access to the administrative window of the primary packaging material contained in the DM	Confection Materials Look Up
Insert/Modify Sterilization Methods	Allows the user access to the administrative window of the sterilisation methods of a DM	Sterilization Methods Look Up
Insert/Modify Resterilization Methods	Allows the user access to the administrative window of the re-sterilisation methods of the DM	Resterilization Methods Look Up
Save	Saves the information inserted	Same.

**Page Name: Materials Look Up**

This page is displayed in look-up format and permits the insertion and deletion of materials contained in the DM that come into direct contact with the patient. This page is activated by clicking on the “Insert/Modify Materials” button, visible on the “Data Sheet” page.

Should the “Material class” field read “Metallic alloys” it will then be necessary to indicate the name of the metal.

When saving the data on the specifications data sheet, the user must indicate at least one of the materials contained in the DM that comes in direct contact with the patient.

DM DIRECT CONTACT WITH THE PATIENT MATERIALS

Material class	Material	Special conditions of disposal	
POLIMERICI	ACRILATI	S	☐
COMPOSITI	FIBRE	S	☐

POLIMERICI

ACRILATI

si

In order to save the DM materials, the "Insert materials" and "Confirm" buttons must be clicked.

Materials contained in the DM Detail Fields

Field Name	Description
Material Class	Type of material that the DM is made up of
Materials	Material that the DM consists of
Special conditions of disposal	Indication of whether the material indicated requires specific disposal
Alloy name	Name of the metal. This field is displayed if in the corresponding “Material Class” field the “Metallics-Alloys” option was selected

**Operations available:**

Action	Description	Page Name
Insert Other Material	Confirms the material indicated by the user, providing a new line in order to chose a new material	Same
Delete	Eliminates the material selected by the user	Same
Confirm	Closes the window, confirming the operations carried out by the user	Data Sheet
Close	Closes the window, with out confirming the actions carried out by the user	Data Sheet

Page Name: Tissues Look Up

This page is displayed in look-up format and allows the user to insert, edit and delete the biological tissues/animal substances contained in the DM.

This page is activated by clicking on the "Insert/Modify materials" button, visible on the "Data Sheet" page.

On the upper part of the page, the list of Biological tissues/animal substances associated with the DM are displayed.

On the lower part of the page, a box is displayed where the user can insert/edit the information related to a biological tissue/animal substance to be associated with the DM.



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TISSUE OR BIOLOGICAL SUBSTANCES ANIMAL DATA (NOT VITAL)															
List of possible biological tissues/animal substances contained in the DM <table border="1"> <thead> <tr> <th>Family</th> <th>State of origin</th> <th>Tissue used part - Substance</th> <th>Documents presence</th> </tr> </thead> <tbody> <tr> <td>BOVINA</td> <td>ITALIA</td> <td>ANNESSI CUTANEI</td> <td>S</td> </tr> </tbody> </table>				Family	State of origin	Tissue used part - Substance	Documents presence	BOVINA	ITALIA	ANNESSI CUTANEI	S				
Family	State of origin	Tissue used part - Substance	Documents presence												
BOVINA	ITALIA	ANNESSI CUTANEI	S												
<table border="1"> <tr> <td> Family membership BOVINA v Other Family: </td> <td> National origin ITALIA v </td> <td> Tissue part used - Substance ANNESSI CUTANEI v Other parts used: </td> </tr> <tr> <td> Availability of documents on tissue origin - substance ☐ </td> <td> Documents: Availability of documents on treatment and inactivation methods ☐ </td> <td> Availability of Health Authority documents ☐ </td> </tr> <tr> <td> Attachment Sfoglia... (dimensione max 8MB) </td> <td> Attachment Sfoglia... (dimensione max 2MB) </td> <td> Attachment Sfoglia... (dimensione max 2MB) </td> </tr> <tr> <td> Email address/web site </td> <td> Email address/web site </td> <td> Email address/web site </td> </tr> </table> Save It recommends to use contained file size to facilitate consultation.				Family membership BOVINA v Other Family: 	National origin ITALIA v	Tissue part used - Substance ANNESSI CUTANEI v Other parts used: 	Availability of documents on tissue origin - substance ☐	Documents: Availability of documents on treatment and inactivation methods ☐	Availability of Health Authority documents ☐	Attachment Sfoglia... (dimensione max 8MB)	Attachment Sfoglia... (dimensione max 2MB)	Attachment Sfoglia... (dimensione max 2MB)	Email address/web site 	Email address/web site 	Email address/web site
Family membership BOVINA v Other Family: 	National origin ITALIA v	Tissue part used - Substance ANNESSI CUTANEI v Other parts used: 													
Availability of documents on tissue origin - substance ☐	Documents: Availability of documents on treatment and inactivation methods ☐	Availability of Health Authority documents ☐													
Attachment Sfoglia... (dimensione max 8MB)	Attachment Sfoglia... (dimensione max 2MB)	Attachment Sfoglia... (dimensione max 2MB)													
Email address/web site 	Email address/web site 	Email address/web site 													
Conferma															

Tissue data Fields

Field Name	Description
Family membership	Family of origin of the biological tissue/animal substance contained in the DM
Other family	Description of the family of origin of the biological tissue/animal substance contained in the DM, if it has not previously been loaded onto the list. This field is required if the corresponding "Family membership" was indicated as "other", otherwise it is not taken into account
State of origin	Original condition of the biological tissue/animal substance
Tissue part used/Substance	Parts of tissue used in DM



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Field Name	Description
Other parts used	Description of the parts of the biological tissue/animal substance used in the DM if they haven't been previously loaded onto the list. This field is required if the corresponding "Tissue part used" was marked "other", otherwise it is not taken into account
Availability of Documents on tissue origin/substance	Indication of the presence of documentation on the origin of the tissue – substance
Attachment (in refer to "Availability of Documents on tissue origin/substance" field)	File containing the documentation on the origin of the tissue – substance. The file must be in pdf format. This field is required if the "Availability of Documents on tissue origin/substance" field has been ticked. This field is an alternative to the "Email Address/web Page" There is a limit to the dimension of the .pdf file to be attached to the DM (in the sample picture, such limit equals 2 MB); for the maximum size allowed, refer to the corresponding value shown by the application
e-mail address /web site (in refer to "Availability of Documents on tissue origin/substance" field)	Email address/Web site from which the origin of the tissue – substance can be traced. This field is required if the "Availability of Documents on tissue origin/substance" field was ticked. This field is an alternative to the "Attachment" field.
Documents: Availability of documents on treatment and inactivation methods	Indication of the presence of documentation on methods of treatment and deactivation
Attachment (in refer to "Documents: Availability of documents on treatment and inactivation methods" field)	File containing the documentation on methods of treatment and deactivation. The file must be in pdf format. This field is required if the "Documents: Availability of documents on treatment and inactivation methods" field was ticked. This field is an alternative to the "email address/web site" field. There is a limit to the dimension of the .pdf file to be attached to the DM (in the sample picture, such limit equals 2 MB); for the maximum size allowed, refer to the corresponding value shown by the application
e-mail address/web site (in refer to "Documents: Availability of documents on treatment and inactivation methods" field)	Email address/web site where the documentation on methods of treatment and deactivation can be found. This field is required if the "Documents: Availability of documents on treatment and inactivation methods" field was ticked. This field is an alternative to the "File da allegare" field.



Field Name	Description
methods” field)	
Availability of Health Authority Documents	Indicate the presence of documentation provided by the Health authority regarding the tissues/substances selected.
Attachment (in refer to “Availability of Health Authority Documents” field)	File containing the documentation provided by the Health authority regarding the tissues/substances selected. The file must be in pdf form. This field is required if the “Availability of Health Authority Documents” field is ticked. This field is an alternative to the “Email Address/web site” field. There is a limit to the dimension of the .pdf file to be attached to the DM (in the sample picture, such limit equals 2 MB); for the maximum size allowed, refer to the corresponding value shown by the application
Email address/web site (in refer to “Availability of Health Authority Documents” field)	Email address/web site where the documentation provided by the health authority regarding the tissue/substance selected can be found. This field is required if the “Availability of Health Authority Documents” field is ticked. This field is an alternative to the “Attachment” field.

Operations available:

Action	Description	Page Name
Insert	Displays a box in which the user can insert information regarding biological tissue/animal substance to be associated with the DM	Same
Edit	Displays a box in which the user can edit information regarding biological tissue/animal substance selected	Same
Delete	Eliminates the selected biological tissue/animal substance, associated with the DM	Same
Save	Saves the information inserted by the user of a biological tissue/animal substance, associated with the DM in the insert/edit box	Same
Confirm	Closes the window, confirming the operations carried out by the user	Data Sheet
Close	Closes the window, without confirming the actions carried out by the user	Data Sheet

Page Name: Substances Look Up

This page is displayed in look-up format and allows one or more active ingredients to be linked to a DM. This is achieved by clicking the “Insert/Modify Principal Activities” button which is found on the “Data Sheet” page.



In the box at the top of the page a list of possible active ingredients associated with the DM is displayed.

In the box in the middle of the page displays the search fields to be determined, (at least one margin must be put in place) in order to obtain the list of active ingredients from which the user may select and then link to the DM.

In the box at the end of the page, a list of consistent active ingredients are visible with the search criteria in place.

ACTIVE SUBSTANCES
?

Active substances		
Active substance code	Active substance name	Type

Principal Actives

Principal Active Code:

Principal Active Name:

Add Medical Device Principal Actives

Active substances			
Active substance code	Active substance name	Type	
142	ACIDO SALICILICO	Nazionale	☐

Add Medical Device Principal Actives

Active Ingredients Search Detail Fields

Field Name	Description
Active Substance Code	Option to search by inserting the active ingredient code
Active Substance Name	Option to search by inserting the active ingredient name (or part there of)

**Active Ingredients List Detail Field**

Field Name	Description
Principal Active Code	Code of the Active ingredient
Principal Active Name	Name of the Active ingredient
Type	Type of Active ingredient

Operations available:

Action	Description	Page Name
Search	Runs a search of the active ingredients base on the search criteria specified	Same
Add Medical Device Principal Actives	Allows the user to link active ingredients selected to the DM	Same
Delete	Allows the user to delete the link between the active ingredients selected and the DM	Same
Confirm	Closes the window, confirming the operations carried out by the user	General Data Sheet
Close	Closes the window, without confirming the actions carried out by the user	Data Sheet

Page Name: LookUpMetodiSteril

This page is displayed in look-up format and allows the user to insert and cancel methods of sterilisation of DM that come in direct contact with the patient. It is activated by clicking on the "Insert/Modify Sterilization Methods" button which is found on the "Data Sheet" page.

When saving the data on the specifications data sheet, it is required to indicate at least one method of sterilisation of the DM in the case that it has been marked as being sterile.



METHODS OF STERILIZATION				?
Methods of sterilization	Maximum period of use (months)	Methods of sterilization validated according to harmonized standards	Other sterilization method description	
ACIDO PERIACETICO E DERIVATI ▼		▼		
Insert Method Delete				
Insert Method				
In order to save the resterilisation methods, the "Insert materials" and "Confirm" buttons must be clicked.				

Methods of sterilisation of DM Detail Fields

Field Name	Description
Methods of Sterilization	Method used to sterilise the DM. This field is required if the "Sterile" field is marked "Yes"
Maximum period of use	Maximum length of use of the DM.
Methods of sterilization validated according to harmonized standards	The method of sterilisation can be validated: - according to the harmonised norms - other.
Other sterilization method description	Description of method of sterilisation if it is not found on the previously loaded list. This field is required if in the "Sterilization Method" field it was marked "Other"

Operations available:

Action	Description	Page Name
Insert method	Confirm the method of sterilisation indicated by the user, providing a new line for the insertion of the new method	Same
Delete	Eliminates the method of sterilisation selected by the user	Same
Confirm	Closes the window, confirming the actions carried out by the user	Data Sheet

**Page Name: Packaging Materials Look Up**

This page is displayed in look-up format and allows the insertion and deletion of the primary material used to package the DM. This is activated by clicking the "insert/modify Materials" button found on the "Data Sheet" page.

Only the primary packaging material of sterile DM need be inserted. The material of non sterile DM, does not need to be specified.

DM PRIMARY PACKAGING MATERIALS

?

Materials	
ACCOPPIATO ALLUMINIO/LAMINATO PLASTICO	☐
ACCOPPIATO CARTA/LAMINATO PLASTICO ▼	☐

In order to save the DM materials, the "Insert materials" and "Confirm" buttons must be clicked.

Primary packaging material of a DM Detail Fields

Field Name	Description
Materials	Material necessary for the primary packaging of the DM

Operations available:

Action	Description	Page Name
Insert Material	Confirms the material indicated by the user, providing a new line so that new material can be selected	Same
Delete	Deletes the material selected by the user	Same
Confirm	Closes the window, confirming the operations carried out by the user	Data Sheet
Close	Closes the window, without confirming the actions carried out by the user	Data Sheet

**Page Name: Resterilization Methods Look Up**

This page is displayed in look-up format and allows the user to insert and delete methods of sterilisation applied to the DM which come in direct contact with the patient. It is activated by clicking the “insert/modify Materials” button found on the “Data Sheet” page.

When saving the specification data, at least one method of sterilisation of the DM must be indicated if the DM has been marked as being Sterile

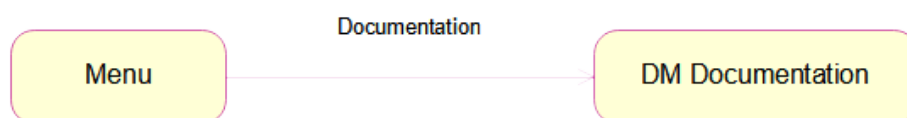
RESTERILISATION METHODS			?
Resterilisation methods	Number of sterilizations	Other sterilization method description	
ALDEIDI E DERIVATI	Unlimited ☐ 		
		Insert Method Delete	
Confirm			
In order to save the resterilisation methods, the "Insert materials" and "Confirm" buttons must be clicked.			

Methods of re-sterilisation of DM Detail Fields

Field Name	Description
Risterilization Methods	Method used to re-sterilise the DM. This field is required if the “Single” field is marked “Yes”
Method of cleaning/disinfection	Method used to clean/disinfect the DM. This field is required if the corresponding “Single” field was marked “No”
Other sterilization method description	Description of method of re-sterilisation if it is not found on the list previously loaded.
Number of sterilizations	Maximum number of times it is permitted to sterilise a DM.. To specify that an illimited number of sterilisations are allowed the option ‘Unlimited’ must by selected. Otherwise the corresponding field must be filled in with the number of sterilisations allowed. The field is editable if the check “Unlimited” its not selected.

*Operations available:*

Action	Description	Page Name
Insert method	Confirms the method of re-sterilisation indicated by the user, providing a new line so that new method can be inserted	Same
Delete	Deletes the method of re-sterilisation selected by the user	Same
Confirm	Closes the window, confirming the actions carried out by the user	Data Sheet

2.4.1.3.1.3 Documentation

This page allows the user to insert documentation attached to a DM. This page is not accessible in the following phases:

- During the insertion phase of the DM after the registration of the general data
- During the editing phase of the DM
- During the insertion phase of the DM by means of coping one that already exists in the system

In the upper section of the page, the principal data of the DM are displayed as well as the “Medical Device General Data” link which opens the page containing the general data of the DM.



User Manual DM Manufacturer Profile



Page Name: DM Documentation

Documentation

Trade name and model: AVANTGUARD 1205 Σ

Code assigned by the manufacturer (catalogue identifier): 1200W1 Σ

Manufacturer: MASTELLI SRL

System progressive attributed to DM: 741

[Medical Device general data](#)

Select the file to attach or indicate the remote link to the document or the e-mail address suitable for this request. It recommends to use contained file size to facilitate consultation.

Document	File to attach	Link /Email Address		Save /Delete File
* Label	221_3_RTI_MDS_2010_03_12_		Open	Delete
Instructions for Use	Sfoglia... (max size 104MB)			Save
DM Image	221_3_RTI_MDS_2010_03_12_		Open	Delete
DM Data Sheet	221_3_RTI_MDS_2010_03_12_		Open	Delete
Scientific bibliography supporting the clinical evidence of the effectiveness and safety of the DM	221_3_RTI_MDS_2010_03_12_		Open	Delete

If the DM does not need Bibliography attach a file containing an explicit statement to that effect.

The format of the files to be annexed must be PDF

Documentation fields Detail

Field Name	Description
Label	File containing the label of the DM. Required. The attached file must be a pdf file. There is a limit to the dimension of the .pdf file to be attached to the DM (in the sample picture, such limit equals 2 MB); for the maximum size allowed, refer to the corresponding value shown by the application
Instructions for Use	File containing the instruction for use of the DM. Field mandatory for class device: - IIb - III otherwise for other classes system present the message “ Field mandatory if the device is accompanied by Instruction for Use ”. In such a case the Declarant must upload the file of Instruction for Use if the device is accompanied by but the system can't control it. In the case that file is not uploaded, the device data signed by Declarant will contain “ Device



User Manual
DM Manufacturer Profile



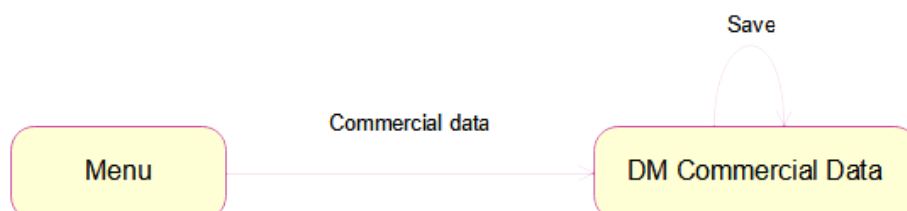
Field Name	Description
	is not accompanied by Instruction for Use”
DM Image	File containing the image of the DM. Not obligatory. The file attached must be a pdf file. There is a limit to the dimension of the .pdf file to be attached to the DM (in the sample picture, such limit equals 2 MB); for the maximum size allowed, refer to the corresponding value shown by the application
DM Data Sheet	The file containing the specifications of the DM or alternatively the link to the site where the same information may be found. Required. The file attached must be in pdf format. There is a limit to the dimension of the .pdf file to be attached to the DM (in the sample picture, such limit equals 2 MB); for the maximum size allowed, refer to the corresponding value shown by the application
Scientific bibliography supporting the clinical evidence of the effectiveness and safety of the DM	File containing the Scientific bibliography, supporting the clinical evidence of the effectiveness and safety of the DM or alternatively a link to a site where the same information may be found. Required. The file attached must be in pdf format. There is a limit to the dimension of the .pdf file to be attached to the DM (in the sample picture, such limit equals 2 MB); for the maximum size allowed, refer to the corresponding value shown by the application

Operations available:

Action	Description	Page Name
Save	Allows a file uploaded or a link entered to be saved	Same
Delete	Allows user to delete a file or link	Same
Open	Allows the user to download the attached document	



2.4.1.3.1.4 Commercial Data



Page Name: DM Commercial Data

This page allows the user to insert/edit the commercial data of a DM. The commercial data of a DM are subdivided in two areas.

- Current data of the DM
- Annual sales details of the DM

The insertion page of commercial data of a DM is accessible by the user in the following cases:

- During the insertion phase of the DM after the registration of the general data
- During the editing phase of the DM
- During the insertion phase of the DM by means of coping one that already exists in the system

In the upper section of the page, the principal data of the DM are displayed as well as the “Medical Device General Data” link which opens the page containing the general data of the DM.

Completion of the page is optional.



Home > Class I, II a /b, III Medical Devices > Medical Device (DM) > Commercial Data ?

Edit Commercial Data

Trade name and model: PROVA2

Code assigned by the manufacturer (catalogue identifier): 123

Manufacturer: BAYER

System progressive attributed to DM: 10022

[Medical Device general data](#)

Actual data

Last update: 26/06/2008

Unit price list of single device without VAT: **%VAT:**

Presence of bar code:

The amounts are expressed in Euro

DM sale data

DM year of sale	No.of pieces sold to the SSN	Type of data	No.of pieces sold to the remaining market	Type of data
		actual ☐ estimated ☐		actual ☐ estimated ☐

[Insert other sale datum](#)

SSN includes: local health companies, hospitals, accredited public and private facilities

[Save](#)

Commercial data Fields

Field Name	Description
Current data	
This medical device will be providing facilities of the National Health Service	Indication whether or not the DM is destined to be used by the SSN



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DM Manufacturer Profile



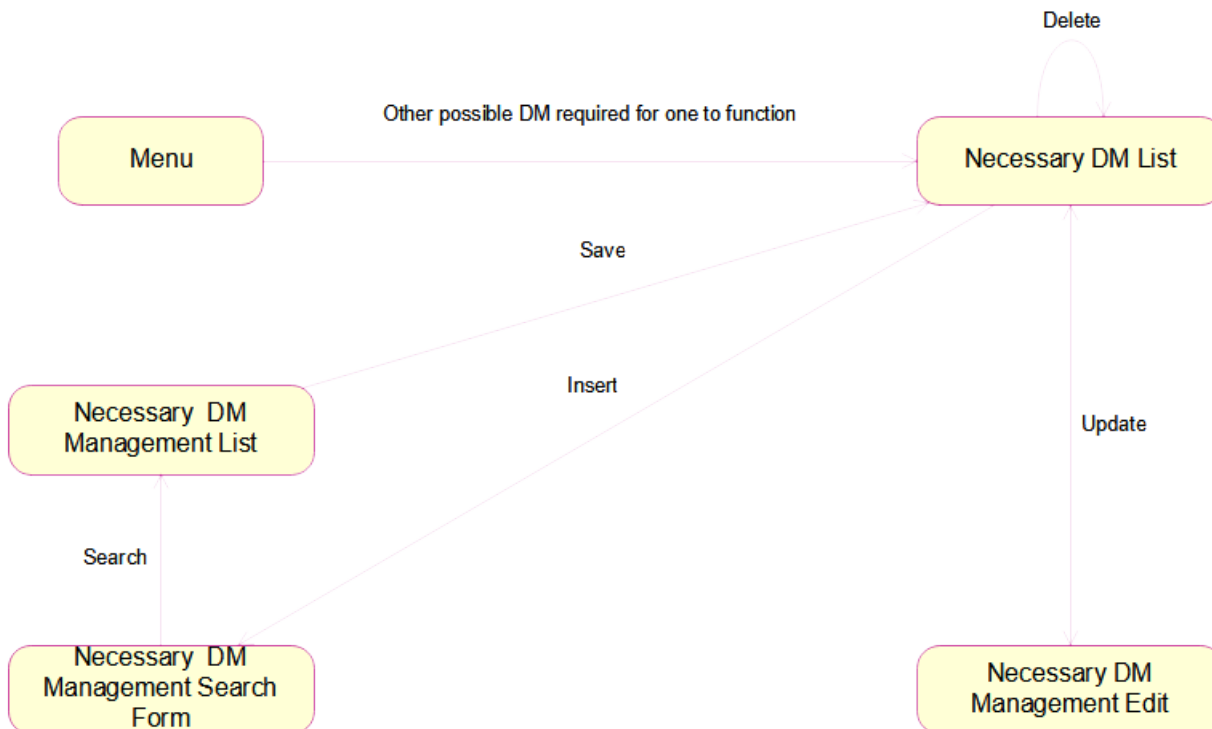
Field Name	Description
Unit price list of single device without VAT	Unit sale price of a DM free of tax
%VAT	Indication of the IVA applied to the DM
Presence of bar code	Indication as to whether or not the DM bears a barcode
DM Sales data	
DM year of sale	Indication of the year DM was sold
No.of pieces sold to the SSN	Indication of the number of pieces sold to the National Health Service. This field is required if the
Type of data	Indication of the type of c
No.of pieces sold to the remaining market	Indication of the number of DM pieces old (excluding pieces sold to the SSN). This field is required if the year of sale has been entered
Type of data	Indication of the type of data (No. of pieces sold to the rest of the market) either estimated or exact This field is required if the year of sale has been entered

Operations available:

Action	Description	Page Name
Insert other sale datum	Adds an empty line in which the user can insert the commercial information of a DM regarding a sales year	Same
Save	Allows the information entered to be saved	Same



2.4.1.3.1.5 Other possible DM required for one to function



2.4.1.3.1.5.1 Needed DMs List

This page allows the user to link one DM to another DM, that are required for its functionality. In the absence of the database of the device(s) needed for the functioning of the device that is being notified, the manufacturer can register such missing devices providing a minimal set of information.

This page is accessible by the user in the following cases:

- During the insertion phase of the DM after the registration of the general data
- During the editing phase of the DM
- During the insertion phase of the DM by means of copying one that already exists in the system

In the upper section of the page, the principal data of the DM are displayed as well as the “Medical Device General Data” link which opens the page containing the general data of the DM.

In correspondence to the “Trade Name and Model” of each correlated DM, there is a link which allows the user to view the general data of the respective DM selected.



Home > Class I, II a /b, III Medical Devices > Medical Device (DM) > Any other DM needed for the operation ?

List Any other DM needed for the operation

Trade name and model: CNDPROVA1

Code assigned by the manufacturer (catalogue identifier): 101010

Manufacturer: BAYER

System progressive attributed to DM: 10372

[Medical Device general data](#)

Other DM needed for the operation					
Manufacturer	Trade name and model	Exclusive use/ Non-exclusive use	Reason for exclusivity	Device status	Select
BAYER	DISPOSITIVO MEDICO	exclusive use	prova	P	☐
BAYER	DISPOSITIVO MEDICO	non-exclusive use		L	☐

This feature allows the linking of medical devices.
It is possible to select the DMs needed among those that were previously included; if the DMs refer to other manufacturers/representatives/resp.Imm.in comm.are selected regardless of their status in the repertoire.
For each of the devices needed, you will be asked to state whether it is the only one that can be used ("exclusive use") or not ("non-exclusive use") for a specific purpose.

Select: Click on one of the squares beside the component(s) in the list depending on operations.

DM required Detail Fields

Field Name	Description
Manufacturer	Manufacturer of the DM required
Trade Name and Model	The commercial name of the DM required
Exclusive use / non-exclusive use	Indicates if the DM to be linked, has an exclusive use regarding the "Father" DM
Reason for exclusivity	Reason for its exclusiveness. This field is activated only if the option 'Exclusive use' has been selected. To modify this field it is necessary to select the image, insert the text into the window and click on the 'Save' button
Product type	The type of product entered as needed for the functioning of the device can be:



Field Name	Description
	- DM: EC marked device notified in a regular form by its manufacturer - DM (*): EC marked device notified in minimal form by the manufacturer of the DM for which it is needed
Device status	Status of the DM in the database. This status can change in the following order: L: in progress V: Valid P: Published

Operations available:

Action	Description	Page Name
Insert	Grants access to the DM search page of the DM to be linked	Necessary DM Management Search Form
Edit	Grants access to the details of the linked DM (selected) in order to edit the data regarding the exclusiveness, or otherwise, of the association .	Necessary DM Management Edit
Cancel	Allows the association between the DM and the DM selected from the list to be removed	Same
DM Management in minimal form	Opens a window where the user has the option to manage the CE marked DM notified in a minimum form. The button is present only if the system / kit manufacturer (para.3) has already notified the devices in a minimum form.	DM in minimal form Search Look Up

2.4.1.3.1.5.2 Search of EC marked DMs to be added as necessary for the functioning of the device

This page can be activated by clicking the “Enter” button present on the page containing the list of the devices needed, and allows the user to set search criteria to view the list of the DMs notified in regular or minimal form to be added as necessary for the functioning of the device.

The user must decide whether he wants to search DMs or DMs in minimal form. Depending on his/her choice, the page will present the user with different search criteria.

There are two options:

- DM
- EC marked device notified in minimal form

In this paragraph we will examine the case in which the user intends to search among DM.



User Manual DM Manufacturer Profile



In the upper section of the page, the principal data of the DM are displayed as well as the “Medical Device General Data” link which opens the page containing the general data of the DM.

Home > Class I, II a /b, III Medical Devices > Medical Device (DM) > Any other DM needed for the operation ?

DM List Search

Trade name and model: BAYE VECCHIO DM

Code assigned by the manufacturer (catalogue identifier): X122

Manufacturer: BAYER

System progressive attributed to DM: 10428

[Medical Device general data](#)

Search

Search: ☒ DM ☐ DM IN MINIMAL FORM

System progressive attributed to DM:

Manufacturer:

Trade name and model:

da:

Code assigned by the manufacturer (catalogue identifier):

a:

Search Detail Fields

Field Name	Description
Search	The user must decide whether he wants to search DMs or DMs in minimal form. Depending on his/her choice, the page will present the user with different search criteria.
System progressive attributed to DM	Option to search a Medical Device by its identification number assigned by the system during registration into the database
Manufacturer	The name or (or beginning thereof) of the Manufacturer of the DM can be specified
Trade Name and Model	The commercial name of the DM (or beginning thereof) can be specified
Code assigned by the manufacturer (identifier catalogue) from/to	Option to indicate the range of codes which includes the product code assigned to the DM by the Manufacturer.

*Operations available:*

Action	Description	Page Name
Search	Runs a search with criteria put in place and displays the DM list or list of Non-DM products that match the same criteria	Searched EC marked DMs list
Reset	Clears the search criteria previously put in place	Same

2.4.1.3.1.5.3 Searched EC marked DMs list

This page displays a list of DM to be linked, according to the criteria put in place in the search page. In the upper section of the page, the principal data of the DM are displayed as well as the “Medical Device General Data” link which opens the page containing the general data of the DM.

Once the DM to be linked have been selected, The “Exclusive use/Non-exclusive use” and “Reason for Exclusivity” fields will automatically become unblocked.

If in the data bank there are no medical devices corresponding to the search criteria inserted, the “DM in minimal form insertion” button is activated and gives the user the possibility to manage the absent device providing only a minimum set of informations (for the insertion of the DM data it is necessary to refer back to the section of the document “Page Name: DM in minimal form Insertion Look Up”)



User Manual DM Manufacturer Profile



Home > Class I, II a /b, III Medical Devices > Medical Device (DM) > Any other DM needed for the operation ?

Search Any other DM needed for the operation

Trade name and model: ASSO
Code assigned by the manufacturer (catalogue identifier): ASSO1
Manufacturer: BAYER_MOD
System progressive attributed to DM: 10544

[Medical Device general data](#)

Research criteria

Search: ☒ DM ☐ DM IN MINIMAL FORM

System progressive attributed to DM:

Manufacturer:

Trade name and model:

da:

Code assigned by the manufacturer (catalogue identifier):

Manufacturer	Code assigned by the manufacturer (catalogue identifier)	Trade name and model	Exclusive use/ Non-exclusive use	Reason for exclusivity (To value selecting the image)	Device status	Select
BAYER STORIC NEW	A12	ALUT 15	Exclusive use v		P	☐

Page 1 of 1

Device status: L=IN LAVORAZIONE C=CONSOLIDATO V=VALIDATO P=PUBBLICATO U=CANCELLATO D'UFFICIO

Select: To add a component, click on one of the squares beside component(s) in the list.

Search Detail Fields

Field Name	Description
Search	The user must decide whether he wants to search DMs or DMs in minimal form. Depending on his/her choice, the page will present the user with different search criteria.
System progressive attributed to DM	Option to search a Medical Device by its identification number assigned by the system during registration into the database
Manufacturer	The name or (or beginning thereof) of the Manufacturer of the DM can be specified
Trade Name and Model	The commercial name of the DM (or beginning thereof) can be specified
Code assigned by	Option to indicate the range of codes which includes the product code assigned to the



User Manual DM Manufacturer Profile



Field Name	Description
the manufacturer(identifier catalogue) from/to	DM by the Manufacturer.

List Detail Fields

Field Name	Description
Manufacturer	the name of the Manufacturer of the DM
Trade Name and Model	The name of the DM as given by the manufacturer
Exclusive use /Non-exclusive use	Indicates if the DM to be linked, has an exclusive use, regarding the "Parent " DM
Reason for Exclusivity	Reason for its exclusiveness
Device status	The status of the DM in the database. It can change status in the following order: L: Processing V: Valid P: Published

Operations available:

Action	Description	Page Name
Search	Runs a search with criteria put in place and displays the DM list or list of Non-DM products that match the same criteria	Same
Reset	Clears the search criteria previously put in place	Same
Save	Saves the actions carried out by the user	Necessary DM Management List
Dm in minimal form Insertion	Opens a window where the user has the option to insert a CE marked DM in a minimum form which has not been notified in a regular form by the relative manufacturer yet. The button is present only if the device sought is in the data bank.	DM in minimal form Insertion Look Up



2.4.1.3.1.5.4 Search of DMs notified in minimal form to be added as necessary for the functioning of the device

This page can be activated by clicking the “Enter” button present on the page containing the list of the devices needed, and allows the user to set search criteria to view the list of the DMs notified in regular or minimal form to be added as necessary for the functioning of the device.

The user must decide whether he wants to search DMs or DMs in minimal form. Depending on his/her choice, the page will present the user with different search criteria.

There are two options:

- DM
- EC marked device notified in minimal form

In this paragraph we will examine the case in which the user wishes to search among the DM notified by the same system or kit manufacturer in a minimum form.

In the upper section of the page, the principal data of the DM are displayed as well as the “Medical Device General Data” link which opens the page containing the general data of the DM.



User Manual DM Manufacturer Profile



Home > Class I, II a /b, III Medical Devices > Medical Device (DM) > Any other DM needed for the operation ?

DM List Search

Trade name and model: BAYE VECHIO DM

Code assigned by the manufacturer (catalogue identifier): X122

Manufacturer: BAYER

System progressive attributed to DM: 10428

[Medical Device general data](#)

Search

Search: ☐ DM ☒ DM IN MINIMAL FORM

Manufacturer:

Trade name:

Description:

Notified Body Code - Name:

[Reset](#) [Search](#)

Search Detail Fields

Field Name	Description
Search	The user must decide whether he wants to search DMs or DMs in minimal form. Depending on his/her choice, the page will present the user with different search criteria.
Trade Name	Name assigned to the device
Description	Description of the device
Manufacturer	Name of the manufacturer of the device
Notified Body - Code - Name	Code and name of the notified body. This field cannot be edited. To select the code of the notified body it is necessary to click on the "Search" link; a page in a look-up format will open with the option to search for the notified body by code and name

Operations available:

Action	Description	Page Name
Search	Runs a search with criteria put in place and displays the DM list or list of Non-DM products that match the same criteria	Same.



New search	Clears the search criteria previously put in place	Same.

2.4.1.3.1.5.5 Searched notified in minimal form DMs list

This page displays the list of the DMs notified in minimal form to be correlated according to the criteria set in the search page.

In the upper section of the page, the principal data of the DM are displayed as well as the “Medical Device General Data” link which opens the page containing the general data of the DM.

Once the DM to be linked have been selected, The “Exclusive use/Non-exclusive use” and “Reason for Exclusivity” fields will automatically become unblocked.



User Manual DM Manufacturer Profile



Home > Class I, II a /b, III Medical Devices > Medical Device (DM) > Any other DM needed for the operation ?

Search Any other DM needed for the operation

Trade name and model: CNDPROVA1

Code assigned by the manufacturer (catalogue identifier): 101010

Manufacturer: BAYER

System progressive attributed to DM: 10372

[Medical Device general data](#)

Research criteria

Search: DM ☐ DM IN MINIMAL FORM ☒

Manufacturer:

Trade name:

Description:

Notified Body Code - Name:

[Search](#)

[Reset](#)

Manufacturer	Trade name and model	Exclusive use/ Non-exclusive use	Reason for exclusivity (To value selecting the image)	Select
fab Dm minimo	dm minimo	Exclusive use v		☐

Page 1 of 1

Device status: L=IN LAVORAZIONE C=CONSOLIDATO V=VALIDATO P=PUBBLICATO U=CANCELLATO D'UFFICIO

Select: To add a component, click on one of the squares beside component(s) in the list.



User Manual DM Manufacturer Profile



Search Detail Fields

Field Name	Description
Search	The user must decide whether he wants to search DMs or DMs in minimal form. Depending on his/her choice, the page will present the user with different search criteria.
Trade Name	Name assigned to the device
Description	Description of the device
Manufacturer	Name of the manufacturer of the device
Notified Body - Code – Name	Code and name of the notified body. This field cannot be edited. To select the code of the notified body it is necessary to click on the “Search” link; a page in a look-up format will open with the option to search for the notified body by code and name

List Detail Fields

Field Name	Description
Manufacturer	the name of the Manufacturer of the DM
Trade Name and Model	The name of the DM as given by the manufacturer
Exclusive use /Non-exclusive use	Indicates if the DM to be linked, has an exclusive use, regarding the “Parent ” DM
Reason for Exclusivity	Reason for its exclusiveness

Operations available:

Action	Description	Page Name
Search	Runs a search with criteria put in place and displays the DM list or list of Non-DM products that match the same criteria	Same.
New search	Clears the search criteria previously put in place	Same.
Save	Saves the actions carried out by the user	Necessary DM Management List



2.4.1.4 DM Editing

The edit feature of a DM in “In progress” phase or “Consolidated” can be activated with the selection, from the DM list, of the device whose information the user intends to edit by clicking in the “Edit” button. Following the completion of these actions, the general data page appears and on it the side menu displays menu options which open the data page of each DM, in editable mode, in order to insert/edit the DM.

For the description of the data pages, see parg. 2.4.1.3.1.

If the device selected for the editing is part of a group of DM similar among them, the editing of any kind of datum – common to the group – implies a differentiation of the selected DM compared to the other similar ones unless the same editing is done to the others too.

Taking into consideration the propable impossibility to edit the validated and published devices, three situations appear:

1. DM similar to the selected one are all validated or published
In this case the editing of one device can not be carried over the others, thus the relation between the DM selected and the group of the similar ones gets eliminated.
Clicking on the “Save” button, present on some detail pages (General data, technic card, documentation,...), the following message can be visualized by the manufacturer

The medical device you wish to modify is similar to published devices or to those in process of being published. Applying the modification will cause any similarity links to be lost.
Proceed with the modification?

Yes **Cancel**

In case if the manufacturer wants to continue editing of the device, it won't be similar to the group of the devices any more.

2. All the DM similar to the selected one are all in processing or consolidated
In this case the editing of the device can be carried over the other ones; thus the selected device will continue to be part of a group of DM similar among them.
Clicking on the “Save” button present on various detail pages (General data, technic card, documentation,...) the following message is shown to the manufacturer:

The medical device you wish to modify is similar to those in progress or consolidated. Do you wish to apply the modifications also to these similar devices?

Yes **No** **Cancel**



Thus the manufacturer will be able to decide whether to edit all the other devices similar to the selected one or edit only one single device rendering it not similar to the other ones any more.

3. The DM similar to the selected one are partially in processing or consolidated and partially validated and published.

In this case editing of the device can be carried over only a part of the DM similar to this one (in processing or consolidated).

Clicking on the "Save" button, present on the various detail pages (General data, technic card, documentation,...) the following message is shown to the manufacturer:

The medical device you wish to modify is similar to published devices or to those in process of being published. Applying the modification will cause any similarity links to be lost..
The information appears similar to medical devices in progress or consolidated. Do you wish to apply the modification to these devices?

The selected device, having been edited, won't be similar to the group of the DM validated or published, for the group of those in processing or consolidated instead, the manufacturer will be able to decide whether to edit them in the same way or not, excluding thus the selected device from the group of the similar ones.



2.4.1.5 Similar DM Insertion

This function allows the user to insert “quickly” the medical devices similar to some others already present in the data base. It is necessary for the inserted DM to have the same characteristics as the starting one but differing from it in the following:

- Code assigned by the manufacturer
- Trade name
- Measurement
- Label

The functionality of the quick insertion of the similar devices differs logically from the copying: in fact, the DM inserted quickly make a real “group” of the devices having a nucleus of common information, which get activated by the same processes and using the same functions.

In the specific, activating a device which is part of a similar DM group, the functionalities which can intervene contemporaneously on the whole group, are the following:

- modification
- detail
- consolidation
- validity
- off-trade

To insert the devices similar to the one already present in the data entry it is necessary to do the following:

1. Activate the DM search (from the option in the menu “Medical Device (DM)”, setting the search criteria and thus selecting the “Search” button).
2. Select a DM having the necessary characteristics – notwithstanding its status
3. Click on the “Insert similar Dm” button.

Following clarification of Ministry of Health on the decree 21 dicembre 2009, in the case that selected DM is of class I or IIA and the file containing Instruction for Use is not uploaded for it, the system present the message “**N.B.: for class I and IIA DM file containing Instruction for Use must be uploaded if DM is accompanied by**”. That is, the Declarant must upload the file of Instruction for Use if the device is accompanied by but the system can’t control it. In the case that file is not uploaded, the device data signed by Declarant will contain “**Device is not accompanied by Instruction for Use**”.



Home > Class I, II a /b, III Medical Devices > Medical Device (DM) > Similar Medical Device Characteristics Data ?

Similar Medical Device Characteristics Data

Similar Medical Device Characteristics Data

*Trade name and model:

*Code assigned by the manufacturer (catalogue identifier):

Measure (where applicable):

* Label : (max size 2MB)

System progressive attributed to DM	Manufacturer	Code assigned by the manufacturer	Trade name and model	Measure (where applicable)	Label
9962	BAYER	A02	DISPOSITIVO MEDICO		prova1.pdf

Page 1 of 1

It recommends to use contained file size to facilitate consultation.

In the underlying part of the page of the insertion of a DM similar to the other one, there is a list of devices which share the same common information.

Detail Fields

Field Name	Description
Trade Name and Model	Denomination assigned by the DM manufacturer
Code assigned by the manufacturer (identifier catalogue)	Univocal code assigned by the DM manufacturer
Measure (where applicable)	Indications of the measurable parameters being used actually and present in the commercial catalogues with the relative measurement DM units.
Label	Pdf file to be attached containing the DM label. To attach the file it is necessary to use the "Browse" button. There is a limit to the dimension of the .pdf file to be attached to the DM (in the sample picture, such limit equals 2 MB); for the maximum size allowed, refer to the corresponding value shown by the application

User Manual
DM Manufacturer Profile*Operations available:*

Action	Description	Page Name
Save	Saves the digitized information, inserting in the data base a new DM similar to the starting one (equal in everything except the four points of information digitized on this page by the manufacturer), proposes again the same page to insert a new similar DM and updates the underlying list.	Same
Back	Comes back to the DM list page.	Dm List Page



2.4.1.6 Similar DM Editing

This function allows the user to edit the characteristic data of a medical device – in processing or consolidated – which is part of a group of similar DM.

To modify the characteristic data of a DM similar to the others, the user must proceed as follows:

1. Run the DM search (from the “Medical Device (DM)” option in the menu, specifying the search parameters and then clicking on “Search” button
2. Choose a DM in processing or consolidated which is part of a group of similar DM
3. Click on the “Edit Similar Dm” button

Following clarification of Ministry of Health on the decree 21 dicembre 2009, in the case that selected DM is of class I or IIA and the file containing Instruction for Use is not uploaded for it, the system present the message “**N.B.: for class I and IIA DM file containing Instruction for Use must be uploaded if DM is accompanied by**”. That is, the Declarant must upload the file of Instruction for Use if the device is accompanied by but the system can’t control it. In the case that file is not uploaded, the device data signed by Declarant will contain “**Device is not accompanied by Instruction for Use**”.



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Home > Class I, II a /b, III Medical Devices > Medical Device (DM) > Similar Medical Device Characteristics Data ?

Similar Medical Device Characteristics Data

Similar Medical Device Characteristics Data

System progressive attributed to DM: 10366

***Trade name and model:** NOME SIMILE 9962

***Code assigned by the manufacturer (catalogue identifier):** COD SIMILE 9962

Measure (where applicable): MIS SIMILE 9962

*** Label :** firmaDm.pdf [Cancel](#)

System progressive attributed to DM	Manufacturer	Code assigned by the manufacturer	Trade name and model	Measure (where applicable)	Label
9962	BAYER	A02	DISPOSITIVO MEDICO		prova1.pdf
10366	BAYER	COD SIMILE 9962	NOME SIMILE 9962	MIS SIMILE 9962	firmaDm.pdf

Page 1 of 1

It recommends to use contained file size to facilitate consultation.

[Save](#) [Back](#)

In the lower part of the page there is a list of the devices similar to the one being in the process of editing.

Detail Fields

Field Name	Description
Trade Name and Model	Denomination assigned by the DM manufacturer
Code assigned by the manufacturer (identifier catalogue)	Univocal code attributed by the DM manufacturer
Measure (where applicable)	Indications of the measurable parameters being used actually and present in the commercial catalogues with the relative measurement DM units.
Label	Pdf file to be attached containing the DM label. To attach the file it is necessary to use the "Browse" button. There is a limit to the dimension of the .pdf file to be attached to the

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	DM (in the sample picture, such limit equals 2 MB); for the maximum size allowed, refer to the corresponding value shown by the application

Operations available:

Action	Description	Page Name
Save	Saves the digitized information	Same
Back	Comes back to the DM list page	DM List page



2.4.1.7 New notification of a DM in the “Published” status

This feature allows to notify again a Medical Device (against major changes applied to the Manufacturer’s data) already in the “Published” status, stating the reason of this new notification and keeping the connection with the original source DM. The new Device will be created as a copy of the original source DM.

To notify again a medical device, the user needs to:

1. activate the DM search (from the ‘Medical Device (DM)’ menu option, setting first the search parameters, and then selecting the ‘Search’ button
2. select a DM in the “Published” status
3. click on the “New notification” button

Home > Class I, II a /b, III Medical Devices > Medical Device (DM) > New notification ?

New notification

System progressive of the linked DM:

Reason for new notification:

[Save](#) [Back](#)

Detail Fields

Field Name	Description
System progressive of the linked DM	Progressive assigned by the system to the DM to be notified again. The field is not editable, and is evaluated by means of the system progressive of the selected DM in the page of the DMs list
Reason for new notification	The reason why a DM is notified again. Amongst such reasons, there might be: • Change of the Manufacturer’s name • Change of the Manufacturer's VAT number • Cession of a manufacturing firm branch • Manufacturing firm merging/acquisition

User Manual
DM Manufacturer Profile*Operations available:*

Action	Description	Page Name
Save	Saves all typed information, entering a new DM in the database as a copy of the original source DM, while keeping the connection with it, and then directs to the details pages of the DM entered in editable mode	Details pages of the DM in editable mode
Back	Go back to the DM list page	DM list



2.4.1.8 DM data consolidation

This page allows the user to view the DM which have begun the process of data approval from the DMs selected. The approval activates a series of congruity and consistency tests on the released data and any errors discovered are noted on the activity list page. If no errors are found, the status of the DM changes to "Consolidated" and it is therefore possible to activate the validation of the device by means of an electronic signature.

Home > Class I, II a /b, III Medical Devices > Medical Device (DM)
?

Medical Device (DM)

Consolidating DM List					
System progressive attributed to DM	Manufacturer	Code assigned by the manufacturer Code assigned by the manufacturer	Trade name and model	CND classifications	Consolidation process status
10022	BAYER	123	PROVA2	L1108 - LEVE PER NEUROCHIRURGIA	Started

To verify the result of consolidation, use the "Go to activities list" button.

Go to activities list

DM List in approval phase Detail Fields

Field Name	Description
System	Unique identification number assigned to each DM in index.



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Progressive attributed to DM	
Manufacturer	Corporate name of the DM Manufacturing Company
Code assigned by the manufacturer (identifier catalogue) from/to	Code attributed to the DM by the manufacturing company (better known as the identification catalogue)
Trade Name and Model	Commercial name or model of the DM
Validation process status	The status of the process. It can change status in the following order: - Initiated - Uninitiated

Operations available:

Action	Description	Page Name
Go to activities list	Allows user to return to the activity list	Activities List

If the medical device selected for consolidation has any similar DM in the same state “in progress”, the manufacturer gets preliminarily directed to the page containing the list – with selectable elements – of these similar devices for which the consolidation operation could be contemporaneously activated. Choosing from the list one or more similar DM and clicking on the “Consolidate” button, the system activates the consolidation process not only of the starting device but of all selected ones too.

Home > Class I, II a /b, III Medical Devices > Select Similar Medical Devices from Consolidate
?

Select Similar Medical Devices from Consolidate

Group

System progressive attributed to DM: 10366

The medical device you want to consolidate is similar to the following DM worked.
Select from the list the devices with which to start the process of consolidating.

System progressive attributed to DM	Manufacturer	Trade name and model	Code assigned by the manufacturer	Measure (where applicable)	Select
10367	BAYER	NOME ALTRO SIM 9962	COD ALTRO SIM 9962		☐

Confirm

*Operations available:*

Action	Description	Page Name
Confirm	Allows the user to consolidate not only the starting DM but all the selected ones from the list too.	Detail page about the Starting process status

The consolidation of a DM won't be successful (the DM will remain in L0 state) if:

- there is at least one certificate notified by a Declarant and without an expiry date connected to the DM¹⁰ (unless it's related to the annex IV/4¹¹);
- there is at least one expired certificate linked to the DM (irrespective of the fact that such certificate has been notified by the Declarant itself or by an Italian ON¹²);
- there is at least one certificate notified by a Declarant with the option "The certificate is relative only to the EC Directive 2003/32", as this option is no longer available.

In all these cases, the DM will remain in processing status and the user will be notified of the impossibility to complete the process with appropriate error messages in the "List of activities". Such messages will also show the number of the related certificate.

¹⁰ The case of certificates notified by Italian OONNs isn't discussed because, in the past, the date of expiry of such certificates has always been mandatorily required upon their notification. Only from now on, it will be possible to omit this date if the ON selects one of the following voices from the field 'Annex according to which the device was certified'

- Directive 93/42/EEC Annex IV
- Directive 90/385/EEC Annex 4

¹¹ The new rules allow an empty date of expiry for the certificates only if the field 'Annex according to which the device was certified' has the value 'Annex IV/4'.

¹² Specifically, the halting check on the expiry date of the certificate starts when the expiry date has a value which is less than the current date, but **is not performed** if the certificate's annex is the IV/4 (or if it's equal to the values of the 'Directive 93/42/EEC Annex IV' and 'Directive 90/385/EEC Annex 4' for certificates notified by Italian OONNs) even if a date of expiry is specified.



2.4.1.9 Download file for off line DM signature

This page is activated by clicking on the "Off line sign" button which is found on the page of the DM list and allows the user to activate the off line signature process of data.

The 'Off line signature' consists of three steps:

1. The user downloads the file in txt format on his computer; this file, automatically generated by the system, contains all the information previously entered. It is possible to simultaneously sign multiple medical devices; to activate the download it is enough to click on the link in this page.
2. The user then proceeds to sign the above mentioned files by using the software he/ she already owns in order to use his/ her signature device (smart card or other device). For the realization of this step it is not necessary to be connected to the "Data Bank and Repertoire of Medical Devices" system.
3. the user uploads the signed file on "Data Bank and Repertoire of Medical Devices" system through the appropriate **upload function** accessible from the menu item "**Off line Signature**".



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Home > Company Data > Off Line Signature		?
Off Line Signature		
Off Line Signature - Off Line Signature - The 'Off line signature' function allows the user to sign the application data locally on his computer, using any digital signature certificate issued by a national certification authority accredited in compliance with Directive 1999/93/EC. - The 'Off line signature' consists of three steps: - download of the file, in txt format, containing all the information on which the digital signature must be affixed (Company's Data, Medical Devices and Systems/Kits notified); - local signature of the file; - upload of the signed file through the appropriate upload function accessible from the menu item "Off line Signature." - For a successful completion of the Off line Signature process it is necessary that: - The user who uploads the file is the same who downloaded it; - The name of the file generated by the system during the download phase is not changed, with the exception of its extension: the digital signature procedure will indeed generate a file with the same name as the original one and with "p7m" extension. The user need only check that the signed file has the "p7m" extension and not, for example, "txt.p7m" (in this case it suffices to cancel the delete "txt"); - The data subject to digital signature (*) are not changed between the time of the download and the subsequent upload. (*) Please note that in case of signature of Medical Devices and Systems /Assembled Kits, the data subject to signature include the name of the Manufacturer / Agent / Marketing Responsible/ Other deputed subject, the EC certificate, the Medical Devices necessary to the operation and the components of the systems / Kits DatiAzienda07022009172817232		

If the medical device selected for the off line signature is similar to other DM in the same state "Consolidated", the manufacturer gets preliminarily directed to the page containing the list – with selectable elements – of these similar devices for which the same process could be contemporaneously activated. Choosing one or more similar DMs from the list and clicking on the "Off line sign" button, the system allows the user to download a txt file containing the data of all selected DM.



Home > [Class I, II a /b, III Medical Devices](#) > Select Similar Medical Devices from Validate ?

Select Similar Medical Devices from Validate

Group

System progressive attributed to DM:

The medical device you want to validate is similar to the following DM consolidated.
Select from the list the devices with which to start the process of validation.

System progressive attributed to DM	Manufacturer	Trade name and model	Code assigned by the manufacturer	Measure (where applicable)	Select
10367	BAYER	NOME ALTRO SIM 9962	COD ALTRO SIM 9962		☐

[Confirm](#)

Operations available:

Action	Description	Page Name
Confirm	Allows the user to access the page of download of txt file containing DM data	Off line signature download page



2.4.1.10 DM Commercial data update

This function allows the user to insert new commercial data of a DM in the status Validated or Published.

It is necessary to do the following:

1. Activate the DM search (from the voice menu 'Medical Device (DM)' compiling the search criteria fields and then select the 'Search' button
2. Select a DM in the status 'Validated' or 'Published'
3. Click on the 'Trade Data Update' button



Home > Class I, II a /b, III Medical Devices > Medical Device (DM) > Commercial Data ?

Update Commercial Data

Trade name and model: GG100

Code assigned by the manufacturer (catalogue identifier): DGDGD

Manufacturer: BAYER

System progressive attributed to DM: 10188

[Medical Device general data](#)

Actual data

Last update: 20/05/2008

Unit price list of single device without VAT: **%VAT:**

Presence of bar code:

The amounts are expressed in Euro

DM sale data

DM year of sale	No. of pieces sold to the SSN	Type of data	No. of pieces sold to the remaining market	Type of data
Insert other sale datum				

SSN includes: local health companies, hospitals, accredited public and private facilities

This page visualizes the general data of the device (status Validated or Published) selected on the search page, visualizes the device eventual sale data already inserted and allows to insert other sale data for the device in question and to update the list price and the IVA percentage.

It is impossible to modify the device sale data visualized and inserted before the device has been published or validated.

Selecting the button "Insert Other Trading data" a new line appears where the user can write the new sale data.



Commercial data update Fields Detail

Field Name	Description
Actual data	
Unit price of the list of single device without VAT	The unit sale price of a DM free of tax
% IVA	Indication of the IVA applied to the DM sale price
Presence of bar code	Indication as to whether or not the DM bears a barcode
DM sales data	
DM year of sale	Indication of the year DM was sold
No. of pieces sold to SSN	Indication of the DM pieces number sold to the SSN. This field is obligatory if the sale year has been inserted.
Data Type	Indication as to whether or not the data type (pieces number sold to the SSN) is respected and effective. This field is obligatory if the sale year has been inserted.
No. of pieces sold to the remaining market	Indication of the DM pieces number sold (pieces sold to the SSN excluded). This field is obligatory if the sale year has been inserted
Data Type	Indication as to whether the data type (number of pieces sold to the rest of the market) is respected or effective. This field is obligatory if the sale year has been inserted

Operations available

Action	Description	Page Name
Insert Other Trading data	Adds a new line where the user can insert the commercial information of a DM relatively to the sale year	Same.
Save	Saves the information inserted.	Same.



2.4.1.11 DM enclosed documentation update

This function allows to update the label, the usage instructions and the Data sheet of a medical device after it has been published.

It is necessary to do the following operations:

1. Activate the DM search (from the voice menu 'Medical Device (DM)', filling the search criteria fields and select the button 'Search')
2. Select a DM in 'Published' status
3. Click on the button 'Documentation Update'

Following clarification of Ministry of Health on the decree 21 dicembre 2009, in the case that published DM is of class I or IIA and the file containing Instruction for Use is not uploaded for it, the system present the message "**N.B.: for class I and IIA DM file containing Instruction for Use must be uploaded if DM is accompanied by**". That is, the Declarant must upload the file of Instruction for Use if the device is accompanied by but the system can't control it. In the case that file is not uploaded, the device data signed by Declarant will contain "**Device is not accompanied by Instruction for Use**".



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Home > Class I, II a /b, III Medical Devices > Medical Device (DM) > Documentation ?

Update Documentation

Trade name and model: ANELLO ACETABOLARE DI RINFORZO CON GANCIO

Code assigned by the manufacturer (catalogue identifier): ARG0056

Manufacturer: MINISTERO DELLA SALUTE

System progressive attributed to DM: 185

[Medical Device general data](#)

Document	File to attach	Save / Delete File
Label	Sfoglia... (max size 5MB)	Save File
Instructions for Use	Sfoglia... (max size 104MB)	Save File
Data sheet	Sfoglia... (max size 5MB)	Save File

Please enter the reasons that led to amending the documentation

Notes

It recommends to use contained file size to facilitate consultation.

[Save](#) [Sign Off line](#)

This page displays the general data of the device selected on the search page and allows to attach the new label files, the instructions for use and the technical sheet. Notes on the reasons for update can also be entered such as, for example: changing the logo, inserting a new warning etc..

Documentation Update Field Details

Field Name	Description
Label	Pdf file to be attached containing the DM label. To attach this file it is necessary to use the button 'Browse'. There is a limit to the dimension of the .pdf file to be attached to the DM (in the sample picture, such limit equals 2 MB); for the maximum size allowed, refer to the corresponding value shown by the application
Instructions	Pdf file to be attached containing the DM usage instructions. To attach this file it is necessary to use the button 'Browse'. There is a limit to the dimension of the .pdf file that is attached to the DM (in the sample picture, such limit equals 2 MB); for the maximum size allowed, refer to the corresponding value shown by the application
Data sheet	Pdf file to be attached containing the DM data sheet.. To attach this file it is necessary to use the button 'Browse'. There is a limit to the dimension of the .pdf file to be attached to the DM (in the sample picture, such limit equals 2 MB); for the maximum size allowed,



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	refer to the corresponding value shown by the application
Notes	Notes indicating the reasons for update of the documentation.

Operations available:

Action	Description	Page Name
Save file	Allows to upload the attached file	Same
Delete	Allows to delete the attached file	Same
Open	Allows to download the attached document	
Save	Saves the information inserted and brings up to signature page of the device modified in this way	Dm signature page
Off line sign	Allows the user to save the information inserted and bring user to off line sign page	Off line signature page



2.4.1.12 Update of the list of DMs needed for functioning

This feature allows to update the list of DMs needed for the functioning of a Medical Device after its publication, as long as during the DM notification stage the “Yes” value has been reported in the section “Relations to other DMs” of the “General data” page, in correspondence with the field “

To carry out its functions, the DM needs other DMs.

To update the list of DMs needed for the functioning of a device in the “Published” status, the user shall:

1. activate the DM search (from the ‘Medical Device (DM)’ menu option, setting first the search parameters, and then selecting the ‘Search’ button”);
2. select a DM in the “Published” status;
3. click on the “Needed DMs” button
4. the system will direct the user to the details pages of the selected device (all in non editable mode, except for the “Other possible DMs needed for functioning” tab)
5. click on the “Other possible DMs needed for functioning” menu option

As to the entry and change of the Devices needed for the functioning, consult the paragraph titled “Other possible DMs needed for functioning”.

Post publication change of the DMs needed shall not be signed, and the previous data are not recorded.



2.4.1.13 Update Agent (Authorized Representative)

From this page, it is possible to update the Agent (Authorised Representatives) of a medical device after its publication, as long as during the DM notification stage an Agent had been declared. This can be activated from the page of the list of DMs, selecting a device in the “Published” status for which an Agent had been declared, and clicking on the “Agent update” button.

Home > Class I, II a /b, III Medical Devices > Medical Device (DM) > New notification ?

New notification

Trade name and model: HUIHUIUH

Code assigned by the manufacturer (catalogue identifier): YUIYUI

Manufacturer: BAYER STORIC NEW

System progressive attributed to DM: 10003

[Medical Device general data](#)

New Agent: [Search](#)

The first page will display the general data of the selected device in the search page, and allows to enter the new Agent, by selecting it from the associated companies.

As the new Agent is saved, the user is automatically redirected to the signature page. As an alternative, the user may sign the update by means of the “Offline signing”: as the user clicks on this button, he/she will be redirected to the download page for the file to be locally signed that contains the data to be saved in the database.

Field Details

Field Name	Description
Agent	New DM Agent name. The field is not editable, and the value can be selected by clicking on the "Search" link; a look-up will open allowing the user to search and select the Agent.

Operations available:

Action	Description	Page Name
Save	Saves the new Agent, recording its former name and directs the user to the signature page of the so modified	DM signature

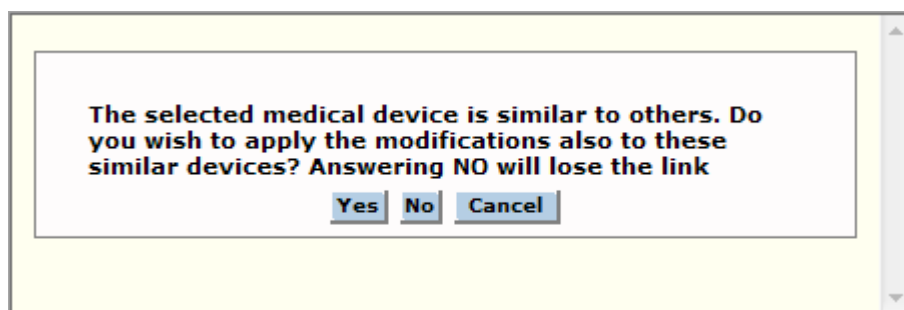


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Action	Description	Page Name
	device	
Off line sign	Allows the user to save the information inserted and bring user to off line sign page	Off line signature page
Back	Comes back to the DM list page.	Dm List Page

If the selected medical device has similar DMs that share the same features with the exception of their trade name, code, size and label, once the new Agent is saved, the user will be asked to change this information even in similar DMs or only in the selected device.



Operations available:

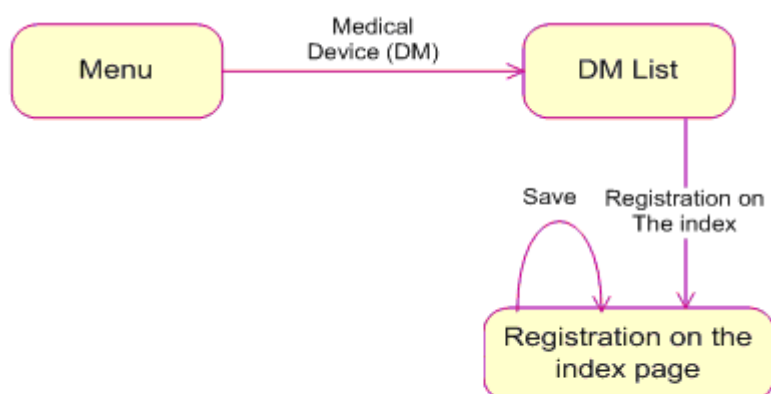
Action	Description	Page Name
Yes	Modifies all DMs similar to the one selected by entering the same Agent, closes the dialog box and directs the user to the signature page of such modified DMs.	DM signature
No	Exclusively modifies the selected device, releasing it from the group of similar DMs it belonged to, closes the dialogue box and directs the user to the signature page of such update DM.	DM signature
Cancel	Closes the dialogue box	Agent update



2.4.1.14 DM registration in the Medical Device Repertoire

In order to register a DM on the index, the user must proceed as follows:

1. Run the DM search (from the “Medical Device (DM)” option in the menu, specifying the search criteria and then clicking on “Search”);
2. Select one or more DM in “Validated” or “Published” status
3. Click on “Repertoire subscription”



This page allows the user to register Medical Devices selected in the repertoire declaring they will be distributed to the facilities of the National Health Service. Only after having done this, the system can register the devices as part of the index.

The same page may be recalled to cancel the registration from the Repertoire of one or more Medical Devices that were previously registered.

For those DMs that are registered in the Repertoire, the ID assigned by the system will be followed by the “/R” character.

The index contains a collection of information supplied by Manufacturers; each Manufacturer assumes full responsibility for the information supplied, be it for the general data as for that regarding single Medical Devices. The publication of data does not represent the approval of the Ministry of Health in any form. The executive management of pharmaceutical products and medical devices reserve the right to carry out an inspection on what has been declared, at any time, as laid out in the legislative decree February 24 1997, No.46

The way a page recalled by the “Repertoire registration” button is displayed depends on different scenarios:

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- the user selects one single DM and the selected DM does not belong to a group of similar DMs.
- the user selects one single DM and the selected DM belongs to a group of similar DMs.
- the user selects more DMs¹³.

All possible scenarios are fully described below. In order to provide a full description, the list of fields displayed on the page and of all available operations will be repeated for each scenario, along with their respective peculiarities.

Regardless of the scenario to be applied, in order to be registered in the Repertoire, a DM entered in the database needs to be in the Validated or Published status.

First scenario

If the user selects one single DM that has not yet been registered in the Repertoire and if the selected DM does not belong to a group of similar DMs, the system will display the following page:

Repertoire registration

Trade name and model: STELO OCEANE+ 12/14 CEM LAT T.4
Code assigned by the manufacturer (catalogue identifier): HCO414
Manufacturer: TORNIER S.A.
System progressive attributed to DM: 288652/R

[Medical Device general data](#)

Will this device be distributed to the facilities of the National Health Service?
YES ▼

In the upper part of the page, the DM main data are displayed along with the "General data" link allowing the user to access and view the device general data.

Once registered, a Medical Device can be cancelled by using the same feature, switching the value beside the question "Will this device be distributed to the facilities of the National Health Service?" from "Yes" to "No".

¹³ The feature will be activated only if the user has selected DMs that are not registered in the Repertoire or that are already registered (to cancel their registration).



User Manual DM Manufacturer Profile



Detail Fields

Field Name	Description
Trade Name and Model	Commercial name or model of the DM
Code assigned by the manufacturer (identifier catalogue)	Code attributed to the DM by the manufacturing company (better known as the identification catalogue)
Manufacturer	Corporate name of the DM Manufacturing Company
System Progressive attributed to DM	Unique identification number assigned to each DM in the database . If /R appears next to the identification number assigned to the DM by the system, it means that the DM has been registered on the index.
Repertoire registration Flag	Flag showing the willingness or unwillingness to distribute the selected medical device to the facilities of the National Health Service (and as such to register it in the Medical Devices Repertoire). The default setting is "No" By selecting "Yes", the user shows their willingness to register the DM in the Repertoire. The same page may be recalled to cancel the registration from the Repertoire of a Medical Device that was previously registered. In that case, by accessing that feature, the flag value will already be equal to "Yes" (past registration) and the user may take the flag to the "No" value, thus showing their willingness to cancel the registration in the Repertoire of the DM.

Operations available:

Action	Description	Page Name



User Manual DM Manufacturer Profile



Update	If the user sets the Repertoire registration flag (see previous table) to “Yes”, by clicking the button, the DM in the form is registered in the Repertoire. If the Repertoire registration flag was previously set to “Yes”, and the user brings it back to “No”, by clicking the button, the DM in the form, is cancelled from the Repertoire.	Same
Back	Takes the user back to the DMs list page without proceeding with registration or cancellation in/from the Repertoire.	Dm List Page

Second scenario

If the initially selected DM that needs to be registered in the repertoire is similar, and has the same features (except the trade name, the code assigned by the manufacturer, the size and the label) to other validated or published devices, the registration page also presents the list – with selectable items – of said similar devices that can be simultaneously registered in the Repertoire (see next picture).



User Manual DM Manufacturer Profile



Repertoire registration

Trade name and model: HLS NOETOS REVISIONE FITTONE TIBIALE E FEMORALE DIAM.16 L.150MM

Code assigned by the manufacturer (catalogue identifier): GDF524

Manufacturer: TORNIER S.A.

System progressive attributed to DM: 260806

[Medical Device general data](#)

This medical device will be providing facilities of the National Health Service ?

The medical device is similar to the following DM published. Select from the list of the devices to which it applies the same statement.

Similar DMs

System progressive attributed to DM	Trade name and model	Code assigned by the manufacturer	Measure (where applicable)	Label	DM status	Select ☐
260810	HLS NOETOS REVISIONE FITTONE TIBIALE E FEMORALE DIAM.18 L.150MM	GDF525		GDF525_H.pdf	P	☐
260803	HLS NOETOS REVISIONE FITTONE TIBIALE E FEMORALE DIAM.14 L.150MM	GDF523		GDF523_H.pdf	P	☐
260798	HLS NOETOS REVISIONE FITTONE TIBIALE E FEMORALE DIAM.12 L.150MM	GDF522		GDF522_H.pdf	P	☐

Even in this case, devices belonging to a group of similar DMs that have been previously registered can be cancelled. The procedure is as follows:

- The user selects one single DM belonging to that group and activates the "Repertoire registration" feature;
- Switches the value beside the question "Will this device be distributed to the facilities of the National Health Service?" from "Yes" to "No".
- Extends cancellation to all similar devices shown on the same page or to a subgroup of theirs (by selecting them);
- Presses the update button to complete the cancellation from the Repertoire concerning the items of interest.

Detail Fields

Field Name	Description
Selected DM data	
Trade Name and Model	Commercial name or model of the DM
Code assigned by the manufacturer (identifier catalogue)	Code attributed to the DM by the manufacturing company (better known as the identification catalogue)



User Manual DM Manufacturer Profile



Field Name	Description
Manufacturer	Corporate name of the DM Manufacturing Company
System Progressive attributed to DM	Unique identification number assigned to each DM in the database . If /R appears next to the identification number assigned to the DM by the system, it means that the DM has been registered on the index.
Repertoire registration Flag	Flag showing the willingness or unwillingness to distribute the selected medical device to the facilities of the National Health Service (and as such to register it in the Medical Devices Repertoire). The default setting is “No” By selecting “Yes”, the user shows their willingness to register the DM in the Repertoire and may even extend the registration to all similar DMs in the form (or to a subgroup of theirs) by <u>selecting</u> them. The same page may be recalled to cancel the registration from the Repertoire of a Medical Device that was previously registered. In that case, by accessing that feature, the flag value will already be equal to “Yes” (past registration) and the user may take the flag to the “No” value, thus showing their willingness to cancel the registration in the Repertoire of the DM, and, if necessary, extend the cancellation to all similar DMs in the form (or to a subgroup of theirs) by <u>selecting</u> them.
Similar DMs List¹⁴	
Measure (where applicable)	Indication of the measurable criteria actually used and present in commercial catalogues with the corresponding unit of measurement of the DM
Label	File containing the label of the DM
DM status	The status of the DM in the database. This status can assume, in this case, the values: • V: Valid • P: Published

¹⁴ Only the fields that are not described in the table are present.



User Manual

DM Manufacturer Profile



Field Name	Description

Operations available:

Action	Description	Page Name
Update	If the user sets the Repertoire registration flag (see previous table) to “Yes”, by clicking the button, the DM in the form, and any other similar DM <u>selected</u> by the user, are registered in the Repertoire. If the Repertoire registration flag was previously set to “Yes”, and the user brings it back to “No”, by clicking the button, the DM in the form, and any other similar DM <u>selected</u> by the user, are cancelled from the Repertoire.	Same
Back	Takes the user back to the DMs list page without proceeding with registration or cancellation in/from the Repertoire.	Dm List Page

Third scenario

If the user selects more than one DM, and if such devices are no longer registered in the Repertoire, the system will display the following page:



User Manual DM Manufacturer Profile



Repertoire registration

Continuing this operation, all medical devices will be distributed to the National Health Service.

DM List

System progressive attributed to DM	Trade name and model	Code assigned by the manufacturer	Manufacturer	DM status	Similar DMs
438034	DYNACUP TAPPO FONDO COTILE	HLP036	TORNIER S.A.	P0	N
438055	DYNACUP INSERTO HXLPE STANDARD PER TESTE Ø22,22MM / COTILE 42AT	HLM801	TORNIER S.A.	P0	Similar
438214	DYNACUP INSERTO HXLPE STANDARD PER TESTE Ø22,22MM / COTILE Ø42ST Ø44AT	HLM802	TORNIER S.A.	P0	Similar
438233	DYNACUP INSERTO HXLPE STANDARD PER TESTE Ø22,22MM / COTILE Ø44ST	HLM803	TORNIER S.A.	P0	Similar

By activating the update button, the system will register in the Repertoire both the selected DMs (displayed on the page) and all similar DMs that are not yet registered in the Repertoire (which can be displayed by activating the 'Similar' button). To register in the Repertoire a subgroup of similar DMs, you only need to search a single DM belonging to the similar DMs group, and then once again activate the 'Repertoire registration' feature. For more details on the Repertoire registration feature, see the User Manual.

[Update](#) [Back](#)

The page will display the list of all selected DMs, and for each of them their belonging to a group of similar DMs, if any, (if the DM does not belong to a group of similar DMs, the last column will read "N" under the "Similar DM" field; if the DM belongs to a group of similar DMs, it will present the "Similar" button).

By activating the "Similar" button (beside a DM), if present, the system will show all DMs belonging to that group (except the one that is selected), their status and Repertoire registration¹⁵ status (see next picture).

¹⁵ DMs belonging to a group of similar DMs may all be displayed as both registered or not registered in the Repertoire. There can also be cases presenting a mixed situation, namely with both registered and not registered DMs. Such condition does not compromise the integrity of the group.



User Manual DM Manufacturer Profile



Presentation - Windows Internet Explorer

Home > Class I, II a

Repertoire regist

Continuing this

DM List

System progressive attributed to DM
438034
438055
438214
438233

By activating the that are not yet subgroup of simi 'Repertoire regis

Similar DMs

System progressive attributed to DM	Trade name and model	Code assigned by the manufacturer	Manufacturer	DM status	Repertoire registration
438214	DYNACUP INSERTO HXLPE STANDARD PER TESTE Ø22,22MM / COTILE Ø42ST Ø44AT	HLM802	TORNIER S.A.	P0	N
438233	DYNACUP INSERTO HXLPE STANDARD PER TESTE Ø22,22MM / COTILE Ø44ST	HLM803	TORNIER S.A.	P0	N
438234	DYNACUP INSERTO HXLPE STANDARD PER TESTE Ø22,22MM / COTILE Ø46AT	HLM804	TORNIER S.A.	P0	N
438235	DYNACUP INSERTO HXLPE STANDARD PER TESTE Ø22,22MM / COTILE Ø46ST Ø48AT	HLM805	TORNIER S.A.	P0	S
438236	DYNACUP INSERTO HXLPE STANDARD PER TESTE Ø22,22MM / COTILE Ø48ST Ø50AT	HLM806	TORNIER S.A.	P0	N
438237	DYNACUP INSERTO HXLPE STANDARD PER TESTE Ø22,22MM / COTILE Ø50ST Ø52AT	HLM807	TORNIER S.A.	P0	N
438239	DYNACUP INSERTO HXLPE STANDARD PER TESTE Ø28MM / COTILE Ø44ST	HLM811	TORNIER S.A.	P0	N
438240	DYNACUP INSERTO HXLPE STANDARD PER TESTE Ø28MM / COTILE	HLM812	TORNIER S.A.	P0	N

Fine

Intranet locale

Update Back

Once closed the (pop-up) window displaying the similar DMs, the user, by activating the “Update” button, declares all selected DMs will be distributed to the National Health Service: in this case, the system will register in the Repertoire both the DMs that have been selected starting from the search form (and that can be displayed on the page), and all DMs similar to such devices, in LV0/P0 status, that are not yet registered in the Repertoire¹⁶.

Finally, if the user selects more than one DM, and if such devices have been previously registered in the Repertoire, the system will display the following page:

¹⁶ In this case the user may select a subgroup of DMs to be registered. All DMs that are similar to the ones selected in LV0/P0 status, and that are not yet registered in the Repertoire, are automatically registered by the system. Instead, if the user wishes to register in the Repertoire only a subgroup of similar DMs, they need to search **only one DM belonging to that group** and then once again activate the "Repertoire registration" feature. This way, the second scenario will apply, and only some items of the group may be selected for distribution to the National Health Service.



User Manual DM Manufacturer Profile



Repertoire registration

Continuing this operation, all medical devices will no longer be distributed to the National Health Service.

DM List

System progressive attributed to DM	Trade name and model	Code assigned by the manufacturer	Manufacturer	DM status	Similar DMs
145475/R	DYNACUP COTILE PRESS FIT	HLM60X	TORNIER S.A.	P0	Similar
249886/R	DWB010 TAPPO METAFISIARIO AEQUALIS REVERSED FRATTURA	DWB010	TORNIER S.A.	P0	N
413594/R	DYNACUP COTILE PRESS FIT Ø 64MM	HLM614	TORNIER S.A.	P0	Similar
413613/R	DYNACUP COTILE PRESS FIT Ø 66MM	HLM615	TORNIER S.A.	P0	Similar

By activating the update button, the system will cancel registration in the Repertoire of both the selected DMs (displayed on the page) and all similar DMs that are already registered in the Repertoire (which can be displayed by activating the 'Similar' button). To cancel registration in the Repertoire of a subgroup of similar DMs, you only need to search a single DM belonging to the similar DMs group, and then once again activate the 'Repertoire registration' feature. For more details on the Repertoire registration feature, see the User Manual.

[Update](#) [Back](#)

The page will display the list of all selected DMs, and for each of them their belonging to a group of similar DMs, if any, (if the DM does not belong to a group of similar DMs, the last column will read "N" under the "Similar DM" field; if the DM belongs to a group of similar DMs, it will present the "Similar" button).

By activating the "Similar" button (beside a DM), if present, the system will show all DMs belonging to that group (except the one that is selected), their status and Repertoire registration status.

Once closed the (pop-up) window displaying the similar DMs, the user, by activating the "Update" button, declares all selected DMs will no longer be distributed to the National Health Service: in this case, the system will cancel the registration from the Repertoire of both the DMs that have been selected starting from the search form (and that can be displayed on the page), and all DMs similar to such devices that are already registered in the Repertoire¹⁷.

Detail Fields

Field Name	Description
System Progressive	Unique identification number assigned to each DM in the database .

¹⁷ In this case the user may not select a subgroup of similar DMs to be cancelled from the Repertoire. All DMs that are similar to the ones selected, and that are already registered in the Repertoire, will be automatically cancelled by the system. Instead, if the user wishes to cancel the registration from the Repertoire of only a subgroup of similar DMs, they need to search **only one already registered DM belonging to that group** of similar DMs and then once again activate the "Repertoire registration" feature. This way, the second scenario will apply, and only some items of the group may be selected to be cancelled from the registration.



User Manual DM Manufacturer Profile



Field Name	Description
attributed to DM	If /R appears next to the identification number assigned to the DM by the system, it means that the DM has been registered on the index.
Trade Name and Model	Commercial name or model of the DM
Code assigned by the manufacturer (identifier catalogue)	Code attributed to the DM by the manufacturing company (better known as the identification catalogue)
Manufacturer	Corporate name of the DM Manufacturing Company
Device status	The status of the DM in the database. This status can assume, in this case, the values: • V: Valid • P: Published

Operations available:

Action	Description	Page Name
Similar	Opens the (pop-up) page displaying DMs similar to the one of interest. The page will display the following data: • System progressive attributed to the DM; • Trade name and model; • Code assigned by the manufacturer (catalogue identifier); • Manufacturer; • Device status; • Repertoire registration (Y/N).	Similar DMs
Update	If the source DMs are not registered in the Repertoire, by activating the button, the user registers those, and this will automatically register all similar DMs in LV0/P0 status that may be present and that are not yet registered ¹⁸ ; If the source DMs are registered in the Repertoire, by activating the button, the user cancels their registration, and this will automatically cancel the registration of all similar DMs that may be present and that are already registered ¹⁹ ;	Same
Back	Takes the user back to the DMs list page without proceeding with registration or cancellation in/from the	Dm List Page

¹⁸ In this case, similar DMs in LV0/P0 status are all automatically registered, and the user cannot select only one subgroup for the registration.

¹⁹ In this case, similar DMs are automatically cancelled from the Repertoire, and the user cannot select only one subgroup for cancellation.

User Manual
DM Manufacturer Profile

Action	Description	Page Name
	Repertoire.	



2.4.1.15 DM off-trade statement

This page allows the user to insert/edit the off-market date of one or more Medical Devices in “Validated” or Published” status.

To enter/update this date, proceed as follows:

1. Run the search for the DM (from the “Medical Device (DM)” option on the menu, setting the search parameters and clicking on the "Search" button);
2. Select one or more Medical Devices in “Validated” or “Published” status;
3. Click on “Off-Trade” button;

The way a page recalled by the “Off-Trade” button is displayed depends on different scenarios:

- the user selects one single DM and the selected DM does not belong to a group of similar DMs.
- the user selects one single DM and the selected DM belongs to a group of similar DMs.
- the user selects more DMs.

All possible scenarios are fully described below. In order to provide a full description, the list of fields displayed on the page and of all available operations will be repeated for each scenario, along with their respective peculiarities.

Regardless of the scenario to be applied, to enter/update the off-trade date of a DM registered in the database, that DM must be in the Validated or Published state.

First scenario

If the user selects one single DM for which a previous off-trade date has not been entered and if the selected DM does not belong to a group of similar DMs, the system will display the following page:



User Manual DM Manufacturer Profile



Home > Class I, II a /b, III Medical Devices > Medical Device (DM) ?

Off-trade

Trade name and model: ETL_TEST_FAB_220M

Code assigned by the manufacturer (catalogue identifier): ETLTSTFAB220M

Manufacturer: MINISTERO DELLA SALUTE

System progressive attributed to DM: 480728

[Medical Device general data](#)

Off-trade date: 20 / 12 / 2012

In the upper part of the page, the principal data of the DM are displayed as well as the “Medical Device General Data” link which opens the page containing the general data of the DM.

Once an off-trade date has been declared, it can be updated using the same feature and editing the value which will appear when the web page opens.

Detail Fields

Field Name	Description
Trade Name and Model	Commercial name or model of the DM
Code assigned by the manufacturer (identifier catalogue)	Code attributed to the DM by the manufacturing company (better known as the identification catalogue)
Manufacturer	Corporate name of the DM Manufacturing Company
System Progressive attributed to DM	Unique identification number assigned to each DM in the database . If /R appears next to the identification number assigned to the DM by the system, it means that the DM has been registered on the index.
Off-Trade date	Off-market date of DM.

Operations available:

Action	Description	Page Name
Update	Save the off-trade date indicated by the user for the selected DM. If a previous off-trade date has been indicated, the old value will be archived in the history and	Same



User Manual DM Manufacturer Profile



Action	Description	Page Name
	the new one will be acquired.	
Back	Takes the user back to the DMs list page without entering/updating the off-trade date.	Dm List Page

Second scenario

If the initially selected DM, for which a trade-off date must be indicated, is similar, and has the same features (except the trade name, the code assigned by the manufacturer, the size and the label) to other validated or published devices, the off-trade statement page also presents the list – with selectable items – of said similar devices that can be simultaneously registered in the Repertoire (see next picture).

Off-trade

Trade name and model: ORTHOPILOT PUNTA SPIRALE D3,2MM 160/80MM

Code assigned by the manufacturer (catalogue identifier): NP615R

Manufacturer: AESCULAP AG

System progressive attributed to DM: 13362

[Medical Device general data](#)

Off-trade date: / /

The medical device is similar to the following Validated/Published DMs. Select from the list the devices to which the same off-trade applies.

Similar DMs

System progressive attributed to DM	Trade name and model	Code assigned by the manufacturer	Measure	Label	DM status	Marketing End Date	Select
369933	ORTHOPLOT INSERTORE VITE RB P.MOTORE	NP618R		NP618R.pdf	P0		☐

Even in this case, a previously indicated off-trade date can be updated. The procedure is as follows:

- The user selects one single DM belonging to that group, for which he has previously indicated an off-trade date and activates the “Off-trade” feature;
- Edits the off-trade date presented by the system;
- Extends the data value to all the similar devices displayed on the same page or to a subset of the similar devices (selecting them);
- Clicks on the update button to complete the operation on the affected elements.

**Detail Fields**

Field Name	Description
Selected DM data	
Trade Name and Model	Commercial name or model of the DM
Code assigned by the manufacturer (identifier catalogue)	Code attributed to the DM by the manufacturing company (better known as the identification catalogue)
Manufacturer	Corporate name of the DM Manufacturing Company
System Progressive attributed to DM	Unique identification number assigned to each DM in the database . If /R appears next to the identification number assigned to the DM by the system, it means that the DM has been registered on the index.
Off-Trade date	Off-market date of DM.
Similar DMs List²⁰	
Measure (where applicable)	Indication of the measurable criteria actually used and present in commercial catalogues with the corresponding unit of measurement of the DM
Label	File containing the label of the DM
DM status	The status of the DM in the database. This status can assume, in this case, the values: • V: Valid • P: Published

Operations available:

Action	Description	Page Name
Update	Activating this button, the off-trade date indicated by the user for the DM on the page and for all the similar DMs <u>selected</u> will be registered. If for one or more of these DMs an previously registered off-trade date is already present in the system, the value will be updated and the old one will be registered in the history.	Same

²⁰ Only the fields that are not described in the table are present.



User Manual

DM Manufacturer Profile



Action	Description	Page Name
Back	Takes the user back to the DMs list page without entering/updating the off-trade date.	Dm List Page

Third scenario

If the user selects more than one DM in "Validated" or "Published" status, the system will display the following page:

Off-trade

Off-trade date: / /

Activating the update button, the system will report the off-trade date present both on the selected DMs (visible on the page) and on every other similar DM in Validated or Published state. To indicate the off-trade date for a subset of similar devices, search one DM belonging to the group of similar DMs and activate the 'Off-trade' function again. For further details on the 'Off-trade' function, please refer to the User Manual.

DM List

System progressive attributed to DM	Trade name and model	Code assigned by the manufacturer	Manufacturer	DM status	Marketing End Date	Similar DMs
13790	ACCULAN II ADATTATORE P.SYNTHES RADIOL.	GA438	AESULAP AG	P0	02/06/2013	Similar
15932	ACCULAN I CARICA ACCUMULATORI	GA604	AESULAP AG	P0	02/06/2013	N
63299	ACCULAN MANDRINI	GB660R	AESULAP AG	P0	02/06/2013	N
326364	ACCULAN 3TI TESTA P.FRESARE HUDSON/ZIMM.	GB656R	AESULAP AG	P0	02/06/2013	Similar

[Update](#)
[Back](#)

This page will allow the user to indicate an off-trade date and will report a list of the selected DMs, showing, if applicable, their belonging to a group of similar DMs (the information "Similar DMs in the last column will show an "N" if the DM belongs to a group of similar DMs and a button labelled "Similar" if the DM belongs to a group of similar DMs).



User Manual DM Manufacturer Profile



By activating the "Similar" button (beside a DM), if present, the system will show all DMs belonging to that group (except the one that is selected), their status and the off-trade date, if already present²¹ (see next picture).

System progressive attributed to DM	Trade name and model	Code assigned by the manufacturer	Manufacturer	DM status	Marketing End Date
394042	ACCULAN II MANDRINO AO	GB412R	AESCULAP AG	P0	02/06/2013
394043	ACCULAN II MAND.3 GANASCE PICC.>D4,0MM	GB415R	AESCULAP AG	P0	02/06/2013
394044	ACCULAN II MAND.3 GANASCE GRD.>D6,5MM	GB416R	AESCULAP AG	P0	02/06/2013
394045	ACCULAN II MAND.3 GANASCE PICC.S.CHIAVE	GB418R	AESCULAP AG	P0	02/06/2013

DM status	Marketing End Date	Similar DMs
P0	02/06/2013	Similar
P0	02/06/2013	N
P0	02/06/2013	N
P0	02/06/2013	Similar

After checking the state of the similar DMs involved in the operation, clicking on the "Update button" the user will validate the off-trade date entered for all the selected DMs. In this case, the system will extend the value to all the selected DMs (visible on the page) beginning from the search mask and to all the similar DMs in the Validated/Published state, updating the date if already present²².

Detail Fields

Field Name	Description
System Progressive attributed to DM	Unique identification number assigned to each DM in the database . If /R appears next to the identification number assigned to the DM by the system, it means that the DM has been registered on the index.
Trade Name and Model	Commercial name or model of the DM

²¹ The DMs belonging to a group of similar DMs could all have the same off-trade date or no date. As a particular case, you could have mixed groups, with some DMs having an off-trade date and others not. Such a condition does not compromise the group integrity.

²² In this case, the user can't select a subset of similar DMs for which he wants to declare the same off-trade date. The system will apply the same date indicated by the user to all the DMs in Valid/Published state similar to those selected. If the user wants to enter/update a specific off-trade date only for a subset of similar DMs, he must search a single DM belonging to the group and activate the "Off-trade" feature again. In this way, he will be able to select only some elements of the group, as in the second scenario.



User Manual

DM Manufacturer Profile



Field Name	Description
Code assigned by the manufacturer (identifier catalogue)	Code attributed to the DM by the manufacturing company (better known as the identification catalogue)
Manufacturer	Corporate name of the DM Manufacturing Company
Device status	The status of the DM in the database. This status can assume, in this case, the values: • V: Valid • P: Published
Off-Trade date	Off-market date of DM.

Operations available:

Action	Description	Page Name
Similar	Opens the (pop-up) page displaying DMs similar to the one of interest. The page will display the following data: • System progressive attributed to the DM; • Trade name and model; • Code assigned by the manufacturer (catalogue identifier); • Manufacturer; • Device status; • Off-Trade date.	Similar DMs
Update	The activation of the button registers the off-trade date indicated by the user for all the selected DMs and for all the similar DMs in Validated/Published state, if present. ²³ . If for one or more of these DMs an previously registered off-trade date is already present in the system, the value will be updated and the old one will be registered in the history.	Same
Back	Takes the user back to the DMs list page without entering/updating the off-trade date.	Dm List Page

²³ In this **case the off-trade date is automatically applied to the similar DMs in Validated/Published state** and the user can't select only a subset.



2.4.1.16 Manufacturing putback of a DM in the “Published” status

This feature allows the user to put a DM in the “Published” status back to manufacturing so as to correct bugs or errors or to implement changes that do not imply a new notification. The DM data are recorded in the exact moment it is put back to manufacturing.

The Device will no longer be displayed to those users having a Region or Health company profile as long as it published again.

Following clarification of Ministry of Health on the decree 21 dicembre 2009, in the case that published DM is of class I or IIA and the file containing Instruction for Use is not uploaded for it, the system present the message “**N.B.: for class I and IIA DM file containing Instruction for Use must be uploaded if DM is accompanied by**”. That is, the Declarant must upload the file of Instruction for Use if the device is accompanied by but the system can’t control it. In the case that file is not uploaded, the device data signed by Declarant will contain “**Device is not accompanied by Instruction for Use**”.

Home > Class I, II a / b, III Medical Devices > Medical Device (DM) > Manufacturing putback
 ?

Manufacturing putback

Trade name and model: 5.5 MM PEEK CORKSCREW® FT SUTURE ANCHOR WITH ONE #2 FIBERWIRE® AND ONE #2 TIGERWIRE®

Code assigned by the manufacturer (catalogue identifier): AR-1927PSF

Manufacturer: BAYER STORIC NEW

System progressive attributed to DM: 11662

[Medical Device general data](#)

*** Why you back in production:** ☐ for correction of errors or inaccuracies ☐ for reasons that do not require the Re-notification

*** Statement of changes planned:**

Fields details

Field Name	Description
Reason for manufacturing putback	Reason why the published selected device is put back to manufacturing. A declarant may independently put back to manufacturing those devices only to correct bugs or errors or to implement changes that do not imply a new notification
Statement of estimated changes	Changes the Declarant estimates to implement to the device during manufacturing



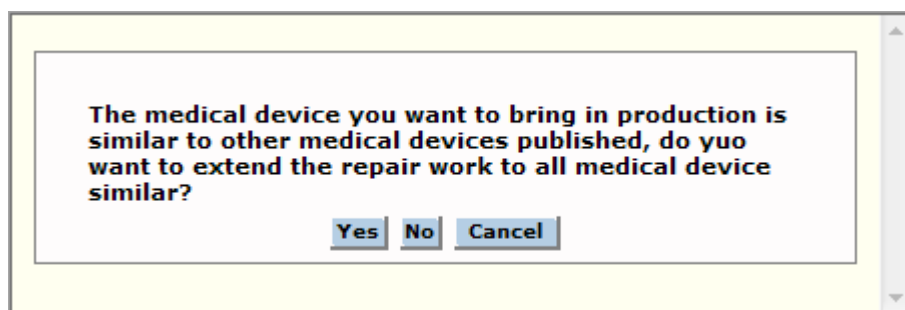
User Manual DM Manufacturer Profile



Operations available:

Action	Description	Page Name
Confirmation	Puts the device back to manufacturing and records all of the information it contains	DM list

If the selected medical device has similar DMs in the “Published” status, in the confirmation stage the users will be asked if they wish to put back to manufacturing all similar DMs or only the selected device.



Operations available:

Action	Description	Page Name
Yes	Puts all similar devices back to manufacturing and closes the dialog box	DM list
No	Puts only the selected device back to manufacturing and closes the dialog box	DM list
Cancel	Closes the dialog box	Manufacturing putback



2.4.1.17 View DM Data

In order to view the data of a DM, the user must proceed as follows:

1. Run the DM search (by clicking on “Medical Device (DM)” in the menu, insert the search criteria by clicking on the “Search” button), in order to select the desired DM
2. Click the “View” button to access the “General data” of the DM
3. Select the menu option corresponding to the specific information of the DM (Specifications data sheet, Documentation, Commercial data, Any other DM needed for the functioning) therefore accessing the DM data pages one by one in order to consult the information.

2.4.1.17.1 Consultation of a DM data pages

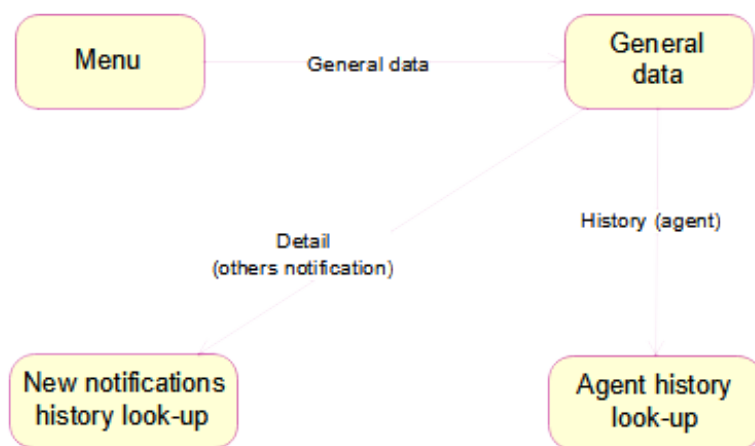
The data pages of a DM in read-only mode can be accessed by all users of the system and allows them to consult the information details of the DM selected on the “DM List page” page.

The data pages are:

1. General Data Page
2. Specifications Page
3. Documentation Page
4. Commercial data Page
5. Possible other DM necessary for its functionality



2.4.1.17.1.1 General Data



Page Name: General data page

This page allows the user to view the general data of a DM. The general data of a DM are subdivided in four areas:

- General data
- Data concerning classifications
- Data concerning certifications
- Links with other DM

In addition to these areas, the characteristic data of the DM similar to this one are used only in the case in which they are present.

In the “Links with other DMs” box the “Any other Dm needed for the functioning” link allows the user to access the page with the list of other possible DM required for the functionality of the “Parent” DM.



User Manual DM Manufacturer Profile



Home > Class I, II a /b, III Medical Devices > Medical Device (DM) > General data

Browsing General data

General data

*Trade name and model: ALTO

*Code assigned by the manufacturer (catalogue identifier): AD110A1

Regulation on prosthetic assistance payable under the National Health Service: Payment conditions and rates:

*User role as to the DM: Other individual delegated by the Manufacturer

Company that entered the DM: MINISTERO DELLA SALUTE [Detail](#)

*Manufacturer: BERTO GUARDUCCI S.R.L. [Detail](#)

Agent: [Detail](#)

Marketing Responsible: [Detail](#)

System progressive attributed to DM: 641

Marketing End Date: 27 11 2008

Was it ever notified to the M.D.S.as provided for by the procedure prescribed before the enforcement of D.M.20/02/07 or under the present procedure? yes ☐ no ☒

Classification

If the declarant does not have the GMDN code can choose the option 'ND' that means GMDN not declared, and proceed with the compilation of next data. Indication of the GMDN code is essential in order to send the information to the European database EUDAMED.

*Complete GMDN repertoire: 44141 - A SINGLE-USE CATHETER BASED ULTRASOUND TRANSDUCER ASSEMBLY ENCLOSED IN

*CND classifications: C0104020102 - CATETERI PER ULTRASONOGRAFIA INTRAVASCOLARE

Certifications

*EC Classification (D.L.46/97 implementation Dir.CE 93/42, D.L.vo 507/92 implementation Dir.CE 90/385): Class IIIa

Annex according to which the device was marked:

☐ Annex II/2

☐ Annex III/3

☒ Annex IV/4

☐ Annex V/5

☐ Annex VI

☒ Annex VII

No. of certificate of the EC marking	Certificate Expiration Date	Notified Body Code-Name	Details of Community harmonized standards and of national transposing rules that may be applied	EC Directive 2003/32	File containing the certificate
BER1	15/06/2015	0373 - ISTITUTO SUPERIORE DI SANITA	NORME	THE CERTIFICATE IS RELATIVE ALSO TO THE EC DIRECTIVE 32/2003	FP_FILE.PDF
NUOVOBER2	30/11/2015	0633 - BERLIN-CERT-PRÜF-UND ZERTIFIZIERSTELLE FÜR MEDIZINPRODUKTE GMBH AN DER TECHNISCHE UNIVERSITÄT BERLIN	NORME	THE CERTIFICATE IS NOT RELATIVE TO THE EC DIRECTIVE 32/2003	CE ATOS.PDF

Link with other DMs

The DM, to perform its function, needs other DM: yes ☒ no ☐

If the answer is affirmative, the other DMs need to be indicated through the function "Any other DM needed for the functioning". [Other eventual DM needed for the operation.](#)



User Manual DM Manufacturer Profile



General DM data Detail Fields

Field Name	Description
General data	
Trade Name and Model	Name of DM as given by the Manufacturer
More DM trade names	List of alternative commercial names that the DM has been called
Code assigned by the manufacturer (identifier catalogue) from/to	Product code assigned to the DM by the Manufacturer.
Regulation on prosthetic assistance payable under the National Health Service: Payment conditions and rates	Name of DM according to the nomenclature charges in force
User role as to the DM	Indicates the role carried out by the user with respect to the DM. The user can adopt the following roles: - Manufacturer - Mandate Holder - Marketing Director - Other individual delegated by the Manufacturer
Man./Agent/Marketing Resp../Other person del. by Man.	Indicates the Manufacturing company / Mandate Holder / Marketing Director / Other individual from the Manufacturer of the DM
Manufacturer	Name of the Manufacturer of the DM.
Agent	Name of the Agent (Authorised Representatives) of the DM.
Marketing responsible	Name of the Marketing responsible of the DM.
System progressive attributed to DM	Consecutive invoice number attributed to the DM by the system. If /R appears next to the consecutive number assigned to the DM by the system, it means that the DM has been registered on the index
Classifications	
Complete GMDN Repertoire	Indicates the classification according to the GMDN(Global Medical Device Nomenclature) of the DM.
CND Classification	Indication of the National classification of the DM.
Certifications	
EC Classification (D.L. 46/97)	Indication of the EC classification of the DM. The EC classification can adopt the following principles:



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DM Manufacturer Profile



Field Name	Description
implementation Dir.CE 93/42; D.L.vo 507/92; implementation Dir.CE 90/385)	- Class I with measurement functions - Class I non sterile and or measurement functions - Class I sterile - Class I sterile with measurement functions - Class IIa - Class IIb - Class III - Active implant devices
Annex according to which the Device was marked	Indication of the annexes according to which the device has been marked.
No.of certificate of the EC marking	Identification number of the EC stamp
Certificate Expiration Date	Expiry date of Certificate
Notified Body Code-Name	Indication of the code and name of the organisation notified.
Details of Community harmonized standards and of national transposing rules that may be applied	Indication of the Essential details of the National and Community norms acknowledged during the fabrication of the DM. If the referenced certificate was notified in the Data Bank of Medical Device by an Italian ON, this field can only be viewed if the certificate is connected to at least one DM in the Validated/Published status (namely, after the user has officially associated a given certificate to a DM).
EC Directive 2003/32	States whether or not the certificate should be issued in compliance with EC Directive 32/2003. The possible values are: - "The certificate is relative ALSO to the EC Directive 32/2003"; - "The certificate is NOT relative to the EC Directive 32/2003"; - "The certificate is relative ONLY to the EC Directive 32/2003"; If the referenced certificate was notified in the Data Bank of Medical Device by an Italian ON, this field can only be viewed if the certificate is connected to at least one DM in the Validated/Published status (namely, after the user has officially associated a given certificate to a DM).
Link with other DMs	
To function, the DM needs other DMs	Indicates whether or not the DM requires other DM for it's fuctionality.



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DM Manufacturer Profile



Operations available

Action	Description	Page Name
History	Opens the window having the Medical Device agents history detail. This button is present only if the agent was modified after publication.	Agent history look-up
Detail	Opens the window having the other DM notifications history detail. This button is present only if other notifications for the device exist.	New notifications history look-up

Page Name: Agent history look-up

This page is activated from the detail of a Device general data by clicking on the “History” button beside the “Agent” field only if such datum was updated after the DM was published, and allows the user to display the history of all associated agents.

Each change implemented to the Agent of the device after publication is reported along with the corresponding date of communication.

Historical data of the Agents associated to DM	
	?
Agent	Valid until
AMNOL CHIMICA BIOLOGICA SRL	10/08/2009
RE	10/08/2009
BAYER STORIC NEW	03/08/2009
BAYER STORIC NEW	02/08/2009
B. BRAUN MILANO S.P.A. MOD	01/08/2009
BAYER_MOD	01/08/2009
B. BRAUN MILANO S.P.A.	01/08/2009
BAYER STORIC NEW	01/08/2009
BAYER (NEW)	01/08/2009
B. BRAUN MILANO S.P.A. MOD	01/08/2009

Close

*Operations available*

Action	Description	Page Name
Close	Closes the window	General data

Page Name: New notifications history look-up

This page is activated from the detail of a Device general data by clicking on the “Detail” button beside the “Other DM notification” field only if some connections for such DM exist, and allows the user to display the notification history of the same Medical Device.

For each notification, other identification data of the DM, the date and reason for new notification are reported

Medical devices connected - Rinotification						
System progressive attributed to DM	Validation Date	Rinotification Date	Reason for new notification	Manufacturer	Code assigned by the manufacturer (catalogue identifier)	Trade name and model
10023	06/02/2008			BAYER STORIC NEW	2	PROVA2AAAAAAA
11883		02/08/2009	Variazione denominazione del fabbricante	BAYER STORIC NEW	2	PROVA2AAAAAAA

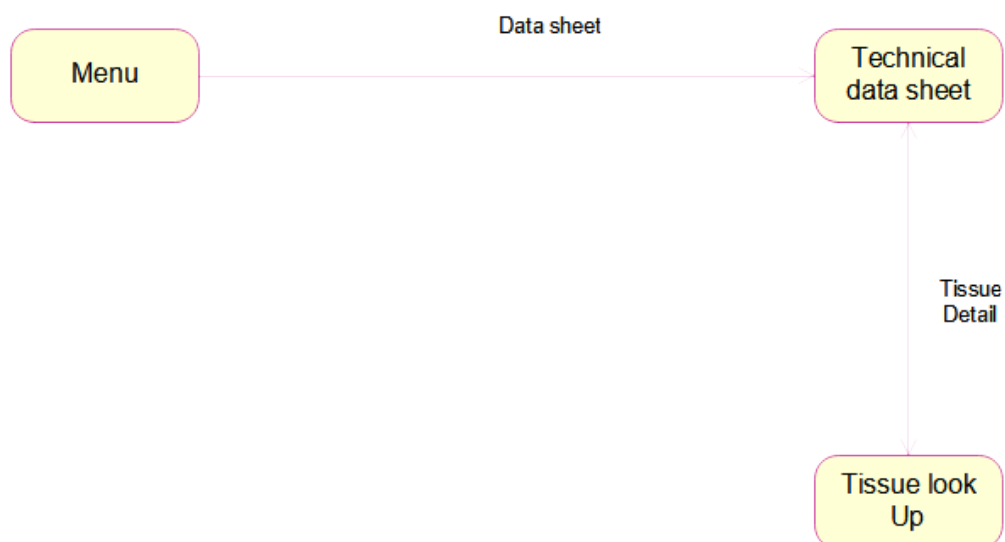
[Close](#)

Operations available

Action	Description	Page Name
Close	Closes the window	General data



2.4.1.17.1.2 Specifications Data Sheet



Page Name: Specifications Data Sheet

This page allows users to view the technical data of a DM. The data on a DM specifications Data Sheet are subdivided in the following areas:

- General technical characteristics
- Sterilisation date
- Material that the DM is made up of that come in direct contact with the Patient. (Each material is marked as to whether or not specific disposal is required)
- Biological tissues or substances of animal origin(not vital) Data. (The family of origin, original condition, the part utilised, the presence or otherwise of documentation associate with the tissue are all specified.
- Presence of medicinal products (the code name of each active ingredient is stated)
- Primary packaging of DM (with the list of materials that form it)
- Directions for use

In the upper section of the page, the principal data of the DM are displayed as well as the “Medical Device General Data” link which opens the page containing the general data of the DM.



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Home > [Medical Devices of class I,IIa/b,III](#) > [Medical Device \(DM\)](#) > ?

Visualizzazione Data sheet

Trade name and model: ANGIOLIPS
Code assigned by the manufacturer (catalogue identifier): B028
Manufacturer: BAYER
System progressive attributed to DM: 10043

[Medical Device general data](#)

General Technology Characteristics

Description:

Intended use according to D.Lgs.46/97 :

Measure (where applicable):

Indicate measurable parameters presently used in commercial catalogs in the relative measurement unit

Medical device materials in direct contact with patient

Material class	Material	Special conditions of disposal
POLIMERICI	ACRILATI	S

***Latex:** both the product and its primary package are latex free

***Latex:** during manufacturing, the product came in contact with latex molecules

Biological tissues or substances of animal origins (non-living) data

***Tissue/Substance Presence**

Family	State of origin	Tissue used part - Substance	Documents presence
View Tissues			

Medicinal Presences

***Medicinal Presences:**

☐ medicines (except those derived from human blood or plasma)
 ☐ medicines or medicinal components derived from human blood
 ☐ medicines or medicinal components derived from human plasma

Active substance code	Active substance name
For the medical device's medicinal contents, select the principle active	

Primary Medical Device Confection

***The prevalent materials of the primary medical device confection require special disposal provisions:**

Only for sterile medical devices, or those to sterilize, indicate the prevalent confection materials:

Materials
-

Sterilization Data

***Sterile:**

Methods of sterilization	Maximum period of use (months)	Methods of sterilization validated according to harmonized standards	Other sterilization method description

Information on the possibility of re-use

Method of cleaning/disinfection:

Reste-rilisation methods	Number of sterilizations	Other sterilization method description

**DM Specifications Data Fields**

Field Name	Description
General technical characteristics	
Description	Description of the general technical characteristics of the DM
Intended use according to D.Lgs.46/97	Intended use In accordance with the D.Lgs.46/97
Measure (where applicable)	Indication of the measurable criteria actually used and present in commercial catalogues with the corresponding unit of measurement of the DM
Sterilisation data	
Sterile	Indication of whether or not the DM is sterile
Methods of sterilization	Method used to sterilise the DM.
Other sterilization method description	Description of the sterilisation method if it is not already present on the loaded list previously.
Methods of sterilization validated according to harmonized standards	The method of sterilisation can be validated: - according to the harmonised norms - other.
Maximum period of use (months)	Maximum length of use of the DM.
Medical device materials in direct contact with patient	
Latex: both the product and its primary package are latex free	Indication as to whether or not the product and its primary package are latex free.
Latex: during manufacturing, the product came in contact with latex molecules	Indication as to whether or not the the product came in contact with latex molecules during manufacturing.
Latex free	Indication as to whether or not the DM contains latex. This field, along with its corresponding value, is present only if the datum was registered during the DM notification stage
Attachment	File containing the Latex free certification. This field, along with its corresponding value, is present only if the datum was registered during the DM notification stage
E-mail/web site	Indication of email or web site where the Latex free certificate can be requested. This field, along with its corresponding value, is present only if the datum was registered during the DM notification stage
Data of biological tissue or substances of animal origin (not vital)	
Tissue/Substance Presence	Indication of whether or not the DM contains Biological tissue/animal substances
Medicinal Presences	



Field Name	Description
Medicinal Presences	Indication as to whether or not the DM contains medicinal products
medicines (except those derived from human blood or plasma)	Indicates if there are medicines present in the DM (excluding those derived from blood or human plasma).
medicines or medicinal components derived from human blood	Indicates if there are medicines present in the DM derived from human blood).
medicines or medicinal components derived from human plasma	Indicates if there are medicines present in the DM derived from human plasma).
Primary medical device confection	
The prevalent materials of the primary medical device confection require special disposal provisions	Indicates if the primary packaging of the DM must be disposed of in a specific manner
Information on the possibility of re-use	
Single	Indicates whether or not the DM is disposable
Resterilisation methods	Method used to re-sterilise the DM.
Other sterilization method description	Description of method of re-sterilisation if it is not found on the previously loaded list.
Method of cleaning/disinfection	Method used to clean/disinfect the DM.
Number of sterilizations	Maximum number of times it is permitted to sterilise a DM.

Operations available:

Action	Description	Page Name
View Tissues	Grants the user access to a window where he can view the detailed information of each biological tissue/animal substance associated with the DM	Tissues Look Up

**Page Name: Tissues Look Up**

This page allows the user to view the data on each biological tissue/animal substance associated with the DM. In particular, this window permits the user to download or view a link to a site where the information of each tissue/substance can be found regarding:

- The origin of the tissue - substance
- The treatment and deactivation methods
- Other documentation provided by the Health Authority

TISSUE OR BIOLOGICAL SUBSTANCES ANIMAL DATA (NOT VITAL)																
List of possible biological tissues/animal substances contained in the DM																
Family	State of origin	Tissue used part - Substance	Documents presence													
BOVINA	ITALIA	ANNESI CUTANEI	S	☐												
View																
<table border="1"> <tr> <td> Family membership BOVINA v Other Family: </td> <td> National origin ITALIA v </td> <td> Tissue part used - Substance ANNESI CUTANEI v Other parts used: </td> </tr> <tr> <td colspan="3"> Documents: Availability of documents on tissue origin - substance ☒ Availability of documents on treatment and inactivation methods ☐ Availability of Health Authority documents ☐ </td> </tr> <tr> <td> Attached file CE MEDICAZIONE.p Open (max size 8MB) </td> <td> Attachment Sfoglia... (max size 2MB) </td> <td> Attachment Sfoglia... (max size 2MB) </td> </tr> <tr> <td>Email address/web site </td> <td>Email address/web site </td> <td>Email address/web site </td> </tr> </table>					Family membership BOVINA v Other Family: 	National origin ITALIA v 	Tissue part used - Substance ANNESI CUTANEI v Other parts used: 	Documents: Availability of documents on tissue origin - substance ☒ Availability of documents on treatment and inactivation methods ☐ Availability of Health Authority documents ☐			Attached file CE MEDICAZIONE.p Open (max size 8MB)	Attachment Sfoglia... (max size 2MB)	Attachment Sfoglia... (max size 2MB)	Email address/web site 	Email address/web site 	Email address/web site
Family membership BOVINA v Other Family: 	National origin ITALIA v 	Tissue part used - Substance ANNESI CUTANEI v Other parts used: 														
Documents: Availability of documents on tissue origin - substance ☒ Availability of documents on treatment and inactivation methods ☐ Availability of Health Authority documents ☐																
Attached file CE MEDICAZIONE.p Open (max size 8MB)	Attachment Sfoglia... (max size 2MB)	Attachment Sfoglia... (max size 2MB)														
Email address/web site 	Email address/web site 	Email address/web site 														
It recommends to use contained file size to facilitate consultation.																

LookUpTessuti Detail Fields

Field Name	Description
Family membership	Family of origin of the biological tissue/animal substance contained in the DM
Other Family	Description of the family of origin of the biological tissue/animal substance contained in the DM
National Origin	Original condition of the biological tissue/animal substance



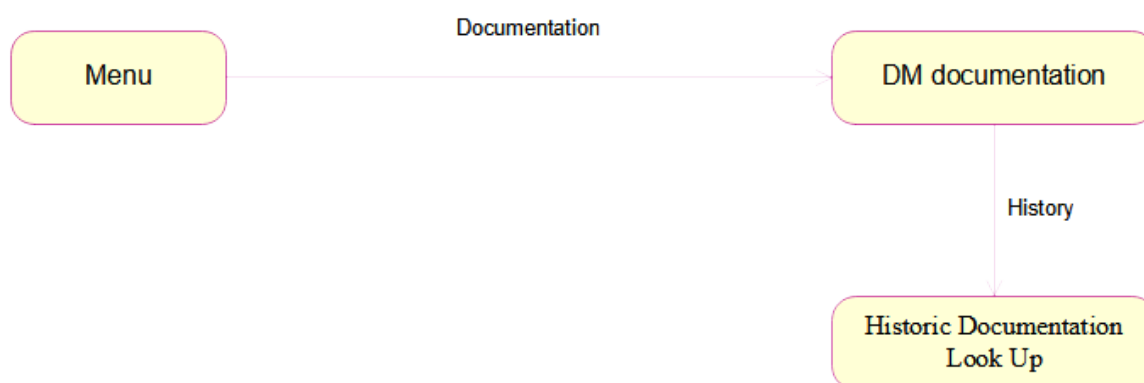
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DM Manufacturer Profile



Field Name	Description
Tissue part used/Substance	Parts of tissue used in DM
Other part used	Description of the parts of the biological tissue/animal substance used in the DM
Availability of Documents on tissue origin/substance	Indication of the presence of documentation on the origin of the tissue – substance
Attachment (in refer to “Availability of Documents on tissue origin/substance” field)	File containing the documentation on the origin of the tissue – substance.
e-mail address /web site (in refer to “Availability of Documents on tissue origin/substance” field)	Email address/Web site from which the origin of the tissue – substance can be traced.
Documents: Availability of documents on treatment and inactivation methods	Indication of the presence of documentation on methods of treatment and deactivation
Attachment (in refer to “Documents: Availability of documents on treatment and inactivation methods” field)	File containing the documentation on methods of treatment and deactivation.
e-mail address/web site (in refer to “Documents: Availability of documents on treatment and inactivation methods” field)	Email address/web site where the documentation on methods of treatment and deactivation can be found.
Availability of Health Authority Documents	Indicates the presence of documentation provided by the Health authority regarding the tissues/substances selected.
Attachment (in refer to “Availability of Health Authority Documents” field)	File containing the documentation provided by the Health authority regarding the tissues/substances selected.
Email address/ web site (in refer to “Availability of Health Authority Documents” field)	Email address/web site where the documentation provided by the health authority regarding the tissue/substance selected can be found

*Operations available:*

Action	Description	Page Name
View	Displays a box in which the user can view information regarding biological tissue/animal substance selected.	Same
Close	Closes the window	Data Sheet

2.4.1.17.1.3 Documentation**Page Name: DM Documentation**

This page allows the user to view the documentation attached to a DM and therefore to download the files attached.

In the upper part of the page, the principal data of the DM are displayed as well as the “Medical Device General Data” link which opens the page containing the general data of the DM.

If the label or the usage instructions or the data sheet of the medical device have been modified after their publication, the system visualizes the button ‘Historic’.



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Documentation

Trade name and model: HLS NOETOS REVISIONE BASE TIBIALE T.6

Code assigned by the manufacturer (catalogue identifier): GDF566

Manufacturer: TORNIER S.A.

System progressive attributed to DM: 261000/R

[Medical Device general data](#)

Select the file to attach or indicate the remote link to the document or the e-mail address suitable for this request. It recommends to use contained file size to facilitate consultation.

Document	File to attach	Link /Email Address	
* Label	GDF566_Hi.pdf		Open
* Instructions for Use	Istruzioni d'uso HLS NOETOS RE		Open
DM Image	IMMAGINE HLS NOETOS REVIS		Open
DM Data Sheet	SCHEDA TECNICA HLS NOETO		Open
Scientific bibliography supporting the clinical evidence of the effectiveness and safety of the DM	BIBLIOGRAFIA HLS NOETOS R		Open

If the DM does not need Bibliography attach a file containing an explicit statement to that effect.

The format of the files to be annexed must be PDF

Documentation Detail Fields

Field Name	Description
Label	File containing the label of the DM.
Direction for use	File containing the direction for use of the DM
Image of DM	File containing the image of the DM. Not obligatory.
DM Data Sheet	The file containing the specifications of the DM or alternatively, a link to the site where the same information may be found.
Scientific bibliography supporting the clinical evidence of the effectiveness and safety of the DM	File containing the Scientific bibliography, supporting the clinical evidence of the effectiveness and the safety of the DM or alternatively a link to a site where the same information may be found

Operations available:

Action	Description	Page Name
Open	Allows the user to download the attached document	
History	Allows access to the page visualizing the old files. The	Historic Documentation



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Action	Description	Page Name
	operation is activated only if the label or the usage instructions or the data sheet files of the DM have been modified after its publication.	Look Up

Page Name: Historic Documentation Look Up

This page allows the user to view the history of the label, usage instructions and data sheet files modified after the publication of the relative medical device and to download these files.

For every modification in the documentation of the device after its publication, there is the date of signature and names – and the relative link – of the files attached on the relative date.

Using these links, it is possible to get access to the file.

Historical publication documentations changes ?

Updated documentation

Signed	Label	Instructions	Data sheet
13/11/2008			D1.pdf

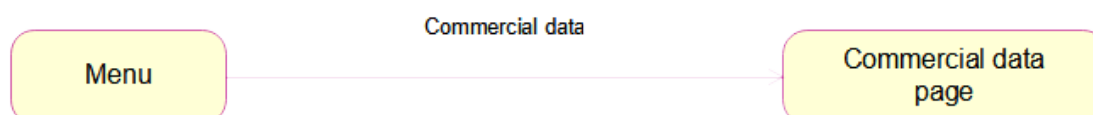
Close

Operations available:

Action	Description	Page Name
Close	Closes the visualization page of the documentation history	Documentation



2.4.1.17.1.4 Commercial Data



Page Name: DM Commercial Data

This page allows the user to insert/edit the commercial data of a DM. The commercial data of a DM are subdivided into two areas.

- Current data of the DM
- Annual sales details of the DM

In the upper section of the page, the principal data of the DM are displayed as well as the “Medical Device General Data” link which opens the page containing the general data of the DM.

If the list price and the IVA percentage have been modified after the publication of the medical device, the last update date is presented in the actual data section.



Home > Class I, II a /b, III Medical Devices > Medical Device (DM) > Commercial Data ?

Browsing Commercial Data

Trade name and model: NOME

Code assigned by the manufacturer (catalogue identifier): CODICE

Manufacturer: BAYER

System progressive attributed to DM: 10210

[Medical Device general data](#)

Actual data

Last update: 22/04/2008

Unit price list of single device without VAT: **%VAT:**

Presence of bar code:

The amounts are expressed in Euro

DM sale data

DM year of sale	No. of pieces sold to the SSN	Type of data	No. of pieces sold to the remaining market	Type of data
2004	5	actual ☐ estimated ☒	4	actual ☐ estimated ☒
2005	5	actual ☒ estimated ☐	55	actual ☒ estimated ☐

SSN includes: local health companies, hospitals, accredited public and private facilities

Commercial data Fields

Field Name	Description
Current data	
Unit price list of single device without VAT	Unit sale price of a DM excluding tax
%VAT	Indication of the IVA applied to the DM
Presence of bar code	Indication as to whether or not the DM bears a barcode
DM Sales data	



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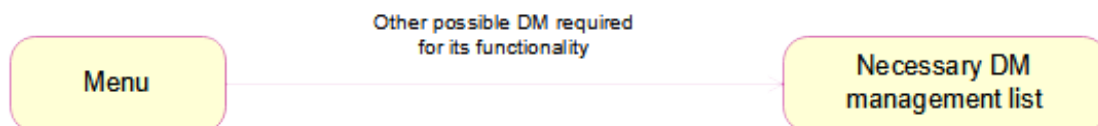


Field Name	Description
DM year of sale	Indication of the year the DM was sold
No.of pieces sold to the SSN	Indication of the number of pieces sold to the National Health Service.
Type of data	Indication of the type of data (No. of pieces sold to the SSN) either estimated or exact
No.of pieces sold to the remaining market	Indication of the number of DM pieces old (excluding pieces sold to the SSN).
Type of data	Indication of the type of data (No. of pieces sold to the rest of the market) either estimated or exact

Operations available: None



2.4.1.17.1.5 Other possible DM required for its functionality



Page Name: Necessary DM Management List

This page allows the user to view the list of DM required for the functionality of a “Parent” DM.

In the upper section of the page, the principal data of the DM are displayed as well as the “Medical Device General Data” link which opens the page containing the general data of the DM.

In correspondence to the “Trade Name and Model” of each correlated DM, there is a link which allows the user to view the general data of the respective DM selected.



Home > Class I, II a /b, III Medical Devices > Medical Device (DM) > Any other DM needed for the operation ?

List Any other DM needed for the operation

Trade name and model: DISPOSITIVO MEDICO

Code assigned by the manufacturer (catalogue identifier): A02

Manufacturer: BAYER

System progressive attributed to DM: 9962/R

[Medical Device general data](#)

Other DM needed for the operation						
Manufacturer	Trade name and model	Exclusive use/ Non-exclusive use	Reason for exclusivity	Product Type	Device status	Select
QUA.SER. S.A.S.	DISPOSITIVO MEDICO	exclusive use	III	DM	L	☐
fabbr	nome	exclusive use	123	DM(*)		☐
fab Dm min prova pag 6	Dm min prova pag 6	non-exclusive use		DM(*)		☐

This feature allows the linking of medical devices.
It is possible to select the DMs needed among those that were previously included; if the DMs refer to other manufacturers/representatives/resp.Imm.in comm.are selected regardless of their status in the repertoire.
For each of the devices needed, you will be asked to state whether it is the only one that can be used ("exclusive use") or not ("non-exclusive use") for a specific purpose.

Select: Click on one of the squares beside the component(s) in the list depending on operations.

DM required Detail Fields

Field Name	Description
Manufacturer	Manufacturer of the DM required
Trade Name and Model	The commercial name of the DM required
Exclusive use /Non-exclusive use/	Indicates if the DM to be linked, has an exclusive use regarding the "Parent" DM
Reason for Exclusivity	Reason for its exclusiveness
Product type	The type of product entered as needed for the functioning of the device can be: - DM: EC marked device notified in a regular form by its manufacturer - DM (*): EC marked device notified in minimal form by the manufacturer of the DM for which it is needed

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Reason Exclusivity	for Reason for its exclusiveness
Device status	Status of the DM in the database. This status can be changed in the following order: • L: in progress • V: Valid • P: Published

Operations available:None



2.4.1.18 Version history

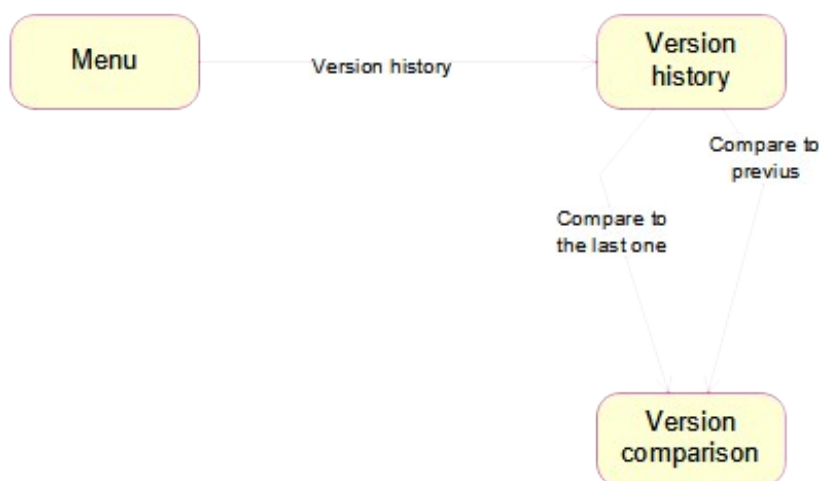
This feature allows the user to consult the various versions of a Medical Device that has been brought from the “Published” status back to the “Manufacturing” status at least once.

Amongst the reasons why a DM can be brought from the “Published” status back to the “Manufacturing” status, there are:

- correcting bugs or errors
- implementing changes that do not imply a new notification
- as per DGFDM request

Pages involved:

- ✓ Version history
- ✓ Version comparison





2.4.1.18.1 DM version history

This page allows the user to consult the version history of the various versions of those DMs that have been brought from the “Published” status back to the “Manufacturing” status at least once.

Home > Class I, II a /b, III Medical Devices > Medical Device (DM) > Historical Versions
 ?

Historical Versions

Trade name and model: PROVA2AAAAAAA

Code assigned by the manufacturer (catalogue identifier): 2

Manufacturer: BAYER STORIC NEW

System progressive attributed to DM: 10023

[Medical Device general data](#)

Manufacturing putback

Validate End Date	Reason for manufacturing putback	Select
06/08/2009	per modifiche che non implicano la rinotifica	☐

Compare with current
Compare with Previous

Operations available

Action	Description	Page Name
Compare to the last one	Allows the user to access the comparison page of the selected version with the last page available for the (actual) DM	Version comparison
Compare to previous	Allows the user to access the comparison page of the selected version with the one that precedes it	Version comparison



2.4.1.18.2 Version comparison

This page allows the user to display all of the differences between the two different versions of a DM.

Home > Class I, II a /b, III Medical Devices > Medical Device (DM) > Compare Versions ?

Compare Versions

Trade name and model: YYYYYY

Code assigned by the manufacturer (catalogue identifier): YY01

Manufacturer: ARKON S.R.L.

System progressive attributed to DM: 10737

[Medical Device general data](#)

Differences between the current version and the version valid until 28/10/2009

Data Updated	Current value	Value until 28/10/2009
No difference between the versions		

[Back](#)

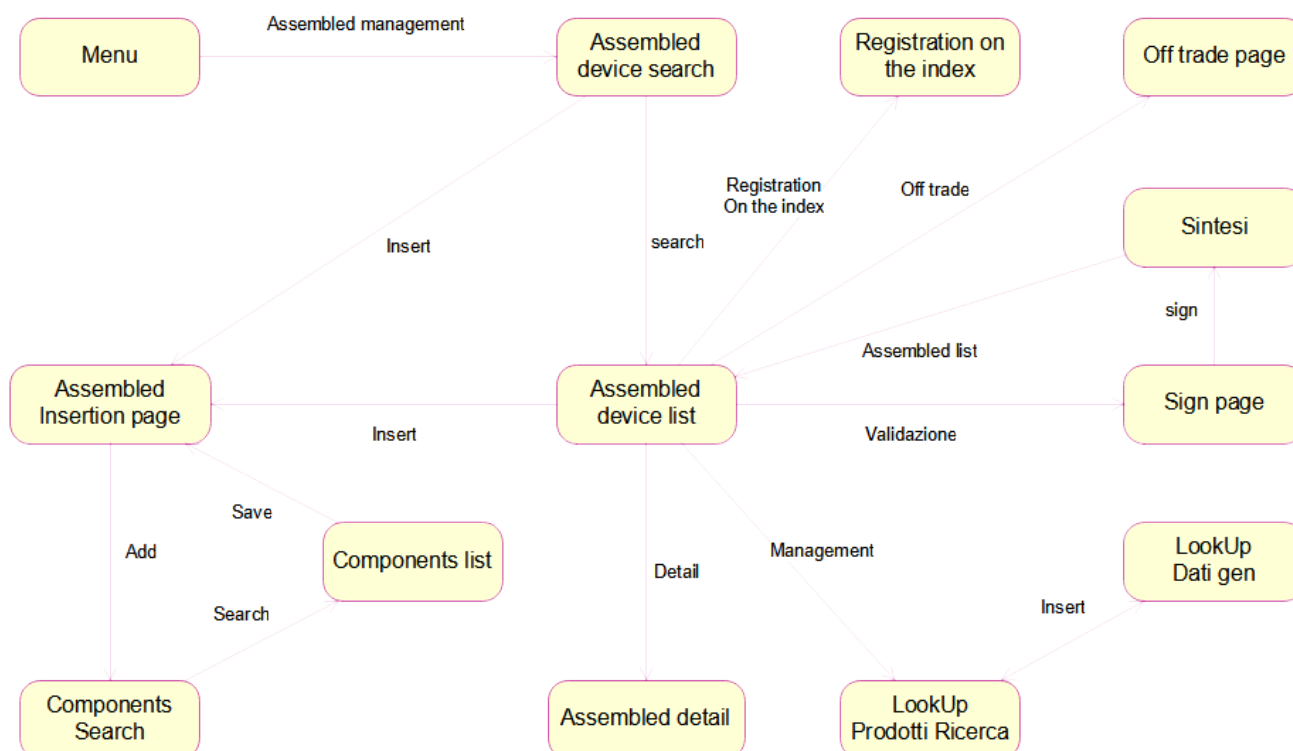
Operations available

Action	Description	Page Name
Back	Directs the user back to the version history page	Version history



2.4.2 Menu option “Systems or assembled kits (c.2 Art.12)”

Screen flowchart:





2.4.2.1 Assembled device search

After selecting “Assembled Management” from the menu, a page appears that allows the user to put criteria in place, to run a search of the assembled systems or kits, according to Para.3 Art 12.

Home > Class I, II a /b, III Medical Devices > Systems or Assembled Kit (c.2 Art.12) ?

Systems or Assembled Kit Search (c.2 Art.12)

Research criteria

Search on all Assembled ☐ Search in Assembled To-do list ☒

WARNING: system detected the presence of 'In progress' Assembled devices in the database, which refer to first notifications / manufacturing putback. Select 'Search in Assembled devices To-do list' option to find the Assembled devices in order to complete the notification process (Validation by signing). User is required to delete data entered by mistake into the system which only refer to first notifications. It's not possible to delete 'In progress' Assembled devices which come from 'manufacturing putback'

System progressive attributed to the assembled:

Assembler:

Type: SYSTEM o KIT

Code assigned by the assembler from:

(catalogue identifier): to:

Trade name and model:

First notify Yes ☐ No ☐ All ☒

State:

User role as to the assembled:

Start working date : from: to:

The user could extend the search to all Assembled devices registered in the system (*Search on all Assembled devices*) whose owner is the user or, otherwise, restrict to the only Assembled devices with status in progress (*Search in Assembled devices To-do list*) which refers both to first notification and manufacturing put back. Also “Consolidated” Assembled devices are generally considered in progress.

Select “*Search in Assembled devices To-do list*” to complete the notification process of a Assembled device using qualified electronic signature the entered data (Validation) or, otherwise, delete data that were entered by mistake into the system. It’s not possible to delete “In progress” Assembled devices which come from “manufacturing put back”.

Set criteria, start the search

**Search Detail Fields**

Field Name	Description
Search on all Assembled	allows the extended search of all Assembled devices registered in the system whose owner is the user;
Search in Assembled To-do list	allows the restricted search of Assembled devices in status in progress;
System progressive attributed to the assembled	Option to search an Assembled device by its identification number assigned by the system during registration into the database.
Assembler	Option to specify the name (or the beginning) of the Assembler
Type	Type of Assembled device.
Code assigned by the assembler (catalogue identifier) from/to	A range of codes which includes the product code assigned to the assembled system or kit by the assembler.
Trade Name and Model	Option to specify the commercial name (or beginning) of the system or kit given by the assembler
First Notification (Yes/No/All) (Applicable only if "Search in Assembled To-do list" selected)	allows the restricted search of Assembled devices in first notification (Yes), the restricted search of Assembled devices in manufacturing put back (No), or extended search of all the Assembled devices in progress which refers both to first notification and manufacturing put back;
Assembled Type	The list contains the types of assembled devices.
State	Option to search an Assembled device by its current status into the system ("In progress", "Consolidated", "Validated", "Published").
User role as to the assembled	Option to search an Assembled device by the role carried out by the user with respect to it ("Assembler", "Agent", "Marketing Responsible", "Other person delegated by Manufacturer")
Notification Start date (from / to) (Applicable only if "Search in Assembled To-do list" selected)	allows to filter Assembled devices by specifying the range of date (from – to) for the start of notification of Assembled device. If not used, the search is extended to all Assembled devices present in To-do List whose owner is the user;
Registered on the index	Option to search an assembled by the registration on the index (registered, not registered)

Operations available

Action	Description	Page Name
Search	Runs a search with criteria entered and displays the assembled system or kit that match that criteria.	Assembled Device List
Reset	Clears the search criteria previously put in place	Same
Insert	Grants access to the systems and kits data entry page	Assembled Detail Insert

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Action	Description	Page Name
		Modify
Products Management	Opens a window where the user has the option to manage (insert, edit, delete, view) Non-DM articles; type "Other"	Products Search Look Up.



2.4.2.2 Searched Assembled devices list

This page allows the user to view the list of assembled system and kits based on the search criteria entered.

The following information is available on each system and kit:

- Identification number assigned to the Assembled device by the system
- Assembler
- Identification code given by the assembler (identification catalogue)
- Commercial name and model of the assembled device
- Type of assembled device
- Status in the database

The list of assembled devices changes depending on the criteria set as well as on the user connected: in this list, a Manufacturer/ Agent/Marketing Responsible can only display the assembled devices he entered, regardless of their status in the database; from this page, he/she can set a new search, or

- a. within the scope of the notifications of the assembled Systems / Kits:
 - Insert a new assembled device
 - Edit an assembled device in the “In progress” stage
 - Delete an assembled device in the “In progress” stage that has never been published
 - Manage all other products;
- b. within the scope of the validation of the notification that has already been made:
 - Consolidate one or more assembled devices in the “In progress” status,
 - Validate an assembled device
 - Activate the off line signature process of a “consolidated” assembled
- c. within the scope of the update of data after their publication:
 - Register the assembled device on the index
 - Insert the off-market date of a “Validated” or “Published” assembled device
 - Set an assembled device in the “Published” status back to “In progress”;
- d. benefiting of some consultation features or utilities:
 - Consult the details of an assembled
 - Consult the history of the versions of a DM reported as “in progress” at least once,
 - Download – in XML format – all notified assembled devices data,
 - View the printable version of the signature page of an assembled device in ‘Validated’ or ‘Published’ status



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Home > Class I, II a /b, III Medical Devices > Systems or Assembled Kit (c.2 Art.12)

?

Systems or Assembled Kit Search (c.2 Art.12)

Research criteria

Search on all Assembled ☐ Search in Assembled To-do list ☒

WARNING: system detected the presence of 'In progress' Assembled devices in the database, which refer to first notifications / manufacturing putback. Select 'Search in Assembled devices To-do list' option to find the Assembled devices in order to complete the notification process (Validation by signing). User is required to delete data entered by mistake into the system which only refer to first notifications. It's not possible to delete 'In progress' Assembled devices which come from 'manufacturing putback'

System progressive attributed to the assembled:

Assembler:

Type: SYSTEM o KIT

Code assigned by the assembler from:
(catalogue identifier): to:

Trade name and model:

First notify Yes ☐ No ☐ All ☒

State:

User role as to the assembled:

Start working date : from:
to:

System progressive attributed to the assembled	Assembler	Code assigned by the assembler (catalogue identifier)	Trade name and model	Assembled type	Device status	Repertoire registration	Select
1	XXXXXXXXXX	PARR-03 KIT	KIT ASSEMBLATO ----- COLLIRIO	PER LAVAGGIO/RIEMPIMENTO	C	N	☐
61	XXXXXXXXXX	2344556667	ASSEBL - TEST DEPLOY 30-01-2009	PER RADIOLOGIA	L	N	☐
30603	XXXXXXXXXX	PV2050NA	KIT ARTERIOSO PER MONITORAGGIO GITTATA CARDIACA IN CONTINUO	ALTRO	C	N	☐

Device status: L=IN LAVORAZIONE C=CONSOLIDATO V=VALIDATO P=PUBBLICATO U=CANCELLATO D'UFFICIO

Select: Click on one of the squares beside the component(s) in the list depending on operations.

Activable operations:

- **Insert:** Allows the user to enter a new Assembled device.
- **Edit:** Allows the user to modify the selected Assembled device to change the data previously entered. The user can modify all Assembled devices that are in the "In progress" or "Consolidated" status.
- **Delete:** Allows the user to delete the selected Assembled device from the database.
- **Products management:** Allows the user to manage (enter, change, delete and view) all 'Other' type non-DM items.
- **Consolidate:** Allows the user to consolidate the data of one or more Assembled devices that are in the "In progress" status.
- **Validates:** Allows the user to digitally sign all selected Assembled devices. The user can modify all Assembled devices that are in the "Consolidated" status.
- **Off line validation:** Allows to digitally sign-off all selected Assembled. The user can modify all Assembled that are in the "Consolidated" status.
- **Off-trade:** Allows the user to state the selected Assembled device off-trade date.



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- **Repertoire registration:** Allows the user to register the selected assembled device in the Repertoire.
- **Manufacturing putback:** Allows to gain access to the manufacturing putback page for the selected assembled system or kit.
- **Detail:** Allows the user to view the data detail of the selected Assembled device.
- **Version history:** Allows to view the history of the different versions of the assembled device put back to manufacturing at least once.
- **Print:** Allows the user to print (in pdf format) a return receipt as evidence of the notification made. Said receipt will report all data signed in the validation stage.
- **Download xml:** Allows the user to download to a compressed file - in the xml format - all selected assembled device data.

Notification of Systems / Assembled Kits

Insert Edit Delete Products management DM Management in minimal form

Notification validation (change of the manufacturing status)

Validation Consolidate Off line validation

Post publication update

Repertoire registration Off trade Manufacturing putback

Consultation and Utilities

Detail Version history Print Download XML

Search Detail Fields

Field Name	Description
Search on all Assembled	allows the extended search of all Assembled devices registered in the system whose owner is the user;
Search in Assembled To-do list	allows the restricted search of Assembled devices in status in progress;
System progressive attributed to the assembled	Option to search an Assembled device by its identification number assigned by the system during registration into the database.
Assembler	Option to specify the name (or the beginning) of the Assembler
Type	Type of Assembled device.
Code assigned by the assembler (catalogue identifier) from/to	Range of codes which includes the product code assigned to the assembled system or kit by the assembler.
Trade Name and Model	Option to specify the commercial name (or beginning) of the system or kit the assembler has given
First Notification (Yes/No/All) (Applicable only if "Search in Assembled To-do list" selected)	allows the restricted search of Assembled devices in first notification (Yes), the restricted search of Assembled devices in manufacturing put back (No), or extended search of all the Assembled devices in progress which refers both to first notification and manufacturing put back;
Assembled Type	The list contains the types of assembled devices.
State	Option to search an Assembled device by its current status into the system ("In progress", "Consolidated", "Validated", "Published").
User role as to the assembled	Option to search an Assembled device by the role carried out by the user with respect to it ("Assembler", "Agent", "Marketing Responsible", "Other person delegated by the Manufacturer")
Notification Start date (from / to)	allows to filter Assembled devices by specifying the range of date (from – to) for the start of notification of Assembled device. If not used, the search is extended to all Assembled devices present in To-do List whose owner is the user;



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Field Name	Description
(Applicable only if “Search in Assembled To-do list” selected)	
Registered on the index	Option to search an assembled by the registration on the index (registered, not registered)

Assembled Devices List Detail Fields

Field Name	Description
System progressive attributed to the assembled	Identification number assigned to the Assembled device by the system during its registration into the database.
Assembler	Name of the Assembler
Code assigned by the assembler (catalogue identifier) from/to	Product code assigned to the assembled system or kit by the assembler (catalogue identification number).
Trade Name and Model	Commercial name of the system or kit the assembler has given
Assembled device Type	Indication of the type of assembled device
Device status	The status of the assembled device in the database. The status can change in the following order: • L: Processing • V: Valid • P: Published

Operations available

Action	Description	Page Name
Search	Runs a search with criteria entered and displays the list of assembled systems or kits that match that criteria.	Same
New search	Clears the search criteria previously put in place	Same
Notification operations of the Assembled Systems /Kits		
Insert	Grants the user access to the insertion page of the assembled systems and kits. (Only visible by “MANUFACTURER” users)	Assembled Device Detail Insert Modify
Edit	Allows the user to access the data page of the assembled system or kit selected in order to edit its details	Assembled Device Detail Insert Modify
Delete	Allows user to delete the system or kit, “In progress”, selected	Same
Products	Opens a window where the user has the option to manage	Products Search Look Up



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Action	Description	Page Name
Management	(insert, edit, delete, view) Non-DM articles; type "Other".	
DM management in minimal form	Opens a window allowing the user to manage (search, edit, delete and view) the EC marked DMs notified in minimal form.	DM notified in minimal form list and search
Notification validation (change of the manufacturing status)		
Consolidate	Allows the user to confirm a system or kit in "In Progress" status. The "Consolidate" action displays the page containing the list of systems and kits in the approval phase, specifying whether the process has been activated or not. Should the process result negative, this will be stated in the activity list, otherwise the state of the system or kit will change to C, that is "Consolidated"	
Validation	Activates the signature page through which the user has the option to validate one or more system or kit in the "Consolidated" stage. (Only visible by "MANUFACTURER" users). Changing the status of the system or kit does not occur simultaneously with the "Validation" action; it is necessary to wait a few moments to verify the successful completion of the process. Should any errors occur during the validation, they will be reported on the activity list, otherwise the system or kit selected will be marked with a V symbol for "Validated"	Validate
Off line validation	Allows the user to access the page of download of txt file containing assembled data	File sign download page
Post publication update actions		
Repertoire registration	Allows the user to access the repertoire registration page for the assembled device he/she selected.	Repertoire registration
Ending Marketing	Grants access to the insertion page of the off-market date of "Validated" or "Published" system or kit selected. (Only visible by "MANUFACTURER" users).	Ending Marketing Management
Manufacturing putback	Allows to gain access to the manufacturing putback page for the selected assembled system or kit.	Manufacturing putback
Consultation actions and utilities		
Detail	Grants the user access to the data page of the system or kit selected, in read-only mode	Assembled Detail View
Version history	Allows to view the history of the different versions of the assembled device put back to manufacturing at least once.	Version history
Print	Makes available the file in pdf form containing the editable version of the signature page of an assembled device validated or published.	Assembled Signature Print Page
Download xml	Allows the user to download to a compressed file - in the xml format - all selected assembled device data.	Same



2.4.2.3 Assembled device data registration/editing

This page allows the user to insert/edit details concerning a system or kit.

In the insertion/editing phase of an assembled device two components must be added , one of which must be a DM.

To save the assembled device data the user must select the check of the self-declaration in according to Directive 93/42/CEE art. 12 c. 2. That check, once selected, is no longer editable in any way.

Corresponding with the "Trade Name and Model" field of each component of the assembled device, a link is provided which allows users to view additional information regarding the component selected.



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Home > Class I, II a /b, III Medical Devices > Systems or Assembled Kit (c.2 Art.12) ?

System or Assembled Kit (c.2 Art.12)

***Trade name and model:**

To indicate the additional trade names, it is necessary to proceed as follows:
 1) click on "Add"
 2) type the additional trade name
 3) any further trade name on the database will be saved along with any other information by clicking on "Save".

More assembled trade names	
	Add Delete

***Type:** SYSTEM o KIT

***Code assigned by the assembler(catalogue identifier):**

***User role as to the assembled:**

Company entering the assembled: [Detail](#)

***Assembler:** [Search](#)

Agent: [Search](#)

Marketing Responsible: [Search](#)

***Assembled type:**

Other assembled type:

*** Self-declaration (medical device directive 93/42/CEE art. 12 c. 2)** ☐

- the mutual compatibility of the devices in accordance with the manufacturer's instructions has been verified and the operation has been carried out following in accordance with these instructions.
- the system or the procedure pack has been packaged and relevant information to users incorporating relevant instructions from the manufacturers has been supplied.
- the whole activity is subject to appropriate methods of check.

System or Kit components				
Trade name and model	Manufacturer/ Holder	Product Type	Device status	Select
Add Delete				

Select: Click on one of the squares beside the component(s) in the list depending on operations.

Assembled Device Data Fields

Field Name	Description
Trade Name and Model	Name of the system or kit the assembler has given
Alternative Commercial name for DM	List of alternative commercial names that the DM has been called
Type	Type of assembled device.
Code assigned by the assembler (catalogue identifier)	Indication of product code assigned to the system or kit by the Assembler.



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Field Name	Description
User role as to the assembled	Indicates the role carried out by the user with respect to the assembled device. The user can adopt the following roles: • Assembler • Manufacturer • Mandate Holder • Marketing Director • Other individual delegated by the Manufacturer In the insertion phase, the Assembler is set to appear by default.
Man./Agent./Marketing Resp./Other person delegated by Man.	Indicates the Manufacturing company / Mandate Holder / Marketing Director / Other individual from the Manufacturer of the DM
Assembler	Name of the assembler of the assembled system or kit. If the user has selected the assembler role with respect to the assembled device, the system automatically chooses the manufacturer entered by the user in the “Company Data Management” page. Should the user choose a role other than assembler, he may select an assembler by clicking on the “Search” link; a look-up will Open where the user has the option to select the assembler desired.
Agent	Name of Mandate Holder (Authorised Representatives) of the assembled system or kit. If the user has selected the role of Mandate holder, regarding the assembled device, the system will automatically display the user’s company, as Mandate holder as stipulated in the “Company Data Management” feature. He can select the Mandate holder by clicking on the “Search” link; a look-up will open where the user has the option to search for and select a Mandate holder. The mandate holder has to be selected if the assembled device is legally registered in a non EU country and it is optional if the manufacturer is registered in a SEE country.
Marketing Responsible	Name of Marketing Director of the assembled system or kit. If the user has selected the role of Marketing Director of the assembled device, the system therefore selects the Marketing Director that has been previously stipulated by the user in the “Company Data Management” feature. He can select the Marketing Director clicking on the “Search” link; a look-up will open, where the user has the option to search for and select a Marketing Director.
Assembled Type	The list contains the types of assembled devices.
Self-declaration (medical device directive 93/42/CEE art. 12 c. 2)	Check to be selected to proceed to the notification of the assembled

**Assembled Components List Data Field**

Field Name	Description
Description	Brief description of the component of the assembled device
Trade Name and Model	Commercial name given to the component.
Code assigned by the assembler (catalogue identifier)	Indication of product code assigned to component.
Manufacturer/Holder	Indication of the Manufacturer/title holder of the component
Product Type	Type of component. The component of an assembled device can be: - Classified Medical Device (DM) - Medical and surgical aids (PMC) - Other (ALT) - EC marked medical device notified in minimal form [DM(*)]
Device status	This field is only given value if the component is a DM. Indicates the status of the DM in the database. The status can be changed in the following order: - L: Processing - V: Valid - P: Published

Operations available

Action	Description	Page Name
Add	Grants access to the search page of the components, in order to add one to a system or kit	Components Search
Cancel	Allows user to delete the association between selected components and an assembled system or kit	Same
Save	Saves the operations carried out by the user	Same
Products Management	Opens a window where the user has the option to manage (insert, edit, delete and view) Non-DM items; type "Other"	Products Search Look Up



2.4.2.3.1 Search of EC marked DMs to be added as assembled device components

This page allows the user to set the components search parameter criteria. Users are required to run their search making a distinction between DMs, non-DM items and EC marked DMs notified in minimal form. Depending on their choice, the page will present the user with different search criteria. In this paragraph, we will examine the search among DMs.

After making a search distinction between DMs, non-DM items and EC marked DMs notified in minimal form, users need to set another search parameter.

The user will be first presented with the detail information of the system or kit that is being entered or edited.

Home > Class I, II a /b, III Medical Devices > Systems or Assembled Kit (c.2 Art.12)
?

Composition of systems or kits (c.2 Art.12)

Trade name and model: SUPER KIT 5
Code assigned by the assembler(catalogue identifier): SUPERKITS
User role as to the assembled: ASSEMBLATORE
Assembler: BAYER_MOD
Agent:
Marketing Responsible:
Assembled type: KIT PER SUPPORTO CARDIOPOLMONARE (C.P.S. E ECMO)
System progressive attributed to DM: 1036

Components research criteria

Search: OTHER PRODUCT ☐ DM ☒ DM IN MINIMAL FORM ☐
System progressive attributed to DM:
Manufacturer:
Trade name and model:
Code assigned by the manufacturer from:
(catalogue identifier) to:

Search New search Assembled detail Products management
DM Management in minimal form



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DM data search Fields

Field Name	Description
Search	Users are required to run their search making a distinction between DMs, non-DM items and EC marked DMs notified in minimal form. Depending on their choice, the page will present the user with different search criteria.
System progressive attributed to DM	Option to search a Medical device by its identification number assigned by the system during registration into the database.
Manufacturer	The user can insert the name (or part thereof) of the Manufacturer of the DM
Trade Name and Model	The DM's name (or beginning of) given by the manufacturer, can be indicated
Code assigned by the manufacturer(identifier catalogue) from/to	Option to indicate the range of codes which includes the product code assigned to the DM by the Manufacturer.

Operations available

Action	Description	Page Name
Search	Runs a search with criteria put in place and displays the DM list that match the same criteria	Components List
New search	Clears the search criteria previously put in place	Same
Assembled Detail	Allows user to return to the data page of the assembled device	Assembled Detail Insert Modify.
Products Management	Opens a window where the user has the option to manage (insert, edit, delete, view) Non-DM items; type "Other"	Products Search Look Up
DM management in minimal form	Opens a window allowing the user to manage (search, edit, delete and view) the EC marked DMs notified in minimal form.	DM notified in minimal form list and search



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2.4.2.3.2 List of searched DM Items

This page allows the user to view the list of DM (to add as components of the assembled system or kit) coherent with the search criteria put in place.

Detailed information concerning the system or kit which is being inserted or edited are displayed.

Home > Class I, II a /b, III Medical Devices > Systems or Assembled Kit (c.2 Art.12)
?

Composition of systems or kits (c.2 Art.12)

Trade name and model: KIT434
Code assigned by the assembler(catalogue identifier): KIT4343
User role as to the assembled: ASSEMBLATORE
Agent:
Marketing Responsible:
Assembled type: KIT PER EMODIALISI
System progressive attributed to DM: 1263

Components research criteria

Search: OTHER PRODUCT ☐ DM ☒ DM IN MINIMAL FORM ☐
System progressive attributed to DM:
Manufacturer:
Trade name and model:
Code assigned by the manufacturer (catalogue identifier) from: to:

Trade name and model	Code assigned by the manufacturer (catalogue identifier)	Manufacturer	Device status	Select
HHHHHHH ----- HHHHHH-01	HH01	SYMBIOS ORTHOPÉDIE SA	L	☐

Page 1 of 1

Device status: L=IN LAVORAZIONE C=CONSOLIDATO V=VALIDATO P=PUBBLICATO U=CANCELLATO D'UFFICIO

Select: To add a component, click on one of the squares beside component(s) in the list.

DM Data Search Fields

Field Name	Description
Search	Users are required to run their search making a distinction between DMs, non-DM items and EC marked DMs notified in minimal form. Depending on their choice, the



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Field Name	Description
	page will present the user with different search criteria.
System progressive attributed to DM	Option to search a Medical device by its identification number assigned by the system during registration into the database.
Manufacturer	The user can insert the name (or part of it)
Trade Name and Model	The DM's name (or beginning of) given by the manufacturer, can be indicated
Code assigned by the manufacturer(identifier catalogue) from/to	Option to indicate the range of codes which includes the product code assigned to the DM by the Manufacturer.

DM Data List

Field Name	Description
Trade Name and Model	Name of the component as given by Manufacturer.
Manufacturer	Manufacturer of the component.
Device status	The status of the DM in the database. The status can change in the following order: • L: Processing • V: Valid • P: Published

Operations available

Action	Description	Page Name
Search	Runs a search with the criteria in place and displays a list of the DM that correspond to the same criteria.	Same
New Search	Clears the search criteria previously entered	Assembled Detail Insert Modify
Add Components	Allows user to add the components selected to the assembled system or kit	Assembled Detail Insert Modify
Assembled detail	Allows the user to return to the data page of the assembled device	Assembled Detail Insert Modify
Products Management	Opens a window where the user has the option to manage (insert ,edit, delete and view) Non-DM items; type "Other"	Products Search Look Up
DM management in minimal form	Opens a window allowing the user to manage (search, edit, delete and view) the EC marked DMs notified in minimal form.	DM notified in minimal form list and search
Registration of a DM in minimal form	This button is enabled only when the user cannot find in the Data Bank of Medical Device an EC marked DM to be used as an assembled device component, and allows the notification of the missing EC DM in minimal form.	Registration of a DM in minimal form



2.4.2.3.3 Search of non-DM items be added as assembled device components

This page allows the user to set the components search parameter criteria. Users are required to run their search making a distinction between DMs, non-DM items and EC marked DMs notified in minimal form. Depending on their choice, the page will present the user with different search criteria. In this paragraph, we will examine the case in which the user wishes to search among non-DM items.

The user may associate the following typology:

1. Medical and surgical aids
2. Other

After choosing to run their search amongst the non-DM items, users need to set another search parameter.

Detailed information concerning the system or kit which is being inserted or edited are displayed.

[Home](#) > [Class I, II a /b, III Medical Devices](#) > [Systems or Assembled Kit \(c.2 Art.12\)](#) ?

Composition of systems or kits (c.2 Art.12)

Trade name and model: KIT434
Code assigned by the assembler(catalogue identifier): KIT4343
User role as to the assembled: ASSEMBLATORE
Assembler: BAYER_MOD
Agent:
Marketing Responsible:
Assembled type: KIT PER EMODIALISI
System progressive attributed to DM: 1263

Components research criteria

Search: OTHER PRODUCT ☒ DM ☐ DM IN MINIMAL FORM ☐

Product Type:

Trade name and model:

Code assigned by the manufacturer (catalogue identifier):

Registration Number:

AIC Code:

Manufacturer:

Holder:

Search

New search

Assembled detail

Products management

DM Management in minimal form

**Non-DM Item Data Search Fields**

Field Name	Description
Search	Users are required to run their search making a distinction between DMs, non-DM items and EC marked DMs notified in minimal form. Depending on their choice, the page will present the user with different search criteria.
Product Type	The user can choose between the following types of non-DM items: • Surgical and medical aids • Other
Trade Name and Model	The DM's name (or beginning of) given by the manufacturer, can be indicated
Code assigned by the manufacturer (identifier catalogue)	Product code assigned to the DM by the Manufacturer.
Registration Number	The registration is only in reference to Medical and surgical aids
Manufacturer	The user can indicate the name (or part thereof) of the Manufacturer (referring to DM that are not stamped, medical and surgical aids and other)

Operations available

Action	Description	Page Name
Search	Runs a search with the criteria in place and displays a list of the non-DM items that correspond to the same criteria.	Components List
New Search	Clears the search criteria previously entered	Same
Assembled detail	Allows the user to return to the data page of the assembled device	Assembled Detail Insert Modify
Products Management	Opens a window where the user has the option to manage (insert ,edit, delete and view) non-DM items; type "Other"	Products Search Look Up
DM management in minimal form	Opens a window allowing the user to manage (search, edit, delete and view) the EC marked DMs notified in minimal form.	DM notified in minimal form list and search

2.4.2.3.4 List of searched non-DM Items

This page allows the user to view the list of non-DM items (to add as components to an assembled system or kit) corresponding to the search criteria in place.

Detailed information concerning the system or kit which is being inserted or edited are displayed.



User Manual DM Manufacturer Profile



Home > Class I, II a /b, III Medical Devices > Systems or Assembled Kit (c.2 Art.12) ?

Composition of systems or kits (c.2 Art.12)

Trade name and model: KIT434

Code assigned by the assembler(catalogue identifier): KIT4343

User role as to the assembled: ASSEMBLATORE

Assembler: BAYER MOD

Marketing Responsible:

Assembled type: KIT PER EMODIALISI

System progressive attributed to DM: 1263

Components research criteria

Search: OTHER PRODUCT ☒ DM ☐ DM IN MINIMAL FORM ☐

Product Type: PRESIDIO MEDICO CHIRURGICO

Trade name and model: PASTA

Code assigned by the manufacturer (catalogue identifier):

Registration Number:

AIC Code:

Manufacturer:

Holder:

Trade name and model	Registration Number	Manufacturer	Select
PASTA DDT EXTRA POTENZIATA	2897	INDUSTRIE CHIMICHE CAFFARO S.P.A -	☐

Page 1 of 1

Device status: L=IN LAVORAZIONE C=CONSOLIDATO V=VALIDATO P=PUBBLICATO U=CANCELLATO D'UFFICIO

Select: To add a component, click on one of the squares beside component(s) in the list.

Non-DM Item Data Search Fields

Field Name	Description
Search	Users are required to run their search making a distinction between DMs, non-DM items and EC marked DMs notified in minimal form. Depending on their choice, the page will present the user with different search criteria.
Product Type	The user can choose between the following types of non-DM items: - Surgical and medical aids - Other
Trade Name and Model	The non-DM item's name (or beginning of) given by the manufacturer or title holder, can be indicated
Code assigned by the manufacturer	Product code assigned to the non-DM item by the Manufacturer.



User Manual DM Manufacturer Profile



Field Name	Description
(identifier catalogue)	
Registration Number	The registration is only in reference to Medical and surgical aids
Manufacturer	The user can indicate the name (or part thereof) of the Manufacturer (referring to DM that are not stamped, medical and surgical aids and other)

Non-DM Item Data List Search Fields

Field Name	Description
Trade Name and Model	Name of non-DM item (or beginning of) given by the manufacturer or Title holder.
Code assigned by the manufacturer (identifier catalogue)	Product code assigned by the Manufacturer to the non-DM item; type "Other".
Registration Number	Registration number (Referring only to Medical and surgical aids)
Manufacturer	Name of the Manufacturer (of medical and surgical aids and other)

Operations available

Action	Description	Page Name
Search	Runs a search with the criteria in place and displays a list of the non-DM items that correspond to the same criteria.	Same
New Search	Clears the search criteria previously entered	Same
Add Components	Allows user to add the components selected to the assembled system or kit	Assembled Detail Insert Modify
Assembled Detail	Allows the user to return to the data page of the assembled device	Assembled Detail Insert Modify
Products Management	Opens a window where the user has the option to manage (insert ,edit, delete and view) non-DM items; type "Other"	Products Search Look Up
DM management in minimal form	Opens a window allowing the user to manage (search, edit, delete and view) the EC marked DMs notified in minimal form.	DM notified in minimal form list and search



2.4.2.3.5 Search of EC marked DMs notified in minimal form to be added as assembled device components

This page allows the user to set the components search parameter criteria. Users are required to run their search making a distinction between DMs, non-DM items and EC marked DMs notified in minimal form. Depending on their choice, the page will present the user with different search criteria. In this paragraph, we will examine the search amongst EC marked DMs notified in minimal form.

The user will be first presented with the information of the system or kit that is being entered or edited.

Home > Class I, II a /b, III Medical Devices > Systems or Assembled Kit (c.2 Art.12) ?

Composition of systems or kits (c.2 Art.12)

Trade name and model: KIT434

Code assigned by the assembler(catalogue identifier): KIT4343

User role as to the assembled: ASSEMBLATORE

Assembler: BAYER_MOD

Agent:

Marketing Responsible:

Assembled type: KIT PER EMODIALISI

System progressive attributed to DM: 1263

Components research criteria

Search: OTHER PRODUCT ☐ DM ☐ DM IN MINIMAL FORM ☒

Manufacturer:

Trade name:

Description:

Notified Body Code - Name: [Search](#) [Reset](#)

[Search](#)
[New search](#)
[Assembled detail](#)
[Products management](#)

[DM Management in minimal form](#)

Search fields detail of EC marked DMs notified in a minimal form

Field Name	Description
Search	Users are required to run their search making a distinction between DMs, non-DM items and EC marked DMs notified in minimal form. Depending on their choice, the page will present the user with different search criteria.
Manufacturer	The user may indicate the name (or the initial part thereof) of the manufacturer of the EC marked medical device notified in minimal form.
Trade Name	The user may indicate the trade name (or the initial part thereof) of the EC marked



User Manual DM Manufacturer Profile



Field Name	Description
	medical device notified in minimal form as assigned by the manufacturer.
Description	Users may describe the general technical features of the EC marked medical device notified in minimal form.
Notified Body Code - Name	Users may indicate both the code and name of the notified body used in the notification of the DM in minimal form.

Operations available

Action	Description	Page Name
Search	Starts a search based on the criteria set, and displays a list of EC marked medical devices notified in minimal form that is consistent with these criteria.	List of EC marked DMs notified in a minimal form
New Search	Clears the search parameters previously set	Same
Assembled Detail	Allows the user to go back to the detail page of the assembled device	Assembled device data registration/editing
Products Management	Opens a window allowing the user to manage (enter, edit, delete and view) 'Other' type non-DM items.	Products search.
DM management in minimal form	Opens a window allowing the user to manage (search, edit, delete and view) the EC marked DMs notified in minimal form.	DM notified in minimal form list and search



2.4.2.3.6 List of EC marked DMs notified in a minimal form

This page allows the user to view the list of EC marked DMs notified in minimal form (to be added to the assembled system or kit as components) based on the search criteria that have been set.

The user will be first presented with the information of the system or kit that is being entered or edited.

Home > Class I, II a /b, III Medical Devices > Systems or Assembled Kit (c.2 Art.12)

Composition of systems or kits (c.2 Art.12)

Trade name and model: KIT434
 Code assigned by the assembler(catalogue identifier): KIT4343
 User role as to the assembled: ASSEMBLATORE
 Assembler: BAYER_MOD
 Agent:
 Marketing Responsible:
 Assembled type: KIT PER EMODIALISI
 System progressive attributed to DM: 1263

Components research criteria

Search: OTHER PRODUCT ☐ DM ☐ DM IN MINIMAL FORM ☒

Manufacturer:

Trade name:

Description:

Notified Body Code - Name:

[Search](#) [Reset](#)

[Search](#) [New search](#)

Trade name and model	Description	Manufacturer	Notified Body Code - Name	Select
turbo111	desc	fabbr		☒

Page 1 of 1

Device status: L=IN LAVORAZIONE C=CONSOLIDATO V=VALIDATO P=PUBBLICATO U=CANCELLATO D'UFFICIO

Select: To add a component, click on one of the squares beside component(s) in the list.

[Add Components](#)
[Assembled detail](#)
[Products management](#)
[DM Management in minimal form](#)



User Manual DM Manufacturer Profile



Search fields detail of EC marked DMs notified in a minimal form

Field Name	Description
Search	Users are required to run their search making a distinction between DMs, non-DM items and EC marked DMs notified in minimal form. Depending on their choice, the page will present the user with different search criteria.
Manufacturer	The user may indicate the name (or the initial part thereof) of the manufacturer of the EC marked medical device notified in minimal form.
Trade Name	The user may indicate the trade name (or the initial part thereof) of the EC marked medical device notified in minimal form as assigned by the manufacturer.
Description	Users may describe the general technical features of the EC marked medical device notified in minimal form.
Notified Body Code - Name	Users may indicate both the code and name of the notified body used in the notification of the DM in minimal form.

List field detail of EC marked DMs notified in a minimal form

Field Name	Description
Manufacturer	Name of the manufacturer of the EC marked medical device notified in minimal form.
Trade Name	Trade name of the EC marked medical device notified in minimal form as assigned by the manufacturer.
Description	Description of the general technical features of the EC marked medical device notified in minimal form.
Notified Body Code – Name	Code and name of the notified body used in the notification of the DM in minimal form.

Operations available

Action name	Description	Recalled page name
Search	Starts a search based on the criteria set, and displays a list of EC marked medical devices notified in minimal form that is consistent with these criteria.	List of EC marked DMs notified in a minimal form
New Search	Clears the search parameters previously set	Same
Add Components	Allows user to add the components selected to the assembled system or kit	Assembled Detail Insert Modify
Assembled Detail	Allows the user to go back to the detail page of the assembled device	Assembled device data registration/editing
Products Management	Opens a window allowing the user to manage (enter, edit, delete and view) 'Other' type non-DM items.	Products search.
DM management in minimal form	Opens a window allowing the user to manage (search, edit, delete and view) the EC marked DMs notified in minimal form.	DM notified in minimal form list and search



2.4.2.4 Other non-DM products search

This page allows the user to put search criteria in place in order to view the list of non-DM products; Type "Other".

Home > Class I, II a /b, III Medical Devices > Medical Device (DM) > Products management ?

Product List research

Product Type:

Trade name and model:

Code assigned by the manufacturer (catalogue identifier):

Manufacturer:

CND classifications: [Search](#)

Product List				
Product Type	Trade name and model	Code assigned by the manufacturer	Manufacturer	Select
ALT	ALTRO ENG.	22A	ENGINEINGG	☐

Page 1 of 1

Select: To perform a possible operation, click on one of the circles beside one of the components of the list.

The item 'OTHER' at the field 'Product type' refers to non-DM articles other than surgical medical devices or proprietary medicinal products.



User Manual
DM Manufacturer Profile

*Detail Fields*

Field Name	Description
Product Type	The product type has already been inserted as a non-DM product; type “other”
Trade Name and Model	Option to specify the commercial name (or beginning) of the product
Code assigned by the assembler (catalogue identifier)	The product code assigned to the product can be specified.
Manufacturer	Option to specify the name (or the beginning) of the Manufacturer.
CND Classification	Indicates the national classification of the DM. Referring solely to Non-CE marked DM to add as components of the assembled system or kit (Para 3 Art 12).

Operations available:

Action	Description	Page Name
Search	Runs a search with criteria entered and displays the list of products that match the criteria.	Same
Close	Closes the non-DM product, management window	Assembled List
Enter	Displays the insertion page of a non-DM product; type “Other”	ArticleGeneral Data Look Up
Edit	Displays the data page of the non-DM product selected from the list (in read-only format)	ArticleGeneral Data Look Up
View	Displays the data page of the non-DM product selected from the list (in read-only format)	ArticleGeneral Data Look Up
Cancel	Deletes the non-DM product selected from the list.	Same



2.4.2.5 Other non-DM products Registration/Editing

This page allows the user to insert/edit the information regarding the non-DM products; type “Other”

Home > Class I, II a /b, III Medical Devices > Medical Device (DM) > Products management ?

Product

***Product Type:** ALTRO ▼

***Trade name and model:**

***Code assigned by the manufacturer (catalogue identifier):**

***Manufacturer:**

***CND classifications:** [Search](#)

The item 'OTHER' at the field 'Product type' refers to non-DM articles other than surgical medical devices or proprietary medicinal products.

Detail Fields

Field Name	Description
Product Type	The product type has already been inserted as a non-DM product; type “Other”
Trade Name and Model	Name assigned to the product by the Manufacturer.
Code assigned by the assembler (catalogue identifier)	Product code assigned to the product by the manufacturer.
Manufacturer	Indication of the Manufacturer of the product.
CND Classification	Indicates the national classification of the DM. Referring solely to Non-CE marked DM to add as components of the assembled system or kit (Para 3 Art 12).

Operations available:

Action	Description	Page Name
Save	Saves the information entered by the user	Same
Close	Closes the product management window	Assembled List



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Action	Description	Page Name
Product List	Allows the user to return to the product list, without saving the information entered.	Product Search Look Up

2.4.2.6 DM notified in minimal form list and search

This page allows the user to search and view the corresponding list of DMs in minimal form notified by the same manufacturer as that of the system or assembled kit (Art. 12, c. 2).

This can be activated by means of the “Management DM in minimal form” button that is present in all pages concerning the make-up of systems or assembled kits if the manufacturer has notified at least one device in minimal form.

Once the user has entered at least one search parameter and clicked on “Search”, the system displays the list of DMs notified in minimal form by the manufacturer. For each device the following information is indicated:

- trade name
- manufacturer

By selecting a device from the list, users may:

- view detail information;
- require its modification, unless it is part of a system or kit under Art. 12 c. 3, that is already signed, it is not needed for the functioning of validated or published devices, or it is not part of a system or assembled kit under Art. 12 c. 2;
- require its deletion, unless such device is part of a signed system or kit under Art. 12 c. 3, it is not needed for the functioning of validated or published devices, or it is not part of a system or assembled kit under Art. 12 c. 2;



User Manual DM Manufacturer Profile



DM in minimal form

DM Search in minimal form

Manufacturer:

Trade name :

Description :

Notified Body Code-Name:

[Search](#) [Reset](#)

Trade name and model	Manufacturer	Select
lete effervescente	nuvolini spa	☒

Page 1 of 1

Select: To perform a possible operation, click on one of the circles beside one of the components of the list.

[Edit](#) [Delete](#) [View](#) [Close](#)

Detail Fields

Field Name	Description
Manufacturer	The user may indicate the name (or the initial part thereof) of the manufacturer of the EC marked medical device notified in minimal form.
Trade Name	The user may indicate the trade name (or the initial part thereof) of the EC marked medical device notified in minimal form as assigned by the manufacturer.
Description	Users may describe the general technical features of the EC marked medical device notified in minimal form.
Notified Body Code - Name	Users may indicate both the code and name of the notified body used in the notification of the DM in minimal form.

*Operations available:*

Action	Description	Page Name
Search	Starts a search based on the criteria set, and displays a list of EC marked medical devices notified in minimal form that is consistent with these criteria.	List of EC marked DMs notified in a minimal form
Edit	Displays the data page of the of the DM notified in minimal form selected from the list	DM notified in minimal form General Data Look Up
Delete	Deletes the DM notified in minimal form selected from the list.	Same
View	Displays the data page of the DM notified in minimal form selected from the list (in read-only format)	DM notified in minimal form General Data Look Up
Close	Closes the window	Assembled List

2.4.2.7 Edit and Detail of EC marked DMs notified in a minimal form

This page, activated by the “Edit” and “View” buttons present on the list page of the devices notified in a minimum form, allows the user to view and modify a device notified in a minimum form.

DM in minimal form

?

DM in minimal form update

***Manufacturer:**

***Trade name :**

***Description :**

EC Classification (D.L.46/97 implementation Dir.CE 93/42, D.L.vo 507/92 implementation Dir.CE 90/385) :

Notified Body Code-Name:

[Search](#) [Reset](#)



User Manual DM Manufacturer Profile



Detail Fields

Field Name	Description
Manufacturer	Name of the manufacturer of the device
Trade Name	Name assigned to the device
Description	Description of the device
EC Classification (D.L. 46/97 implementation Dir.CE 93/42; D.L.vo 507/92; implementation Dir.CE 90/385)	Indication of the EC Classification of the DM.
Notified Body - Code - Name	Code and name of the notified body. This field cannot be edited. To select the code of the notified body it is necessary to click on the "Search" link; a page in look-up format will open with the option to search for the notified body by code and name.

Operations available:

Action	Description	Page Name
Save	Saves the information inserted by the user and closes the look-up.	Searched Assembled devices list
Close	Closes the look-up.	Searched Assembled devices list



2.4.2.8 Notification of EC marked DMs in minimal form

This page allows the user to register in a minimum form a CE marked medical device which has not been notified in a regular form by the relative manufacturer yet.

DM in minimal form

?

DM in minimal form insertion

You can record an EC marked Medical Device by simply providing the minimum data needed for its identification, only in the event that the manufacturer has not yet taken steps to complete its registration. Please note that both the regions and the facilities of the National Health Service authorized to consult the class Medical Devices registered in the repertoire will have evidence of any EC marked DM - present as System or Assembled Kit components (Article 12, paragraph 2) or as any other DM needed for the functioning - registered in such minimal form for lack of complete information by its manufacturer

***Manufacturer:**

***Trade name:**

***Description:**

EC Classification (D.L.46/97 implementation Dir.CE 93/42, D.L.vo 507/92 implementation Dir.CE 90/385) :

Notified Body Code-Name:

[Search](#) [Reset](#)

Detail Fields

Field Name	Description
Manufacturer	Name of the manufacturer of the device
Trade Name	Name assigned to the device
Description	Description of the device
EC Classification (D.L. 46/97 implementation Dir.CE 93/42; D.L.vo 507/92; implementation Dir.CE 90/385)	Indication of the EC Classification of the DM.
Notified Body -	Code and name of the notified body. This field cannot be edited.

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Field Name	Description
Code - Name	To select the code of the notified body it is necessary to click on the “Search” link; a page in look-up format will open with the option to search for the notified body by code and name

Operations available:

Action	Description	Page Name
Save	Saves the information inserted and closes the look-up.	Searched Assembled devices list
Close	Closes the window of insertion	Searched Assembled devices list



2.4.2.9 Assembled device data consolidation

This page allows the user to view the list of assembled devices in the approval phase. The activation of approval corresponding to one or more assembled devices involves the activation of consistency and coherency tests on the information entered. Should errors arise in this phase, these will be visible on the activity list feature on the menu option "Activity in progress". Should the tests result positive, the device's status is updated to "Consolidated"; a preliminary stage before the validation, while awaiting the electronic signature.

Home > Class I, II a /b, III Medical Devices > Systems or Assembled Kit (c.2 Art.12) ?

Systems or Assembled Kit (c.2 Art.12)

Consolidating assembled List			
System progressive attributed to the assembled	Assembler	Code assigned by the assembler (catalogue identifier)	Consolidation process status
483	BAYER	78958	Started

To verify the result of consolidation, use the "Go to activities list" button..

[Go to activities list](#)

Consolidating assembled list details

Field Name	Description
Progressive system attributed to DM or Assembled	Product code assigned to each assembled device
Assembler	Name of the assembler
Code assigned by the assembler (catalogue identifier)	Indication of product code assigned to the system or kit by the Assembler.
Consolidation Process status	The status of the process. It can change status in the following order: Initiated Not Initiated

*Operations available*

Action	Description	Page Name
Go to activities List	Allows user to return to the activity list	Activities List

2.4.2.10 Off line signature page

This page is activated by clicking on the “Off line sign” button which is found on the page of the assembled list and allows the user to activate the off line signature process of data.

The 'Off line signature' consists of three steps:

- The user downloads the file in txt format on his computer; this file, automatically generated by the system, contains all the information previously entered. It is possible to simultaneously sign multiple assembled devices; to activate the download it is enough to click on the link in this page.
- the user then proceeds to sign the above mentioned files by using the software he already owns in order to use their signature device (smart card or other device). For the realization of this step it is not necessary to be connected to the “Data Bank and Repertoire of Medical Devices” system.
- the user uploads the signed file on “Data Bank and Repertoire of Medical Devices” system through the appropriate **upload function** accessible from the menu item "**Off line Signature**".



User Manual DM Manufacturer Profile



Home > Company Data > Off Line Signature
?

Off Line Signature

Off Line Signature

- Off Line Signature

- The 'Off line signature' function allows the user to sign the application data locally on his computer, using any digital signature certificate issued by a national certification authority accredited in compliance with Directive 1999/93/EC.
- The 'Off line signature' consists of three steps:
 - download of the file, in txt format, containing all the information on which the digital signature must be affixed (Company's Data, Medical Devices and Systems/Kits notified);
 - local signature of the file;
 - upload of the signed file through the appropriate upload function accessible from the menu item "Off line Signature."
- For a successful completion of the Off line Signature process it is necessary that:
 - The user who uploads the file is the same who downloaded it;
 - The name of the file generated by the system during the download phase is not changed, with the exception of its extension: the digital signature procedure will indeed generate a file with the same name as the original one and with "p7m" extension. The user need only check that the signed file has the "p7m" extension and not, for example, "txt.p7m" (in this case it suffices to cancel the delete "txt");
 - The data subject to digital signature (*) are not changed between the time of the download and the subsequent upload.

(*) Please note that in case of signature of Medical Devices and Systems /Assembled Kits, the data subject to signature include the name of the Manufacturer / Agent / Marketing Responsible/ Other deputed subject, the EC certificate, the Medical Devices necessary to the operation and the components of the systems / Kits

[DatiAzienda07022009172817232](#)



2.4.2.11 Assembled device registration in the Medical Device Repertoire

To register an assembled device that contains at least one DM the user must proceed as follows:

1. Run a search for DM (by clicking on “Medical Device (DM)” in the menu, insert the search criteria and then click on the “Search” button);
2. Select an assembled device found in the “Validated” or “Published” stage;
3. Click on the “Repertoire registration” button.

Home > Class I, II a /b, III Medical Devices > Systems or Assembled Kit (c.2 Art.12) ?

System or Assemblato Kit detail (c.2 Art.12))

Trade name and model: 123
Type: SOK
Code assigned by the assembler (catalogue identifier): 123
Company entering the assembled: BAYER
User role as to the assembled: ASSEMBLATORE
Assembler: BAYER
Agent:
Marketing Responsible:
Assembled type: KIT PER BIOFILTRAZIONE
Other assembled type:

Will this assembled be delivered to the structure of the National Health Service?

no ▼

Enroll

The user must then state that he wishes to make the assembled device available to the S.S.N. by entering “Yes”. The system alerts the user that the choice made cannot be changed and checks that all of the components have been registered on the index. If the check results positive, the assembled device is then registered on the index, otherwise a message stating the opposite is sent to the user.



2.4.2.12 Assembled device off-trade statement

This page allows the user to insert the off-market date in reference to an assembled system or kit in the “Validated” or “Published” stage.

Home > Class I, II a /b, III Medical Devices > Systems or Assembled Kit (c.2 Art.12)

System or Assemblato Kit marketing end (c.2 Art.12)

Trade name and model: 123

Type: SISTEMA o KIT

Code assigned by the assembler(catalogue identifier): 123

User role as to the assembled: ASSEMBLATORE

Assembler: BAYER

Agent:

Marketing Responsible:

Assembled type: KIT PER BIOFILTRAZIONE

System progressive attributed to DM: 544

Marketing End Date:

Marketing End Date: / /

Save

Fields Detail

Field Name	Description
Ending Marketing	Off-market date of DM.

Operations available

Action	Description	Page Name
Save	Saves the information entered	Assembled List



2.4.2.13 Manufacturing putback of an Assembled device in the “Published” status

This feature allows the user to put a system or a kit in the “Published” status back to manufacturing so as to correct bugs or errors or to implement changes that do not imply a new notification. The assembled device data are recorded in the exact moment it is put back to manufacturing. The system or kit will no longer be displayed to those users having a Region or Health company profile as long as it published again.

Home > Class I, II a /b, III Medical Devices > Systems or Assembled Kit (c.2 Art.12) ?

Manufacturing putback

Trade name and model: ROBERTA
Type: SOK
Code assigned by the assembler(catalogue identifier): RB7
Company entering the assembled: BAYER_MOD
User role as to the assembled: ASSEMBLATORE
Assembler: BAYER
Agent:
Marketing Responsible:
Assembled type: KIT PER BIOFILTRAZIONE
Other assembled type:

* **Reason for manufacturing putback:** ☐ to correct bugs or errors
☐ or to implement changes that do not imply a new notification

* **Statement of changes planned:**

Confirm

Fields detail

Field name	Description
Reason for manufacturing putback	Reason why the published selected assembled system or kit is put back to manufacturing. A declarant may independently put back to manufacturing those systems or kits only to correct bugs or errors or to implement changes that do not imply a new notification
Statement of estimated changes	Changes the Declarant estimates to implement to the assembled device during manufacturing

Operation available

Action	Description	Page Name
Confirm	Puts the assembled device or kit back to manufacturing and records all of the information it contains	Assembled List



2.4.2.14 Read-only details view of an Assembled device

This page allows the user to view information regarding an assembled system or kit in read-only mode.

In order to view the data of a Assembled device, the user must proceed as follows:

1. Run the search for the assembled device (by clicking on “Assembled Management” in the menu, insert the search criteria by clicking on the “Search” button)
2. Select the desired device and click on the “View” button to access the data page.

Home > Class I, II a /b, III Medical Devices > Systems or Assembled Kit (c.2 Art.12) ?

System or Assemblato Kit detail (c.2 Art.12))

Trade name and model: SISTEMA DI PROVA
Type: SYSTEM o KIT
Code assigned by the assembler(catalogue identifier): ASS01
Company entering the assembled: BAYER_MOD
User role as to the assembled: ASSEMBLATORE
Assembler: BAYER
Agent:
Marketing Responsible:
Assembled type: SISTEMI PER RADIOLOGIA
Other assembled type:
Self-declaration (medical device directive 93/42/CEE art. 12 c. 2) ☒

- the mutual compatibility of the devices in accordance with the manufacturer's instructions has been verified and the operation has been carried out following in accordance with these instructions.
- the system or the procedure pack has been packaged and relevant information to users incorporating relevant instructions from the manufacturers has been supplied.
- the whole activity is subject to appropriate methods of check.

System or Kit components					
Description	Trade name and model	Code assigned by the manufacturer (catalogue identifier)	Manufacturer/ Holder	Product Type	Device status
	DISPOSITIVO MEDICO	A02	QUA.SER. S.A.S.	DM	L
	ASET AQUA		JOHNSON & JOHNSON	PMC	
	NUOVA PROVA	890	FABBRICANTE	ALT	
	ALTRO ENG. OLD	22A-OLD	ENGINEERINGG	ALT	

Assembled List



User Manual DM Manufacturer Profile



Assembled Device Data Fields

Field Name	Description
Trade Name and Model	Name of the system or kit the manufacturer has given
Type	Type of assembled device.
Code assigned by the assembler (catalogue identifier)	Indication of product code assigned to the system or kit by the Assembler.
Assembler	Name of the assembler of the assembled system or kit.
Agent	Name of Mandate Holder (Authorised Representatives) of the assembled system or kit.
Marketing Responsible	Name of Marketing Director of the assembled system or kit.
User role as to the assembled	Indicates the role carried out by the user with respect to the assembled device. The user can adopt the following roles: • Assembler • Manufacturer • Mandate Holder • Marketing Director • Other individual delegated by the Manufacturer.
Assembled Type	Indication of the type of assembled devices.
Self-declaration (medical device directive 93/42/CEE art. 12 c. 2)	User declaration on compliance with the obligation of the assembler

Assembled Components List Data Fields

Field Name	Description
Description	Brief description of the component of the assembled device
Trade Name and Model	Commercial name given to the component.
Code assigned by the assembler (catalogue identifier)	Indication of product code assigned to component.
Manufacturer/Holder	Name of the Manufacturer/title holder of the component
Product Type	Type of component. The component of an assembled device can be: • Classified Medical Device (DM) • Medical and surgical aids (PMC) • Medicines (SPM) • Other (ALT) • EC marked medical device notified in minimal form [DM(*)]
Device Status	This field is only given value if the component is a DM. Indicates the status of the DM in the database. The status can change in the following

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Field Name	Description
	order: • L: Processing • V: Valid • P: Published

Operations available

Action	Description	Page Name
List of assembled devices	Allows the user to return to the list of the assembled devices	Assembled List



2.4.2.15 Version history

This feature allows the user to consult the various versions of a system or assembled kit that has been brought from the “Published” status back to the “Manufacturing” status at least once. Amongst the reasons why an assembled can be brought from the “Published” status back to the “Manufacturing” status, there are:

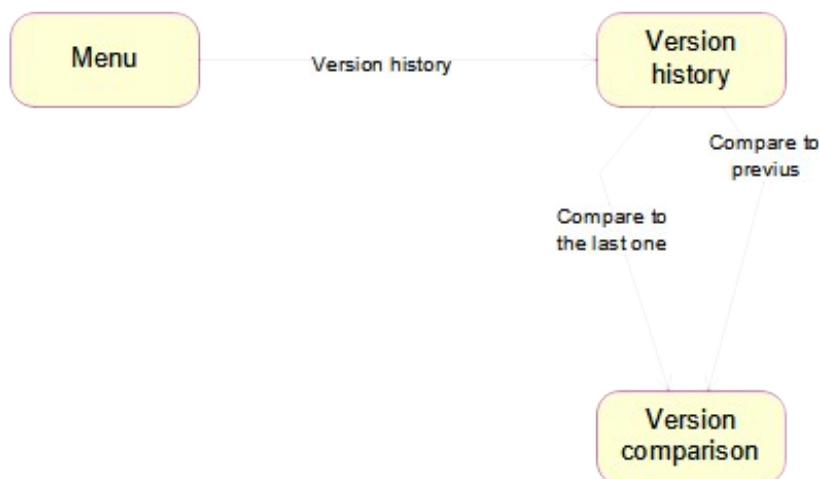
- correcting bugs or errors
- implementing changes that do not imply a new notification
- as per DGFDm request

To consult the version history of an assembled system or kit, the user needs to:

- search the assembled devices (by clicking on the “Assembled Management” menu option, setting the search criteria by clicking on the “Search” button)
- select an assembled device that has been put back to manufacturing at least once, and click on the “Version history” button

Pages involved:

- ✓ Version history
- ✓ Version comparison



2.4.2.15.1 Version history

This page allows the user to consult the version history of the various versions of those Assembled that have been brought from the “Published” status back to the “Manufacturing” status at least once.



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Home > Class I, II a /b, III Medical Devices > Systems or Assembled Kit (c.2 Art.12) ?

Historical Versions

Trade name and model: ROBERTA
Type: SOK
Code assigned by the assembler(catalogue identifier): RB7
Company entering the assembled: BAYER_MOD
User role as to the assembled: ASSEMBLATORE
Assembler: BAYER
Agent:
Marketing Responsible:
Assembled type: KIT PER ANESTESIA COMBINATA PERIDURALE E SPINALE
Other assembled type:

Manufacturing putback		
Validate End Date	Reason for manufacturing putback	Select
10/09/2009	per modifiche che non implicano la rinotifica	☐
24/07/2009	per correzione di errori o imprecisioni	☐

[Compare with current](#)
[Compare with Previous](#)

Operations available

Action	Description	Page Name
Compare to the last one	Allows the user to access the comparison page of the selected version with the last page available for the (actual) assembled	Version comparison
Compare to previous	Allows the user to access the comparison page of the selected version with the one that precedes it	Version comparison



2.4.2.15.2 Version comparison

This page allows the user to display all of the differences between the two different versions of an assembled

Home > Class I, II a /b, III Medical Devices > Systems or Assembled Kit (c.2 Art.12) > Compare Versions ?

Compare Versions

Trade name and model: ROBERTA
Type: SOK
Code assigned by the assembler(catalogue identifier): RB7
Company entering the assembled: BAYER_MOD
User role as to the assembled: ASSEMBLATORE
Assembler: BAYER
Agent:
Marketing Responsible:
Assembled type: KIT PER ANESTESIA COMBINATA PERIDURALE E SPINALE
Other assembled type:

Differences between the current version and the version valid until 10/09/2009

Data Updated	Current value	Value until 10/09/2009
Assembled type	KIT PER ANESTESIA COMBINATA PERIDURALE E SPINALE	KIT PER BIOFILTRAZIONE
Components - DM	Trade name and model: ANGIOLIPS Manufacturer: BAYER STORIC NEW ----- Trade name and model: AFSESE Manufacturer: BAYER STORIC NEW	

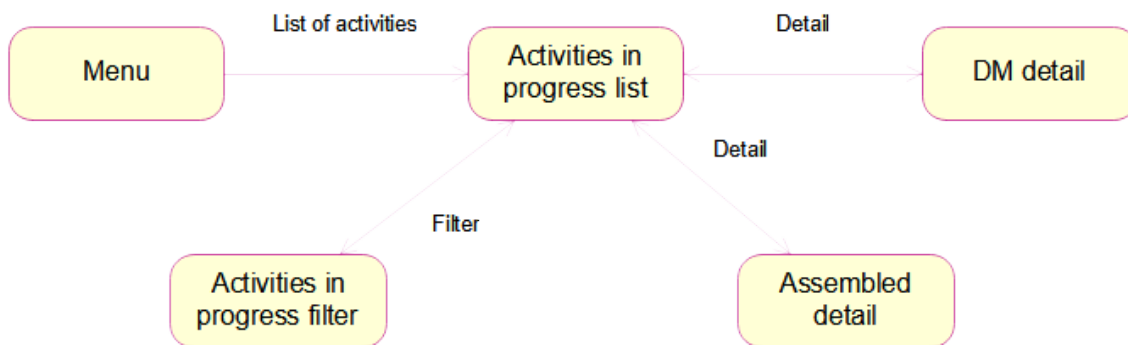
[Back](#)

Action	Description	Page Name
Back	Directs the user back to the version history page	Version history



2.4.3 Menu option “Activities in progress”

Screen flowchart:



2.4.3.1 List of the activities in progress

In order to gain access to the page containing the list of activities in progress, the user must click on the “Activities List” menu option.

This page allows the user to view the activity list in progress, referring to DM am assembled systems or kits (Para.2 Art.12) that have been validated by the respective user.

The user may receive the following messages in reference to each DM validated:

- Successful publication by the DGFDM department
- Modification request from the DGFDM department
- Modification request due to failure to pass the following automatic tests:
 1. Missing required general data and attached documentation for the DM
 2. Missing required data for the assembled systems or kits
 3. Failure to indicate at least two assembled system and kit components (DM), in accordance with Para.2 Art.12.
 4. Failure to publish all systems and kit components, in accordance with Para.2 Art.12.

Clicking on the link corresponding with the “Comunications and Error Messages” column, displays the data page containing the principal data for the selected activity in progress.



Home > Medical Devices of the Class I, II a / b, III, Download Area Personal data

?

Activities underway		Filter
Progressive system attributed to DM or Assembled	Error Messages for the Manufacturer and Communications	Communication Data
15744	Messaggio di rifiuto pubblicazione	05/06/2008
15741	Messaggio di pubblicazione	06/06/2008
15744	Messaggio di pubblicazione	06/06/2008
15681	Messaggio di mancanza dati	18/06/2008
15682	Messaggio di mancanza dati	18/06/2008
14805	Messaggio di mancanza dati	23/06/2008
10189	Messaggio di mancanza dati	24/06/2008
10210	Messaggio di mancanza dati	24/06/2008
10366	Messaggio di mancanza dati	26/06/2008
10372	Messaggio di mancanza dati	01/07/2008

Pagina 1 di 2 [Successiva >>](#)

Detail Fields

Field Name	Description
System progressive attributed to DM or Assembled	Consecutive System number of DM or Assembled device
Error Messages for the Manufacturer and Communications	Indicates the type of communication. There can be three types of communication regarding a validated DM or assembled device: Successful publication by the DGFDM department. Modification request from the DGFDM department Modification request due to failure to pass the automatic tests in the system.
Communication Data	Indicates the data where the activity is assigned to the DGFDM department

Operations available:

Action	Description	Page Name
Filter	Opens a window from where the user has the option to filter the activity in progress list based on search criteria inserted.	Activities in progress Filter



2.4.3.2 Filter the list of the activities in progress

This page is displayed in look-up format and allows the user to filter the activity in progress list based on search criteria put in place.

Worklist's Filters	
Filter by:	
Progressivo di sistema attribuito al DM o Assemblato	
Messaggi d'errore per il Fabbrikante e Comunicazioni	
Data Comunicazione	
Search Clear Filters Close	

Detail Fields

Field Name	Description
System progressive attributed to DM or Assembled	Consecutive System number of DM or Assembled device
Error Messages for the Manufacturer and Communications	Indicates the type of communication. There can be three types of communication regarding a validated DM or assembled device: • Successful publication by the DGFDM department. • Modification request from the DGFDM department • Modification request due to failure to pass the automatic tests in the system.
Communication Data	Indicates the data where the activity is assigned to the DGFDM department

Operations available:

Action	Description	Page Name
Filter	Runs a search of the activities in progress based on search criteria inserted.	Activities in progress List
Clear Filters	Clears the search criteria previously put in place	Same
Close	Closes the search margin window, without running the search.	Activities in progress List



2.4.3.3 Viewing of the details of DM activities in progress

This page allows the user to view the principal information regarding the activity in progress resulting in validation/publication.

There are three possible types of communication for a validated DM:

1. Successful publication in the DGFDM department. In this case at the top of the page the phrase "E' stata accettata la richiesta di pubblicazione per la dispositivo..." (The publication request has been accepted for the DM) will appear and then the principal data of the DM will be synthesised.

Home > Dispositivi Medici di Classe I,IIa/b,III

DM DMP02M - BRISTOL Pubblicato

E' stata accettata la richiesta di pubblicazione per il dispositivo:

Dati del dispositivo

Tipo DM:	DISPOSITIVO
Nome commerciale e modello:	DISPOSITIVO MEDICO DI PROVA 2 MANDATAR
Codice attribuito dal fabbricante (identificativo catalogo):	DMP02M
Fabbricante:	BRISTOL
Progressivo di Sistema Attribuito al DM:	1833

Note di rettifica:

[Chiudi attivita'](#) [Torna alla Lista attivita'](#)

2. Modification request from the DGFDM department. In this case at the top of the page the phrase "Non e' stata accettata la richiesta di pubblicazione per la dispositivo..." (The publication request hasn't been accepted for the DM) will appear and then the principal data of the DM will be synthesised.



Home > Dispositivi Medici di Classe I,IIa/b,III

DM DMP02M - BRISTOL non Pubblicato

Non è stata accettata la richiesta di pubblicazione per il dispositivo:

Dati del dispositivo

Nome commerciale e modello:	DISPOSITIVO MEDICO DI PROVA 2 MANDATAR
Codice attribuito dal fabbricante (identificativo catalogo):	DMP02M
Fabbricante:	BRISTOL
Progressivo di Sistema Attribuito al DM:	1833

Note di rettifica:

[Chiudi attività'](#) [Torna alla Lista attività'](#)

3. Modification request due to failure to pass the automatic tests in the system. In this case the list of errors which determined the failure to pass the automatic tests in the system is displayed with the principal data of the DM.



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[Home](#) > Dispositivi Medici di Classe I,IIa/b,III

Il DM C03 COPIA COPIA - PLUTO ha dei campi incompleti

Il DM C03 COPIA COPIA - PLUTO non puo' essere validato perche' non tutti i campi obbligatori sono stati valorizzati. Vedi la lista dei campi obbligatori mancanti, diseguito riportata.

Dati del dispositivo

Nome commerciale e modello: CODICE ZERO TRE

Codice attribuito dal fabbricante
(identificativo catalogo): C03 COPIA COPIA

Fabbricante: PLUTO

Progressivo di Sistema Attribuito
al DM: 1113

Campi Mancanti

I DM necessari al funzionamento non sono tutti pubblicati

Allegati errati per la classificazione CE : Classe IIa

Documentazione incompleta

[Vai al DM](#)

[Chiudi attivita'](#)

[Torna alla Lista attivita'](#)

Detail Fields

Field Name	Description
Trade Name and Model	Denomination of the DM, as assigned by the Manufacturer
Code assigned by the manufacturer (identifier catalogue)	Specific code attributed to the DM by the manufacturer
Manufacturer	Name of the Manufacturer of the DM
System Progressive attributed to DM	Consecutive number of DM device by the system
Note for the Modification	Indication of the reasons that made the DGFDM reject the request for publication of the DM
Missing fields	The list of errors that caused the DM to fail the automatic tests of the system for the validation of the DM

*Operations available:*

Action	Description	Page Name
Go to DM	Grants access to the general data page of the DM	General Data Page
Close Activity	Allows the user to return to the activities in progress list, eliminating the activity previously selected	Activities in progress List
Back to Activity List	Allows the user to return to the list of activities in progress	Activities in progress List

2.4.3.4 Viewing of the details of Assembled devices activities in progress

This page allows the user to view the principal data of the activity in progress resulting in validation/publication.

There are three possible types of communication for a validated assembled device.

1. Successful publication in the DGFDM department. In this case at the top of the page the phrase "E' stata accettata la richiesta di pubblicazione dell'assemblato..." (The publication request has been accepted for the DM) will appear and then the principal data of the assembled device will be synthesised.

Home > Dispositivi Medici di Classe I,IIa/b,III

L'Assemblato PRV0101 - DATEX-OHMEDA SPA Pubblicato

E' stata accettata la richiesta di pubblicazione dell'Assemblato:

Dati dell'assemblato

Nome commerciale e modello:

Codice attribuito dall'Assemblatore:

Assemblatore:

Progressivo di sistema attribuito all'Assemblatore:

Inserire eventuali note per il rifiuto:



2. Modification request from the DGFDM department. In this case at the top of the page the phrase "Non e' stata accettata la richiesta di pubblicazione dell'assemblato ..." (The publication request has been accepted for the DM) will appear and then the principal data of the assembled device will be synthesised.

Modification request due to failure to pass the automatic tests in the system. In this case the list of errors which determined the failure to pass the automatic tests in the system is displayed with the principal data of the Assembled.

Detail Fields

Field Name	Description
Trade Name and Model	Denomination of the system or kit, as assigned by the Assembler
Code assigned by the manufacturer (identifier catalogue) from/to	Specific code attributed to the Assembled system or kit by the Assembler.
Assembler	Name of the Assembler of the Assembled system or kit
System progressive attributed to the DM	Consecutive number of Assembled device by the system
Note for the Modification	Indication of the reasons that made the DGFDM reject the request for publication of the Assembled Device
Missing fields	The list of errors that caused the Assembled Device to fail the automatic tests of the system for the validation of the Assembled Device.

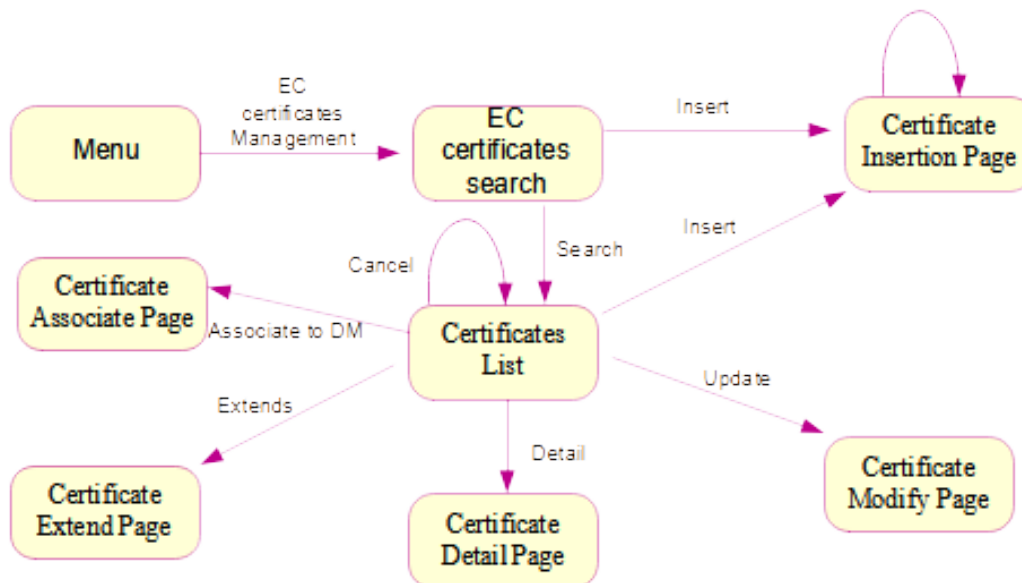
Operations available:

Action	Description	Page Name
Go to Assembled DM	Grants access to the general data page of the Assembled device	Assembled Deatil Insert Modify
Close Activity	Allows the user to return to the activities in progress list, eliminating the activity previously selected	Activities in progress List
Back to Activity List	Allows the user to return to the list of activities in progress	Activities in progress List



2.4.4 Menu option “EC Certificates”

Screen flowcharts:



2.4.4.1 EC certificates search

Having clicked on “EC Certificates > EC Certificates Management” on the menu, a page appears which allows the user to define the search criteria of the EC certificates.

The user may search two types of certificates:

- ✓ Certificates entered by the Declarant on behalf of the Manufacturer;
- ✓ Certificates entered by the Italian OONNs.

The user may search the certificates entered directly by the Italian OONNs only if they know their number, issuing notified body and issue date. The expiry date won't be mandatorily required during the search phase as it's no more mandatory in the presence of the Directive on implantable medical devices (90/385/EEC) – Annex 4 or Directive concerning medical devices (93/42/EEC) – Annex IV.

The user can also view the complete details of a given certificate, but only if that certificate is associated to a DM in the Validated/Published status.

From this page, the user may also access the insertion page of a new certificate clicking on the “Insert” button.



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EC certificates search

Research criteria

No.of certificate of the EC marking:

Issue date: / /

Certificate Expiration Date : / /

Notified Body Code-Name: [Search](#) [Reset](#)

Run a search on all Certificates that have been notified in the data base by the Italian Notified Bodies: ☐

Select: Click on one of the squares beside the component(s) in the list depending on operations.

By means of the Edit button, the system allows the user to correct those certificate data that have not been properly entered. However, the user may be faced with two scenarios:

- Scenario 1:** The certificate is linked to a DM in the "In progress" or "Consolidated" status. Unlike all of the other fields, here, the certificate Manufacturer cannot be edited. If the user edits the 'EC Directive 2003/32' field, all other DMs in the "Consolidated" status linked to that certificate will be put back to manufacturing.
- Scenario 2:** The certificate is linked to a DM in the "Validated" or "Published" status. To edit that certificate, the user should first ask, via e-mail, the FVG Support for permission, and they will release the certificate. Once it is released, when the user selects the certificate, the 'Edit' button will be active, and they will be able to apply the changes required. Obviously, the certificate Manufacturer cannot be edited. Once such changes have been saved, the certificate will be blocked again and cannot be edited.

To defer or extend the certificate, use the specific button

Detail Fields

Field Name	Description
No.of certificate of the EC marking	Identification number of the EC certificate. This field is mandatory only in the case where the individual that has performed the notification of the certificate in Data Bank of Medical Device is an Italian ON.
Certificate issue date	Certificate issue date. This field is mandatory only in the case where the individual that has performed the notification of the certificate in Data Bank of Medical Device is an Italian ON. If the "Run a search on all Certificates that have been notified by the Italian Notified Bodies in Data Bank of Medical Device" check box is not selected, the date cannot be entered.
Certificate Expiration Date	Expiry date of the Certificate.
Notified Body Code-Name	Indication of the code and name of the organization notified. This field cannot be edited. To select the code of the organization notified it is necessary to click on the "Search" link; a look-up will open from which it will be possible to search for the organization notified by code and name.
Run a search on	By selecting this check box, the user can look for a certificate amongst those notified in



Field Name	Description
all Certificates that have been notified by the Italian Notified Bodies in Data Bank of Medical Device	the Data Bank of Medical Device directly by the Italian OONNs. In that case, all input fields of the page, with the exception of the expiry date of the certificate, will be mandatory, which means that in order to enter the reference of a certificate that was notified directly by an Italian ON in one of their own DM, the user will have to mandatorily know its name, issue date and the Italian ON that issued that certificate. If this check box is not selected, the search will be performed on the EC Certificates that have been notified in the Data Bank of Medical Device directly by the user.

Operations available:

Action	Description	Page Name
Search	Starts the certificates search, entered by the Declarant on behalf of the Manufacturer and the Italian ON, that are consistent with the parameters that have been set.	Certificates List Page
New search	Clears the search criteria previously defined	Same
Insert	Allows access to the insertion page of a new EC certificate	Certificate Insertion Page

2.4.4.2 List of searched EC certificates

This page displays the list of the EC certificates which correspond to the criteria defined in the relative search page. For every certificate the following information is displayed²⁴:

- the certificate number of the EC stamp
- the expiry date
- the organization notified which issued it
- the essential details of the National and Community harmonized norms acknowledged and eventually applied
- the file attached containing the image of the certificate

In the case of certificates entered directly by the Italian OONNs, the last two fields listed can only be viewed if the certificate is associated to at least one DM in the Validated/Published status (namely, after the user has officially associated a given certificate to a DM at least once).

As an alternative, from that page the user may:

- request the registration of a new certificate by clicking on the “Enter” button, that can always be enabled.
- replace a given certificate with a new one within the DM notification;
- for all certificates that had been previously entered by the Declarant, select a certificate from the list and:

²⁴ Some of the specified fields may not appear in the list because, not being mandatory, they could have been left empty when the certificate was entered.

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- ✓ view its “Details”;
- ✓ request its “Amendment”, in those cases where the selected certificate is not associated to an extension nor to a medical device in the validated or published status; or when it is associated to signed DMs, but was set to be amended by an authorized office;
- ✓ request the “Deletion” of the certificate only if the selected certificate is not associated to any extension nor to any medical device. When activating the “Delete button, the system will ask the user if he/she wishes to delete the selected certificate, and in that case it will proceed with the deletion. After that, the list of remaining certificates will be displayed;
- ✓ access the “Extension” page of that certificate only if the selected certificate is not associated to any extension or, even in the case in which it is, if it still appears as associated to a validated or published device.
- ✓ associate the selected certificate to one or more medical devices of the same manufacturer
- for all certificates that have been entered by the Italian OONN, select a certificate from the list and:
 - ✓ associate the selected certificate to one or more medical devices;
 - ✓ view its “Details” only if the certificate is connected to a DM in the Validated/Published status.

If the user needs to amend a given certificate that he/she has previously entered, and that is associated to validated or published Medical Devices, then he/she must request, via e-mail, the FVG Support for permission, and he/she will have the certificate released. Certificates entered by the Italian OONNs cannot be released, as they can be put back to manufacturing in order to correct bugs or errors only by the OONNs themselves.



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EC certificates search

Research criteria

No. of certificate of the EC marking:

Issue date: / /

Certificate Expiration Date : / /

Notified Body Code-Name: [Search](#) [Reset](#)

Run a search on all Certificates that have been notified in the data base by the Italian Notified Bodies: ☐

[Search](#) [New search](#)

No. of certificate of the EC marking	Certificate Expiration Date	Notified Body	Details of Community harmonized standards and of national transposing rules that may be applied	File containing the certificate	Select
132	02/12/2008	ISTITUTO SUPERIORE DI SANITA			☐

Page 1 of 1

Select: Click on one of the squares beside the component(s) in the list depending on operations.

By means of the Edit button, the system allows the user to correct those certificate data that have not been properly entered. However, the user may be faced with two scenarios:

- Scenario 1:** The certificate is linked to a DM in the "In progress" or "Consolidated" status. Unlike all of the other fields, here, the certificate Manufacturer cannot be edited. If the user edits the 'EC Directive 2003/32' field, all other DMs in the "Consolidated" status linked to that certificate will be put back to manufacturing.
- Scenario 2:** The certificate is linked to a DM in the "Validated" or "Published" status. To edit that certificate, the user should first ask, via e-mail, the FVG Support for permission, and they will release the certificate. Once it is released, when the user selects the certificate, the 'Edit' button will be active, and they will be able to apply the changes required. Obviously, the certificate Manufacturer cannot be edited. Once such changes have been saved, the certificate will be blocked again and cannot be edited.

To defer or extend the certificate, use the specific button

[Insert](#) [Detail](#) [Edit](#) [Delete](#) [Extend / Extension](#) [Associate to DM](#) [Substitution](#)

Detail Fields

Field Name	Description
No. of certificate of the EC marking	Identification number of the EC certificate. This field is mandatory only in the case where the individual that has performed the notification of the certificate in Data Bank of Medical Device is an Italian ON.
Certificate issue date	Certificate issue date. This field is mandatory only in the case where the individual that has performed the notification of the certificate in Data Bank of Medical Device is an Italian ON. If the "Run a search on all Certificates that have been notified by the Italian Notified Bodies in Data Bank of Medical Device" check box is not selected, the date cannot be



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Field Name	Description
	entered.
Certificate Expiration Date	Expiry date of the Certificate.
Notified Body	Indication of the code and name of the organization notified. This field cannot be edited. To select the code of the organization notified it is necessary to click on the “Search “ link; a look-up will appear from which it will be possible to search for the organization notified by code and name
Run a search on all Certificates that have been notified by the Italian Notified Bodies in Data Bank of Medical Device:	By selecting this check box, the user can look for a certificate amongst those notified in the Data Bank of Medical Device directly by the Italian OONNs. In that case, all input fields of the page, with the exception of the expiry date of the certificate, will be mandatory, which means that in order to enter the reference of a certificate that was notified directly by an Italian ON in one of their own DM, the user will have to mandatorily know its name, issue date and the Italian ON that issued that certificate. If this check box is not selected, the search will be performed on the EC Certificates that have been notified in the Data Bank of Medical Device directly by the user.

Operations available:

Action	Description	Page Name
Search	Starts the certificates search, entered by the Declarant on behalf of the Manufacturer and the Italian ON, that are consistent with the parameters that have been set.	Page Lists Certificates
New search	Clears the search criteria previously defined.	Same
Insert	Allows access to the registration page of a new EC certificate. When OONNs can enter their certificates independently, the Declarant can no longer enter certificates issued by Italian OONNs into the system. A check will in fact be performed on the saving of the registration form data of a new certificate, so as to prevent this action from being performed.	Certificate Insertion Page
Detail	Allows access to a details page of the data associated to an EC certificate. If the selected certificate was entered by an Italian ON, the feature will be enabled only if that certificate is connected to a DM in the Validated/Published status.	Certificate Detail Page
Edit	It allows to access the amendment page for the selected certificate, only in the case where that certificate had been	Certificate Modify Page



Action	Description	Page Name
	previously entered by the Declarant, it is not associated to an extension nor to any validated or published medical device, or if it is associated to signed DMs, but was set to be amended by an authorized office.	
Delete	Deletes the selected certificate, only in the case where that certificate had been previously entered by the Declarant, it is not associated to an extension nor to any medical device.	Same
Extend/ Extentions	Allows the user to access the extension page of the selected certificate, only in the case where that certificate had been previously entered by the Declarant, it is not associated to an extension or, if it is, it still appears as associated to a validated or published device.	Certificate Extend Page
Associate to DM	Allows the user to access the association page of the selected certificate to the medical devices.	Certificate Associate Page
Substitution	Allows the user to replace the selected certificate with a new one within the notification of more DMs.	Substitution Page

2.4.4.3 New EC certificate registration

This page allows the user to insert a new EC certificate.

The page is activated by clicking on the “Insert” button, present on the pages of search and visualization of the EC certificates list.

If the user inserts a certificate having “No. of certificate of the EC marking” and “Notified Body – Code- Name” which coincide with those of a certificate already present in data base, the system will ask the user to insert such a certificate as an extension of that one which already exists (see paragraph 2.3.5.6)

When OONNs can enter their certificates independently, the Declarant can no longer enter certificates issued by Italian OONNs into the system. A check will in fact be performed on the saving of the registration form data of a new certificate, so as to prevent this action from being performed.



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Certificate Data

Certificate Data

***Manufacturer:** [Search](#)
[Detail](#)

***Notified Body Code-Name:** [Search](#)

***No.of certificate of the EC marking:**

First Release Date /update /renewal: / /

Certificate Expiration Date : / /

Details of Community harmonized standards and of national transposing rules that may be applied:

EC Directive 2003/32:

The certificate also concerns the EC Directive 2003/32: ☐
The certificate does not concern the EC Directive 2003/32: ☐
The certificate only concerns the EC Directive 2003/32 (choise no longer usable): ☐

***Annex according to which the device was certified:**

***File containing the certificate:** [Sfoglia...](#)
(max size 2MB)

It recommends to use contained file size to facilitate consultation.

[Save](#) [Back](#)

Detail Fields

Field Name	Description
Manufacturer	Indication of the manufacturer of the DM for which the certificate has been issued. To select a manufacturer it is necessary to click on the “Search” link; there will appear a look-up from which it is possible to make a search.
Notified Body – Code- Name	Indication of the code and name of the organization notified. This field cannot be edited. To select the code of the organization notified it is necessary to click on the “Search”link ; a look-up will appear from which it will be possible to search for the organization notified by code and name.
No.of certificate of the EC marking	Identification number of the EC certificate. Such number cannot contain blank spaces.
First Release	Date of first release/update/renewal of the certificate.



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Field Name	Description
Date /update /renewal	
Certificate Expiration Date	Expiry date of the Certificate. This field is always mandatory, except if the user has selected the value 'Annex IV/4' in the field 'Annex according to which the device was certified'.
Details of Community harmonized standards and of national transposing rules that may be applied	The essential details of the National and Community norms acknowledged during the fabrication of the DM .
EC Directive 2003/32	States whether or not the certificate should be in compliance with EC Directive 32/2003: the user will have to indicate whether the certificate is relative ALSO to the EC Directive 32/2003 or is NOT relative to the EC Directive 32/2003. When entering a new certificate, the item "The certificate only concerns the EC Directive 2003/32" is disabled, though still visible on the page (it's not possible to select this option, because it's no longer available).
Annex according to which the device was certified	Indication of the annex according to which the device has been changed.
File to attach	A .pdf file to be attached containing the image of the EC certificate. To attach this file it is necessary to use the "Browse" button. There is a limit to the dimension of the .pdf file that can be attached to the DM (in the sample picture, such limit equals 2 MB); for the maximum size allowed, refer to the corresponding value shown by the application.

Operations available:

Action	Description	Page Name
Save	Memorizes the information relative to the certificate inserted in the data base and comes back to the previous page	Certificates List Page



Action	Description	Page Name
Back	Voids the insertion and comes back to the previous page	Certificates List Page

2.4.4.4 EC certificate detail

Activated by the page “Certificates List”, selecting a certificate and clicking on the “Detail” button, the page allows the user to visualize, in non editable mode, the following detailed informations concerning a certificate²⁵:

- the manufacturer of the device or devices for which the certificate has been issued
- the organization notified which issued the certificate
- the certificate number of the EC stamp
- the date of issue/adjournment/renewal
- the expiry date of the certificate
- the essential details of the National and Community norms acknowledged and eventually applied
- indication of whether or not the certificate should be in compliance with EC Directive 32/2003²⁶;
- the annex according to which the device has been certificated
- the file attached containing the image of the certificate

Moreover, if the certificate is associated with the medical devices, the page will give evidence of it, displaying the list of the devices connected.

²⁵ Some of the specified fields could have no value displayed in the page because, not being mandatory, they may have been left empty when the certificate was entered.

²⁶ One of the three items – “The certificate only concerns the EC Directive 2003/32” – will remain visible on the page but it won't be possible to select it any more because the option is no longer available.

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Certificate Data

Certificate Data

***Manufacturer:**

***Notified Body Code-Name:**

No. of certificate of the EC marking:

First Release Date /update / renewal: / /

***Certificate Expiration Date :** / /

Details of Community harmonized standards and of national transposing rules that may be applied:

EC Directive 2003/32:

The certificate also concerns the EC Directive 2003/32: ☒
 The certificate does not concern the EC Directive 2003/32: ☐
 The certificate only concerns the EC Directive 2003/32 (choise no longer usable): ☐

***Annex according to which the device was certified:**

***File to attach:** [facsimile dichiarazione impresa.pdf](#)

Connected devices list					
System progressive attributed to DM	Manufacturer	Code assigned by the manufacturer (catalogue identifier)	Trade name and model	CND classifications	Device status
813914	MINISTERO DELLA SALUTE	ZZZ_24	ZZZ_24	C0104020102 - CATETERI PER ULTRASONOGRAFIA INTRAVASCOLARE	C
842	MINISTERO DELLA SALUTE	PARR-SISTEMA-02 BIS	KIT PARR 3	C0104020102 - CATETERI PER ULTRASONOGRAFIA INTRAVASCOLARE	L
821	MINISTERO DELLA SALUTE	PARR-SISTEMA-02	KIT PARR	C0104020102 - CATETERI PER ULTRASONOGRAFIA INTRAVASCOLARE	L
51422	MINISTERO DELLA SALUTE	1122334455667788990011	BHUWUHWREFUYWEUFYWFY	Z129080 - STRUMENTAZIONE VARIA PER ESPLORAZIONI FUNZIONALI ED INTERVENTI TERAPEUTICI - COMPONENTI ACCESSORI HARDWARE	C
813909	MINISTERO DELLA SALUTE	ZZZ_11	ZZZ_11	C0104020102 - CATETERI PER ULTRASONOGRAFIA INTRAVASCOLARE	L

[Back](#)

If the certificate to be viewed was entered by an Italian ON and is connected to at least one DM in the Validated/Published status (namely, after the user has officially associated a given certificate to



a DM), information details, displayed in non-editable mode, will be as follows (see the picture below)²⁷:

- the Italian notified body issuing the certificate;
- the notification type;
- the manufacturer of the device or devices for which the certificate has been issued (belonging to the Customers database of the Italian ON and not to that of the Declarant);
- the certificate number of the EC marking;
- the Manufacturer's file identification number;
- the issue date of the certificate;
- the expiry date of the certificate;
- the details of both national and Community transposition rules that might have been applied;
- the description of the purpose of the certificate (in Italian);
- the description of the purpose of the certificate (in English);
- indication of whether or not the certificate should be in compliance with EC Directive 32/2003;
- the attachment by which the device has been certified;
- the attached file containing the certificate image;
- the details of the certificate connected to the one that is being examined;

²⁷ Some of the specified fields could have no value displayed in the page because, not being mandatory, they may have been left empty when the certificate was entered.



Certificate Data

Certificate Data

Notified Body Code-Name: 0373 - ISTITUTO SUPERIORE DI SANITÀ

Type of notification: Rinnovo

Manufacturer: FARMAC-ZABBAN S.P.A. [Dettaglio](#)

EC marking certificate number: 062CTP057012

File identification number: MCE/183/10

Issue date: 02 / 02 / 2012

Expiration date: 01 / 02 / 2017

Details of Community harmonized standards and of national transposing rules that may be applied:

Description of the purpose of the certificate (information requested in Italian and English)

Italian
MATERIALI PER MEDICAZIONE, STERILE: MEDICAZIONI IDROCOLLOIDI; ALGINATE DRESSING; IDROGEL.

English
DRESSING MATERIAL, STERILE: HYDROCOLLOID DRESSING; ALGINATE

EC Directive 2003/32

The certificate also concerns the EC Directive 2003/32: ☐

Directive and Annex according to which the device was certificate: Direttiva 93/42/CEE Allegato III

File containing the certificate: [062 CTP 0570 12.PDF](#)

Connected certificate

Certificate No	Issue date	Expiration date	Type of notification	Declarant
062CTP236	03/11/2005	03/11/2010	Inserimento	Dichiarante

[Back](#)

Operations available:

Action	Description	Page Name
Back	Comes back to the previous page	Certificates List Page

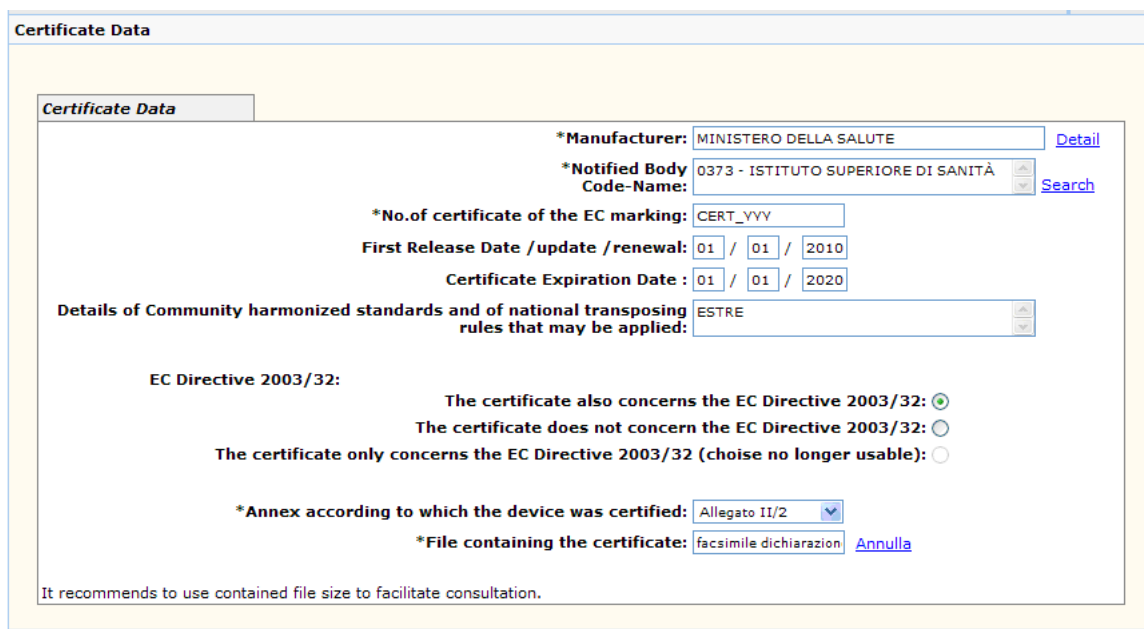


2.4.4.5 Editing of EC certificate

This page is activated by the page “Certifications List”, selecting a certificate and clicking on button “Edit”, allows the user to modify the data of the certificate (only if it was previously entered by the Declarant²⁸) which has no extension and no medical devices inserted or which has been set editable by an authorized office (Ministry)

If the selected certificate has medical devices associated, the manufacturer is not editable.

If the selected certificate is associated with Medical Devices already signed, the user must use the off line signature process, that allows to sign data by using any electronic signature certificate issued by one of the certification providers, according to Directive 1999/93/CE, by click on the button “Off line sign”.



Certificate Data

Certificate Data

*Manufacturer: MINISTERO DELLA SALUTE [Detail](#)

*Notified Body Code-Name: 0373 - ISTITUTO SUPERIORE DI SANITÀ [Search](#)

*No. of certificate of the EC marking: CERT_YYY

First Release Date / update / renewal: 01 / 01 / 2010

Certificate Expiration Date : 01 / 01 / 2020

Details of Community harmonized standards and of national transposing rules that may be applied: ESTRE

EC Directive 2003/32:

The certificate also concerns the EC Directive 2003/32: ☒

The certificate does not concern the EC Directive 2003/32: ☐

The certificate only concerns the EC Directive 2003/32 (choise no longer usable): ☐

*Annex according to which the device was certified: Allegato II/2

*File containing the certificate: facsimile dichiarazione [Annulla](#)

It recommends to use contained file size to facilitate consultation.

Detail Fields

Field Name	Description
Manufacturer	Indication of the manufacturer of the DM for which the certificate has been issued. To select a manufacturer it is necessary to click on the “Search” link; there will appear a look-up from which it is possible to make a search.
Notified Body Code-Name	Indication of the code and name of the organization notified. This field cannot be edited. To select the code of the organization notified it is necessary to click on the “Search” link; a look-up will appear from which it will be possible to search for the organization notified by code and name.

²⁸ Certificates that have been notified in the Data Bank of Medical Device by the Italian OONNs cannot be amended by the Declarants, but only by the ONs themselves.



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Field Name	Description
No. of certificate of the EC marking	Identification number of the EC certificate. Such number cannot contain blank spaces.
First Release Date /update /renewal	Date of issue/update/ renewal of the EC Certificate.
Certificate Expiration Date	Expiry date of the Certificate. This field is always mandatory, except if the user has selected the value 'Annex IV/4'. in the field 'Annex according to which the device was certified.
Details of Community harmonized standards and of national transposing rules that may be applied	The essential details of the National and Community norms acknowledged during the fabrication of the DM.
EC Directive 2003/32	States whether or not the certificate should be in compliance with EC Directive 32/2003: the user will have to indicate whether the certificate is relative ALSO to the EC Directive 32/2003 or is NOT relative to the EC Directive 32/2003. The item "The certificate only concerns the EC Directive 2003/32" is disabled, though still visible on the page (it's not possible to select this option, because it's no longer available). If the certificate you are editing has been previously assigned this value, the user will have to choose one of the two remaining options ("The certificate is also concerns the EC Directive 2003/32" or "The certificate does not concern the EC Directive 2003/32").
Annex according to which the device was certified	Indication of the annex according to which the device has been changed.
File containing	A pdf file to be attached containing the image of the EC certificate. To attach another file



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Field Name	Description
the certificate	it is necessary to use the “Cancel” button. Then it is necessary to use the button “Browse” to individuate a new pdf file which is supposed to be attached.

Operations available:

Action	Description	Page Name
Save	Memorizes the changes in the data base and comes back to the previous page. Active only if there are no validated device in association	Certificates List Page
Off signature line	Allows the user to access the page of download of txt file containing data. Active only if there are validated device in association	Sign file download page
Back	VOIDS the insertion and comes back to the previous page.	Certificates List Page



2.4.4.6 Extension/expansion registration for an existing EC certificate

Activated by the page “Certificates List”, selecting a certificate and clicking on the “Extend/Extension” button, the page allows the user to insert an extension of validity periods to an existent certificate or an expansion of the set of medical devices covered by the certificate (only if it was previously entered by the Declarant), if it has never been extended/expanded before, or if it has already been extended/expanded, and associates it with at least one device validated or published.

When OONNs can enter their certificates independently, the Declarant can no longer enter into the system Extensions referring to certificates issued by an Italian ON. A check will in fact be performed on the saving of the extension form data, so as to prevent this action from being performed.

The page called is divided in two sections: in the first section, “Certificate Data Existing”, informations concerning the certificate in expiry are visualized in non editable mode; the second one, “Certificate of Extension Data”, gives the same informations which can be edited to allow the user to insert the data of the certificate of extension.

Moreover, if the certificate is associated with medical devices, the page will give evidence of it visualizing the list – with elements selected – of all the devices associated. Specifically, the devices in processing will be visualized as those devices already validated and published that need a new signature.

When selecting the elements, the user is offered to extend the association for all the medical devices already associated with the certificate extended to that of extension. All the same the user will be able to exclude, deselecting them, one or more medical devices, expressing thus a wish to exclude the fact that certificate of extension should be associated with DM selected.

That is why, if the user has had a wish to extend the association existent for the devices subscribed with the certificate extended to the certificate of extension, the user must use the off line signature process, that allows to sign data by using any electronic signature certificate issued by one of the certification providers, according to Directive 1999/93/CE, by click on the button “Off line sign”.



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Certificate Data

Certificate Data Existing

*Manufacturer: MINISTERO DELLA SALUTE

*Notified Body Code-Name: 0373 - ISTITUTO SUPERIORE DI SANITÀ

No. of certificate of the EC marking: CERT_VVY

First Release Date /update /renewal: 01 / 01 / 2010

*Certificate Expiration Date : 01 / 01 / 2020

Details of Community harmonized standards and of national transposing rules that may be applied: ESTRE

EC Directive 2003/32:

The certificate also concerns the EC Directive 2003/32: ☒

The certificate does not concern the EC Directive 2003/32: ☐

The certificate only concerns the EC Directive 2003/32 (choise no longer usable): ☐

*Annex according to which the device was certified: Allegato II/2

*File containing the certificate: facsimile dichiarazione

Certificate of Extension Data

*Manufacturer: MINISTERO DELLA SALUTE [Detail](#)

Detail Fields

Field Name	Description
Manufacturer	Indication of the manufacturer of the DM for which the certificate has been issued. To select a manufacturer it is necessary to click on the “Search” link; there will appear a look-up from which it is possible to make a search.
Notified Body Code-Name	Indication of the code and name of the organization notified. This field cannot be edited. To select the code of the organization notified it is necessary to click on the “Search” link; a look-up will appear from which it will be possible to search for the organization notified by code and name.
No. of certificate of the EC marking	Identification number of the EC certificate. Such number cannot contain blank spaces.
First Release Date /update /renewal	Date of issue/update/ renewal of the EC Certificate.
Certificate Expiration Date	Expiry date of the Certificate. This field is always mandatory, except if the user has selected the value ‘Annex IV/4’. in the field ‘Annex according to which the device was certified’ . The date of expiry of the certificate of extension/expansion, when present, can be only greater or equal to that of the certificate which must be extended.
Details of Community harmonized standards and of national transposing rules that may be applied	The essential details of the National and Community norms acknowledged during the fabrication of the DM .
EC Directive	States whether or not the certificate should be in compliance with EC Directive 32/2003:



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2003/32	the user will have to indicate whether the certificate is relative ALSO to the EC Directive 32/2003 or is NOT relative to the EC Directive 32/2003. When entering a new certificate prolonging/extending the previous one, the item “The certificate only concerns the EC Directive 2003/32” is disabled, though still visible on the page (it’s not possible to select this option, because it’s no longer available).
Annex according to which the device was certified	Indication of the annex according to which the device has been changed.
File containing the certificate	A pdf file to be attached containing the image of the EC certificate. To attach another file it is necessary to use the “Cancel” button. Then it is necessary to use the button “Browse” to individuate a new pdf file which is supposed to be attached.

Operations available:

Action	Description	Page Name
Save	Memorizes the changes in the data base and comes back to the previous page. Activated only if there is no need to sign data.	Certificates List Page
Off line signature	Allows the user to access the page of download of txt file containing data. Activated only if there is need to sign data.	Sign file download page
Back	VOIDS the insertion and comes back to the previous page.	Certificates List Page

2.4.4.7 Association of an EC certificate to a DM

This page presents itself in the form of a lookup and allows the search and association of the medical devices to CE certificate selected. It gets activated by clicking on the button ‘Associate to DM’ present on the ‘certificates List’ page.

It won't be possible to associate an expired certificate to a medical device

In the upper part of the page there are the search fields which should be compiled (it is necessary to define at least one search criterion) in order to get the DM list from which the user will be able to select those that must be associated to the certificate. The medical devices that it is possible to associate are those coming from the same Manufacturer to whom the selected certificate was issued.

In the lower part of the page the list is displayed – with selectable elements – of the DM associable coherent with the search criteria defined.

Whenever the user selects the published devices for the association, complete the operation using “Confirm” button.



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Research criteria

System progressive attributed to Device:

Code assigned by the manufacturer (catalogue identifier) from: to:

Trade name and model:

CND classifications: [Search](#)

DM status:

Fields detail

Field Name	Description
System progressive attributed to DM	It is possible to search on the base of the identification code (progressive of the system) attributed to the DM
Code assigned by the manufacturer (identifier catalogue) from/to	It is possible to indicate the interval of the codes into which the univocal code attributed by the DM manufacturer is included.
Trade Name and Model	It is possible to specify the commercial name (or the initial part) of the DM.
CND Classification	It is possible to search on the base of the National classification of the DM. This field cannot be edited. To select a CND classification the user should click on the 'Search' link; a look-up will open from which it is possible to search a CND classification by code or by description or by its part.
DM Status	It is possible to search on the base of the status of the DM (in progress, consolidated, published) .

Operations available

Action	Description	Page Name
Search	Activates a search with parameters set up and displays the DM list coherent with these parameters.	Same
New search	Clears the search criteria previously defined.	Same
Confirmation	Closes the look up page, associates the device or the devices selected to the certificate. Activated only if there are no validated devices in association.	Certificates List Page



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Cancel	Closes the look up page without saving the operations performed by the user.	Certificates List Page



2.4.4.8 Replacing certificates within the DM notification

This page allows the user to replace a certificate within the notification of more DMs simultaneously, while keeping the history of the associations in the Data Bank of Medical Device system.

The user may look for a certificate (that he had previously entered into the system or that had been notified by an Italian Notified Body) and activate the replacement feature. The “Replace” button will be active only if the certificate that has been selected is connected to at least one DM while the action is being performed. In that case, the form that will be displayed will contain the details of the certificate that has been selected, the DMs that are connected to it (along with their status) and a button allowing the user to look for the new certificate to be replaced within the DM notification.

If the **new certificate selected** for the substitution is expired, it won't be possible to confirm the operation, whether it was notified by its Declarant or an Italian ON²⁹.

Moreover, if the new certificate selected for the substitution is at the same time:

- Entered in the system by a Declarant,
- without a date of expiry, even though the annex according to which the device was certified is different from the IV/4³⁰,

it won't be possible to confirm the new certificate to complete the process of substitution of the starting certificate³¹.

Finally, it won't be possible to substitute the certificate if the new certificate replacing the previous one has been notified by a Declarant with the option “The certificate only concerns the EC Directive 2003/32”, as this option is no longer available.

In all these cases a message will notify the user of the impossibility to complete the operation.

²⁹ Specifically, the halting check on the expiry date of the certificate starts when the expiry date has a value which is less than the current date, but **is not performed** if the certificate's annex is the IV/4 (or if it's equal to the values of the ‘Directive 93/42/EEC Annex IV’ and ‘Directive 90/385/EEC Annex 4’ for certificates notified by Italian OONNs) even if a date of expiry is specified.

³⁰ The new rules allow an empty date of expiry for the certificates only if the field ‘Annex according to which the device was certified’ has the value ‘Annex IV/4’.

³¹ The case of certificates notified by Italian OONNs isn't discussed because, in the past, the date of expiry of such certificates has always been mandatorily required upon their notification. Only from now on, it will be possible to omit this date if the ON selects one of the following voices from the field ‘Annex according to which the device was certified’

- Directive 93/42/EEC Annex IV
- Directive 90/385/EEC Annex 4

in the same way as what happens for the certificates notified by Declarants.



Once the new certificate is found, and the DMs to be replaced have been selected, the operation needs to be signed by means of the offline signing procedure, if at least one DM amongst those that have been selected is in the Published status.

If the user does not select all the DMs that belong to one group of similar DMs, the system will warn the user about the fact that the integrity of the initial group cannot be preserved if they proceed with that operation.

This feature may be used in these situations:

- DIC – DIC: to replace a certificate entered by the Declarant within the notification of one or more DMs with a new certificate also entered by the Declarant. This situation occurs, for instance, if the Manufacturer of the DMs decides to address an external ON other than the one reported in the first certificate. In that case, the extension feature does not allow the user to change the ON and the MANUFACTURER within the new certificate (thus keeping those from the first certificate): as a result, the only way to replace the DM connected to the former certificate with the new certificate is to use this feature;
- DIC – ON: to replace a certificate entered by the Declarant within the notification of one or more DMs with a new certificate entered by an Italian ON. This situation occurs when the Declarants can no longer notify certificates issued by the Italian ONs. In this situation, if the Italian ON issues a renewal certificate, an extension, a limitation etc., the Declarant must replace the certificate he/she personally entered with the one entered by the Italian ON;
- ON – ON: to replace a certificate entered by an Italian ON within the notification of one or more DMs with a new certificate also entered by the Italian ON. This situation occurs when the Declarants can no longer notify certificates issued by the Italian ONs. In this situation, the Declarant will only have to associate the certificate entered by the Italian ON to their own DMs. If then the Italian ON issues a new certificate for the same DMs, the Declarant has to replace the first certificate (entered by the Italian ON) with the one updated, (also entered by the Italian ON);
- ON – DIC: to replace a certificate entered by the Italian ON within the notification of one or more DMs with a new certificate entered by the Declarant. This situation occurs when, for instance, the manufacturer of the DMs that notifies his/hers certificates independently, after addressing an Italian ON decides to address an external ON other than the one reported in the first certificate. At that point, the Declarants themselves must enter the certificate and may replace it within the DMs where the certificate entered by the Italian ON is present, by means of this feature.



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Certificate reference replacement

Certificate Data

Manufacturer: MINISTERO DELLA SALUTE

Notified Body Code-Name: 0373 - ISTITUTO SUPERIORE DI SANITÀ

No. of certificate of the EC marking: CERT_YYY

First Release Date /update / renewal: 01 / 01 / 2010

Certificate Expiration Date : 01 / 01 / 2020

Details of Community harmonized standards and of national transposing rules that may be applied: ESTRE

EC Directive 2003/32:

The certificate also concerns the EC Directive 2003/32: ☐

The certificate does not concern the EC Directive 2003/32: ☐

The certificate only concerns the EC Directive 2003/32 (choise no longer usable): ☐

Annex according to which the device was certified:

File to attach: [facsimile dichiarazione impresa.pdf](#)

Search New Reference EC

List of devices associated with this certificate:

Connected devices list						
System progressive attributed to DM	Manufacturer	Code assigned by the manufacturer (catalogue identifier)	Trade name and model	CND classifications	Device status	Select
813914	MINISTERO DELLA SALUTE	ZZZ_24	ZZZ_24	C0104020102 - CATETERI PER ULTRASONOGRAFIA INTRAVASCOLARE	C	☒
842	MINISTERO DELLA SALUTE	PARR-SISTEMA-02 BIS	KIT PARR 3	C0104020102 - CATETERI PER ULTRASONOGRAFIA INTRAVASCOLARE	L	☒

Operations available

Action name	Description	Recalled page name
Search New Certificate	Allows to access the search look up of the new certificate to be replaced within the DM notification.	Certificate search look up
Save	Replaces, within the database, the first certificate present within the selected devices notification, with the new certificate. Activated only if there are non validated device associated.	Signature
Offline signing	Allows the user to save the information entered and redirects him to the download page of the .txt file containing the data of the new certificate and of the associated DMs to be signed locally.	Signature file download



Action name	Description	Recalled page name
	Activated only if there are validated device associated.	
Back	Cancels the certificate replacement operation and takes the user back to the previous page.	Certificates List

2.4.4.8.1 Search look up of the new certificate replacing the previous one

This page appears as a look up and allows the user to look for the new certificate replacing the one that had been selected within the DMs notification. It is activated by clicking the "Search New Certificate" button at the certificates replacement page within the DM notification (see previous paragraph).

The user may search two types of certificates:

- ✓ Certificates entered by the Declarant on behalf of the Manufacturer;
- ✓ Certificates entered by the Italian OONNs.

The user may search the certificates entered directly by the Italian OONNs only if they know their number, issuing notified body and issue date. The expiry date won't be mandatorily required during the search phase as it's no more mandatory in the presence of the Directive on implantable medical devices (90/385/EEC) – Annex 4 or Directive concerning medical devices (93/42/EEC) – Annex IV. Also, they can view the complete details, only if the certificate is associated to a DM in the Validated/Published status (namely, after the user has officially associated a given certificate to a DM).

As already mentioned, If the **new certificate selected** for the substitution is expired, it won't be possible to confirm the operation, whether it was notified by its Declarant or an Italian ON³².

Moreover, if the new certificate selected for the substitution is at the same time:

- Entered in the system by a Declarant,
- without a date of expiry, even though the annex according to which the device was certified is different from the IV/4³³,

it won't be possible to confirm the new certificate to complete the process of substitution of the starting certificate³⁴.

³² Specifically, the halting check on the expiry date of the certificate starts when the expiry date has a value which is less than the current date, but **is not performed** if the certificate's annex is the IV/4 (or if it's equal to the values of the 'Directive 93/42/EEC Annex IV' and 'Directive 90/385/EEC Annex 4' for certificates notified by Italian OONNs) even if a date of expiry is specified.

³³ The new rules allow an empty date of expiry for the certificates only if the field 'Annex according to which the device was certified' has the value 'Annex IV/4'.

³⁴ The case of certificates notified by Italian OONNs isn't discussed because, in the past, the date of expiry of such certificates has always been mandatorily required upon their notification. Only from now on, it will be possible to omit this date if the ON selects one of the following voices from the field 'Annex according to which the device was certified'



Finally, it won't be possible to substitute the certificate if the new certificate replacing the previous one has been notified by a Declarant with the option "The certificate only concerns the EC Directive 2003/32", as this option is no longer available.

In all these cases a message will notify the user of the impossibility to complete the operation.

Detail Fields

Field Name	Description
No .of certificate of the EC marking	Identification number of the EC certificate. . This field is mandatory only in the case where the individual that has performed the notification of the certificate in Data Bank of Medical Device is an Italian ON.
Certificate issue	Certificate issue date. This field is mandatory only in the case where the individual that has

- Directive 93/42/EEC Annex IV
- Directive 90/385/EEC Annex 4

in the same way as what happens for the certificates notified by Declarants.



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Field Name	Description
date	performed the notification of the certificate in Data Bank of Medical Device is an Italian ON. If the “Run a search on all Certificates that have been notified by the Italian Notified Bodies in Data Bank of Medical Device” check box is not selected, the date cannot be entered.
Certificate Expiration Date	Expiry date of the Certificate.
Notified Body	Indication of the code and name of the organization notified. This field cannot be edited. To select the code of the organization notified it is necessary to click on the “Search “ link; a look-up will appear from which it will be possible to search for the organization notified by code and name.
Run a search on all Certificates that have been notified by the Italian Notified Bodies in Data Bank of Medical Device	By selecting this check box, the user can look for a certificate amongst those notified in the Data Bank of Medical Device directly by the Italian OONNs. In that case, all input fields of the page, with the exception of the expiry date of the certificate, will be mandatory, which means that in order to enter the reference of a certificate that was notified directly by an Italian ON in one of their own DM, the user will have to mandatorily know its name, issue date and the Italian ON that issued that certificate. If this check box is not selected, the search will be performed on the EC Certificates that have been notified in the Data Bank of Medical Device directly by the user.

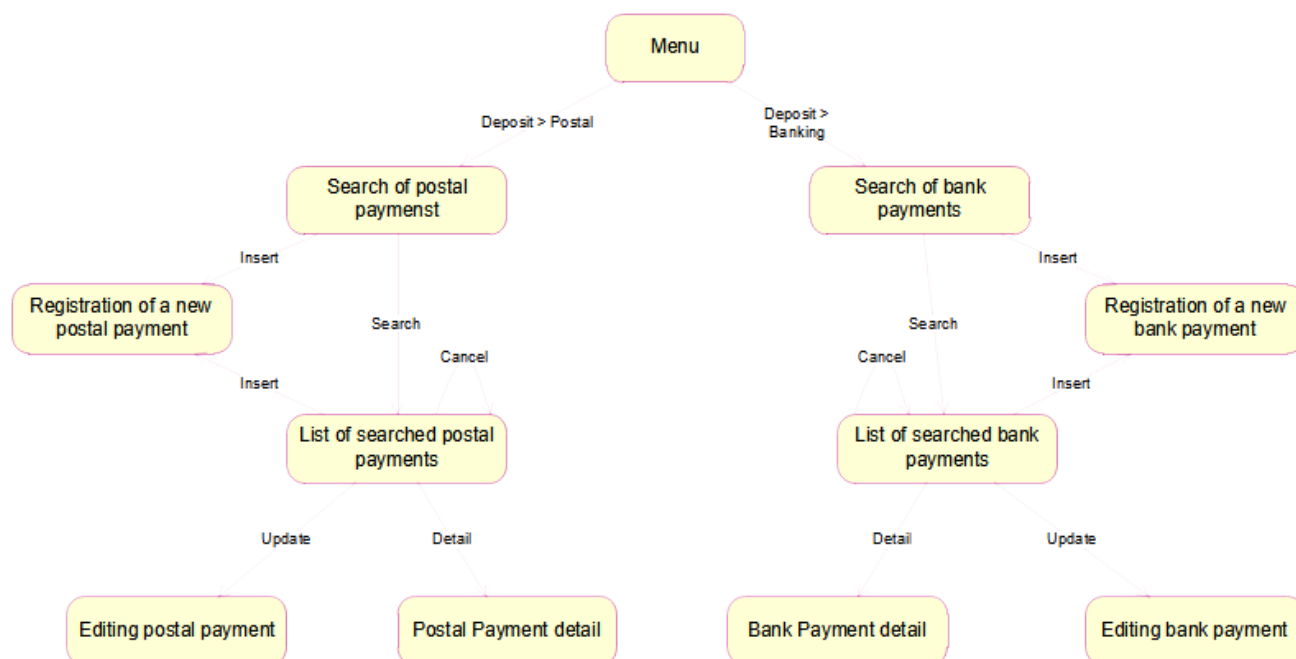
Operations available:

Action name	Description	Recalled page name
Search	Starts the certificates search, entered by the Declarant on behalf of the Manufacturer and the Italian ON, that is consistent with the parameters that have been set.	Same.
New Search	Clears the search parameters previously set.	Same.
Confirmation	Closes the look up and takes the selected certificate back to the recalling replacement page. Verifies that: - the selected certificate isn't expired. If it's expired, the procedure will be stopped; - if entered by a Declarant, the selected certificate has an expiry date, when the annex according to which was notified is different from the IV/4. If it has no expiry date, the procedure will be stopped; - the selected certificate is not relative only to the EC Directive 32/2003. If it is, the procedure will be stopped.	Certificate replacement page.
Cancel	Closes the look up page without saving the operations performed by the user.	Certificate replacement page.



2.4.5 Menu option “Payments”

Screen flowcharts:



2.4.5.1 Search of postal payments

After clicking on the menu option “Deposit > Postal” the page is displayed which allows the user to set the postal payments search criteria already present in the data base. In order to run the search of these payments, it is necessary to define at least one search critetion.

Moreover, from this page the user can access the page of a new payment extremes insertion using the “Insert” button.



Home > Class I, II a /b, III Medical Devices > ?

postal

Research criteria

*Manufacturer: [Search Detail](#)

Section:

Post Office:

Operations progressive:

Reason payment: ▼

Payment date from: / / to: / /

Detail Fields

Field Name	Description
Manufacturer	Denomination of the manufacturer of the device or devices for which the postal payment in question was made. To select a Manufacturer it is necessary to click on the "Search" link; a look-up will open from which it will be possible to make the search.
Post Office	Extremes of the post office where the payment was made
Section	Department of the office where the payment was made
Payment date from/to	Temporal interval containing the date when the payment was made
Operations progressive	Progressive of the current postal account
Reason payment	Reason why the payment was made

Operations available:

Action	Description	Page Name
Search	Runs the search of the postal payments coherent with the parameters defined	Postal Payments List Page
New search	Deletes the search criteria previously defined	Same
Insert	Allows the user to access the page of a new postal payment extremes insertion.	Postal Payment Insertion Page



2.4.5.2 List of searched postal payments

This page presents the list of postal payments which correspond to the criteria defined on the relative search page. For every payment the following information is given:

- motivation
- date
- amount

From the page the user can ask to insert a new postal payment clicking on the “Insert” button always activated.

Selecting the payment from the list, he will also be able to do the following operations:

- view the “Detail”
- ask the “Update”;
- ask the “Cancellation” only if the payment selected has no medical device associated to it.
- Activating the “Cancel” button, the system will ask the user to confirm whether to eliminate the extremes of the postal payment selected or not, and if the answer is a positive one it will proceed with the cancellation. Afterwards the remaining payments list will be visualized.
- view the “DM associated” list.

Home > Class I, II a / b, III Medical Devices > Deposits

postal

Research criteria

*Manufacturer: [Search Detail](#)

Section:

Post Office:

Operations progressive:

Reason payment:

Payment date from: / / to: / /

Manufacturer	Section	Post Office	Operations progressive	Payment date	Select
BAYER (NEW)	YYYYY	POSTA	123123	31/12/2001	☐

Page 1 of 1

*Detail Fields*

Field Name	Description
Manufacturer	Denomination of the manufacturer of the device or devices for which the postal payment in question was made. To select a Manufacturer it is necessary to click on the "Search" link; a look-up will open from which it will be possible to make the search.
Post Office	Extremes of the post office where the payment was made
Section	Department of the office where the payment was made
Payment date from/to	Temporal interval containing the date when the payment was made
Operations progressive	Progressive of the current postal account
Reason payment	Reason why the payment was made

Operations available:

Action	Description	Page Name
Search	Runs the search of the postal payments coherent with the parameters defined	Postal Payments List Page
New search	Deletes the search criteria previously defined	Same
Insert	Allows the user to access the page of a new postal payment extremes insertion.	Postal Payment Insertion Page
Detail	Allows the user to access the payment detail page with the data which can not be edited	Postal Payments detail Page
Edit	Allows the user to access the payment editing page	CertificateModify Page
Cancel	Deletes the payment selected	Same
DM associated	Allows the user to access to list related DM page	Detail related DM

2.4.5.3 Registration of a new postal payment

This page allows the user to insert the extremes of a new postal payment. It is activated by the "Insert" button present on the pages of search and visualization of the postal payments list.



User Manual DM Manufacturer Profile



Home > Class I, II a /b, III Medical Devices > Deposits > Deposit Data ?

Deposit Data

Deposit Data

*Manufacturer: [Search Detail](#)

*Section:

*Payment date: / /

*Post Office:

*Operations progressive:

Postal account progressive:

*Amount paid:

Postal Rates:

Reason payment: ▼

Detail Fields

Field Name	Description
Manufacturer	Denomination of the manufacturer of the device or devices for which the postal payment in question was made. To select a Manufacturer it is necessary to click on the "Search" link; a look-up will open from which it will be possible to make the search
Amount paid	Amount which was paid
Payment date	Date when the postal payment was made
Section	Department of the office where the payment was made
Post office	Extremes of the post office where the payment was made
Operation progressive	Progressive number of the operations carried out
Postal account progressive	Progressive of the current postal account
Postal rates	Postal tax paid for the payment made
Reason payment	Reason why the payment was made

Operations available:

Action	Description	Page Name
Save	Memorizes in the data base the extremes of the postal payment inserted and comes back to the previous page	Page List Postal Payments



2.4.5.4 Postal payment detail

Activated by the page containing the postal payments list, when selecting a payment and clicking on the “Details” button, this page allows the user to visualize in a non editable way all the detailed information of the payment selected.

Home > Class I, II a /b, III Medical Devices > Deposits > Deposit Data		?
Deposit Data		
Deposit Data		
*Manufacturer:	BAYER	Detail
*Section:	SEZIONE	
*Operation date:	01 / 01 / 2008	
*Post Office:	UFFICIO	
*Operations progressive:	2	
Postal account progressive:		
*Amount paid:	100,56	
Postal Rates:		
Reason payment:	inserimento delle informazioni ai fini dell'istituzione e della gestione del repertorio	
Back		

Operations available:

Action	Description	Page Name
Back	Comes back to the previous page	Page List Postal Paymentsi



2.4.5.5 Editing of postal payment

This page is activated by the page containing the postal payments list, when selecting a payment and clicking on the “Edit” button, and allows the user to edit the data of a payment.

If the selected payment has medical devices related, the manufacturer is not editable.

Home > Class I, II a /b, III Medical Devices > Deposits > Deposit Data ?

Deposit Data

Deposit Data

*Manufacturer: [Search Detail](#)

*Section:

*Payment date: / /

*Post Office:

*Operations progressive:

Postal account progressive:

*Amount paid:

Postal Rates:

Reason payment: ▼

Detail Fields

Field Name	Description
Manufacturer	Denomination of the manufacturer of the device or devices for which the postal payment in question was made. To select a Manufacturer it is necessary to click on the “Search” link; a look-up will open from which it will be possible to make the search
Amount paid	Amount which was paid
Payment Date	Date when the postal payment was made
Section	Department of the office where the payment was made
Post Office	Extremes of the post office where the payment was made
Operations Progressive	Progressive number of the operations carried out
Postal account progressive	Progressive of the current postal account
Postal rates	Postal tax paid for the payment made
Reason payment	Reason why the payment was made

*Operations available:*

Action	Description	Page Name
Save	Memorizes in the data base the editing made and comes back to the previous page	Page List Postal Payments
Back	VOIDS the insertion and comes back to the previous page	Page List Postal Payments

2.4.5.6 List of related DM to postal payment

Being activated by the page containing the postal payments list, when selecting a payment and clicking on the “DM associated” button, this page allows the user to view the list of DM associated to the selected payment and to cancel the relation.

Home > Class I, II a /b, III Medical Devices > Deposits > Deposit Data ?

Deposit Data and DM associated

Deposit Data

Manufacturer: BAYER (NEW)
 Section: YYYYYY
 Operation date: 31 / 12 / 2001
 Post Office: POSTA
 Operations progressive: 123123
 Postal account progressive: 124567
 Amount paid: 100
 Postal Rates: 1
 Reason payment: inserimento delle informazioni ai fini dell'istituzione e della gestione del repertorio

Connected devices list

System progressive attributed to DM	Manufacturer	Code assigned by the manufacturer (catalogue identifier)	Trade name and model	CND classifications	Device status	Sign	Select
10429	BAYER (NEW)	X_BAYER(NEW)	DM BAYER (NEW)	Y061899 - PROTESI DI ARTO SUPERIORE - ALTRE	P	To be signed	☐

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[Back](#)
[Delete references](#)

*Detail Fields*

Field Name	Description
Manufacturer	Denomination of the manufacturer of the device or devices for which the postal payment in question was made.
Amount paid	Amount which was paid
Payment Date	Date when the postal payment was made
Section	Department of the office where the payment was made
Post Office	Extremes of the post office where the payment was made
Operations Progressive	Progressive number of the operations carried out
Postal account progressive	Progressive of the current postal account
Postal rates	Postal tax paid for the payment made
Reason payment	Reason why the payment was made

Operations available:

Action	Description	Page Name
Back	Comes back to the previous page	List postal payment
Save	Delete the selected relations and refresh the list of DM related to the payment	Same

2.4.5.7 Search of bank payments

Having clicked on the menu option “Deposit > banking” the page is displayed which allows the user to set the search criteria of the bank payments already present in the data base. To run the search of these payments it is necessary to define at least one search criterion.

Moreover, from this page the user will be able to access the insertion page of new payment extremes using the “Insert” button.



Home > Class I, II a /b, III Medical Devices > Deposits ?

Bank

Research criteria

*Manufacturer: [Search Detail](#)

Bank and Agency:

(R.O.C.) or other identification:

IBAN:

Reason payment: ▼

Operation date from: / / to: / /

Detail Fields

Field Name	Description
Manufacturer	Denomination of the manufacturer of the device or devices for which the postal payment in question was made. To select a Manufacturer it is necessary to click on the “Search” link; a look-up will open from which it will be possible to make the search
Bank and agency	Bank extremes where the payment was made
Operation date from / to	Temporal interval containing the date when the payment was made
IBAN	Identifying IBAN code of the current bank account
R.C.O. or other identification	Operation Reference Code or other identification code
Reason payment	Reason why the payment was made

Operations available:

Action	Description	Page Name
Search	Runs the search of the bank payments coherent with the criteria defined	Page List Bank Payments
New search	Deletes the search criteria previously defined	Same.
Insert	Allows the user to access the insertion page of a new payment extremes	Registration of a new bank payment



2.4.5.8 Registration of a new bank payment

This page presents the list of the bank payments which correspond to the criteria defined on the relative search page. For every payment the following information is given:

- motivation
- date
- amount

From the page the user can ask for the insertion of a new bank payment clicking on the “Insert” button always activated.

Selecting the payment form the list, the user will also be able to do the following operations:

- view the “Detail”
- ask for the “Update”
- ask for the “Cancellation” only in case if the payment selected is not associated to a medical device. When activating the button “Cancel” the system will ask the user to confirm whether to eliminate the extremes of the selected bank payment or not, and it will proceed with the cancellation after having received an affirmative response. Afterwards, the list of remaining payments will be visualized.
- view the “DM associated” list.

Home > [Class I, II a /b, III Medical Devices](#) > Deposits ?

Bank

Research criteria

*Manufacturer: [Search Detail](#)

Bank and Agency:

(R.O.C.) or other identification:

IBAN:

Reason payment:

Operation date from: / / to: / /

Manufacturer	Bank and Agency	(R.O.C.) or other identification	IBAN	Operation date	Select
BAYER	IO	33445	22332233224	12/02/2003	☐

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Detail Fields

Field Name	Description
Manufacturer	Denomination of the manufacturer of the device or devices for which the postal payment in question was made. To select a Manufacturer it is necessary to click on the "Search" link; a look-up will open from which it will be possible to make the search
Bank and agency	Bank extremes where the payment was made
Operation date from / to	Temporal interval containing the date when the payment was made
IBAN	Identifying IBAN code of the current bank account
R.C.O. or other identification	Operation Reference Code or other identification code
Reason payment	Reason why the payment was made

Operations available:

Action	Description	Page Name
Search	Runs the search of the bank payments coherent with the criteria defined	Page List Bank Payments
New search	Deletes the search criteria previously defined	Same
Insert	Allows the user to access the insertion page of a new payment extremes	Bank payment insert
Detail	Allows the user to access the payment detail page with the data which can not be edited	Bank payment detail
Update	Allows the user to access the bank payment modification page	Bank payment modify
Cancel	Deletes the selected payment	Same
DM associated	Allows the user to access to list related DM page	Detail related DM



2.4.5.9 Registration of a new bank payment

This page allows the user to insert the extremes of a new bank payment.

It is activated by the “Insert” button present on the pages of search and visualization of the bank payments list.

Home > Class I, II a /b, III Medical Devices > Deposits > Deposit Data ?

Deposit Data

Deposit Data

*Manufacturer: UNIVISION SRL [Search Detail](#)

Mandate number:

*Bank and Agency: UNIPOL

*IBAN: 3232DESWE3232323232

ABI Code:

CAB Code:

*Amount paid: 100

*Operation date: 06 / 06 / 2008

*(R.O.C.) or other identification: 22344445

BIC:

Reason payment: inserimento delle informazioni ai fini dell'istituzione e della gestione del repertorio ▼

Detail Fields

Field Name	Description
Manufacturer	Denomination of the manufacturer of the device or devices for which the bank payment in question was made. To select a Manufacturer it is necessary to click on the “Search” link; a look-up will open from which it will be possible to make the search
Amount paid	Amount which was paid
Operation date	Date when the bank payment was made
Mandate number	Mandate number of the payment
Bank e agency	Bank extremes where the payment was made
ABI code	ABI code of the current bank account
CAB code	CAB code of the current bank account
R.C.O. or other	Operation Reference Code or other identification code



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Field Name	Description
identification	
BIC	BIC code of the current bank account
IBAN	Identifying IBAN code of the current bank account
Reason payment	Reason why the payment was made

Operations available:

Action	Description	Page Name
Save	Memorizes in the data base the extremes of the bank payment inserted and comes back to the previous page	Page List Bank Payments
Back	VOIDS the insertion and comes back to the previous page	Page List Bank Payments



2.4.5.10 Detail of bank payment

Activated by the page containing the bank payments list when selecting a payment and clicking on the "Details" button, this page allows the user to view in a non editable way all the detailed information of the selected payment.

Home > Class I, II a /b, III Medical Devices > Deposits > Deposit Data ?

Deposit Data

Deposit Data

Manufacturer: UNIVISION SRL [Detail](#)

Mandate number:

Bank and Agency: UNIPOL

IBAN: 3232DESWE3232323232

ABI Code:

CAB Code:

Amount paid: 100

Operation date: 06 / 06 / 2008

(R.O.C.) or other identification: 22344445

BIC:

Reason payment: inserimento delle informazioni ai fini dell'istituzione e della gestione del repertorio

[Back](#)

Operations available:

Action	Description	Page Name
Back	Comes back to the previous page	Page List Bank Payments



2.4.5.11 Editing of bank payment

This page is activated by the page containing the bank payments list, when selecting a payment and clicking on the “Modifica” button, and allows the user to edit the data of a payment.

Home > Class I, II a /b, III Medical Devices > Deposits > Deposit Data ?

Deposit Data

Deposit Data

*Manufacturer: UNIVISION SRL [Search Detail](#)

Mandate number:

*Bank and Agency: UNIPOL

*IBAN: 3232DESWE3232323232

ABI Code:

CAB Code:

*Amount paid: 100

*Operation date: 06 / 06 / 2008

*(R.O.C.) or other identification: 22344445

BIC:

Reason payment: inserimento delle informazioni ai fini dell'istituzione e della gestione del repertorio ▼

[Save](#) [Back](#)

Detail Fields

Field Name	Description
Manufacturer	Denomination of the manufacturer of the device or devices for which the bank payment in question was made. To select a Manufacturer it is necessary to click on the “Search” link; a look-up will open from which it will be possible to make the search
Amount paid	Amount which was paid
Operation date	Date when the bank payment was made
Mandate number	Mandate number of the payment
Bank and agency	Bank extremes where the payment was made
ABI code	ABI code of the current bank account
CAB code	CAB code of the current bank account
R.C.O. or other identification	Operation Reference Code or other identification code
BIC	BIC code of the current bank account



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IBAN	Identifying IBAN code of the current bank account
Reason payment	Reason why the payment was made

Operations available:

Action	Description	Page Name
Save	Memorizes in the data base the editing carried out by the user and comes back to the previous page	Page List Bank Payments
Back	VOIDS the insertion and comes back to the previous page	Page List Bank Payments

2.4.5.12 List of related DM to bank payment

Activated by the page containing the bank payments list, after selecting a payment and clicking on the "DM associated" button, this page allows the user to view the list of DM associated to the selected payment and to cancel the relation.

Deposit Data

Deposit Data

Manufacturer: BAYER
Mandate number: 555
Bank and Agency: IO
IBAN: 22332233224
ABI Code: 400
CAB Code: 897
Amount paid: 300
Operation date: 12 / 02 / 2003
(R.O.C.) or other identification: 33445
BIC:
Reason payment: inserimento delle informazioni ai fini dell'istituzione e della gestione del repertorio

Connected devices list

System progressive attributed to DM	Manufacturer	Code assigned by the manufacturer (catalogue identifier)	Trade name and model	CND classifications	Device status	Sign	Select
10294	BAYER	111	PROVA2QQQA	Z12040111 - EMOFLUSSIMETRI	L		☐
10366	BAYER	COD SIMILE 9962	NOME SIMILE 9962	Z1212012002 - ADATTOMETRI	V	To be signed	☐

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[Delete references](#)



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Detail Fields

Field Name	Description
Manufacturer	Denomination of the manufacturer of the device or devices for which the bank payment in question was made.
Amount paid	Amount which was paid
Operation date	Date when the bank payment was made
Mandate number	Mandate number of the payment
Bank and agency	Bank extremes where the payment was made
ABI code	ABI code of the current bank account
CAB code	CAB code of the current bank account
R.C.O. or other identification	Operation Reference Code or other identification code
BIC	BIC code of the current bank account
IBAN	Identifying IBAN code of the current bank account
Reason payment	Reason why the payment was made

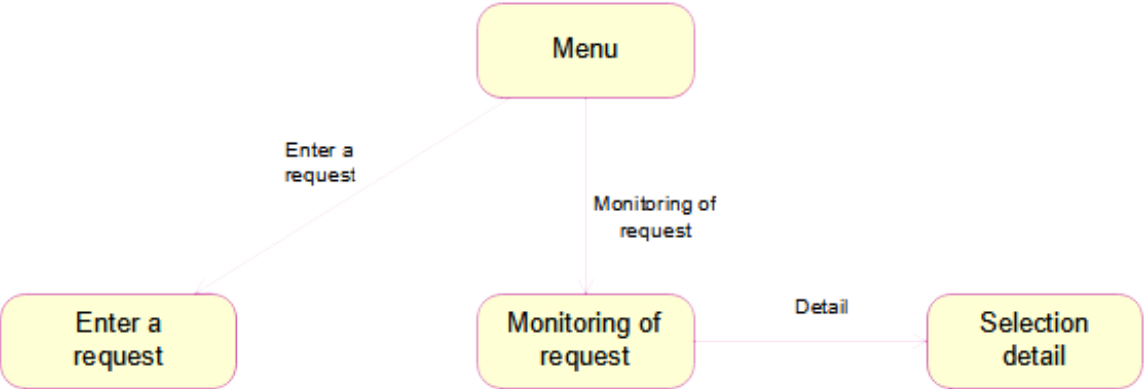
Operations available:

Action	Description	Page Name
Back	Comes back to the previous page	List postal payment
Save	Delete the selected relations and refresh the list of DM related to the payment	Same



2.4.6 The “Entered DMs data download” menu option

Screen flowchart:





2.4.6.1 Entering a request for data download

This page, which can be recalled by the “Entered DMs data download > Enter a request” menu option, allows the user to enter a request for data download in xml format. The set of DMs for which a request is made is identified by setting up specific search criteria on all validated or published Medical Devices that have been entered by the user. The request for data download will not be processed on the fly.

After setting up said search criteria, the number of validated or published Medical Devices that have been entered by the user matching the criteria set in that very moment is displayed; the number of DMs downloaded subsequently in batch mode may differ from that evaluated upon request, due to the operations carried out by the user in the lapse of time between the moment the request was entered and the moment it was processed.

Controls

Field Name	Description
Supply number	Identifier assigned to supplies sent for mass uploading of data.
Type	A medical device can be: ➤ Medical Device ➤ Assembled System or Kit
CND classification	Indicates the national classification of the DM.
Manufacturer / Assembler	Name or part of the name of the Manufacturer / Assembler of DMs/Assembled devices
Code assigned by the manufacturer / assembler	Code or initial part of the univocal code assigned by the Manufacturer/Assembler of DMs/Assembled devices



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Field Name	Description
(catalogue identifier)	
Trade name and model	Name or part of the name of the DM/Assembled device assigned by the Manufacturer/Assembler
Marketing	The user may choose based on the off-trade date. All possible values are: - Still marketed – DMs and Assembled devices the off-trade date of which is not evaluated or is set later than their search date. - No longer marketed – DMs and Assembled devices the off-trade date of which is set earlier than their search date.
Registered in the Repertoire	The user may select DMs and Assembled devices based on their presence in the Repertoire - Registered in the Repertoire - Not registered in the Repertoire

Operations available

Action name	Description	Recalled page name
Select DM	Starts the search of those validated or published DMs and Assembled devices entered by the user that match the selection criteria that have been set, displaying the number of DMs found and storing the download request along with the selection set for the next processing.	Same



2.4.6.2 Monitoring of all entered requests

This page, which can be recalled by the “Entered DMs data download > Request monitoring” menu option, allows the user to monitor the requests for data download entered to check their processing status.

The page is subdivided into three sections:

- requests that are being processed – where all those requests entered by the user that are not yet processed by the batch are reported
- processed requests – where all those processed requests that have not expired nor have been used, and for which the file generated after batch processing can be downloaded, are reported
- history of requests – where all processed requests for which the file generated after processing can no longer be downloaded because it has already been or the terms for use have expired are reported.

For any request, the following information is displayed:

- the entering date
- the processing date, visible for all those requests that have already been processed (in any status).
- the expiry date of the file generated after processing, visible only for those requests that have been processed but that have not expired nor have been used;
- the number of expected DMs (namely, all those validated or published DMs that have been entered by the user and that, upon entering the request for data download, match the search criteria that have been set), visible only for those requests that have not been processed yet;
- the number of DMs found when processing, visible for all processed requests;
- the request status (expired or used), visible for all registered requests.

For any request in the page, the user may:

- view those details of the search criteria set by the user that will detect, for all requests that have not been processed yet, or have detected, for all processed requests, those Medical Devices that are downloaded in batch mode;
- delete the request, if this has not been processed yet (requests that are being processed section);
- download the xml file generated after batch processing, if the request was processed and can still be used (processed requests section);
- enter a new download request having the same selection criteria of a request that has already been processed and that has expired or has been used.



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Monitoring of requests

Requests that are being processed

Entering date	Expected number of DMs	Detail	Remove
09/03/2012	2713	Detail	Remove

Processed requests

Entering date	Processing date	Expiry date	Number of DMs found	Detail	Download

History of requests

Entering date	Processing date	Number of DMs found	Status	Detail	Reselect

Operations available

Action name	Description	Recalled page name
Detail	Opens a window with the detail of all selection criteria set when entering the selected request for data download.	Request detail
Remove	Removes the selected request for data download that has not been processed yet.	Same
Download	Allows the user to save the file generated after batch processing and containing data – in xml format – of those validated or published devices that match the selection criteria that have been set.	Same
Reselect	Enters a new request for data download with the same selection criteria of the selected request.	Same



2.4.6.3 Displaying details of a download request

This page - recalled from the monitoring page of requests after clicking on the “Detail” link of an entered request - allows the user to view the details of those selection criteria set when entering the selected request for data download.

Monitoring of requests		?																		
Selection detail <table border="1"> <thead> <tr> <th>Filter</th> <th>Worth</th> </tr> </thead> <tbody> <tr> <td>Id Supply</td> <td></td> </tr> <tr> <td>Type</td> <td></td> </tr> <tr> <td>Manufacturer / Assembler</td> <td></td> </tr> <tr> <td>Code assigned by the Manufacturer / Assembler (catalogue identifier)</td> <td></td> </tr> <tr> <td>Trade name and model</td> <td></td> </tr> <tr> <td>CND classifications</td> <td></td> </tr> <tr> <td>Marketing</td> <td></td> </tr> <tr> <td>Registered on the index</td> <td>Registered on the index</td> </tr> </tbody> </table> Close			Filter	Worth	Id Supply		Type		Manufacturer / Assembler		Code assigned by the Manufacturer / Assembler (catalogue identifier)		Trade name and model		CND classifications		Marketing		Registered on the index	Registered on the index
Filter	Worth																			
Id Supply																				
Type																				
Manufacturer / Assembler																				
Code assigned by the Manufacturer / Assembler (catalogue identifier)																				
Trade name and model																				
CND classifications																				
Marketing																				
Registered on the index	Registered on the index																			

Operations available

Action name	Description	Recalled page name
Close	Closes the detail window of the selection criteria that have been set and takes the user back to the page containing the monitoring of all entered requests.	Monitoring of requests



2.4.7 Menu Item “Multiple Notifications of similar DMs”

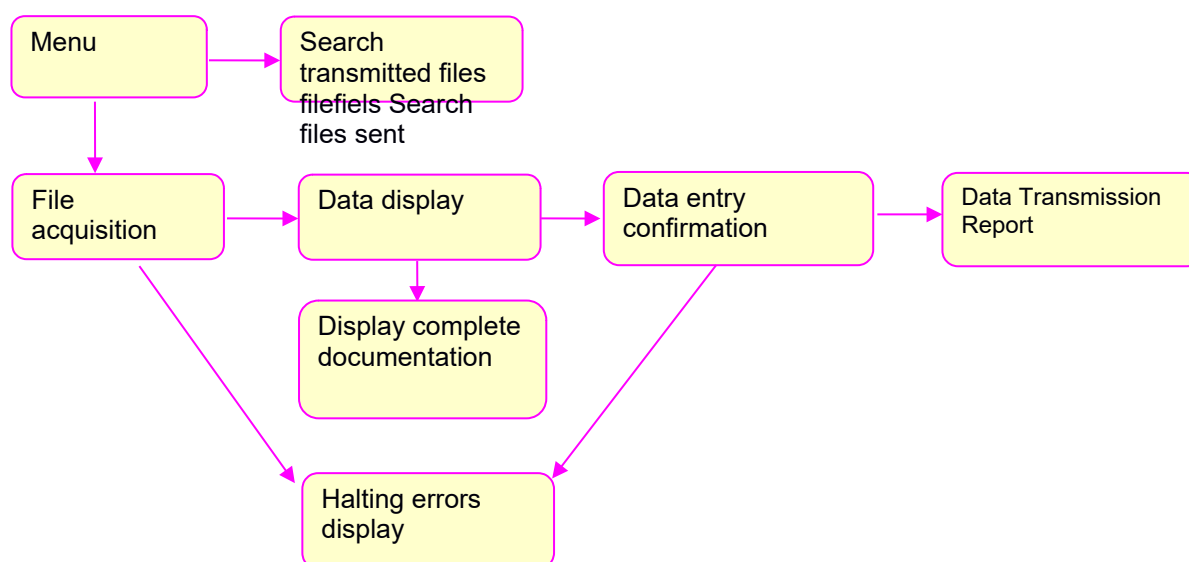
The multiple notification of similar medical devices makes the ‘similar medical devices’ registration process easier. It allows the user to transmit to the database a file – previously signed in offline mode – containing a list of catalogue identifiers, with their respective descriptions (trade name and model), related to products which need to be notified as similar to a device already registered in the database.

The file acquisition procedure consists of the following steps:

1. Upload of the signed file (CSV or XML format)
2. Display of the data which must be transmitted / errors encountered in the verification phase
3. Confirmation of the data (if no errors are present)
4. Notification report showing the progressive codes assigned by the system to the acquired medical devices

Successfully transmitted and acquired files will become searchable through database interrogation. If necessary, every file can be retrieved with its ‘notification report’ receipt.

Following clarification of Ministry of Health on the decree 21 dicembre 2009, the system present the message “**N.B.: for class I and IIA DM file containing Instruction for Use must be uploaded if DM is accompanied by**”. That is, the Declarant must upload the file of Instruction for Use if the device is accompanied by but the system can’t control it. In the case that file is not uploaded, the device data signed by Declarant will contain “**Device is not accompanied by Instruction for Use**”.

**Flow Chart:****How to set up the files in XML or CSV format:****General indications**

Every file can be in one of the accepted formats: CSV (in which the “,” symbol is used as a value separator ;) or XML. The specific data that must be entered into the file refer to:

- progressive number of the medical device used as a reference to acquire similar products;
- a list of the catalogue identifiers, with their respective descriptions (trade name and model), specific to similar devices

The values of the reference medical devices already present in the system, including the label file but without the optional measurement, will be used for the remaining data.

It is allowed to enter in the same file different groups of similar devices to already notified products. In this case, the same structure must be provided for every group (reference medical device – list of similar products).

On the whole, every file must be prepared in accordance with the intended purpose, i.e.:

- providing more details for product codes already present into the database and related to general notifications (existing notifications update);
- quicker loading of similar DMs (notification of new medical devices similar to existing ones)



Independently from the number of the above-mentioned groups, there is a limitation on the number of rows, and consequently of devices, which can be added to each file. This limit is shown on the 'file acquisition' page. When processing the file, the system checks the number of rows present, halting the acquisition when the threshold is crossed.

CSV format: each row of the .csv file contains 3 data separated by the ; **symbol** (semicolon). The first information refers to the 'progressive number of the reference device', while the second and third respectively refer to the 'catalogue identifier' and 'description' (trade name and model) of the similar dm. Generally, it is required to add in the file a number of rows equal that are to the number of similar medical devices which are to be notified. **In each row, the first data is the 'progressive number of the reference device'**. It is possible to add more than one list of similar devices, each one assigned to its respective reference medical device. The following example refers to the case in which 2 groups of similar devices are to be notified with reference to 2 different medical devices already present in the database with the following progressive numbers: 100 e 101

Example.csv

```
100;catalogue identifier 1;description 1
100;catalogue identifier 2;description 2
100;catalogue identifier 3;description 3
100;catalogue identifier 4;description 4
100;catalogue identifier 5;description 5
101;catalogue identifier 6;description 6
101;catalogue identifier 7;description 7
101;catalogue identifier 8;description 8
101;catalogue identifier 9;description 9
101;catalogue identifier 10;description 10
```

Excel can be used to prepare the CSV file. If this is the case, after adding the rows, the file should be saved as: "CSV (delimited by list separator)". While setting up the file, it is not required to enter column headers in the first row.

XML format: in the XML structure, which **uses Tags**, each medical device, and its list of similar medical devices, must be added in a structure identified by the tag pair: **<dm_collection>** , **</dm_collection>**. For example, to notify two lists of medical devices similar to reference devices already notified, it is necessary to add in the xml file two pairs of the above-mentioned tags, one representing the first list of similar devices, the other representing the second list. For each list, the 'progressive number of the reference device' (**tag: cod_dm_origine**) will have to be entered together with the catalogue identifier (**tag: dm cod**) and description (**tag: desc**) of each similar device which will be registered.

**Example.xml:**

```

<?xml version="1.0" encoding="ISO-8859-1" ?>
<dm_simili xmlns=http://www.eng.it/rdm/NotificheMultiple_dmSimili
  xmlns:xsi=http://www.w3.org/2001/XMLSchema-instance>
  <dm_collection>
    <cod_dm_origine>100</cod_dm_origine>
    <dm cod="catalogue identifier 1" desc="description 1" />
    <dm cod="catalogue identifier 2" desc="description 2" />
    <dm cod="catalogue identifier 3" desc="description 3" />
    <dm cod="catalogue identifier 4" desc="description 4" />
    <dm cod="catalogue identifier 5" desc="description 5" />
  </dm_collection>
  <dm_collection>
    <cod_dm_origine>101</cod_dm_origine>
    <dm cod="catalogue identifier 6" desc="description 6" />
    <dm cod="catalogue identifier 7" desc="description 7" />
    <dm cod="catalogue identifier 8" desc="description 8" />
    <dm cod="catalogue identifier 9" desc="description 9" />
    <dm cod="catalogue identifier 10" desc="description 10" />
  </dm_collection>
</dm_simili>

```

2.4.7.1 File acquisition

This page opens when clicking on the menu item “Multiple Notifications of Similar DMs - > File transmission”. It allows to acquire specific data related to devices declared similar to products already registered into the database. To be suitable for notification, the file must be digitally signed, using qualified electronic signature, in offline mode.

Follow the steps below:

- Specify the purpose of use of the multiple notifications of similar DMs feature:
 - providing more details for products codes already present into the database and related to general notifications (existing notifications update);
 - quicker loading of similar DMs (notification of new medical devices similar to existing ones)
- Browse for the signed file from your computer having specified the file format (CSV, XML);
- Choose whether or not to register on the repertoire the codes of the products under acquisition;
- Click on ‘Next’ to start checking the data contained in the selected file



User Manual DM Manufacturer Profile



Medical Devices of the Class I, II a / b, III, Download Area Personal data

- Medical Device (DM)
- Systems or Assembled Kits (c.2 Art.12)
- Activity in progress
- EC certificates
- Deposit
- Data Transmission
- Entered DMs data download
- Documentation
- Aggiornamento Mandatorio
- Multiple Notifications similar DMs
 - File transmission
 - Search transmitted files

Home > Class I, II a / b, III Medical Devices > Medical Device (DM) > Multiple acquisition similar DMs

Multiple acquisition similar DMs

The multiple acquisition feature allows to transmit to the Ministry of Health a signed file containing the catalogue identifiers and descriptions (trade name and model) related to DMs similar to a device already present in the database. Both text format (*.csv) and XML format (*.xml) following the [layouts](#) set by the Ministry are accepted. A single file can contain a maximum of 200 DMs

The file acquisition procedure consists of the following steps:

1. Upload of the signed file (CSV or XML format).
2. Display of the data which must be transmitted / possible errors encountered in the verification phase
3. Confirmation of the data (if no errors are present)
4. Notification report showing the progressive codes assigned by the system to the acquired medical devices

1. Upload the file
2. Display data/errors
3. Confirmation
4. Report

1. Uploads the file with the similar DMs

Specify the purpose of use of the multiple notifications of similar DMs feature;
Specify the file format (CSV or XML);
Browse for the signed file, previously signed [offline](#), containing the catalogue identifiers and descriptions of the similar DMs which must be acquired;
Select the checkbox "Register the codes on the repertoire" if the new catalogue identifiers are to be registered in the national Repertoire;
Click on the "Next" button to start the processing...

Specific data of similar DMs

* The feature is used to: ☒ Update previous generic notifications ☐ Notify new devices

* File Type:

* Similar DMs file:

Register the codes on the repertoire: ☐

* Mandatory data

Fields Description

Field Name	Description
Purpose of use of the feature (option)	This option button allows to state the purpose of use of the feature by: providing more details for products codes already present into the database and related to <u>general notifications</u> (existing notifications update); quicker loading of similar DMs (notification of new medical devices similar to existing ones)
File type (drop-down list)	Type of the file containing the codes to be acquired (xml or csv format)
Similar DMs file (text field)	Xml/csv file, signed offline, containing the codes to be acquired
Register the codes on the repertoire (check box)	This checkbox allows to choose whether or not to register on the repertoire the codes of the products under acquisition

User Manual
DM Manufacturer Profile*Operations available:*

Activity	Description	Page Opened
Browse	Browse the system folders and select the file to be processed	'File Selection' pop-up
Next	The signed file is acquired and its contents verified	Data/errors display



2.4.7.2 Display of the data

This page opens when the contents of the file to be acquired have been verified and accepted as valid for registration. The checking procedure can be started from the 'File Acquisition' window clicking on the 'Next' button.

This page shows some important data for every reference medical device present in the upload file (such as the medical device manufacturer, its catalogue identifier and description, some data pertaining to its classification, its label file). It shows also the product codes list and the descriptions of the similar devices to be acquired.

To access the contents of the label file, use the link 'show label'.

If necessary, the complete documentation (label, instruction of use...) of the reference device can be examined using the **associated link**.

The list of reference devices can be browsed using the navigation bar (previous  / next  buttons).

If a reference device is already associated with a group of similar DMs, an (*) will be displayed next to its progressive number. In this case, the medical devices acquired from a file and associated to this reference device will be put in the already existing group.

If the uploaded file contains information already present in the database, a warning will be shown for the rows (product code, description) containing the duplicate. If product codes and descriptions already registered in the database are found during the verification phase, they will be marked with a red warning (▲) and will be subsequently ignored during the registration phase. Entries with the same catalogue identifier of an already registered product, but with a different description (trade name and model), will be marked with a yellow warning (▲), allowing the user to decide whether to register the product or not.

Click on 'Next' to go the 'Confirm registration' page. To quit the registration procedure and go back to the 'File acquisition' page, click on the 'Back' button



User Manual DM Manufacturer Profile



Home > Class I, II a /b, III Medical Devices > Medical Device (DM) > Multiple acquisition similar DMs

Multiple acquisition similar DMs

1. Upload the file 2. Display data/errors 3. Confirmation 4. Report

File Name: Multiple notifications.csv

2. Display of the data which must be transmitted

Verify that the data to be notified are correct.

If the uploaded file contains more groups of similar medical devices, to verify the data of each group, select the progressive of the reference device using the ◀ (previous button) and ▶ (next button). If a reference device is already associated with a group of similar DMs, an (*) will be displayed next to its progressive number. In this case, the medical devices acquired from a file and associated to this reference device will be put in the already existing group.

Click on "next" to proceed with the acquisition or click on "back" to cancel the operation.

Group 1/2 - Progressive of the reference DM: 641

◀ 641 (*) 480434 (*) ▶



Complete
documentation

Code Manufacturer: AD110A-XX
Trade Name and Model: Catheter generic model ...
Manufacturer: : xxxxxxxxxxxx
System Progressive: 641

GMDN Code: 44141 - A single-use catheter based ultrasound transducer assembly enclosed in a fluid resistant or waterproof acoustically and electrically insulated housing designed for insertion into the vascular system's, i.e. vein or artery, and positioned by the operator. Also known as a vascular probe or transducer, it is frequently incorporated as part of, or used with, devices requiring ultrasound guidance and placement, e.g. endoscopy equipment or needle biopsy equipment. The device is composed of either a single transducer element or an array of transducer elements, i.e. piezoelectric element(s), active element(s), or crystal(s) and associated damping, backing, and matching layer materials.

CND Code: C0104020102 - CATETERI PER ULTRASONOGRAFIA INTRAVASCOLARE

SIMILAR DMs UNDER ACQUISITION FOR THIS GROUP:

Code Manufacturer	Trade Name and Model
AD110A--01	Catheter model A01
AD110A--02	Catheter model A02
AD110A--03	Catheter model A03
AD110A--04	Catheter model A04
AD110A--05	Catheter model A05
AD110A--06	Catheter model A06
AD110A--07	Catheter model A07
AD110A--08	Catheter model A08
AD110A--09	Catheter model A09
AD110A--10	Catheter model A10

Back Next



User Manual DM Manufacturer Profile



Group 2/2 - Progressive of the reference DM: 480434

641 (*)
480434 (*)

Complete documentation

Code Manufacturer: ADS10B-XX

Trade Name and Model: Catheter generic B model ...

Manufacturer: xxxxxxxxxxxx

System Progressive: 480434

GMDN Code: 44141 - A single-use catheter based ultrasound transducer assembly enclosed in a fluid resistant or waterproof acoustically and electrically insulated housing designed for insertion into the vascular system's, i.e. vein or artery, and positioned by the operator. Also known as a vascular probe or transducer, it is frequently incorporated as part of, or used with, devices requiring ultrasound guidance and placement, e.g. endoscopy equipment or needle biopsy equipment. The device is composed of either a single transducer element or an array of transducer elements, i.e. piezoelectric element(s), active element(s), or crystal(s) and associated damping, backing, and matching layer materials.

CND Code: C0104020102 - CATETERI PER ULTRASONOGRAFIA INTRAVASCOLARE

SIMILAR DMs UNDER ACQUISITION FOR THIS GROUP:

Code Manufacturer	Trade Name and Model
ADS10B0--01	Catheter model B1
ADS10B0--02	Catheter model B2
ADS10B0--03	Catheter model B3
ADS10B0--04	Catheter model B4
ADS10B0--05	Catheter model B5
ADS10B0--06	Catheter model B6
ADS10B0--07	Catheter model B7
ADS10B0--08	Catheter model B8
ADS10B0--09	Catheter model B9
ADS10B0--10	Catheter model B0

Back
Next

Fields Description

Field Name	Description
Trade name (alphanumeric)	Trade name and model of the reference medical device
Manufacturer's code	(alphanumeric)Product code assigned by the manufacturer to the reference medical device (catalogue identifier)
Manufacturer (alphanumeric)	Name of the Manufacturer of the reference medical device
System Progressive (numeric)	Unique identification number assigned to the reference medical device
GDMN code (alphanumeric)	GDMN code with description of the related reference medical device
CND code (alphanumeric)	CND classification (description and code) assigned to the reference device
Label	Link to the pdf label



User Manual
DM Manufacturer Profile



(link)	
Original DM Group number (numeric)	List of the system progressive numbers of every medical device used as the reference DM for groups of similar devices
Number of similar DMs in the group	Number of DM similar to the selected reference DM present in the upload file
DM to be associated with an original DM	List of the DM to be associated with the selected reference DM. The following information is shown for every medical device: - Warning (optional) - Manufacturer's code (mandatory) - Trade name (mandatory)

Operations available:

Action Name	Description	Page Opened
< (previous)	Shows the previous item in the navigation bar	Same page
> (next)	Shows the following item in the navigation bar	Same page
Back	Goes back to the previous page cancelling the acquisition procedure	File acquisition
Next	Goes on with the acquisition procedure	Data entry confirmation
Label	Shows the pdf file with the label of the selected reference device	Popup
Complete documentation	Allows to examine the complete documentation (label, instructions of use, etc), of the reference medical device.	Complete documentation



2.4.7.3 Data entry confirmation

Through this page it is possible to start the registration of the uploaded similar medical device in the database. For the purposes of notification, these medical devices, characterised by a specific catalogue identifier and description (trade name and model), will inherit the remaining data, including the label file, from the device chosen as a reference (with the exception of the optional measurement).

If some non-halting warnings (indicating that some of the catalogue identifiers in the file are already registered in the database, although with a different description) have been detected during the verification phase, the user can decide whether or not to enter also these codes; a decision must be taken by clicking on the corresponding radio button

Click on 'Next' to proceed with the registration process or click on the 'Back' button to cancel and go back to the 'File Acquisition' page.

The medical devices which will be registered in the database will also be registered on the repertoire if the corresponding option has been selected ('File acquisition' page - check: register the codes on the repertoire)

If the medical device chosen as a reference doesn't already belong to a group of similar DMs (in which case every similar device acquired will be included in the same group), a new group of medical devices made up of the DM chosen as a reference and all the similar devices acquired will be created by the system.

Home > Class I, II a /b, III Medical Devices > Medical Device (DM) > Multiple acquisition similar DMs

Multiple acquisition similar DMs

1. Upload the file

2. Display data/errors

3. Confirmation

4. Report

File Name: Multiple notifications.csv

3. Confirm the similar DMs registration

The confirmation starts the registration of the DMs in the database/repertoire.
If the medical device chosen as a reference doesn't already belong to a group of similar DMs (in which case every similar device acquired will be included in the same group), a new group of medical devices made up of the DM chosen as a reference and all the similar devices acquired will be created by the system.
After the operation has been completed, the system reports the identification code of each similar DM.

Click on the "Next" button to confirm the registration
Click on "Back" to cancel the operation

Back Next

*Fields Description*

Field Name	Description
Acquisition of duplicate DM (radio button)	This radio button allows to choose whether or not to enter the catalogue identifiers already present in the database with a different description. Visible only if the uploaded file contains information already present in the database.

Operations available:

Action Name	Description	Page Opened
Next	it goes on with the acquisition procedure, registering in the database all the similar devices present in the file. If the corresponding option has been selected, the medical devices with a duplicate product code – but with a different description (trade name and model) – will also be acquired. In any case, the medical devices whose product code and description are already present in the database won't be registered. If the corresponding option has been selected, the system will register the medical devices on the repertoire (step 1: 'File acquisition – check "Register the codes on the repertoire").	Data Transmission Report
Back	Goes back to the previous page cancelling the entry procedure	File acquisition

2.4.7.4 Data Transmission Report

This page opens after the acquired medical devices have been registered in the database. The report shows the progressive number assigned by the system to every registered device. If the corresponding option has been selected, the devices registered on the repertoire will be shown with /R following the progressive number.

The status of these devices will be 'validated', waiting to be published.

This page allows also to export the data loading report, a CVS or XML file, containing the list of the acquired product codes and descriptions with the number of the corresponding database/repertoire. The file will also contain those catalogue identifiers not acquired due to (yellow/red) system warnings.

Click on 'Done' to complete the acquisition process.



User Manual DM Manufacturer Profile



Home > Class I, II a /b, III Medical Devices > Medical Device (DM) > Multiple acquisition similar DMs

Multiple acquisition similar DMs

1. Upload the file 2. Display data/errors 3. Confirmation 4. Report

File Name: Multiple_notifications.csv

4. Transmition Report

The data have been successfully registered, a progressive number has been assigned to each medical device. The progressives are shown in the table below.
Clicking on icon  it is possible to download the 'Notification Report' receipt, a CSV or XML file containing both a list of the similar devices registered with the corresponding database/repertoire numbers and a list of the catalogue identifiers not acquired (if any) due to (yellow/red) system warnings.
Click on the 'Done' button to go back to the first page of the acquisition procedure of similar DMs

PROCESSING REPORT

SIMILAR DMs REGISTERED FOR THE REFERENCE DM N°: 641 - Catheter generic model ...

Code Manufacturer	Trade Name and Model	System Progressive
AD110A--01	Catheter model A01	484473
AD110A--02	Catheter model A02	484474
AD110A--03	Catheter model A03	484475
AD110A--04	Catheter model A04	484476
AD110A--05	Catheter model A05	484477
AD110A--06	Catheter model A06	484478
AD110A--07	Catheter model A07	484479
AD110A--08	Catheter model A08	484480
AD110A--09	Catheter model A09	484481
AD110A--10	Catheter model A10	484482

SIMILAR DMs REGISTERED FOR THE REFERENCE DM N°: 480434 - Catheter generic B model

Code Manufacturer	Trade Name and Model	System Progressive
ADS10B0--01	Catheter model B1	484483
ADS10B0--02	Catheter model B2	484484
ADS10B0--03	Catheter model B3	484485
ADS10B0--04	Catheter model B4	484486
ADS10B0--05	Catheter model B5	484487
ADS10B0--06	Catheter model B6	484488
ADS10B0--07	Catheter model B7	484489
ADS10B0--08	Catheter model B8	484490
ADS10B0--09	Catheter model B9	484491
ADS10B0--10	Catheter model B0	484492

Done

*Fields Description*

Field Name	Description
Reference DM (numeric)	Identification code of the DM used as a reference for the group (system progressive)
Manufacturer's (alphanumeric)	Product code assigned to the medical device by the manufacturer (catalogue identifier)
Trade name and model	Trade name and model of the medical device
System Progressive (numeric)	Identification code assigned by the system to the medical device. If /R appears next to the identification number

Request download file 'Notification Report':

Select the format of the file to be downloaded:

CSV Format ☒ XML Format ☐

Download Cancel

Notification Report (csv format)



User Manual DM Manufacturer Profile



A	B	C	D	E	F	G
reference md	manufacturer code	denomination	update	aquired	warning	system progressive
641	AD110A-XX	CATHETER GENERIC MODEL				
641	AD110A-01	Catheter model A01	Y	Y		484473
641	AD110A-02	Catheter model A02	Y	Y		484474
641	AD110A-03	Catheter model A03	Y	Y		484475
641	AD110A-04	Catheter model A04	Y	Y		484476
641	AD110A-05	Catheter model A05	Y	Y		484477
641	AD110A-06	Catheter model A06	Y	Y		484478
641	AD110A-07	Catheter model A07	Y	Y		484479
641	AD110A-08	Catheter model A08	Y	Y		484480
641	AD110A-09	Catheter model A09	Y	Y		484481
641	AD110A-10	Catheter model A10	Y	Y		484482
480434	ADS10B-XX	CATHETER GENERIC B MODEL				
480434	ADS10B0-01	Catheter model B1	Y	Y		484483
480434	ADS10B0-02	Catheter model B2	Y	Y		484484
480434	ADS10B0-03	Catheter model B3	Y	Y		484485
480434	ADS10B0-04	Catheter model B4	Y	Y		484486
480434	ADS10B0-05	Catheter model B5	Y	Y		484487
480434	ADS10B0-06	Catheter model B6	Y	Y		484488
480434	ADS10B0-07	Catheter model B7	Y	Y		484489
480434	ADS10B0-08	Catheter model B8	Y	Y		484490
480434	ADS10B0-09	Catheter model B9	Y	Y		484491
480434	ADS10B0-10	Catheter model B0	Y	Y		484492

Fields Description

Field Name	Description
Reference DM (numeric)	Identification code of the DM used as a reference for the group (system progressive)
Manufacturer's code (alphanumeric)	Product code assigned to the medical device by the manufacturer (catalogue identifier)
Denomination	Trade name and model of the medical device
Update	Flag (Y/N) stating the purpose of use of the feature. Y – the feature was used to update existing (generic) notifications adding additional details to the product codes; N – the feature was used to quickly notify new product codes related to medical devices similar to existing ones
Acquired	Flag (Y/N) Y – the medical device has been registered in the database / repertoire N – the medical device has not been registered in the database / repertoire
Warning	Warnings shown by the system while processing the file. allowed values: not present / WG / WR



	not present – no alert; the medical device has been registered in the database / repertoire WG – there is a medical device with the same manufacturer's code, but different description (trade name and model), registered in the database / repertoire WR – there is a medical device with the same manufacturer's code and description registered in the database / repertoire
System Progressive (numeric)	Identification code assigned to the medical device (valid only for those devices which have been registered in the database and that are recognized by /R that appears next to the identification number)

Operations available:

Action Name	Description	Page Opened
Export	Downloads a CSV/XML file containing the list of the product codes and descriptions registered in the database, with the progressive number assigned by the system. The file contains also any catalogue identifier not acquired due to (yellow/red) system warnings.	Same page
Done	Completes the acquisition process	File acquisition



2.4.7.5 Halting errors display

This page opens if the system detects halting errors during the verification phase. The entire file will be discarded by the system even if some of the product codes and descriptions have got through the verification.

If possible, to facilitate reading errors will be grouped based on reference medical device.

Click on 'Back' to go back to the 'File acquisition page'

Shown below are shown all the possible halting errors

File structure verification:

- Error S01: Wrong signed file format
- Error S02: The signer certificate has expired
- Error S03: The signer certificate is not trusted
- Error S04: The structure of the file does not respect the expected layout (xml/csv)

File contents verification:

- Error B092: The medical device chosen as a reference to manage similar DMs is not present in the database;
- Error B289: the user is not allowed to notify medical devices for registering/manufacturing company specified in the reference medical device;
- Error B172: The medical device chosen as a reference to manage similar DMs is not in the Validated or Published status;
- Error B290: The medical device chosen as a reference is already notified as specific to 'more details'.
- Error B291: For the medical device chosen as a reference have been found invalid information

Generic errors:

- A system error has occurred. Couldn't complete the file acquisition procedure.



User Manual DM Manufacturer Profile



Home > Class I, II a /b, III Medical Devices > Medical Device (DM) > Multiple acquisition similar DMs

Multiple acquisition similar DMs

1. Upload the file 2. Display data/errors 3. Confirmation 4. Report

File Name: Multiple notifications.csv

ERROR IN THE MULTIPLE ACQUISITION OF SIMILAR DMs

⚠ CAUTION! The following halting errors have been detected. It's not possible to proceed with the file acquisition procedure. Correct the errors and upload the signed file again.

- * Reference DM N° 28312:
Error B289 - the user is not allowed to notify medical devices for the registering/manufacturing company specified in the reference medical device;
- * Reference DM N° 480435:
Error B092 - The medical device chosen as a reference to manage similar DMs is not present in the database;

[Back](#)

Fields Description

Field Name	Description
Reference DM N° (numeric)	Identification code assigned to the medical device used as a reference for a group of similar devices (system progressive)
Error code (alphanumeric)	The code of the error detected during file verification
Error description (alphanumeric)	Description of the error detected during file verification
Manufacturer's (alphanumeric)	Catalogue identifier present in the duplicate row
DM description (alphanumeric)	Description (trade name and model) of the product (catalogue identifier) present in the duplicate row

Operations available:

Action Name	Description	Page Opened
Back	Quits the acquisition procedure interrupted due to halting errors	File acquisition



2.4.7.6 Search transmitted files

This page opens when clicking on the menu item “Multiple notifications of similar DMs -> Search transmitted files”. It allows the user to search successfully transmitted and acquired files, and also to download the ‘notification report’ receipt.

It is possible to filter the search by:

transmission date of the file;
name of the transmitted file (partial text search is allowed);
purpose of use (update of existing notifications/notification of new similar DMs).

When the parameters have been defined, start the search.

The system will list all the transmitted files, if any, based on the selected parameters ...

For each file, the following information will be displayed:

- Transmission date;
- Transmitted file;
- Purpose of use;
- Notification report (csv / xml format).

It is possible to download both the transmitted files and the notification reports.

Medical Devices of the Class I, II a / b, III, Download Area Personal data

- Medical Device (DM)
- Systems or Assembled Kits (c.2 Art.12)
- Activity in progress
- EC certificates
- Deposit
- Data Transmission
- Entered DMs data download
- Documentation
- Aggiornamento Mandatario
- Multiple Notifications similar DMs
 - File transmission
 - Search transmitted files

Home > Class I, II a / b, III Medical Devices > Medical Device (DM) > Multiple acquisition similar DMs

Search transmitted files

This feature allows to search the files containing the notifications of similar DMs successfully transmitted and acquired by the system. It is possible to filter the search setting one or more of the following parameters: file transmission date, name of the transmitted file, purpose of use of the feature. When the parameters have been defined, start the search... As a result, the system will list all the transmitted files (if any), allowing the user to download both the transmitted files and the notification reports.

Search

Transmission date: from to

File Name:

Purpose of use:

Transmission date	File Name	Purpose of use	Report file (Csv / Xml)
11/02/2013	Multiple notifications.csv	Update of previous generic notifications	

*Detail Fields*

Field Name	Description
from - to	Time interval containing the date when the multiple notifications file has been transmitted
File name	Name of the transmitted file
Purpose of use	Purpose of use of the feature: ✓ Y - the feature was used to update existing (generic) notifications adding additional details to the product codes; ✓ N - the feature was used to quickly notify new product codes related to medical devices similar to existing ones

Operations available

Action Name	Description	Page Opened
Search	Start searching with the selected parameters	
New search	Clears the defined parameters (if any)	Same page.
Download 'Multiple notifications file'	Downloads the multiple notifications file	File Download
Download 'Report'	Downloads the file acquisition report, available in csv / xml format	File Download



2.4.8 “Documentation” Menu option

2.4.8.1 View support's documents

This page, activated by the "Documentation > See Documentation" menu option, allows the user to view and download the support's documents.

Documentation

TECNICAL

In the section below there is the **User manual** to support the use of the System.

For users of the features of **mass uploading of data** are also availables documents **Data and Flow Check** with its **annexes** and **formatted XML Schema**.

Tecnica		
Document	Valid from	
User Manual Manufacturer Profile	17/10/2011	Open
Data and Flow Check document	26/03/2010	Open
Attachments (Data and Flow Check document)	26/03/2010	Open
Xml schema	26/03/2010	Open

TECNICA

Nella sezione sottostante e' presente il **Manuale Utente** di supporto all'utilizzo del Sistema.

Per gli utilizzatori delle funzionalita' del **Caricamento Massivo** sono presenti inoltre i documenti inerenti a **Dati e controlli flussi** con relativi **allegati** e **Schema XML**.

Tecnica		
Document	Valid from	
Manuale Utente Profilo Fabbricante	17/10/2011	Open
Documento Dati e Controllo Flussi	26/03/2010	Open
Allegati (Documento Dati e Controlli Flussi)	26/03/2010	Open
Tracciato xml	26/03/2010	Open

Operations available:

Action name	Description	Recalled page name
Open	Allows to open or download the corresponding file	



2.5 Detailed description of the “In Vitro diagnostic medical Device” Functional area

Following access to the functional area "In Vitro diagnostic medical devices", the menu of functions available in that area is displayed on the left side of the page.

- ▶ Medical Device (IVD)
- ▶ Activities in progress
- ▶ EC certificates
- ▶ Multiple Notifications similar IVDs
- ▶ User Documentation

Before inserting the devices not yet present in the Repertoire it is important to make sure that preliminary activities have been completed, especially the declarations of the entities for which the user is empowered to operate (see 'Company Data' application area) and, except for IVDs for performance evaluation, the inclusion of EC certificates, if any, issued by Notified Bodies (see 'Certificate Management' function of this application area).

- EC CERTIFICATES (only for CE marked device)

The user can use this menu item to insert a certificate not yet present in the repertoire (issued by a Notified Body) or search EC certificates already entered.

The user can refer to the user manual and online help for the rules applicable to editing and updating certificates.

- MEDICAL DEVICE (IVD)

This menu item allows the user to enter a CE Marked medical device does not yet exist in the Repertoire or to search for existing CE marked devices.

- ACTIVITY IN PROGRESS (only for CE marked device)

This menu item displays all messages from the system or from the Ministry relating to:

- device consolidation errors (missing data, ...) reported by the system,
- request for modification of a device validated/published by the Ministry,
- completed publication of a device.

- MULTIPLE NOTIFICATION OF SIMILAR IVD (only for CE marked device)

The function capturing multiple similar IVD is an operational simplification that allows the user to issue a bulk notification of multiple devices having the same information except for the catalogue code and description (trade name and model).

- USER DOCUMENTATION

This item allows the user to download supporting documents for the use of the Medical Device system.

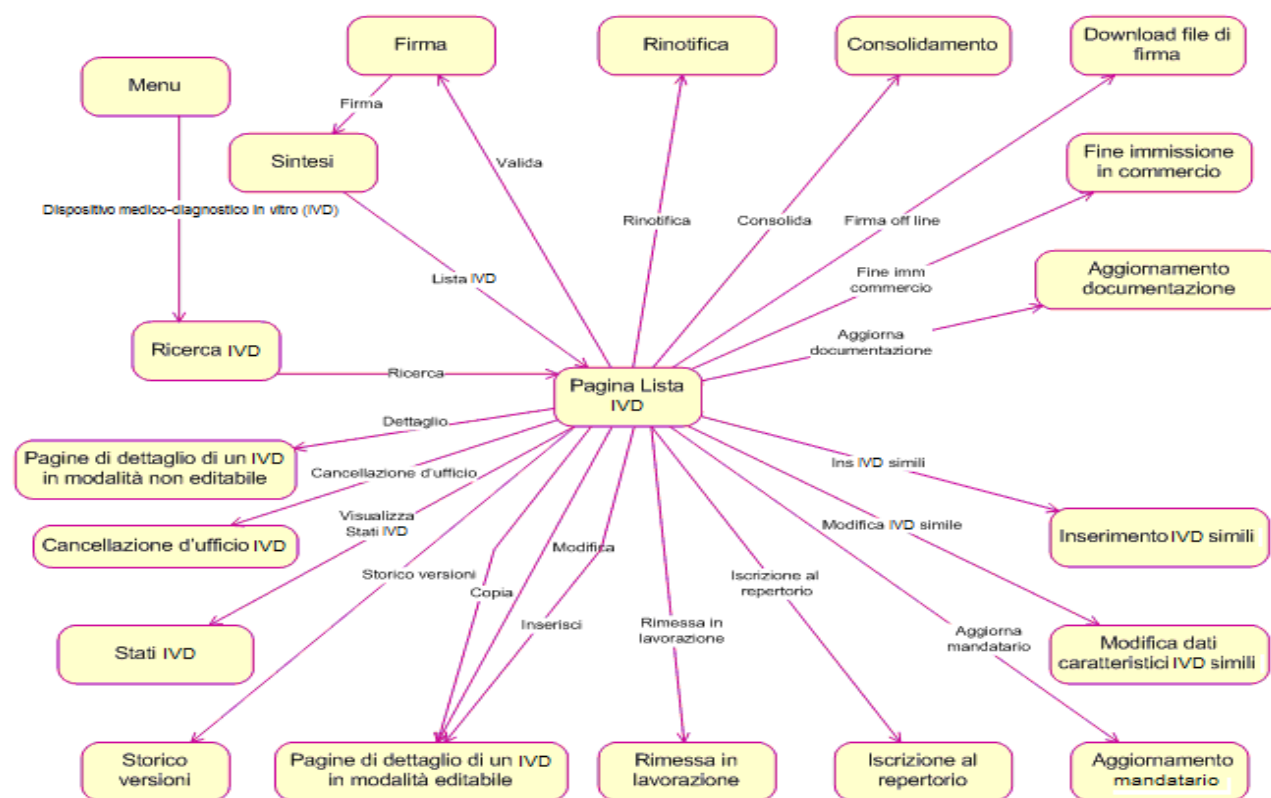


- MEDICAL DEVICE FOR PERFORMANCE EVALUATION

This menu item allows the user to enter a medical device form performance evaluation (PE) does not yet exist in the Medical Device Data Bank or to search for existing PE devices.

2.5.1 “Medical Device (IVD)” Menu option

Flusso delle videate:





2.5.1.1 IVDs search

Having clicked on “Medical Device (IVD)” on the menu, a page appears which allows the user to define the search criteria of the IVD registered on the system

The user could extend the search to all IVDs registered in the system (*Search on all IVDs*) whose owner is the user or, otherwise, restrict to the only IVDs with status in progress (*Search in IVD To-do list*) which refers both to first notification and manufacturing put back. Also “Consolidated” IVDs are generally considered in progress.

Select “*Search in IVD To-do list*” to complete the notification process of a IVD using qualified electronic signature the entered data (Validation) or, otherwise, delete data that were entered by mistake into the system. It’s not possible to delete “In progress” IVDs which come from “manufacturing putback”

Set the criteria, start the search.

From this page, the user may also access to the insert page of the general data of a IVD (Insert button)

*Details of IVD search Fields*

Field Name	Description
Search on all IVDs	allows the extended search of all IVDs registered in the system whose owner is the user;
Search in IVD To-do list	allows the restricted search of IVDs in status in progress;
System Progressive attributed to IVD	Option to search a in Vitro medical device by its identification number assigned by the system during registration into the database.
Manufacturer	Option to specify the name (or the beginning) of the Manufacturer of the IVD
Code assigned by the manufacturer (identifier catalogue) from/to	Option to indicate the range of codes which includes the product code assigned to the IVD by the Manufacturer.
Trade Name and Model	Option to specify the commercial name (or beginning) of the IVD
CND Classification	Option to run a search using the National classification of the IVD. This field cannot be edited. To select a classified CND and click on the “Search” link. A look-up will then open where the user has the option to search a CND by code or by description or part thereof.
First Notification (Yes/No/All) (Applicable only if “Search in IVD To-do list” selected)	allows the restricted search of IVDs in first notification (Yes), the restricted search of IVDs in manufacturing put back (No), or extended search of all the IVDs in progress which refers both to first notification and manufacturing put back;
IVD state	Option to search a medical device by its current status into the system (“In progress”, “Consolidated”, “Validated”, “Published”).
User role as to the IVD	Option to search a medical device by the role carried out by the user with respect to that medical device (“Manufacturer”, “Agent”, “Other person delegated by the Manufacturer”)
Notification Start date (from / to) (Applicable only if “Search in IVD To-do list” selected)	allows to filter IVDs by specifying the range of date (from – to) for the start of notification of IVD. If not used, the search is extended to all IVDs present in To-do List whose owner is the user;
Marketing	Option to search a medical device by the end trade date. There are three types: “Still on the market”, are sought for the IVD whose end date marketing is not valued or is next to the search “No longer marketed”, the IVD are searched for which the end date for placing on the market earlier than research
Registered on the index	Option to search a medical device by the registration on the index (registered, not registered)

*Operations available*

Action	Description	Page Name
Insert	Allows access to the IVD general data entry page	IVD detail pages in editable procedures
Search	Activates a search on the basis of the criteria inserted	IVD List Page
New search	Clears the search criteria previously defined	Same

2.5.1.2 Searched IVDs list

When at least one of the search criteria has been entered, and the user has clicked the “Search” button, the search is activated and a list of IVD corresponding to the criteria specified comes up on screen.

For every IVD, the following information is displayed:

- Identification number assigned to the IVD by the system
- Manufacturer
- Product code assigned to the IVD by the manufacturer
- Commercial name and model of the IVD
- CND classification
- Status of the IVD
- End trade date

If /R appears next to the consecutive number assigned to the IVD by the system, it means that the IVD has been registered on the index.

The IVDs list changes, not only on the basis of the criteria set, but also depending on the user connected: the Manufacturer/Agent will see only those IVDs coming from the company he/she represents, regardless of their status in the database; from this page, he/she may set a new search, or:

- e. within the scope of the IVDs notifications:
 - insert a new IVD;
 - insert a new IVD by copying an existing IVD;
 - edit a IVD with an “In Progress” or “Consolidated” status;
 - delete a IVD that has never been published. Only IVD in the status "In progress" or "Consolidated" can be deleted;
 - insert quickly one or more IVD similar to the selected one indicating only some characteristic data;
 - edit the characteristic data of IVD in processing inserted by means of the quick insertion functionality;



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- notify again a IVD in the “Published” status keeping the connection with the same original source device;
- f. within the scope of the validation of the notification that has already been made
 - consolidate one or more IVD in "In progress" status
 - validate one or more IVD in "Consolidated" status
 - quickly validate one or more in "In progress" status
 - activate the off line signature process for one or more IVD in “Consolidated” status
- g. within the scope of the update of data after their publication:
 - update the documentation (label and instructions for use) for the IVD in ‘Validated’ or ‘Published’ status
 - update the Agent for the IVDs in the “Published” status
 - register on the index one or more IVDs in the “Validated” or “Published” status declaring they will be distributed to the facilities of the National Health Service,
 - insert the issue date of the placement of a IVD on the market marked “Validated” or “Published”
 - set a IVD in the “Published” status back to “in progress”;
- h. benefiting of some consultation features or utilities:
 - consult the details of a IVD
 - consult the history of the versions of a DM IVD as “in progress” at least once
 - visualize the editable version – in pdf form – of the signature page of a IVD in ‘Validated’ or ‘Published’ status

Research criteria

Search on all IVDs
☒
Search in IVD To-do list
☐

WARNING: system detected the presence of 'In progress' IVDs in the database, which refer to first notifications / manufacturing putback. Select 'Search in IVD To-do list' option to find the IVDs in order to complete the notification process (Validation by signing). User is required to delete data entered by mistake into the system which only refer to first notifications. It's not possible to delete 'In progress' IVDs which come from 'manufacturing putback'

System progressive attributed to IVD:

Manufacturer:

Code assigned by the manufacturer (catalogue identifier):

from:
to:

Trade name and model:

CND classifications:

IVD status:

User role as to the IVD:

Marketing:

Registered on the index:



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System progressive attributed to IVD	Manufacturer	Code assigned by the manufacturer (catalogue identifier)	Trade name and model	CND classifications	Device status	End Trade Date	Select ☐
1153087	MINISTERO DELLA SALUTE	Code reagent 01	NAME AND MODEL	W0103010299 - TEST PER EMOGLOBINA - ALTRI	L		☐

Page 1 of 1

Device status: L=IN LAVORAZIONE C=CONSOLIDATO V=VALIDATO P=PUBBLICATO U=CANCELLATO D'UFFICIO

If the System progressive attributed to the IVD is followed by the symbol (*), this means that in the database there are links with other notifications.

If more pages match the search results, by checking 'Select All', only the records in the current page will be selected, leaving out those in the following pages. To select the records in the remaining pages, use the 'previous / next' links and activate the corresponding check ('Select All') for each page.

Select: Click on one of the squares beside the component(s) in the list depending on operations.

Activable operations:

- **Insert:** Allows the user to enter a new IVD.
- **Copy:** Allows the user to make a copy of the selected IVD, in order to simplify the entry of another IVD reusing the information already entered.
- **Edit:** Allows the user to modify the selected IVD to change the data previously entered. The user can modify all IVDs that are in the "In progress" or "Consolidated" status.
- **Delete:** Allows the user to delete the selected IVD from the database.
- **Insert similar IVD:** Allows the user to "quickly" enter the Medical Devices similar to the selected IVD having the same features with the following exceptions: Code assigned by the manufacturer, trade name, size and label. The functionality differs from that of the "Copy" since the so entered IVDs form a "group" of medical devices having a core of information in common, and on which it is possible to act simultaneously activating the same processes ("Consolidation" and "Validation") or using the same functions (data "Editing" and "Off-trade").
- **Update similar IVD:** Allows the user to access the editing page of the sole specific data of a Medical Device entered through the quick entry feature (Code assigned by the manufacturer, trade name, size and label).
- **New notification:** If the Manufacturer's data have varied significantly, it allows the user to make simplified notifications for a published medical device, ensuring the link to the previous notification.
- **Consolidate:** Allows the user to consolidate the data of one or more Medical Devices that are in the "In progress" status.
- **Validate:** Allows the user to digitally sign all selected IVDs. The user can modify all IVDs that are in the "Consolidated" status.
- **Validation Fast:** Allows to validate Medical Devices that are in the "In progress" status, without having to switch from the "Consolidated" status, speeding the process of applying for publication while keeping all the checks for the validity of data entered.
- **Off line validation:** Allows to digitally sign-off all selected IVDs. The user can modify all IVDs that are in the "Consolidated" status.
- **Documentation:** Allows the user to edit the label "pdf" files, the instructions for use of the selected IVD and to edit the data sheet. The feature can be activated on the Medical Devices in the "Published" status present in the database.
- **Needed IVDs:** Allows to change the list of IVDs needed for the functioning of the selected IVD in the "Published" status.
- **Agent:** Allows to change the Agent for the selected IVD in the "Published" status.
- **Repertoire registration:** Allows the user to enroll the Medical Device in the selected Repertoire.
- **Off-trade:** Allows the user to state the selected IVD off-trade date.
- **Manufacturing putback:** Allows to gain access to the manufacturing putback page for the selected IVD.
- **Detail:** Allows the user to view the data detail of the selected IVD.
- **Version history:** Allows to view the history of the different versions of the IVD put back to manufacturing at least once.
- **Print:** Allows the user to print (in pdf format) a return receipt as evidence of the notification made. Said receipt will report all data signed in the validation stage.

Medical Devices notification

[Insert](#) [Copy](#) [Edit](#) [Delete](#) [Insert Similar IVD](#) [Update Similar IVD](#) [New notification](#)

Notification validation (change of the manufacturing status)

[Consolidate](#) [Validate](#) [Validation Fast](#) [Off line validation](#)

Post publication update

[Documentation](#) [Needed IVDs](#) [Agent](#) [Repertoire registration](#) [Off trade](#) [Manufacturing putback](#)

Consultation and Utilities

[Detail](#) [Version history](#) [Print](#)

*Details of IVD search Fields*

Field Name	Description
Search on all IVDs	allows the extended search of all IVDs registered in the system whose owner is the user;
Search in IVD To-do list	allows the restricted search of IVDs in status in progress;
System Progressive attributed to IVD	Option to search a in Vitro medical device by its identification number assigned by the system during registration into the database.
Manufacturer	Option to specify the name (or the beginning) of the Manufacturer of the IVD
Code assigned by the manufacturer (identifier catalogue) from/to	Option to indicate the range of codes which includes the product code assigned to the IVD by the Manufacturer.
Trade Name and Model	Option to specify the commercial name (or beginning) of the IVD
CND Classification	Option to run a search using the National classification of the IVD. This field cannot be edited. To select a classified CND and click on the “Search” link. A look-up will then open where the user has the option to search a CND by code or by description or part thereof.
First Notification (Yes/No/All) (Applicable only if “Search in IVD To-do list” selected)	allows the restricted search of IVDs in first notification (Yes), the restricted search of IVDs in manufacturing put back (No), or extended search of all the IVDs in progress which refers both to first notification and manufacturing put back;
IVD state	Option to search a medical device by its current status into the system (“In progress”, “Consolidated”, “Validated”, “Published”).
User role as to the IVD	Option to search a medical device by the role carried out by the user with respect to that medical device (“Manufacturer”, “Agent”, “Other person delegated by the Manufacturer”)
Notification Start date (from / to) (Applicable only if “Search in IVD To-do list” selected)	allows to filter IVDs by specifying the range of date (from – to) for the start of notification of IVD. If not used, the search is extended to all IVDs present in To-do List whose owner is the user;
Marketing	Option to search a medical device by the end trade date. There are three types: “Still on the market”, are sought for the IVD whose end date marketing is not valued or is next to the search “No longer marketed”, the IVD are searched for which the end date for placing on the market earlier than research
Registered on the index	Option to search a medical device by the registration on the index (registered, not registered)



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IVD Detail Fields

Field Name	Description
System Progressive attributed to IVD	Unique identification number assigned to each IVD in the database. If /R appears next to the consecutive number assigned to the IVD by the system, it means that the IVD has been registered on the index.
Manufacturer	Name of the IVD Manufacturing Company
Code assigned by the manufacturer (identifier catalogue) from/to	Code attributed to the IVD by the manufacturing company (better known as the identification catalogue)
Trade Name and Model	Commercial name and model of the IVD
CND Classification	CND Classification assigned to the IVD
State IVD	The status of the IVD in the database. It can change status in the following order: L: Processing C: Confirmed V: Valid P: Published
End trade date	End trade date

Operations available

Action	Description	Page Name
Search	Activates a search based on the criteria inserted	Same
New Search	Clears the search criteria previously defined	Same
DMs notification actions		
Insert	Allows access to the IVD general data entry page	IVD detail pages in editable procedures
Copy	Allows the user to copy a IVD in order to insert a new IVD which has the same characteristics as the copied IVD	IVD detail pages in editable procedures
Edit	Allows the user to access the pages containing details of the IVD selected and to edit those details	IVD detail pages in editable procedures
Delete	Allows the user to delete the IVD selected. Only IVD in the states "In progress" or "Consolidated" that have never been published can be deleted.	Same
Insert Similar IVD	Allows the user to access the page of quick insertion of a IVD similar to the selected ones (with the same characteristics except some characteristic data)	Insert similar IVD page
Update Similar IVD	Allows the user to access the editing page only for the characteristic data of a IVD inserted through the quick insertion functionality	Update similar IVD page
New notification	Allows to notify again a IVD in the "Published" status keeping the connection with the original source DM	New notification page



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Notification validation actions (change of the manufacturing status)		
Consolidate	Allows the approval of a IVD in “In Progress” status. The “Consolidate” action brings up the page with the list of IVD in the approval phase; specifying whether the process has been activated or not. The outcome of the process, if negative, will be marked on the activity list or will change it’s status to C, that is “Consolidated”	Detail page about the Starting process status
Validate	Activates the signature page through which Option to validate one or more IVD with “Consildated” status. Changing the status of the IVD does not occur simultaneously with the “Validate” action.	Firm page
Validation fast	Activate the check integrity and completeness of the information notified and, if successful, can validate the data reported.	Detail page about the process status
Off line signature	Allows the user to access the page of download of txt file containing IVD data	Sign file download page
Post publication update actions		
Documentation	Grants access to the modification of the page for the Label and IFU documentation files for the published IVD selected	Documentation update
Agent	Allows to change the Agent (Authorised Representatives) for the selected IVD in the “Published” status	Agent update
Off trade	Grants access to the off trade data entry page of the IVD selected	Off trade IVD page
Repertoire registration	Allows the user to access the repertoire registration page for the IVDs devices he/she selected.	Registration on the index
Manufacturing putback	Allows to gain access to the manufacturing putback page for the selected IVD.	Manufacturing putback
Consultation actions and utilities		
Detail	Allows the user to enter the details of the IVD selected onto the detail page in read-only form	IVD detail pages in uneditable procedures
Version history	Allows to view the history of the different versions of the IVD put back to manufacturing at least once.	Version history
Print	Makes the pdf file containing the editable version of the signature page of a IVD validated or published available	Same



2.5.1.3 New IVD registration

In order to insert a new IVD, the user must proceed as follows:

1. Run the IVD search (from the “Medical Device (IVD)” option in the menu, specifying the search parameters and then clicking on “Search”) after having verified the IVD you wish to insert is not already on the index
2. Click on the “Insert” button
3. Insert the information relative to “General data” and confirm the action by clicking on the “Save” button
4. Insert the specific information that corresponds to the menu options that will then be accessible after the “General data” has been saved using the “Save” button

2.5.1.3.1 IVD details for registration / editing

The detail pages of a IVD allow to insert new IVDs and also to edit a IVD selected from the “IVD List page”.

The detail pages are:

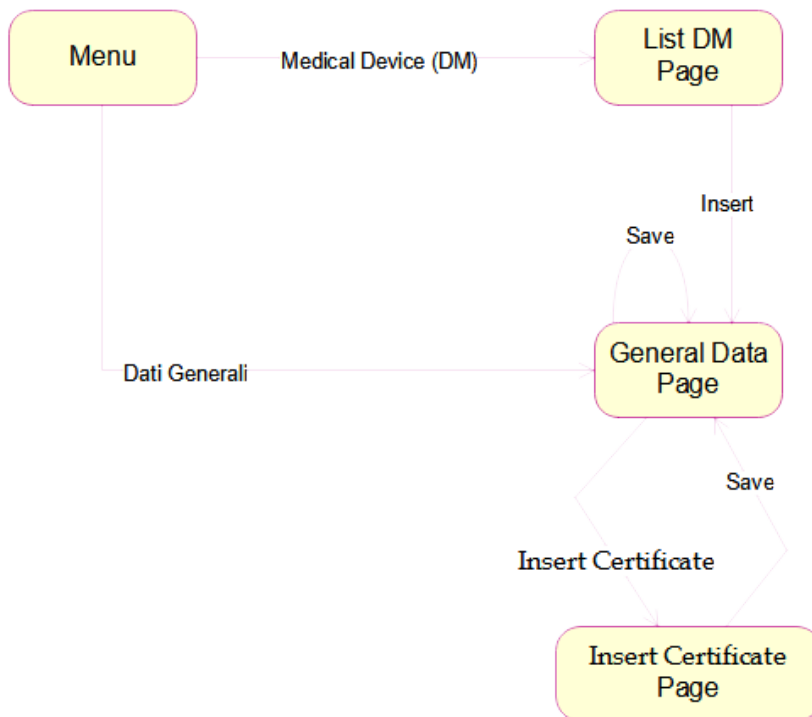
6. General Data
7. Specifications
8. Documentation

In particular if it's in insertion mode, the General Data page will become active once the user clicks on the “Insert” button on the list page and only after the data has been saved on the “General data page” will the options on the menu become available and allow the user access to other pages.

If it is in edit mode, the General Data page will become available following the selection of a IVD from the list and the menu option will become visible simultaneously to allow access to other pages.



2.5.1.3.2 General Data



In order to insert a new IVD, the user must first specify general data of the IVD, in order to then go on to register other information (specifications and documentation) from the relative page accessible through the corresponding menu options.

The General Data page, subdivided in four areas, allows the user to insert general data regarding a IVD:

- General data
- Classification data
- Certification data
- Links with other IVD

In addition to these areas the characteristic data of the IVD similar to this one can also be visualized, but only in case if they are present.

It will be necessary to consult the General Data page of a IVD in the following cases:

- In the insertion phase of the IVD
- In the editing phase of the IVD

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- In the insertion phase of the IVD, by coping a IVD that already exists

Home > In Vitro Diagnostic Medical Devices > Medical Device (IVD) > General data

Insertion General data

General data

*IVD type: ☐ reagent, reagent products, kits, control materials, calibrators
☐ Instruments, Devices, Equipment, Systems
☐ Sample Containers

*Trade name and model:

More IVD trade names [Add](#)

To indicate the additional trade names, it is necessary to proceed as follows:
1) click on "Add"
2) type the additional trade name
3) any further trade name on the database will be saved along with any other information by clicking on "Save".

*Code assigned by the manufacturer (catalogue identifier):

Sales package contents:

*Registrant's role with respect to the device:

Company that entered the IVD: [Detail](#)

*Manufacturer: [Search](#) [Detail](#)

Agent: [Search](#) [Detail](#)

*Indication of "new" device pursuant to article 10 paragraph 4 of Italian Legislative Decree number 332/2000? ☐ Yes ☐ No

Note: a device is "new" if:

- there has been no such device continuously available on the Community market during the previous three years for the relevant analyte or other parameter;
- the procedure involves analytical technology not continuously used in connection with a given analyte or other parameter on the Community market during the previous three years.

Classification

Complete GMDN repertoire: [Search](#) [Reset](#)

EDMA Classification: [Cerca](#) [Reset](#)

*CND classifications: [Search](#)



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Certifications

*EC Classification (D.L.vo n. 332/2000):

Annex according to which the device was marked:

☐ Annex III

☐ Annex IV

☐ Annex V

☐ Annex VI

☐ Annex VII

* Conformity with common technical specifications: ☐ Yes ☐ No

File containing the EC Compliance Statement:

(max size 2MB)

No.of certificate of the EC marking	Certificate Expiration Date	Notified Body Code-Name	File containing the certificate	Select
Clear Reference EC Insert Reference EC				

other devices (classified DM/IVD) for operation

* Other devices needed for operation? ☐ Yes ☐ No

Other device are: ☐ all present in the package

☐ partly present in the package

☐ not present in the package

Briefly specify any exclusive-use devices and whether they are present in the retail package or otherwise.

The brief specification is required to report:

- the manufacturer's name, trade name and model of the device, as well as the code assigned by the manufacturer, if the exclusive-use devices are required to be referred to other manufacturers;
- the progressive database identification numbers assigned to registered ?exclusive-use? medical devices if they refer to the same manufacturer, as well as any other information that the manufacturer considers important.

In both cases, please also specify the reason for exclusive use.

Brief information for the device	In retail package	Add
	☐	

Proceed as follows to specify exclusive-use devices::

- 1) click the 'Add' button
- 2) type the required values
- 3) exclusive-use devices will be entered into the database at the same time as the other information contained in the 'General Data' sheet by clicking the 'save' button



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Detail: General IVD Data Fields

Field Name	Description
General Data	
IVD type	IVD type specification, in the sense of reference macro category. Alternatively, indicate only one of the following items: - Reagents, reagent products, control material, kit, calibrators, - Instruments, devices, equipment, systems, - Sample containers Depending on the IVD type specified, the system will request the compilation or otherwise of specific information sections in the 'technical datasheet'. In addition, in order to maintain data consistency, if the user subsequently decides to change the 'IVD type', the system will automatically remove the data present on the 'technical specifications' page, if these are validated, applicable only to the type modified. Therefore please check whether it is necessary to validate the specific technical data applicable to the new type assigned to the IVD.
Trade Name and Model	Denomination of the IVD, as given by the Manufacturer
More IVD trade names	List of commercial names subsequently assigned to the same IVD
Code assigned by the manufacturer (identifier catalogue)	Specific code attributed to the IVD by the manufacturer.
Sales package contents	Brief description of the contents of the sales package
Registrant's role with respect to the device	Indication of the registrant's role with reference to the device. The registrant can play the following roles: - Manufacturer - Authorised Representative - Other entity appointed by the manufacturer
Company that entered the device	Registrant company registered in the Register of Companies - General registrant information (this field is not editable)
Manufacturer	Name of the device Manufacturer (this field is not editable) If the user has selected the item "manufacturer" as the Registrant Company's role with reference to the device, the system specifies as the manufacturing company the company entered by the user in "General Registrant Data". If the user selected a different role than manufacturer, the user can select the manufacturer by clicking on the "Search" link; in this case a look-up opens where the user can search and select the manufacturer.



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Field Name	Description
Agent	Name of the device Authorised Representative (this field is not editable) If the user selected the item "authorised representative" as the registrant's role with reference to the device, the system proposes as the authorised representative the user's own company entered in "General Registrant Data". By choosing a different role than "authorised representative", the user can select Authorised representative by clicking on the 'Search' link; in this case a look-up opens where the user can search and select the authorised representative. The authorised representative is: - Mandatory: if the manufacturer has its registered office in a non-EU Member country except an EEA country/Turkey - Optional: if the manufacturer has its registered office in an EEA country/Turkey - Cannot be validly entered: if the manufacturer has its registered office in an EU member country. The Country's authorised representative must be in the EU/EEA /Turkey.
Indication of "new" device pursuant to article 10 paragraph 4 of Italian Legislative Decree number 332/2000	Indicate whether the device is considered "new" or otherwise (yes/no). Note: a device is "new" if: a) there has been no such device continuously available on the Community market during the previous three years for the relevant analyte or other parameter; b) the procedure involves analytical technology not continuously used in connection with a given analyte or other parameter on the Community market during the previous three years
System Progressive attributed to IVD	Unique identification number assigned to each IVD by the system. This field is not editable and is visible only when editing the IVD.
Classifications	
GMDN nomenclature complete	Indication of the classification of the device according to the GMDN nomenclature (Global Medical Device Nomenclature) - non-editable field which is Mandatory if the EDMA classification is not specified. The user is required to click on the link "search" in order to select an item according to the GMDN nomenclature; a look-up opens where the user can look up the entry by code and description (or part of it). For each GMDN item found the system will indicate whether the GMDN is associated with one CND code or several CND codes.
EDMA Classification	Device classification according to EDMA (European Diagnostic Manufacturers Association). This field is not editable and Mandatory unless the GMDN classification is specified. To select an EDMA classification please click on the link "Search"; a look-up opens where the user can search for the classification code and description (or part thereof) by getting the list of entries that match the search criteria. Each entry is expandable in case it is not



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Field Name	Description
	terminal, it is only selectable if it is a terminal item.
CND classification	Indication of the classification of the device according to the CND - non-editable field; Mandatory. The system automatically populates this field if the user selected a GMDN with associated CND Terminal, editable in any case. The user can alternatively search and select a specific CND classification by clicking the "Search" link; a look-up opens where the user can search for this classification code and description (or part thereof) by getting the list of entries that match the search criteria. Each entry is expandable in case it is not terminal, it is only selectable if it is a terminal item. It is possible to search only in the context of the class "W" of the CND associated to the IVD. The user can search the CND as a function of the previously selected GMDN or otherwise.
Certifications	
IVD classification referred to in Italian Legislative Decree number 332/2000	Indication of the classification of the device referred to in Italian Legislative Decree number 332/2000. Choosing one of the following four options: • Annex II – List A • Annex II – List B • Self-diagnosis test (not included in Annex II) • Other IVD types (Mandatory field)
Annexes according to which the device was marked	Indication of the annexes to Italian Legislative Decree number 332/2000 provided for the assessment of compliance for EC marking purposes (selectable from list) The following options are permissible: • Annex IV or Annex V + Annex VII, if the IVD is classified as Annex II – list A • Annex IV or Annex V + Annex VI or annex V + Annex VII, in case of classification: Annex II – List B: • Annex III or Annex IV or Annex V + Annex VI or annex V + Annex VII, in case of classification: Self-diagnosis test (not included in Annex II) • Annex III, in case of classification: Other IVD types (Mandatory field)
Compliance with common technical specifications	(Yes/No) specification regarding the compliance with common technical specifications (Article 6, Italian Legislative Decree number 332/2000)
EC declaration of compliance	PDF file containing the EC declaration of Compliance The file must be provided if the EC classification is "Other IVD type".
Other devices (DM/IVD) needed for operation	



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Field Name	Description
Are other devices required for operation?	This provides for (Yes/No) specification if the notified device requires other devices (classified DM/IVD) for operation (mandatory field)
Devices are	If the device notified requires other devices for operation, it is <u>mandatory</u> to specify whether these devices are: - all present in the package, - partly present in the package, - not present in the package,
Device brief information	In the case of <u>exclusive-use</u> devices, the following must be stated succinctly: - the manufacturer's name, trade name and model of the device, as well as the code assigned by the manufacturer, in the case where the exclusive-use devices are to be referred to <u>other manufacturers</u> ; - progressive references in the database assigned to 'exclusive-use' medical devices, if registered, in case the products are to be referred to the <u>same manufacturer</u> , as well as other indications, if these are considered important by the manufacturer. In both cases the user must specify, in addition, the reason for exclusive use.

Operations available:

Action Name	Description	Page Called
Save	Save the information entered on the page 'general information'	If it is the same
Add EC Reference	This provides for access to the association of EC certificates page	Insert Certificates Page
Delete EC Reference	Remove association with selected EC Certificate	If it is the same
Add	This allows the user to add: - additional trade names assigned to the device; - summary description of any exclusive-use medical devices, required for the operation of the device subject to notification	If it is the same
Remove	This provides for removing: - additional trade names assigned to the device; - summary description of any exclusive-use medical devices, required for the operation of the device subject to notification	If it is the same
Detail.	This function provides for displaying detail data of a company referenced in various capacities in the notification of the device (the Company that entered the medical device, the manufacturer, authorised representative, other	Look up company data



	entity appointed by the manufacturer)	

Page Name: Certificates ("Insert Reference EC")

This page is displayed in look-up format and allows the user to search and associate the EC certificates with the IVD. This feature is activated by clicking on the "Insert Reference EC" button found on the "General data" page.

The system allows the user to associate certificates that have been issued only by the same manufacturer indicated on the IVD that is being notified (as declared on the general data page).

In correspondence to every IVD - with the exception of Other IVD types - it is necessary to associate at least one certificate.

EC marking certification

No. of certificate of the EC marking:
 Certificate Expiration Date : / /
 Notified Body: [Search](#)
[Reset](#)

[Search](#) [New search](#) [Confirmation](#) [Cancel](#)

In order to associate the Certificate(s) to device:
 - search a certificate, already exist, in the section "Certificates CE" (enter at least one search criteria and click on "Search");
 - Select a certificate from the list and click on "Confirm".

If a searched certificate selected as 'EC reference' is expired, it won't be possible to confirm it in the IVD notification

Certificates with EC stamp Detail Fields

Field Name	Description
No. EC certificate	Identification number of the EC Certificate.
Certificate issue date	Certificate issue date.
Certificate expiration date	Expiry date of Certificate.
Reference Notified Body	Indication of the code and name of the organisation notified. This field cannot be edited.



Field Name	Description
-Code - Name	To select the code of the organisation notified it is necessary to click on the “Search” link; a look-up will open which will allow the user to search for the notified Organisation by name and code.

Operations available:

Action	Description	Page Name
Search	Starts the certificates search that are consistent with the parameters that have been set.	Same
New search	Clears the search criteria previously defined.	Same
Confirmation	Check that the selected certificate has not expired. If it has, notify the failure to proceed with the choice of the certificate. Otherwise, closes the search look up, the medical device is associated with the selected certificate or certificates and the corresponding list in the 'General data' sheet is updated	General data page
Cancel	Closes the look-up without saving the work done by user.	General data page

2.5.1.3.3 Specifications (technical details)

Page Name: Specifications

The “Technical Data Sheet” page, subdivided in the following areas, allows the user to insert/edit information on the technical data of a IVD:

- General technical characteristics
- Specific technical data for reagent, reagent products, kits, control materials, calibrators
- Specific technical data for Instruments, Devices, Equipment, Systems
- Specific technical data for Sample Containers
- Technical datasheet of tissues of human origin or Substances derived from them (Italian Legislative Decree number 332/2000, Annex III, section 3.d)
- Technical data of biological tissues or substances of animal origin (non vital)

The “Technical Data Sheet” page is accessible to users in the following cases:

- During the insertion phase of the IVD after the registration of the data
- During the editing phase of the IVD
- During the insertion phase of the IVD by coping one that already exists in the system



In the upper part of the page the principal data of the IVD are displayed; as well as the “Medical Device General data” link, which allows the user to see the general data of the IVD.

General technical characteristics

Intended use pursuant to Italian Legislative Decree number 332/2000:

Sterile or other special microbiological state of the device (if any):

If the device is sterile, indicate the sterilisation methods:

Sterilization method	Valid entry according to the regulation	Other sterilization method description	
CALORE SECCO	NON NOTO		Add
			Delete
			Delete

Proceed as follows to indicate the sterilisation methods::
1) click the 'Add' button
2) type the required values
3) sterilisation methods will be entered into the database at the same time as the other information contained in the datasheet by clicking the 'save' button

Disposal special conditions:

Specific technical data for reagent, reagent products, kits, control materials, calibrators

Methodology (principle of the method):

Presence of calibrators: ☒ Yes ☐ No

Positive controls: ☒ Yes ☐ No



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Negative controls: ☒ Yes ☐ No

Storage conditions:

Indication of the period of validity of the unopened package:
(expressed as number of months)

Indication of the storage period, in days, of the reagent/kit
after first opening the primary container.:
(expressed as number of days)

Number of performable tests:
alternatively, specify the amount of reagent and the quantity of reagent for each
individual calculation (volume/mass)

*Disposable: ☒ Yes ☐ No

Number of units contained in the sales package:

Tissues of human origin or Substances derived from them (Italian Legislative Decree number 332/2000, Annex III, section 3.d)

Indicate the tissues of human origin or substances derived from them:

Part used	State of origin	Origin documents	Treatment Methods documents	Health Authority documents	
					Add
					Delete

Proceed as follows to indicate the tissues or substances::
1) click the 'Add' button
2) type the required values
3) the Tissue or Substances shall be inserted in the database concurrently with the inclusion of other information contained in the datasheet by clicking the 'save' button

Tissue or Biological Substances Animal data (not vital)

Indicate the tissues or substances of animal origin, not vital (if any):

Family	Part used	State of origin	Origin documents	Treatment Methods documents	Health Authority documents	
						Add
						Delete

Proceed as follows to indicate the tissues or substances::
1) click the 'Add' button
2) type the required values
3) the Tissue or Substances shall be inserted in the database concurrently with the inclusion of other information contained in the datasheet by clicking the 'save' button

*Datasheet Field Detail*

Field Name	Description
General technical characteristics:	
Intended use pursuant to Italian Legislative Decree number 332/2000	Indication of the intended use of the device in accordance with Italian Legislative Decree number 332/2000 (optional field)
Sterile or other special microbiological state of the device (if any)	Indication of infertility or other microbiological state of the device. The following values are allowed: sterile/other special microbiological state (optional field)
General technical characteristics – sterilisation data	
Sterilisation method (if any)	Indication of the method used for device sterilisation (required field if the device is "Sterile")
Sterilisation method validated according to harmonised standards	Indicate (Yes/No/Don't know) if the sterilisation method is validated according to harmonised standards (this field is mandatory if the device is "Sterile")
Description of another sterilisation method	Description of the sterilisation method if it is not present in the default list. (required field if the "sterilisation method" specified was "Other".
Special disposal conditions	Indication of any special conditions for the disposal of the device (optional field)
Specific technical data for reagent, reagent products, kits, control materials, calibrators	
Methodology (principle of the method)	Indication of the method used (from default list) (optional field)
Presence of calibrators	Specify (Yes/No) regarding the presence of calibrators (optional field)
Positive controls	Specify (Yes/No) regarding the presence of positive controls (optional field)
Negative controls	Specify (Yes/No) regarding the presence of negative controls (optional field)
Storage conditions	Indication of any storage conditions laid down for the reagent/kit (optional field)
Shelf life of unopened package	Indication of the period of validity of the unopened package expressed in number of months (optional field)



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Shelf-life after first opening the primary container	Indication of the storage period, in days, of the reagent/kit after first opening the primary container. (optional field)
Number of performable tests	Indication of the number of performable tests, or, alternatively, the amount of reagent and the amount of reagent for an individual calculation (volume/mass) (optional field)
Disposable	Specify (Yes/No) as to whether the device is disposable or not (mandatory field) (device designed for single use for only one patient).
Number of units contained in the sales package	Indication of the number of units contained in the sales package (optional field) Applicable in cases where a sales package contains several packs not sold individually.
Specific technical data for Instruments, Devices, Equipment, Systems	
Testing volume (number of tests/hour)	Indicate the number of tests performed per hour (optional field)
Modes of operation	Indication of instrument operating modes (optional field)
Specific technical data for Sample Containers	
Measurement	Indication of the size of containers and the relative measurement units
Disposable	Specify (Yes/No) as to whether the device is disposable or not (mandatory field) (device designed for single use for only one patient)
Number of units contained in the sales package	Indication of the number of units contained in the sales package (optional field) Applicable in cases where a sales package contains several packs not sold individually.
Additive type contained	Indication of the type of additive contained in the sales package (from the default list) - (optional field)
Other additive contained	Specify type 'Other additive' (free text) if it is not present in the default list



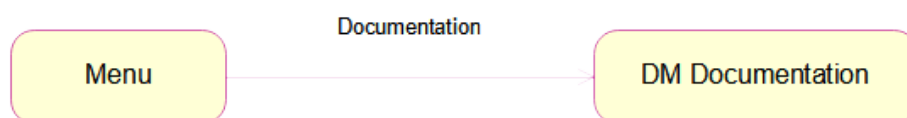
Technical datasheet of tissues of human origin or Substances derived from them (Italian Legislative Decree number 332/2000, Annex III, section 3.d)	
Part used	Specify the part used: tissue/substance/both (optional field)
State of origin	State of origin of the tissue of human origin/substance derived from it contained in the device. (optional field)
Documentation regarding the origin of the tissue or substance	File (pdf) containing the documentation regarding the origin of the tissue/substance or e-mail address or website where the user can find this documentation (optional field)
Documentation on treatment and inactivation methods	File (pdf) containing documentation on treatment and inactivation methods or e-mail address or website where the user can find this documentation (optional field)
Health authority documentation	File (pdf) containing the documentation prepared by the Health Authority or e-mail address or website where the user can find this documentation (optional field)
Technical data of biological tissues or substances of animal origin (non vital)	
Family of origin	Indication of family of origin of biological tissue/animal substance contained in the device (optional field)
Other Family	Description of the family of organic tissue/animal substance contained in the device if it is not listed. (mandatory field if the "Family of origin" field specified was "Other", otherwise it should not be entered.)
State of origin	Indication of the state of origin of the biological tissue/animal substance contained in the device. (optional field)
Part of tissue used	Specify the part of the tissues used. (optional field)
Other part used	Description of the part used of the organic tissue/animal substance contained in the device if it is not listed. (mandatory field if the "Part of tissue used" field specified was "Other", otherwise it should not be entered)
Documentation regarding the origin of the tissue or substance	File (pdf) containing the documentation regarding the origin of the tissue/substance or e-mail address or website where the user can find this documentation (optional field)
Documentation on treatment and inactivation methods	File (pdf) containing documentation on treatment and inactivation methods or e-mail address or website where the user can find this documentation (optional field)
Health authority documentation	File (pdf) containing the documentation prepared by the Health Authority or e-mail address or website where the user can find this documentation



	(optional field)

Operations available:

Action Name	Description	Page Called
Save	Save the information entered in the technical datasheet	If it is the same.
Add	This allows the user to add: - sterilisation methods (if any); - other type of additive (if not listed) - tissues of human origin/derived substances contained in a device; - biological tissue or substance of animal origin contained in a device	If it is the same
Remove	This provides for removing: - sterilisation methods (if any); - other type of additive (if not listed) - tissues of human origin/derived substances contained in a device; - biological tissue or substance of animal origin contained in a device	If it is the same

2.5.1.3.4 Documentation

This page allows the user to insert documentation attached to a IVD. This page is accessible in the following phases:

- During the insertion phase of the IVD after the registration of the general data
- During the editing phase of the IVD
- During the insertion phase of the IVD by means of coping one that already exists in the system

In the upper section of the page, the principal data of the IVD are displayed as well as the “Medical Device General Data” link which opens the page containing the general data of the IVD.



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Page Name: IVD Documentation

Document	File to attach	Link /Email Address	Acquire/ Delete
Results of the performance evaluation	Sfoglia... (max size 2MB)		Acquire
* Label	Sfoglia... (max size 5MB)		Acquire
Instructions for Use	Sfoglia... (max size 104MB)		Acquire
IVD Image	Sfoglia... (max size 2MB)		Acquire
Scientific bibliography supporting the clinical evidence of the effectiveness and safety	Sfoglia... (max size 5MB)		Acquire

If the IVD does not need Bibliography attach a file containing an explicit statement to that effect.

The format of the files to be annexed must be PDF

Detail of Documentation Fields

Field Name	Description
Performance evaluation results	File containing the results of the performance evaluation. Information provided <u>mandatorily</u> for IVD annex II – list A and B, self-diagnosis testing (not included in annex II). The attached file must be a pdf file. There is a limit to the dimension of the .pdf file to be attached to the IVD (in the sample picture, such limit equals 2 MB); for the maximum size allowed, refer to the corresponding value shown by the application
Label	File containing the label of the device (<u>Mandatory</u>) and indication of the link of the site where the user can obtain it (optional). The attached file must be a pdf file. There is a limit to the dimension of the .pdf file to be attached to the DM; for the maximum size allowed, refer to the corresponding value shown by the application
Instructions for use	File containing the instructions for use of the device. <u>Mandatory</u> for IVD annex II – list A and B, self-diagnosis testing (not included in annex II); optional, <u>but recommended</u> for other IVD types to ensure the exhaustiveness of the information provided to the National Health Service. It is permitted, in addition, to indicate the link of the website where the user can obtain it (optional). The attached file must be a pdf file. There is a limit to the dimension of the .pdf file to be attached to the IVD; for the maximum size allowed, refer to the corresponding value shown by the application



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Image of IVD	File containing the image of the device or, alternatively, the link to the website where the user can obtain this information. <u>Optional</u>. The attached file must be a pdf file. There is a limit to the dimension of the .pdf file to be attached to the IVD; for the maximum size allowed, refer to the corresponding value shown by the application
Scientific bibliography supporting the clinical evidence of the effectiveness and safety	File containing the Scientific Bibliography supporting the clinical evidence of performance and safety of the device or, alternatively, the link of the website where the user can obtain this information or an e-mail address for requesting it. <u>Optional</u>. The attached file must be a pdf file. There is a limit to the dimension of the .pdf file to be attached to the IVD; for the maximum size allowed, refer to the corresponding value shown by the application

Operations available:

Action Name	Description	Page Called
Browse	This function allows the user to select the pdf file to be uploaded from the user's workstation	'Select file' pop-up
Upload	This allows the user to upload the attached pdf file	If it is the same
Delete	This function provides for deleting the attached pdf file and/or the link of the website where the user can obtain it.	If it is the same
Open	This function allows the user to download the attached document	Pdf Reader
Off-line signature	This function provides access to the download page of the txt file that contains the information entered (pdf files and/or links) for locally affixing electronic signature	Download signature file page



2.5.1.4 IVD Editing

The IVD edit function can be activated for a medical device in the states "Processing" or "Consolidated". This function ('Edit' button) is activated after selecting the device for which the user wants to edit the associated information from the list of devices. Once the modification has been requested, the user accesses, in editable mode, the general data page; to access the following pages using the same procedures: 'Technical datasheet' and 'Documentation,' use the corresponding access links on the left side menu.

For a description of the pages, and related information, please refer to paragraph *Errore: sorgente del riferimento non trovata.*

If the device selected for editing is part of a group of similar devices, changing any data – common to the group – makes the selected device different to other similar devices, unless the same change is applied to the entire group.

Given the impossibility of editing data in validated or published devices, three distinct situations arise:

1. Similar devices of the group of the medical device subject to modification are all validated or published. In this case the modification to the device cannot be extended to the entire group, therefore, if we proceed with the registration of modifications, this removes the relationship between the device and the group of similar devices.

Specifically, by clicking the "Save" button on the detail pages (General data, technical datasheet, documentation) the following message is displayed

In case the user wants to proceed with the modification of the device, this will no longer be similar to all the devices belonging to the group

2. Similar devices of the group of the medical device subject to modification are all processing or consolidated.

In this case the modification to the device can be extended to the entire group and saved. By clicking the "Save" button on the detail pages (General data, technical datasheet, documentation) the following message is displayed:

the user can then decide whether to extend the change to all similar devices belonging to the group or modify only the specific device, thus making it no longer similar to the other devices; in this case, the modified device is removed from the group.

3. Similar devices of the group of the medical device subject to modification are partly processing and partly validated or published.

In this case the modification to the device can be extended only to a part of the devices similar to it, specifically to devices in the states processing or consolidated.



By clicking the "Save" button on the detail pages (General data, technical datasheet, documentation) the following message is displayed:

As a result of the change, the selected device will no longer be similar to the subset of the group devices validated or published, otherwise, for the subset of devices in the states processing or consolidated, the user can decide whether to apply the same edit or not. If the user decides not to apply the modification ("No" button) the modified device is removed from the Group

2.5.1.5 Similar IVD Insertion

This function allows the user to insert "quickly" the medical devices similar to some others IVD,s already present in the data base. It is necessary for the inserted IVD to have the same characteristics as the starting one but differing from it in the following:

- Code assigned by the manufacturer
- Trade name
- Measurement
- Label

The functionality of the quick insertion of the similar devices differs logically from the copying: in fact, the IVD inserted quickly make a real "group" of the devices having a nucleus of common information, which get activated by the same processes and using the same funtions. In the specific, activating a device which is part of a similar IVD group, the functionalities which can intervene contemporaneously on the whole group, are the following:

- modification
- detail
- consolidation
- validation
- off-trade

To insert the devices similar to the one already present in the data entry it is necessary to do the following:

- Activate the IVD search: from the 'Medical Device (IVD)' menu option, set the search parameters and click the "Search" button;
- Select a IVD having the necessary characteristics – notwithstanding its status
- Click on the "Insert similar IVD" button.



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Home > In Vitro Diagnostic Medical Devices > Medical Device (IVD) > Insert Similar IVD

Insert Similar IVD

Insert Similar IVD

*Trade name and model:

*Code assigned by the manufacturer (catalogue identifier):

Measure (where applicable):

* Label (File) : [Sfoglia...](#) [Cancel](#)
(max size 5MB)

Label (Link) :

It recommends to use contained file size to facilitate consultation.
The measurement can only be validly entered for the type 'Sample Containers'

System progressive attributed to IVD	Manufacturer	Code assigned by the manufacturer	Trade name and model	Measure (where applicable)	Label
1153087	MINISTERO DELLA SALUTE	Code reagent 01	NAME AND MODEL		

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[Save](#) [Back](#)

In the underlying part of the page of the insertion of a IVD similar to the other one, there is a list of devices which share the same common information.

Detail Fields

Field Name	Description
Trade Name and Model	Trade name and model assigned by the IVD manufacturer
Code assigned by the manufacturer (identifier catalogue)	Univocal code assigned by the IVD manufacturer
Measure (where applicable)	Indications of the measurable parameters being used actually and present in the commercial catalogues with the relative measurement IVD units (Used only for "Sample Containers")
Label (file)	Pdf file to be attached containing the IVD label (mandatory). To attach the file it is necessary to use the "Browse" button. There is a limit to the dimension of the .pdf file to be attached to the IVD; for the maximum size allowed, refer to the corresponding value shown by the application
Label (link)	indication of the link of the site where the user can obtain it (optional).

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Action	Description	Page Name
Save	Saves the digitized information, inserting in the data base a new IVD similar to the starting one (equal in everything except the four points of information digitized on this page by the manufacturer), proposes again the same page to insert a new similar IVD and updates the underlying list.	Same
Back	Comes back to the IVD list page.	IVD List Page



2.5.1.6 Similar IVD Editing

This function allows the user to edit the characteristic data of a medical device – in processing or consolidated – which is part of a group of similar IVD.

To modify the characteristic data of a IVD similar to the others, the user must proceed as follows:

- Activate the IVD search: from the 'Medical Device (IVD)' menu option, set the search parameters and click the "Search" button;
- Choose a IVD in processing or consolidated which is part of a group of similar IVD
- Click on the "Edit Similar IVD" button

Home > In Vitro Diagnostic Medical Devices > Medical Device (IVD) > Update Similar IVD

Update Similar IVD

Update Similar IVD

System progressive attributed to IVD: 1159627

*Trade name and model: Name and Model (Similar IVD)

*Code assigned by the manufacturer (catalogue identifier): Code reagent 02

Measure (where applicable):

* Label (File) : RicevutaFirma_offline.pdf [Cancel](#)

Label (Link) :

It recommends to use contained file size to facilitate consultation.
The measurement can only be validly entered for the type 'Sample Containers'

System progressive attributed to IVD	Manufacturer	Code assigned by the manufacturer	Trade name and model	Measure (where applicable)	Label
1159627	MINISTERO DELLA SALUTE	CODE REAGENT 02	NAME AND MODEL (SIMILAR IVD)		RicevutaFirma_offline.pdf

Page 1 of 1

[Save](#) [Back](#)

In the lower part of the page there is a list of the devices similar to the one being in the process of editing.

Detail Fields

Field Name	Description
Trade Name and Model	Trade name and model assigned by the IVD manufacturer
Code assigned by the manufacturer	Univocal code assigned by the IVD manufacturer



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(identifier catalogue)	
Measure (where applicable)	Indications of the measurable parameters being used actually and present in the commercial catalogues with the relative measurement IVD units (Used only for 'Sample Containers')
Label (file)	Pdf file to be attached containing the IVD label (mandatory). To attach the file it is necessary to use the "Browse" button. There is a limit to the dimension of the .pdf file to be attached to the IVD; for the maximum size allowed, refer to the corresponding value shown by the application
Label (link)	indication of the link of the site where the user can obtain it (optional).

Operations available:

Action	Description	Page Name
Save	Saves the digitized information	Same
Back	Comes back to the DM list page	IVD List page



2.5.1.7 New notification of a IVD in the “Published” status

This feature allows to notify again a in vitro diagnostic medical device (against major changes applied to the Manufacturer’s data) already in the “Published” status, stating the reason of this new notification and keeping the connection with the original source IVD. The new Device will be created as a copy of the original source IVD.

To notify again a medical device, the user needs to:

- activate the IVD search: from the ‘Medical Device (IVD)’ menu option, set the search parameters and click the "Search" button;
- select a IVD in the “Published” status;
- click on the “New notification” button

Detail Fields

Field Name	Description
System progressive of the linked IVD	Progressive assigned by the system to the IVD to be notified again. The field is not editable, and is evaluated by means of the system progressive of the selected IVD in the page of the IVDs list
Reason for new notification	The reason why a IVD is notified again. Amongst such reasons, there might be: • Change of the Manufacturer’s name • Change of the Manufacturer's VAT number • Cession of a manufacturing firm branch • Manufacturing firm merging/acquisition

Operations available:

Action	Description	Page Name
Save	Saves all typed information, entering a new IVD in the database as a copy of the original source IVD, while keeping the connection with it, and then directs to the details pages of the IVD entered in editable mode	Details pages of the IVD in editable mode
Back	Go back to the IVD list page	IVD list



2.5.1.8 IVD data consolidation

This function allows the user to consolidate the inclusion of information related to medical device to be notified, by activating specific targeted controls to verify the congruence and consistency of data entered in the relevant factsheets (General data, technical datasheets, documentation). The user can check the outcome of consolidation, with evidence of any errors encountered, by accessing the 'work in progress' page; in the absence of errors, the device status changes to 'consolidated' and in this case the user can enable the 'Validation' procedure (off-line) using qualified electronic signature of data entered

Proceed as follows to consolidate data for a device:

- Activate the search for devices present in the database (menu item "Medical Device (IVD)": set the search parameters and click the "Search" button);
- Select the medical device in process that the user intends to consolidate;
- Click the button "Consolidate"

Home > In Vitro Diagnostic Medical Devices > Medical Device (IVD)					?
Medical Device (IVD)					
Consolidating IVD List					
System progressive attributed to IVD	Manufacturer	Code assigned by the manufacturer	Trade name and model	CND classifications	Consolidation process status
1153087	MINISTERO DELLA SALUTE	Code reagent 01	NAME AND MODEL	W0103010299 - TEST PER EMOGLOBINA - ALTRI	Started

There follows the conditions checked in the data consolidation stage and the solutions to be applied if the controls indicate a lack of information

	Reference section	Error message	Solution
1	Company data	The manufacturer's mandate file granted to the registrant has not been uploaded yet	Register the mandate file with reference to the manufacturer or authorised representative (if any)
2	General Data	The authorised representative must be specified as the manufacturer does not have its registered office in an EU member country	In the case of correctly specified manufacturer, edit the device by inserting a reference to the Authorised Representative
3	General Data	The Country of the DM authorised representative is not foreseen by law	Edit the device by inserting a reference to the Authorised Representative based in a country allowed by law
4	General Data	The Authorised Representative must not to be specified as the	In the case of correctly specified manufacturer, edit the device by



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		manufacturer's registered office is in an EU Member country	removing the reference to the Authorised Representative
5	General Data	The GMDN code is no longer valid	Change the device by inserting a valid GMDN code
6	General Data	The CND code is no longer valid	Change the device by inserting a valid CND code
7	General Data	The EMMA code is no longer valid	Change the device by inserting a valid EMMA code
8	General Data	It is necessary to indicate the full GMDN Nomenclature or the EDMA Classification	Change the device by entering at least one code, either GMDN or EDMA Classification
9	General Data	EC marking certificate not present but required for EC Class specified	In the case of correctly indicated EC Classification, change the device by entering a valid certificate
10	General Data	The attachments according to which the device was marked are incorrect for the EC class specified	In the case of correctly specified EC Class, edit the device by inserting a value for "attachments according to which the device was marked"
11	General Data	File containing the EC Declaration of Compliance missing	In the case of correctly specified EC Class, change the device by uploading the pdf file containing the EC Declaration of Compliance
12	General Data	Specify whether other devices are required for operation	Edit the device indicating whether other devices are required for operation
13	General Data	Specify whether the devices required for operation are present or not in the package	In the case of correct specification of other device requirements, indicate whether or not these are present in the package
14	Documentation	The file containing the results of the performance evaluation is missing.	In the case of correctly indicated EC Classification, change the device by uploading the file containing the results of the performance evaluation
15	Documentation	The document containing the IVD label is missing	Change the device by uploading the pdf file for the label
16	Documentation	The document containing the instructions for the use of IVD is missing	Change the device by uploading the pdf file for the IFU



17	Technical datasheet	The Device was declared as Sterile but no sterilisation method was specified	In case of correct sterility indication, change the device by inserting the sterilisation method
18	Technical datasheet	One or more sterilisation methods were specified but the device was not declared sterile	Change the device by adding the device sterility specification
19	Technical datasheet	Other sterilisation method not specified	In case of absence from the list provided by the system, edit the device by free-text validation of the sterilisation method
20	Technical datasheet	The Other sterilisation method must not be specified	In the case of presence in the relevant list provided by the system, change the device by removing the free-text validation of the sterilisation method
21	Technical datasheet	The user did not specify whether the IVD is single use or otherwise	Change the device by adding the indication of whether or not it is disposable
22	Technical datasheet	In the section Tissues of human origin or substances derived from these, in one or more instances some required fields were not specified: Part used and State of origin	Edit the device by indicating all required data for Tissues of human origin or substances derived from them
23	Technical datasheet	In the section Biological Tissues or substances of animal origin, some required fields were not specified in one or more instances: Family, Part used and State of origin	Edit the device by indicating all required data for Biological Tissues or substances of animal origin
24	EC Certification	It is necessary to upload the file Attached to the EC certificate	Change the certificate by registering its pdf file.
25	EC Certification	The certificate XXXX has expired	Change references to the certificate indicating a currently valid certificate.
26	EC Certification	The expiry date of the certificate XXXX must be validated it is mandatory when the attachment is different from type IV section 6, VI and VII section 5	In the case of correct attachment specification, register the expiry date of the certificate



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Home > In Vitro Diagnostic Medical Devices > Medical Device (IVD) ?

Medical Device (IVD)

Consolidating IVD List					
System progressive attributed to IVD	Manufacturer	Code assigned by the manufacturer	Trade name and model	CND classifications	Consolidation process status
1153087	MINISTERO DELLA SALUTE	Code reagent 01	NAME AND MODEL	W0103010299 - TEST PER EMOGLOBINA - ALTRI	Started

To verify the result of consolidation, use the "Go to activities list" button.

[Go to activities list](#)

Detail fields IVD List in consolidation phase

Field Name	Description
System Progressive attributed to IVD	Unique identification number assigned to each IVD
Manufacturer	Name of the Manufacturing Company of the device
Code assigned by the manufacturer (identifier catalogue) from/to	Code attributed to the IVD by the manufacturing company (identification catalogue)
Trade Name and Model	Commercial name and model of the IVD
Validation process status	The status of the process. It can change status in the following order: - Initiated - Uninitiated

Operations available:

Action Name	Description	Page Called
Go to the Activities List	This function provides access to the activities in progress list to check the outcome of the consolidation and validation operation	Task List



If the medical device selected for consolidation is similar to other in vitro devices in the same "processing" state, the user will be preliminarily directed to a page containing the list – with selectable items – of the aforementioned similar devices for which the consolidation operation could be simultaneously enabled. By selecting one or more similar devices from the list and clicking the "Confirm" button, the system activates the consolidation process, for the initial device as well as all similar devices selected.

Home > In Vitro Diagnostic Medical Devices > Consolidate ?

Consolidate

Group

System progressive attributed to IVD: 1159627

The medical device you want to consolidate is similar to the following

Select from the list the devices with which to start the process of consolidating.

System progressive attributed to IVD	Manufacturer	Trade name and model	Code assigned by the manufacturer	Measure (where applicable)	Select
1153087	MINISTERO DELLA SALUTE	NAME AND MODEL	Code reagent 01		☐

Confirm

Implementable operations:

Action Name	Description	Page Called
Confirm	This function allows the user to enable the consolidation process simultaneously on the list of similar medical devices selected, in addition to the device initially selected as a result of the search	Detail page on the process state.



2.5.1.9 Download file for off line IVD signature

The user can request the off-line validation of data for in vitro devices entered in the database as long as these have successfully passed the "consolidation" process. The off-line signature is activated from the page containing the list of in vitro devices identified by a search, specifically the user is required to select the list of devices in the "consolidated" state that they intend to sign according to this procedure and subsequently use the "Off-line validation" button

Here are the steps for data signature in off-line mode:

- Download *the files*, in txt format, generated by clicking the 'Validate off-line' button. Specifically, this file contains the complete data of medical devices to be signed (it is possible to simultaneously sign multiple medical devices); to download, simply activate the link that corresponds with the name of the generated file ;
- Sign the aforementioned file locally using the software and signature device (smart card or other device) provided. For the realization of this step it is not necessary to be connected to the "Data Bank and Repertoire of Medical Devices".
- upload the signed file using the specific function of the "off-line signature" area.

Home > In Vitro Diagnostic Medical Devices > Download Off Line Signature ?

Download Off Line Signature

Download Off Line Signature

Off Line Validation .

- This process allows the signing of the data stored in the "Data Bank and Repertoire of Medical Devices" as an alternative to the on-line signature using:
 - Any electronic signature certificate issued by one of the certification providers, according to Directive 1999/93/CE.
 - The software already owned by the user in order to use the signature device (smart card or other device). Format of signed data must be **PKCS #7** standard compliant.
- The "Off line signature" consists of three steps:
 1. The user downloads the file in txt format on his computer (download); this file, automatically generated by the system, contains all the information previously entered. It is possible to simultaneously sign multiple medical devices; to activate the download it is enough to click on the link below.
 2. the user then proceeds to sign the above mentioned files by using the software he already owns in order to use their signature device (smart card or other device). For the realization of this step it is not necessary to be connected to the "Data Bank and Repertoire of Medical Devices" system.
 3. the user uploads the signed file on "Data Bank and Repertoire of Medical Devices" system through the appropriate upload function accessible from the menu item "Off line Signature".
- For a successful completion of the Off line Validation process it is necessary that:
 - the user (or users of the same company for those accessing through "Impresa.gov") who uploads the file is the same who downloaded it.
 - the petitioner of the data must be the same person delegated to the data notification.
 - the name (except for the extension) of the signed file, acquired by the system during the upload phase, must be the same that is automatically assigned by the system in the download phase.
 - The data subject to signature (*) are not modified in the "Data Bank and Repertoire of Medical Devices" between the time of the download and the subsequent upload.

(*) Please note that in case of signature of Medical Devices and Systems /Assembled Kits, the data subject to signature include the name of the Manufacturer / Agent / Marketing Responsible/ Other deputed subject, the EC certificate, the Medical Devices necessary to the operation and the components of the systems / Kits.

DatiIVD03062014150533768684

If the medical device selected for the off line signature is similar to other IVD in the same state "Consolidated", the manufacturer gets preliminarily directed to the page containing the list - with



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selectable elements - of these similar devices for which the same process could be contemporaneously activated. Choosing one or more similar IVDs from the list and clicking on the "Off line sign" button, the system allows the user to download a txt file containing the data of all selected IVD.

Home > In Vitro Diagnostic Medical Devices > Validate ?

Validate

Group

System progressive attributed to IVD: 1153087

The medical device you want to validate is similar to the following IVD consolidated.
Select from the list the devices with which to start the process of validation.

System progressive attributed to IVD	Manufacturer	Trade name and model	Code assigned by the manufacturer	Measure (where applicable)	Select
1159627	MINISTERO DELLA SALUTE	NAME AND MODEL (SIMILAR (IVD))	CODE REAGENT 02		☐

Confirm

Operations available:

Action	Description	Page Name
Confirm	Allows the user to access the page of download of txt file containing IVD data	Off line signature download page



2.5.1.10 IVD enclosed documentation update

This function allows to update the label and the usage instructions (IFU) of a medical device after it has been published.

It is necessary to do the following operations:

- Activate the search for devices present in the database (menu item "In vitro diagnostic medical device (IVD)": set the search parameters and click the "Search" button);
- Select a device in 'Published' status;
- Click on the button 'Documentation Update'

Home > In Vitro Diagnostic Medical Devices > Medical Device (IVD) > Documentation ?

Update Documentation

Trade name and model: **Name and Model IVD**
Code assigned by the manufacturer (catalogue identifier): **Code 01**
Manufacturer: **MINISTERO DELLA SALUTE**
System progressive attributed to Device: **1159613**

[Medical Device general data](#)

Document	File to attach	Acquire/ Delete
Label	Sfoglia... (max size 5MB)	Acquire
Instructions for Use	Sfoglia... (max size 104MB)	Acquire

Please enter the reasons that led to amending the documentation

Notes:

It recommends to use contained file size to facilitate consultation.

[Sign Off line](#)

This page displays the general data of the device selected on the search page and allows to attach the new label files, the instructions for use. Notes on the reasons for update can also be entered such as, for example: changing the logo, inserting a new warning etc..

The user is automatically redirected to the data signature page by saving the information entered. Alternatively the information provided can be saved and the updates can be signed using the "off line signature" function, by clicking the above button the user is redirected to the download page of the file to be signed locally, which contains the data to be saved in the database.

**Documentation Update Field Details**

Field Name	Description
Label	File containing the label of the device (<u>Mandatory</u>) The attached file must be a pdf file. There is a limit to the dimension of the .pdf file to be attached to the IVD; for the maximum size allowed, refer to the corresponding value shown by the application
Instructions for use	File containing the instructions for use of the device. <u>Mandatory</u> for IVD annex II – list A and B, self-diagnosis testing (not included in annex II); optional, <u>but recommended</u> for other IVD types to ensure the exhaustiveness of the information provided to the National Health Service. The attached file must be a pdf file. There is a limit to the dimension of the .pdf file to be attached to the IVD; for the maximum size allowed, refer to the corresponding value shown by the application
Notes	Notes indicating the reasons for update of the documentation.

Operations available:

Action	Description	Page Name
Acquire	Allows to upload the attached file	Same
Delete	Allows to delete the attached file	Same
Open	Allows to download the attached document	
Off line sign	Allows the user to save the information inserted and bring user to off line sign page	Off line signature page



2.5.1.11 Agent update

From this page, it is possible to update the Agent (Authorised Representatives) of a medical device after its publication, as long as during the IVD notification stage an Agent had been declared. This can be activated from the page of the list of IVDs, selecting a device in the “Published” status for which an Agent had been declared, and clicking on the “Agent update” button.

Home > In Vitro diagnostic medical device > Medical Device (IVD) > New notification ?

New notification

Trade name and model: name and model

Code assigned by the manufacturer (catalogue identifier): code 01

Manufacturer: BAYER STORIC NEW

System progressive attributed to DM: 10003

[Medical Device general data](#)

New Agent: [Search](#)

The first page will display the general data of the selected device in the search page, and allows to enter the new Agent, by selecting it from the associated companies.

As the new Agent is saved, the user is automatically redirected to the signature page. As an alternative, the user may sign the update by means of the “Offline signing”: as the user clicks on this button, he/she will be redirected to the download page for the file to be locally signed that contains the data to be saved in the database.

Field Details

Field Name	Description
Agent	New IVD Agent name. The field is not editable, and the value can be selected by clicking on the "Search" link; a look-up will open allowing the user to search and select the Agent.

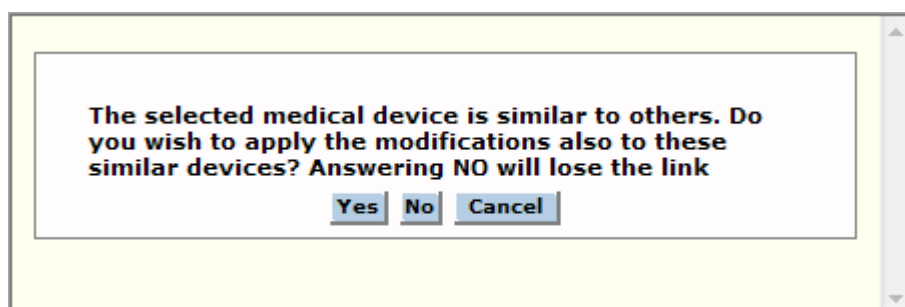
Operations available:

Action	Description	Page Name
Save	Saves the new Agent, recording its former name and directs the user to the signature page of the so modified device	IVD signature



Action	Description	Page Name
Off line sign	Allows the user to save the information inserted and bring user to off line sign page	Off line signature page
Back	Comes back to the IVD list page.	IVD List Page

If the selected medical device has similar IVDs that share the same features with the exception of their trade name and model, code, size and label, once the new Agent is saved, the user will be asked to change this information even in similar IVDs or only in the selected device.



Operations available:

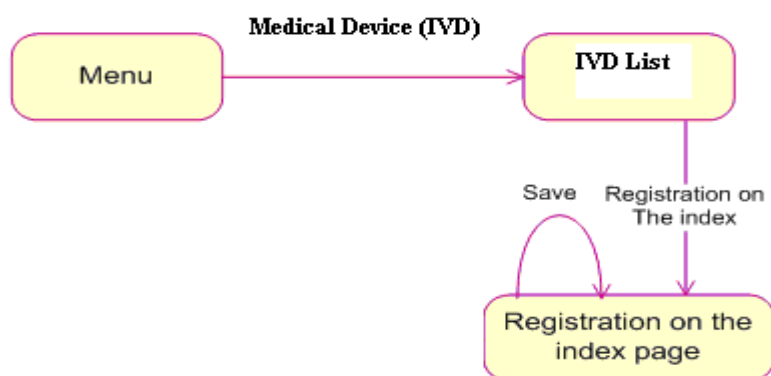
Action	Description	Page Name
Yes	Modifies all IVDs similar to the one selected by entering the same Agent, closes the dialog box and directs the user to the signature page of such modified IVDs.	IVD signature
No	Exclusively modifies the selected device, releasing it from the group of similar IVDs it belonged to, closes the dialogue box and directs the user to the signature page of such update IVD.	IVD signature
Cancel	Closes the dialogue box	Agent update



2.5.1.12 IVD registration in the Medical Device Repertoire

In order to register a IVD in the Repertoire, the user must proceed as follows:

- Activate the search for devices present in the database (menu item "In vitro diagnostic medical device (IVD)": set the search parameters and click the "Search" button);
- Select one or more IVD in "Validated" or "Published" status;
- Click on "Repertoire subscription"



This page allows the user to register medical devices selected in the repertoire declaring they will be distributed to the facilities of the National Health Service. Only after having done this, the system can register the devices as part of the index.

The same page may be recalled to cancel the registration from the Repertoire of one or more medical devices that were previously registered.

For those IVDs that are registered in the Repertoire, the ID assigned by the system will be followed by the "/R" character.

The Repertoire contains a collection of information supplied by Manufacturers; each Manufacturer assumes full responsibility for the information supplied, be it for the general data as for that regarding single medical devices. The publication of data does not represent the approval of the Ministry of Health in any form. The Ministry reserve the right to carry out an inspection on what has been declared.



The way a page recalled by the “Repertoire registration” button is displayed depends on different scenarios:

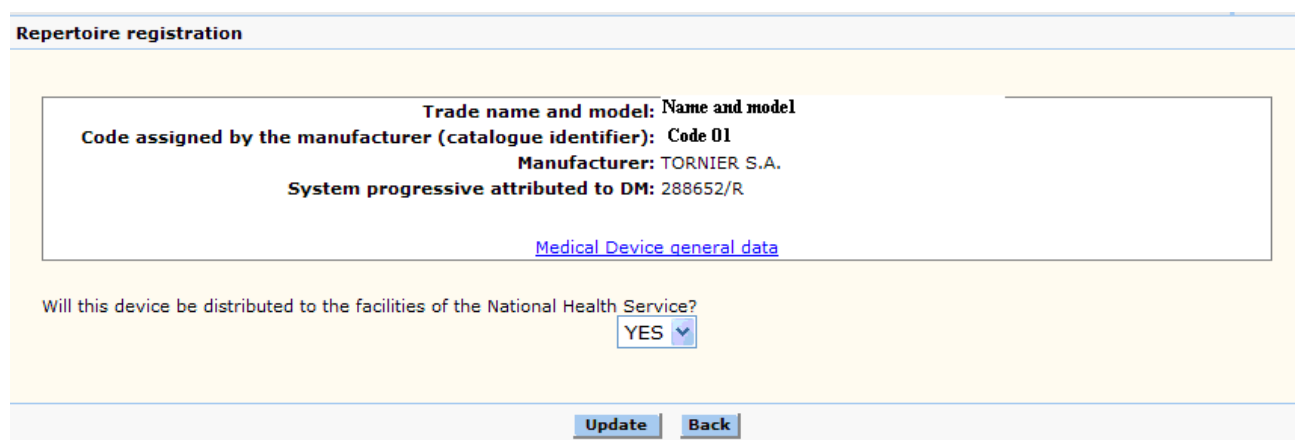
- the user selects one single IVD and the selected IVD does not belong to a group of similar IVDs.
- the user selects one single IVD and the selected IVD belongs to a group of similar IVDs.
- the user selects more IVDs³⁵.

All possible scenarios are fully described below. In order to provide a full description, the list of fields displayed on the page and of all available operations will be repeated for each scenario, along with their respective peculiarities.

Regardless of the scenario to be applied, in order to be registered in the Repertoire, a IVD entered in the database needs to be in the Validated or Published status.

First scenario

If the user selects one single IVD that has not yet been registered in the Repertoire and if the selected IVD does not belong to a group of similar IVDs, the system will display the following page:



In the upper part of the page, the IVD main data are displayed along with the “General data” link allowing the user to access and view the device general data.

Once registered, a medical device can be cancelled by using the same feature, switching the value beside the question "Will this device be distributed to the facilities of the National Health Service ?" from "Yes" to "No".

³⁵ The feature will be activated only if the user has selected IVDs that are not registered in the Repertoire or that are already registered (to cancel their registration).



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Detail Fields

Field Name	Description
Trade Name and Model	Commercial name and model of the IVD
Code assigned by the manufacturer (identifier catalogue)	Code attributed to the IVD by the manufacturing company (better known as the identification catalogue)
Manufacturer	Corporate name of the IVD Manufacturing Company
System Progressive attributed to IVD	Unique identification number assigned to each IVD in the database. If /R appears next to the identification number assigned to the IVD by the system, it means that the IVD has been registered in the repertoire.
Repertoire registration Flag	Flag showing the willingness or unwillingness to distribute the selected medical device to the facilities of the National Health Service (and as such to register it in the Medical Devices Repertoire). The default setting is “No” By selecting “Yes”, the user shows their willingness to register the IVD in the Repertoire. The same page may be recalled to cancel the registration from the Repertoire of a Medical Device that was previously registered. In that case, by accessing that feature, the flag value will already be equal to “Yes” (past registration) and the user may take the flag to the “No” value, thus showing their willingness to cancel the registration in the



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Field Name	Description
	Repertoire of the IVD.

Operations available:

Action	Description	Page Name
Update	If the user sets the Repertoire registration flag (see previous table) to “Yes”, by clicking the button, the IVD in the form is registered in the Repertoire. If the Repertoire registration flag was previously set to “Yes”, and the user brings it back to “No”, by clicking the button, the IVD in the form, is cancelled from the Repertoire.	Same
Back	Takes the user back to the IVDs list page without proceeding with registration or cancellation in/from the Repertoire.	IVD List Page

Second scenario

If the initially selected IVD that needs to be registered in the repertoire is similar, and has the same features (except the trade name, the code assigned by the manufacturer, the size and the label) to other validated or published devices, the registration page also presents the list – with selectable items – of said similar devices that can be simultaneously registered in the Repertoire (see next picture).



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Repertoire registration

Trade name and model: name and model
 Code assigned by the manufacturer (catalogue identifier): Code 01
 Manufacturer: TORNIER S.A.
 System progressive attributed to DM: 260806

[Medical Device general data](#)

This medical device will be providing facilities of the National Health Service ?

NO

The medical device is similar to the following DM published. Select from the list of the devices to which it applies the same statement.

Similar DMs

System progressive attributed to DM	Trade name and model	Code assigned by the manufacturer	Measure (where applicable)	Label	DM status	Select ☐
260810	name and model 01	code 01		GDF525_H.pdf	P	☐
260803	name and model 02	code 02		GDF523_H.pdf	P	☐
260798	name and model 03	code 03		GDF522_H.pdf	P	☐

Even in this case, devices belonging to a group of similar IVDs that have been previously registered can be cancelled. The procedure is as follows:

- The user selects one single IVD belonging to that group and activates the "Repertoire registration" feature;
- Switches the value beside the question "Will this device be distributed to the facilities of the National Health Service?" from "Yes" to "No".
- Extends cancellation to all similar devices shown on the same page or to a subgroup of theirs (by selecting them);
- Presses the update button to complete the cancellation from the Repertoire concerning the items of interest.

Detail Fields

Field Name	Description
Selected DM data	
Trade Name and Model	Commercial name and model of the IVD
Code assigned by the manufacturer	Code attributed to the IVD by the manufacturing company (better known as the identification catalogue)



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Field Name	Description
(identifier catalogue)	
Manufacturer	Corporate name of the IVD Manufacturing Company
System Progressive attributed to IVD	Unique identification number assigned to each IVD in the database. If /R appears next to the identification number assigned to the IVD by the system, it means that the IVD has been registered on the index.
Repertoire registration Flag	Flag showing the willingness or unwillingness to distribute the selected medical device to the facilities of the National Health Service (and as such to register it in the Medical Devices Repertoire). The default setting is “No” By selecting “Yes”, the user shows their willingness to register the IVD in the Repertoire and may even extend the registration to all similar IVDs in the form (or to a subgroup of theirs) by <u>selecting</u> them. The same page may be recalled to cancel the registration from the Repertoire of a Medical Device that was previously registered. In that case, by accessing that feature, the flag value will already be equal to “Yes” (past registration) and the user may take the flag to the “No” value, thus showing their willingness to cancel the registration in the Repertoire of the IVD, and, if necessary, extend the cancellation to all similar IVDs in the form (or to a subgroup of theirs) by <u>selecting</u> them.
Similar IVDs List³⁶	
Measure (where applicable)	Indication of the measurable criteria actually used and present in commercial catalogues with the corresponding unit of measurement of the IVD

³⁶ Only the fields that are not described in the table are present.



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Field Name	Description
Label	File containing the label of the IVD
IVD status	The status of the IVD in the database. This status can assume, in this case, the values: • V: Valid • P: Published

Operations available:

Action	Description	Page Name
Update	If the user sets the Repertoire registration flag (see previous table) to “Yes”, by clicking the button, the IVD in the form, and any other similar IVD <u>selected</u> by the user, are registered in the Repertoire. If the Repertoire registration flag was previously set to “Yes”, and the user brings it back to “No”, by clicking the button, the IVD in the form, and any other similar IVD <u>selected</u> by the user, are cancelled from the Repertoire.	Same
Back	Takes the user back to the IVDs list page without proceeding with registration or cancellation in/from the Repertoire.	IVD List Page

Third scenario

If the user selects more than one IVD, and if such devices are no longer registered in the Repertoire, the system will display the following page:



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Repertoire registration

Continuing this operation, all medical devices will be distributed to the National Health Service.

DM List

System progressive attributed to DM	Trade name and model	Code assigned by the manufacturer	Manufacturer	DM status	Similar DMs
438034	name and model 01	code 01	TORNIER S.A.	P0	N
438055	name and model 02	code 02	TORNIER S.A.	P0	Similar
438214	name and model 03	code 03	TORNIER S.A.	P0	Similar
438233	name and model 04	code 04	TORNIER S.A.	P0	Similar

By activating the update button, the system will register in the Repertoire both the selected DMs (displayed on the page) and all similar DMs that are not yet registered in the Repertoire (which can be displayed by activating the 'Similar' button). To register in the Repertoire a subgroup of similar DMs, you only need to search a single DM belonging to the similar DMs group, and then once again activate the

The page will display the list of all selected IVDs, and for each of them their belonging to a group of similar IVDs, if any, (if the IVD does not belong to a group of similar IVDs, the last column will read "N" under the "Similar IVD" field; if the IVD belongs to a group of similar IVDs, it will present the "Similar" button).

By activating the "Similar" button (beside a IVD), if present, the system will show all IVDs belonging to that group (except the one that is selected), their status and Repertoire registration³⁷ status (see next picture).

³⁷ IVDs belonging to a group of similar IVDs may all be displayed as both registered or not registered in the Repertoire. There can also be cases presenting a mixed situation, namely with both registered and not registered IVDs. Such condition does not compromise the integrity of the group.



Similar IVDs

System progressive attributed to DM	Trade name and model	Code assigned by the manufacturer	Manufacturer	DM status	Repertoire registration
438214	name and model 01	HLM802	TORNIER S.A.	P0	N
438233	name and model 02	HLM803	TORNIER S.A.	P0	N
438234	name and model 03	HLM804	TORNIER S.A.	P0	N
438235	name and model 04	HLM805	TORNIER S.A.	P0	S
438236	name and model 05	HLM806	TORNIER S.A.	P0	N

Once closed the (pop-up) window displaying the similar IVDs, the user, by activating the “Update” button, declares all selected IVDs will be distributed to the National Health Service: in this case, the system will register in the Repertoire both the IVDs that have been selected starting from the search form (and that can be displayed on the page), and all IVDs similar to such devices, in LV0/P0 status, that are not yet registered in the Repertoire³⁸.

Finally, if the user selects more than one DM, and if such devices have been previously registered in the Repertoire, the system will display the following page:

³⁸ In this case the user may select a subgroup of IVDs to be registered. All IVDs that are similar to the ones selected in LV0/P0 status, and that are not yet registered in the Repertoire, are automatically registered by the system. Instead, if the user wishes to register in the Repertoire only a subgroup of similar IVDs, they need to search **only one IVD belonging to that group** and then once again activate the "Repertoire registration" feature. This way, the second scenario will apply, and only some items of the group may be selected for distribution to the National Health Service.



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Repertoire registration

Continuing this operation, all medical devices will no longer be distributed to the National Health Service.

IVD List

System progressive attributed to DM	Trade name and model	Code assigned by the manufacturer	Manufacturer	DM status	Similar DMs
145475/R	name and model 01	HLM60X	TORNIER S.A.	P0	Similar
249886/R	name and model 02	DWB010	TORNIER S.A.	P0	N
413594/R	name and model 03	HLM614	TORNIER S.A.	P0	Similar
413613/R	name and model 04	HLM615	TORNIER S.A.	P0	Similar

By activating the update button, the system will cancel registration in the Repertoire of both the selected DMs (displayed on the page) and all similar DMs that are already registered in the Repertoire (which can be displayed by activating the 'Similar' button). To cancel registration in the Repertoire of a subgroup of similar DMs, you only need to search a single DM belonging to the similar DMs group, and then once again activate the 'Repertoire registration' feature. For more details on the Repertoire registration feature, see the User Manual.

[Update](#) [Back](#)

The page will display the list of all selected IVDs, and for each of them their belonging to a group of similar IVDs, if any, (if the IVD does not belong to a group of similar IVDs, the last column will read "N" under the "Similar IVD" field; if the IVD belongs to a group of similar IVDs, it will present the "Similar" button).

By activating the "Similar" button (beside a IVD), if present, the system will show all IVDs belonging to that group (except the one that is selected), their status and Repertoire registration status.

Once closed the (pop-up) window displaying the similar IVDs, the user, by activating the "Update" button, declares all selected IVDs will no longer be distributed to the National Health Service: in this case, the system will cancel the registration from the Repertoire of both the IVDs that have been selected starting from the search form (and that can be displayed on the page), and all IVDs similar to such devices that are already registered in the Repertoire³⁹.

Detail Fields

Field Name	Description
System Progressive attributed to IVD	Unique identification number assigned to each IVD in the database. If /R appears next to the identification number assigned to the IVD by the system, it

³⁹ In this case the user may not select a subgroup of similar IVDs to be cancelled from the Repertoire. All IVDs that are similar to the ones selected, and that are already registered in the Repertoire, will be automatically cancelled by the system. Instead, if the user wishes to cancel the registration from the Repertoire of only a subgroup of similar IVDs, they need to search **only one already registered IVD belonging to that group** of similar IVDs and then once again activate the "Repertoire registration" feature. This way, the second scenario will apply, and only some items of the group may be selected to be cancelled from the registration.



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Field Name	Description
	means that the IVD has been registered in the Repertoire.
Trade Name and Model	Commercial name and model of the IVD
Code assigned by the manufacturer (identifier catalogue)	Code attributed to the IVD by the manufacturing company (better known as the identification catalogue)
Manufacturer	Corporate name of the IVD Manufacturing Company
Device status	The status of the IVD in the database. This status can assume, in this case, the values: • V: Valid • P: Published

Operations available:

Action	Description	Page Name
Similar	Opens the (pop-up) page displaying IVDs similar to the one of interest. The page will display the following data: • System progressive attributed to the IVD; • Trade name and model; • Code assigned by the manufacturer (catalogue identifier); • Manufacturer; • Device status; • Repertoire registration (Y/N).	Similar IVDs
Update	If the source IVDs are not registered in the Repertoire, by activating the button, the user registers those, and this will automatically register all similar IVDs in LV0/P0 status that may be present and that are not yet registered ⁴⁰ ; If the source IVDs are registered in the Repertoire, by activating the button, the user cancels their registration, and this will automatically cancel the registration of all similar IVDs that may be present and that are already registered ⁴¹ ;	Same
Back	Takes the user back to the IVDs list page without proceeding with registration or cancellation in/from the Repertoire.	IVD List Page

⁴⁰ In this case, similar IVDs in LV0/P0 status are all automatically registered, and the user cannot select only one subgroup for the registration.

⁴¹ In this case, similar IVDs are automatically cancelled from the Repertoire, and the user cannot select only one subgroup for cancellation.



Action	Description	Page Name

2.5.1.13 IVD off-trade statement

This page allows the user to insert/edit the off-trade date of one or more IVD in “Validated” or Published” status.

To enter/update this date, proceed as follows:

- Activate the search for devices present in the database (menu item "In vitro diagnostic medical device (IVD)": set the search parameters and click the "Search" button);
- Select one or more IVD in “Validated” or “Published” status;
- Click on “Off-Trade” button;

The way a page recalled by the “Off-Trade” button is displayed depends on different scenarios:

- the user selects one single IVD and the selected IVD does not belong to a group of similar IVDs.
- the user selects one single IVD and the selected IVD belongs to a group of similar IVDs.
- the user selects more IVDs.

All possible scenarios are fully described below. In order to provide a full description, the list of fields displayed on the page and of all available operations will be repeated for each scenario, along with their respective peculiarities.

Regardless of the scenario to be applied, to enter/update the off-trade date of a IVD registered in the database, that IVD must be in the Validated or Published state.

First scenario

If the user selects one single IVD for which a previous off-trade date has not been entered and if the selected IVD does not belong to a group of similar IVDs, the system will display the following page:



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Home > In Vitro medical device > Medical Device (IVD) ?

Off-trade

Trade name and model: name and model IVD

Code assigned by the manufacturer (catalogue identifier): code 01

Manufacturer: MINISTERO DELLA SALUTE

System progressive attributed to DM: 480728

[Medical Device general data](#)

Off-trade date: 20 / 12 / 2012

In the upper part of the page, the principal data of the IVD are displayed as well as the “Medical Device General Data” link which opens the page containing the general data of the IVD.

Once an off-trade date has been declared, it can be updated using the same feature and editing the value which will appear when the web page opens.

Detail Fields

Field Name	Description
Trade Name and Model	Commercial name or model of the IVD
Code assigned by the manufacturer (identifier catalogue)	Code attributed to the IVD by the manufacturing company (better known as the identification catalogue)
Manufacturer	Corporate name of the IVD Manufacturing Company
System Progressive attributed to IVD	Unique identification number assigned to each IVD in the database. If /R appears next to the identification number assigned to the IVD by the system, it means that the IVD has been registered in the repertoire.
Off-Trade date	Off-trade date of IVD.

Operations available:

Action	Description	Page Name
Update	Save the off-trade date indicated by the user for the selected IVD. If a previous off-trade date has been indicated, the old value will be archived in the history and the new one will be acquired.	Same



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Action	Description	Page Name
Back	Takes the user back to the IVDs list page without entering/updating the off-trade date.	IVD List Page

Second scenario

If the initially selected IVD, for which a trade-off date must be indicated, is similar, and has the same features (except the trade name, the code assigned by the manufacturer, the size and the label) to other validated or published devices, the off-trade statement page also presents the list – with selectable items – of said similar devices that can be simultaneously registered in the Repertoire (see next picture).

Off-trade

Trade name and model: **name and model 01**
 Code assigned by the manufacturer (catalogue identifier): **code 01**
 Manufacturer: AESCULAP AG
 System progressive attributed to DM: 13362

[Medical Device general data](#)

Off-trade date: / /

The medical device is similar to the following Validated/Published DMs. Select from the list the devices to which the same off-trade applies.

Similar IVDs

System progressive attributed to DM	Trade name and model	Code assigned by the manufacturer	Measure	Label	DM status	Marketing End Date	Select
369933	name and model 02	code 02		NP618R.pdf	P0		☐

Even in this case, a previously indicated off-trade date can be updated. The procedure is as follows:

- The user selects one single IVD belonging to that group, for which he has previously indicated an off-trade date and activates the “Off-trade” feature;
- Edits the off-trade date presented by the system;
- Extends the data value to all the similar devices displayed on the same page or to a subset of the similar devices (selecting them);
- Clicks on the update button to complete the operation on the affected elements.

Detail Fields



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Field Name	Description
Selected DM data	
Trade Name and Model	Commercial name and model of the IVD
Code assigned by the manufacturer (identifier catalogue)	Code attributed to the IVD by the manufacturing company (better known as the identification catalogue)
Manufacturer	Corporate name of the IVD Manufacturing Company
System Progressive attributed to IVD	Unique identification number assigned to each IVD in the database. If /R appears next to the identification number assigned to the IVD by the system, it means that the IVD has been registered in the repertoire.
Off-Trade date	Off-trade date of IVD.
Similar IVDs List⁴²	
Measure (where applicable)	Indication of the measurable criteria actually used and present in commercial catalogues with the corresponding unit of measurement of the IVD
Label	File containing the label of the IVD
IVD status	The status of the DM in the database. This status can assume, in this case, the values: • V: Valid • P: Published

Operations available:

Action	Description	Page Name
Update	Activating this button, the off-trade date indicated by the user for the IVD on the page and for all the similar IVDs <u>selected</u> will be registered. If for one or more of these IVDs an previously registered off-trade date is already present in the system, the value will be updated and the old one will be registered in the history.	Same
Back	Takes the user back to the IVDs list page without	IVD List Page

⁴² Only the fields that are not described in the table are present.



Action	Description	Page Name
	entering/updating the off-trade date.	

Third scenario

If the user selects more than one IVD in “Validated” or “Published” status, the system will display the following page:

Off-trade

Off-trade date: / /

Activating the update button, the system will report the off-trade date present both on the selected DMs (visible on the page) and on every other similar DM in Validated or Published state. To indicate the off-trade date for a subset of similar devices, search one DM belonging to the group of similar DMs and activate the 'Off-trade' function again. For further details on the 'Off-trade' function, please refer to the User Manual.

IVD list

System progressive attributed to DM	Trade name and model	Code assigned by the manufacturer	Manufacturer	DM status	Marketing End Date	Similar IVDs
13790	name and model 01	code 01	AESCUAP AG	P0	02/06/2013	Similar
15932	name and model 02	code 02	AESCUAP AG	P0	02/06/2013	N
63299	name and model 03	code 03	AESCUAP AG	P0	02/06/2013	N
326364	name and model 04	code 04	AESCUAP AG	P0	02/06/2013	Similar

[Update](#)
[Back](#)

This page will allow the user to indicate an off-trade date and will report a list of the selected IVDs, showing, if applicable, their belonging to a group of similar IVDs (the information "Similar IVDs in the last column will show an "N" if the IVD belongs to a group of similar IVDs and a button labelled "Similar" if the IVD belongs to a group of similar IVDs).

By activating the “Similar” button (beside a IVD), if present, the system will show all IVDs belonging to that group (except the one that is selected), their status and the off-trade date, if already present⁴³ (see next picture).

⁴³ The IVDs belonging to a group of similar IVDs could all have the same off-trade date or no date. As a particular case, you could have mixed groups, with some IVDs having an off-trade date and others not. Such a condition does not compromise the group integrity.

**Similar IVDs**

System progressive attributed to DM	Trade name and model	Code assigned by the manufacturer	Manufacturer	DM status	Marketing End Date
394042	name and model 01	code 01	AESULAP AG	P0	02/06/2013
394043	name and model 02	code 02	AESULAP AG	P0	02/06/2013
394044	name and model	code 03	AESULAP AG	P0	02/06/2013
394045	name and model 04	code 04	AESULAP AG	P0	02/06/2013

[Close](#)

After checking the state of the similar IVDs involved in the operation, clicking on the "Update button" the user will validate the off-trade date entered for all the selected IVDs. In this case, the system will extend the value to all the selected IVDs (visible on the page) beginning from the search mask and to all the similar IVDs in the Validated/Published state, updating the date if already present⁴⁴.

Detail Fields

Field Name	Description
System Progressive attributed to IVD	Unique identification number assigned to each IVD in the database. If /R appears next to the identification number assigned to the IVD by the system, it means that the IVD has been registered in the repertoire.
Trade Name and Model	Commercial name and model of the IVD
Code assigned by the manufacturer (identifier catalogue)	Code attributed to the IVD by the manufacturing company (better known as the identification catalogue)
Manufacturer	Corporate name of the IVD Manufacturing Company
Device status	The status of the IVD in the database. This status can assume, in this case, the values: • V: Valid • P: Published

⁴⁴ In this case, the user can't select a subset of similar IVDs for which he wants to declare the same off-trade date. The system will apply the same date indicated by the user to all the IVDs in Valid/Published state similar to those selected. If the user wants to enter/update a specific off-trade date only for a subset of similar IVDs, he must search a single IVD belonging to the group and activate the "Off-trade" feature again. In this way, he will be able to select only some elements of the group, as in the second scenario.



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Field Name	Description
Off-Trade date	Off-trade date of IVD.

Operations available:

Action	Description	Page Name
Similar	Opens the (pop-up) page displaying IVDs similar to the one of interest. The page will display the following data: • System progressive attributed to the IVD; • Trade name and model; • Code assigned by the manufacturer (catalogue identifier); • Manufacturer; • Device status; • Off-Trade date.	Similar IVDs
Update	The activation of the button registers the off-trade date indicated by the user for all the selected IVDs and for all the similar IVDs in Validated/Published state, if present. ⁴⁵ . If for one or more of these IVDs an previously registered off-trade date is already present in the system, the value will be updated and the old one will be registered in the history.	Same
Back	Takes the user back to the IVDs list page without entering/updating the off-trade date.	IVD List Page

⁴⁵ In this **case the off-trade date is automatically applied to the similar IVDs in Validated/Published state** and the user can't select only a subset.



2.5.1.14 Manufacturing putback of a IVD in the “Published” status

This feature allows the user to put a IVD in the “Published” status back to manufacturing so as to correct bugs or errors or to implement changes that do not imply a new notification. The IVD data are recorded in the exact moment it is put back to manufacturing.

Home > In Vitro Diagnostic Medical Devices > Medical Device (IVD) > Manufacturing putback ?

Manufacturing putback

Trade name and model: name and model IVD
Code assigned by the manufacturer (catalogue identifier): code 01
Manufacturer: MINISTERO DELLA SALUTE
System progressive attributed to IVD: 1159613

[Medical Device general data](#)

*** Reason for manufacturing putback:** ☐ to correct bugs or errors
☐ or to implement changes that do not imply a new notification

*** Statement of changes planned:**

Warning!
 The 'subsequent notifications' of IVD resulting from previously published devices put back in processing status must be completed, using an electronic signature for the data, within 7 calendar days from their return to processing status. After time limit, those data which haven't been validated with an electronic signature, will be deleted from the BD/RDM system and the previous notification will remain to all intents and purposes.

Confirm

Fields details

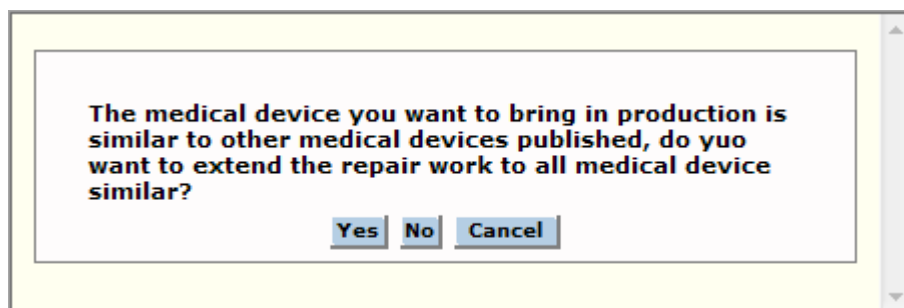
Field Name	Description
Reason for manufacturing putback	Reason why the published selected device is put back to manufacturing. A declarant may independently put back to manufacturing those devices only to correct bugs or errors or to implement changes that do not imply a new notification
Statement of estimated changes	Changes the Declarant estimates to implement to the device during manufacturing

Operations available:

Action	Description	Page Name
Confirmation	Puts the device back to manufacturing and records all of the information it contains	IVD list



If the selected medical device has similar IVDs in the “Published” status, in the confirmation stage the users will be asked if they wish to put back to manufacturing all similar IVDs or only the selected device.



Operations available:

Action	Description	Page Name
Yes	Puts all similar devices back to manufacturing and closes the dialog box	IVD list
No	Puts only the selected device back to manufacturing and closes the dialog box	IVD list
Cancel	Closes the dialog box	Manufacturing putback



2.5.1.15 View IVD Data

In order to view the data of a IVD the user must proceed as follows:

- Activate the search for devices present in the database (menu item "In vitro diagnostic medical device (IVD)": set the search parameters and click the "Search" button);
- Select the desired IVD;
- Click the "View" button to access the "General data" of the IVD;
- Select the menu option corresponding to the specific information of the IVD (Specifications data sheet, Documentation) therefore accessing the IVD data pages one by one in order to consult the information.

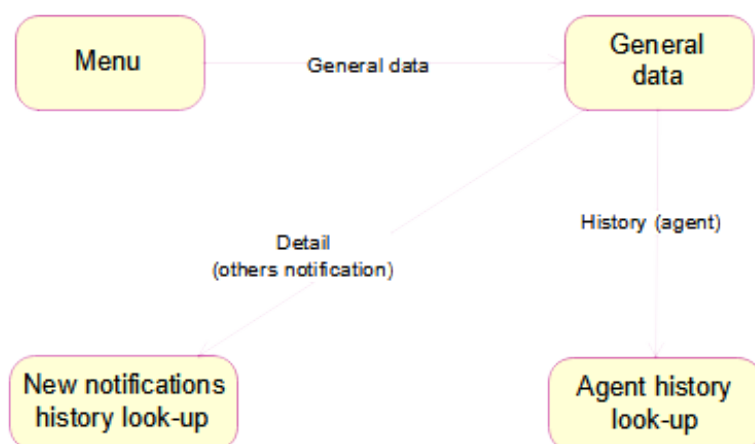
2.5.1.15.1 Consultation of a IVD data pages

The data pages of a IVD, in read-only mode, allows to consult the information details of the IVD selected on the "IVD List page"

The data pages are:

- General Data;
- Specifications;
- Documentation

2.5.1.15.1.1 General Data



**Page Name: General data page**

This page allows the user to view the general data of a IVD. The general data of a IVD are subdivided in four sections:

- General data
- Data concerning classifications
- Data concerning certifications
- Links with other IVD

In addition to these sections the characteristic data of the IVD similar to this one can also be visualized, but only in case if they are present.



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Home > In Vitro Diagnostic Medical Devices > Medical Device (IVD) > General data ?

Browsing General data

General data

***IVD type:** ☒ reagent, reagent products, kits, control materials, calibrators
☐ Instruments, Devices, Equipment, Systems
☐ Sample Containers

***Trade name and model:** NAME AND MODEL

***Code assigned by the manufacturer (catalogue identifier):** Code reagent 01

Sales package contents:

***Registrant's role with respect to the device:** FABBRICANTE

Company that entered the IVD: MINISTERO DELLA SALUTE [Detail](#)

***Manufacturer:** MINISTERO DELLA SALUTE [Detail](#)

Agent: [Detail](#)

***Indication of new device pursuant to article 10 paragraph 4 of Italian Legislative Decree number 332/2000?** ☒ Yes ☐ No

Note: a device is "new" if:

- there has been no such device continuously available on the Community market during the previous three years for the relevant analyte or other parameter;
- the procedure involves analytical technology not continuously used in connection with a given analyte or other parameter on the Community market during the previous three years.

System progressive attributed to IVD: 1153087

Classification

Complete GMDN repertoire: A test system consisting of one or multiple reagents and other items intended to determine the carboxy-

EDMA Classification: Disopyramide

***CND classifications:** TEST PER EMOGLOBINA - ALTRI

Certifications

***EC Classification (D.L.vo n. 332/2000):** Altro tipo di IVD

Annex according to which the device was marked: ☒ Annex III
☐ Annex IV
☐ Annex V
☐ Annex VI
☐ Annex VII



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* Conformity with common technical specifications: ☒ Yes ☐ No

File containing the EC Compliance Statement: [Carr_etichettaGH.pdf](#)

other devices (classified DM/IVD) for operation

* Other devices needed for operation? ☒ Yes ☐ No

Other device are: ☐ all present in the package
☒ partly present in the package
☐ not present in the package

Briefly specify any exclusive-use devices and whether they are present in the retail package or otherwise.

The brief specification is required to report:

- the manufacturer's name, trade name and model of the device, as well as the code assigned by the manufacturer, if the exclusive-use devices are required to be referred to other manufacturers;
- the progressive database identification numbers assigned to registered ?exclusive-use? medical devices if they refer to the same manufacturer, as well as any other information that the manufacturer considers important.

In both cases, please also specify the reason for exclusive use.

Brief information for the device	In retail package
Brief information	☒

Similar IVD

System progressive attributed to IVD	Trade name and model	Code assigned by the manufacturer	Measure (where applicable)	Label	Task status
1159627	NAME AND MODEL (SIMILAR IVD)	CODE REAGENT 02		RicevutaFirma_offline.pdf	C

Detail: General IVD Data Fields

Field Name	Description
General Data	
IVD type	IVD type specification, in the sense of reference macro category. Alternatively, indicate only one of the following items: - Reagents, reagent products, control material, kit, calibrators, - Instruments, devices, equipment, systems, - Sample containers Depending on the IVD type specified, the system will request the compilation or otherwise of specific information sections in the 'technical datasheet'. In addition, in order to maintain data consistency, if the user subsequently decides to change the 'IVD type', the system will automatically remove the data present on the 'technical specifications' page, if these are validated, applicable only to the type modified. Therefore please check whether it is necessary to validate the specific technical data applicable to the new type assigned to the IVD.
Trade Name and Model	Denomination of the IVD, as given by the Manufacturer
More IVD trade	List of commercial names subsequently assigned to the same IVD



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Field Name	Description
names	
Code assigned by the manufacturer (identifier catalogue)	Specific code attributed to the IVD by the manufacturer.
Sales package contents	Brief description of the contents of the sales package
Registrant's role with respect to the device	Indication of the registrant's role with reference to the device. The registrant can play the following roles: - Manufacturer - Authorised Representative - Other entity appointed by the manufacturer
Company that entered the device	Registrant company registered in the Register of Companies - General registrant information (this field is not editable)
Manufacturer	Name of the device Manufacturer (this field is not editable) If the user has selected the item "manufacturer" as the Registrant Company's role with reference to the device, the system specifies as the manufacturing company the company entered by the user in "General Registrant Data". If the user selected a different role than manufacturer, the user can select the manufacturer by clicking on the "Search" link; in this case a look-up opens where the user can search and select the manufacturer.
Agent	Name of the device Authorised Representative (this field is not editable) If the user selected the item "authorised representative" as the registrant's role with reference to the device, the system proposes as the authorised representative the user's own company entered in "General Registrant Data". By choosing a different role than "authorised representative", the user can select Authorised representative by clicking on the 'Search' link; in this case a look-up opens where the user can search and select the authorised representative. The authorised representative is: - Mandatory: if the manufacturer has its registered office in a non-EU Member country except an EEA country/Turkey - Optional: if the manufacturer has its registered office in an EEA country/Turkey - Cannot be validly entered: if the manufacturer has its registered office in an EU member country. The Country's authorised representative must be in the EU/EEA/Turkey.
Indication of "new" device pursuant to	Indicate whether the device is considered "new" or otherwise (yes/no).



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Field Name	Description
article 10 paragraph 4 of Italian Legislative Decree number 332/2000	Note: a device is "new" if: a) there has been no such device continuously available on the Community market during the previous three years for the relevant analyte or other parameter; b) the procedure involves analytical technology not continuously used in connection with a given analyte or other parameter on the Community market during the previous three years
System Progressive attributed to IVD	Unique identification number assigned to each IVD by the system. This field is not editable and is visible only when editing the IVD.
Classifications	
GMDN nomenclature complete	Indication of the classification of the device according to the GMDN nomenclature (Global Medical Device Nomenclature) - non-editable field which is Mandatory if the EDMA classification is not specified. The user is required to click on the link "search" in order to select an item according to the GMDN nomenclature; a look-up opens where the user can look up the entry by code and description (or part of it). For each GMDN item found the system will indicate whether the GMDN is associated with one CND code or several CND codes.
EDMA Classification	Device classification according to EDMA (European Diagnostic Manufacturers Association). This field is not editable and Mandatory unless the GMDN classification is specified. To select an EDMA classification please click on the link "Search"; a look-up opens where the user can search for the classification code and description (or part thereof) by getting the list of entries that match the search criteria. Each entry is expandable in case it is not terminal, it is only selectable if it is a terminal item.
CND classification	Indication of the classification of the device according to the CND - non-editable field; Mandatory. The system automatically populates this field if the user selected a GMDN with associated CND Terminal, editable in any case. The user can alternatively search and select a specific CND classification by clicking the "Search" link; a look-up opens where the user can search for this classification code and description (or part thereof) by getting the list of entries that match the search criteria. Each entry is expandable in case it is not terminal, it is only selectable if it is a terminal item. It is possible to search only in the context of the class "W" of the CND associated to the IVD. The user can search the CND as a function of the previously selected GMDN or otherwise.
Certifications	
IVD classification referred to in Italian Legislative Decree	Indication of the classification of the device referred to in Italian Legislative Decree number 332/2000. Choosing one of the following four options:



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Field Name	Description
number 332/2000	- Annex II – List A - Annex II – List B - Self-diagnosis test (not included in Annex II) - Other IVD types (Mandatory field)
Annexes according to which the device was marked	Indication of the annexes to Italian Legislative Decree number 332/2000 provided for the assessment of compliance for EC marking purposes (selectable from list) The following options are permissible: - Annex IV or Annex V + Annex VII, if the IVD is classified as Annex II – list A - Annex IV or Annex V + Annex VI or annex V + Annex VII, in case of classification: Annex II – List B: - Annex III or Annex IV or Annex V + Annex VI or annex V + Annex VII, in case of classification: Self-diagnosis test (not included in Annex II) - Annex III, in case of classification: Other IVD types (Mandatory field)
Compliance with common technical specifications	(Yes/No) specification regarding the compliance with common technical specifications (Article 6, Italian Legislative Decree number 332/2000)
EC declaration of compliance	PDF file containing the EC declaration of Compliance The file must be provided if the EC classification is "Other IVD type".
Other devices (DM/IVD) needed for operation	
Are other devices required for operation?	This provides for (Yes/No) specification if the notified device requires other devices (classified DM/IVD) for operation (mandatory field)
Devices are	If the device notified requires other devices for operation, it is <u>mandatory</u> to specify whether these devices are: - all present in the package, - partly present in the package, - not present in the package,
Device brief information	In the case of <u>exclusive-use</u> devices, the following must be stated succinctly: - the manufacturer's name, trade name and model of the device, as well as the code assigned by the manufacturer, in the case where the exclusive-use devices are to be referred to <u>other manufacturers</u>; - progressive references in the database assigned to 'exclusive-use' medical devices, if registered, in case the products are to be referred to the <u>same manufacturer</u>, as well as other indications, if these are considered important by the manufacturer. In both cases the user must specify, in addition, the reason for exclusive use.

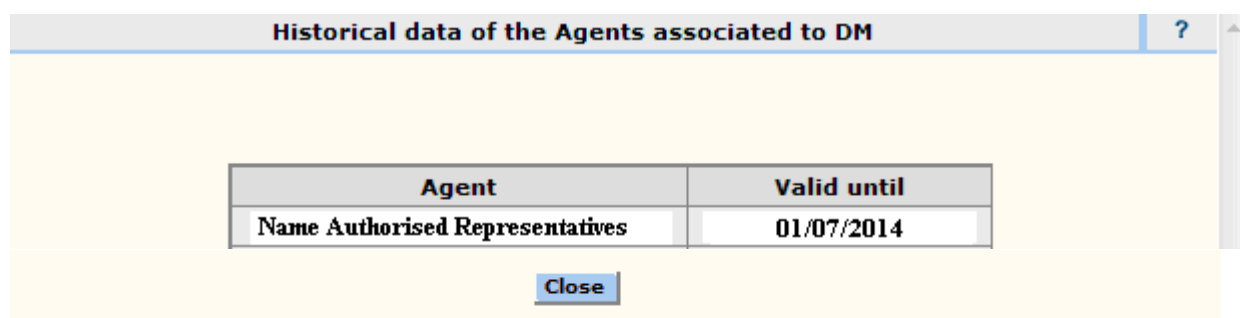
*Operations available*

Action	Description	Page Name
History	Opens the window having the IVD agents history detail. This button is present only if the agent was modified after publication.	Agent history look-up
Detail	Opens the window having the other IVD notifications history detail. This button is present only if other notifications for the device exist.	New notifications history look-up

Page Name: Agent history look-up

This page is activated from the detail of a IVD general data by clicking on the “History” button beside the “Agent” field only if such datum was updated after the IVD was published, and allows the user to display the history of all associated agents.

Each change implemented to the Agent of the device after publication is reported along with the corresponding date of communication.

*Operations available*

Action	Description	Page Name
Close	Closes the window	General data

**Page Name: New notifications history look-up**

This page is activated from the detail of a IVD general data by clicking on the “Detail” button beside the “Other IVD notification” field only if some connections for such IVD exist, and allows the user to display the notification history of the same IVD.

For each notification, other identification data of the IVD, the date and reason for new notification are reported

Medical devices connected - Rinotification						?
System progressive attributed to DM	Validation Date	Rinotification Date	Reason for new notification	Manufacturer	Code assigned by the manufacturer (catalogue identifier)	Trade name and model
10023	01/06/2014			Manufact. IVD	code 01	Name IVD
11883		01/07/2014	Variazione denominazione del fabbricante	Manufact. IVD	code 02	Name IVD

[Close](#)

Operations available

Action	Description	Page Name
Close	Closes the window	General data

2.5.1.15.1.2 Specifications Data Sheet**Page Name: Specifications Data Sheet**

This page allows users to view the technical data of a IVD. The data on a IVD specifications data sheet are subdivided in the following areas:

- General technical characteristics
- Specific technical data for reagent, reagent products, kits, control materials, calibrators
- Specific technical data for Instruments, Devices, Equipment, Systems
- Specific technical data for Sample Containers
- Technical datasheet of tissues of human origin or Substances derived from them (Italian Legislative Decree number 332/2000, Annex III, section 3.d)



- Technical data of biological tissues or substances of animal origin (non vital)

In the upper section of the page, the principal data of the IVD are displayed as well as the “Medical Device General Data” link which opens the page containing the general data of the IVD.

Home > In Vitro Diagnostic Medical Devices > Medical Device (IVD) > Technical Data ?

Browsing Technical Data

Trade name and model: NAME AND MODEL

Code assigned by the manufacturer (catalogue identifier): Code reagent 01

Manufacturer: MINISTERO DELLA SALUTE

System progressive attributed to IVD: 1153087

[Medical Device general data](#)

General technical characteristics

Intended use pursuant to Italian Legislative Decree number 332/2000:

Sterile or other special microbiological state of the device (if any):

If the device is sterile, indicate the sterilisation methods:

Sterilization method	Valid entry according to the regulation	Other sterilization method description
CALORE SECCO	NON NOTO	

Disposal special conditions:



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Specific technical data for reagent, reagent products, kits, control materials, calibrators					
Methodology (principle of the method):					
Presence of calibrators: ☒ Yes ☐ No					
Positive controls: ☒ Yes ☐ No					
Negative controls: ☒ Yes ☐ No					
Storage conditions:					
Indication of the period of validity of the unopened package: (expressed as number of months)					
Indication of the storage period, in days, of the reagent/kit after first opening the primary container.: (expressed as number of days)					
Number of performable tests: alternatively, specify the amount of reagent and the quantity of reagent for each individual calculation (volume/mass)					
*Disposable: ☒ Yes ☐ No					
Number of units contained in the sales package:					
Tissues of human origin or Substances derived from them (Italian Legislative Decree number 332/2000, Annex III, section 3.d)					
Indicate the tissues of human origin or substances derived from them:					
Part used	State of origin	Origin documents	Treatment Methods documents	Health Authority documents	
Sostanza	AFGHANISTAN	CEalfa.pdf	CEalfa.pdf	CEalfa.pdf	
Tissue or Biological Substances Animal data (not vital)					
Indicate the tissues or substances of animal origin, not vital (if any):					
Family	Part used	State of origin	Origin documents	Treatment Methods documents	Health Authority documents
ALTRO	ALTRO	AFGHANISTAN	CEalfa.pdf	CEalfa.pdf	CEalfa.pdf

Field Detail

Field Name	Description
General technical characteristics:	
Intended use pursuant to Italian	Indication of the intended use of the device in accordance with Italian Legislative Decree number 332/2000



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Legislative Decree number 332/2000	(optional field)
Sterile or other special microbiological state of the device (if any)	Indication of infertility or other microbiological state of the device. The following values are allowed: sterile/other special microbiological state (optional field)
General technical characteristics – sterilisation data	
Sterilisation method (if any)	Indication of the method used for device sterilisation (required field if the device is "Sterile")
Sterilisation method validated according to harmonised standards	Indicate (Yes/No/Don't know) if the sterilisation method is validated according to harmonised standards (this field is mandatory if the device is "Sterile")
Description of another sterilisation method	Description of the sterilisation method if it is not present in the default list. (required field if the "sterilisation method" specified was "Other".
Special disposal conditions	Indication of any special conditions for the disposal of the device (optional field)
Specific technical data for reagent, reagent products, kits, control materials, calibrators	
Methodology (principle of the method)	Indication of the method used (from default list) (optional field)
Presence of calibrators	Specify (Yes/No) regarding the presence of calibrators (optional field)
Positive controls	Specify (Yes/No) regarding the presence of positive controls (optional field)
Negative controls	Specify (Yes/No) regarding the presence of negative controls (optional field)
Storage conditions	Indication of any storage conditions laid down for the reagent/kit (optional field)
Shelf life of unopened package	Indication of the period of validity of the unopened package expressed in number of months (optional field)
Shelf-life after first opening the primary container	Indication of the storage period, in days, of the reagent/kit after first opening the primary container. (optional field)
Number of performable tests	Indication of the number of performable tests, or, alternatively, the amount of reagent and the amount of reagent for an individual calculation (volume/mass) (optional field)



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Disposable	Specify (Yes/No) as to whether the device is disposable or not (mandatory field) (device designed for single use for only one patient).
Number of units contained in the sales package	Indication of the number of units contained in the sales package (optional field) Applicable in cases where a sales package contains several packs not sold individually.
Specific technical data for Instruments, Devices, Equipment, Systems	
Testing volume (number of tests/hour)	Indicate the number of tests performed per hour (optional field)
Modes of operation	Indication of instrument operating modes (optional field)
Specific technical data for Sample Containers	
Measurement	Indication of the size of containers and the relative measurement units
Disposable	Specify (Yes/No) as to whether the device is disposable or not (mandatory field) (device designed for single use for only one patient)
Number of units contained in the sales package	Indication of the number of units contained in the sales package (optional field) Applicable in cases where a sales package contains several packs not sold individually.
Additive type contained	Indication of the type of additive contained in the sales package (from the default list) - (optional field)
Other additive contained	Specify type 'Other additive' (free text) if it is not present in the default list
Technical datasheet of tissues of human origin or Substances derived from them (Italian Legislative Decree number 332/2000, Annex III, section 3.d)	
Part used	Specify the part used: tissue/substance/both (optional field)
State of origin	State of origin of the tissue of human origin/substance derived from it contained in the device. (optional field)
Documentation	File (pdf) containing the documentation regarding the origin of the tissue/substance or e-mail



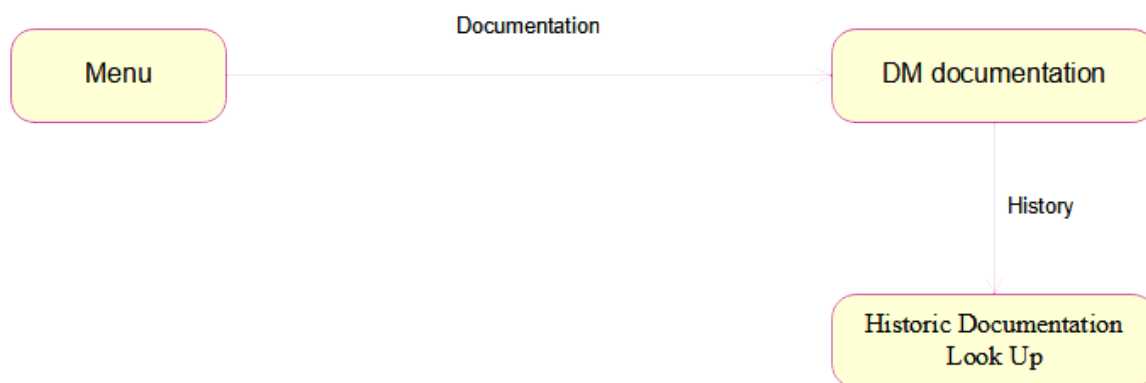
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regarding the origin of the tissue or substance	address or website where the user can find this documentation (optional field)
Documentation on treatment and inactivation methods	File (pdf) containing documentation on treatment and inactivation methods or e-mail address or website where the user can find this documentation (optional field)
Health authority documentation	File (pdf) containing the documentation prepared by the Health Authority or e-mail address or website where the user can find this documentation (optional field)
Technical data of biological tissues or substances of animal origin (non vital)	
Family of origin	Indication of family of origin of biological tissue/animal substance contained in the device (optional field)
Other Family	Description of the family of organic tissue/animal substance contained in the device if it is not listed. (mandatory field if the "Family of origin" field specified was "Other", otherwise it should not be entered.)
State of origin	Indication of the state of origin of the biological tissue/animal substance contained in the device. (optional field)
Part of tissue used	Specify the part of the tissues used. (optional field)
Other part used	Description of the part used of the organic tissue/animal substance contained in the device if it is not listed. (mandatory field if the "Part of tissue used" field specified was "Other", otherwise it should not be entered)
Documentation regarding the origin of the tissue or substance	File (pdf) containing the documentation regarding the origin of the tissue/substance or e-mail address or website where the user can find this documentation (optional field)
Documentation on treatment and inactivation methods	File (pdf) containing documentation on treatment and inactivation methods or e-mail address or website where the user can find this documentation (optional field)
Health authority documentation	File (pdf) containing the documentation prepared by the Health Authority or e-mail address or website where the user can find this documentation (optional field)



2.5.1.15.1.3 Documentation



Page Name: IVD Documentation

This page allows the user to view the documentation attached to a IVD and therefore to download the files attached. In the upper part of the page, the principal data of the IVD are displayed as well as the “Medical Device General Data” link which opens the page containing the general data of the IVD. If the Label or the IFU of the medical device have been modified after their publication, the system visualizes the button ‘Historic’.



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Home > In Vitro Diagnostic Medical Devices > Medical Device (IVD) > Documentation ?

Browsing Documentation

Trade name and model: NAME AND MODEL

Code assigned by the manufacturer (catalogue identifier): Code reagent 01

Manufacturer: MINISTERO DELLA SALUTE

System progressive attributed to IVD: 1153087

[Medical Device general data](#)

Document	File to attach	Link /Email Address	
Results of the performance evaluation			
* Label	RicevutaFirma_offline.pdf		Open
Instructions for Use			
IVD Image			
Scientific bibliography supporting the clinical evidence of the effectiveness and safety			

If the IVD does not need Bibliography attach a file containing an explicit statement to that effect.

Documentation Detail Fields

Field Name	Description
Performance evaluation results	File (pdf) containing the results of the performance evaluation. Information provided <u>mandatorily</u> for IVD annex II – list A and B, self-diagnosis testing (not included in annex II).
Label	File (pdf) containing the label of the device (<u>Mandatory</u>) and indication of the link of the site where the user can obtain it (optional).
Instructions for use	File (pdf) containing the instructions for use of the device. <u>Mandatory</u> for IVD annex II – list A and B, self-diagnosis testing (not included in annex II); optional, <u>but recommended</u> for other IVD types to ensure the exhaustiveness of the information provided to the National Health Service. It is permitted, in addition, to indicate the link of the website where the user can obtain it (optional).
Image of IVD	File (pdf) containing the image of the device or, alternatively, the link to the website where the user can obtain this information. <u>Optional</u> .
Scientific bibliography supporting the clinical evidence of the effectiveness and	File (pdf) containing the Scientific Bibliography supporting the clinical evidence of performance and safety of the device or, alternatively, the link of the website where the user can obtain this information or an e-mail address for requesting it. <u>Optional</u> .



safety	

Operations available:

Action	Description	Page Name
Open	Allows the user to download the attached document	
History	Allows access to the page visualizing the old files. The operation is activated only if the Label or the IFU of the IVD have been modified after its publication.	Historic Documentation Look Up

Page Name: Historic Documentation Look Up

This page allows the user to view the history of the Label and Instructions for use modified after the publication of the relative medical device and to download these files.

For every modification in the documentation of the device after its publication, there is the date of signature and names – and the relative link – of the files attached on the relative date.

Using these links, it is possible to get access to the file (download).

Historical publication documentations changes								
Updated documentation <table> <tr> <th>Signed</th><th>Label</th><th>Instructions</th></tr> <tr> <td>10/05/2014</td><td>IVD label</td><td></td></tr> </table> Close			Signed	Label	Instructions	10/05/2014	IVD label	
Signed	Label	Instructions						
10/05/2014	IVD label							

Operations available:

Action	Description	Page Name
Close	Closes the visualization page of the documentation history	Documentation



2.5.1.16 Version history

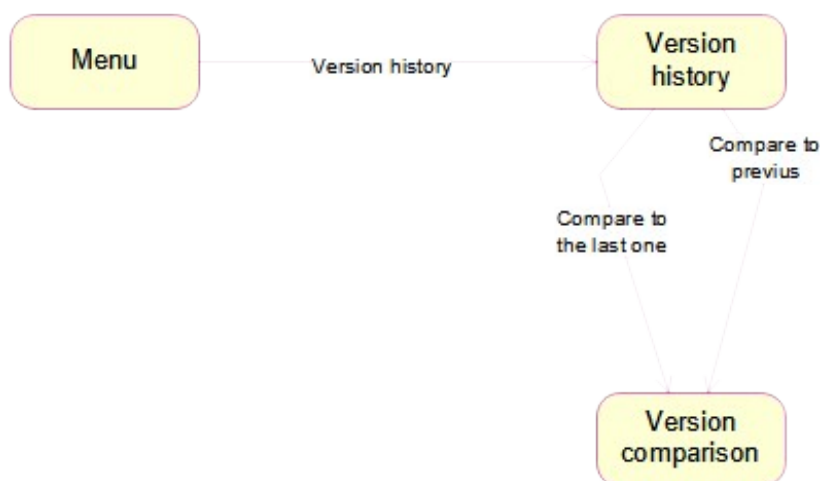
This feature allows the user to consult the various versions of a IVD that has been brought from the “Published” status back to the “Manufacturing” status at least once.

Amongst the reasons why a IVD can be brought from the “Published” status back to the “Manufacturing” status, there are:

- correcting bugs or errors
- implementing changes that do not imply a new notification
- Ministry of Health request

Pages involved:

- ✓ Version history
- ✓ Version comparison





2.5.1.16.1 IVD version history

This page allows the user to consult the version history of the various versions of those IVDs that have been brought from the “Published” status back to the “Manufacturing” status at least once.

Home > In vitro diagnostic medical device > Medical Device (IVD) > Historical Versions ?

Historical Versions

Trade name and model: Name and model ...

Code assigned by the manufacturer (catalogue identifier): code 01

Manufacturer: IVD manufacturer

System progressive attributed to DM: 10023

[Medical Device general data](#)

Manufacturing putback		
Validate End Date	Reason for manufacturing putback	Select
10/05/2014	per modifiche che non implicano la rinotifica	☐

[Compare with current](#)
[Compare with Previous](#)

Operations available

Action	Description	Page Name
Compare with current	Allows the user to access the comparison page of the selected version with the last page available for the (actual) IVD	Version comparison
Compare with previous	Allows the user to access the comparison page of the selected version with the one that precedes it	Version comparison



2.5.1.16.2 Version comparison

This page allows the user to display all of the differences between the two different versions of a IVD

Home > In vitro diagnostic medical device > Medical Device (IVD) > Compare Versions ?

Compare Versions

Trade name and model: name and model IVD ...

Code assigned by the manufacturer (catalogue identifier): code 01

Manufacturer: manufacturer IVD

System progressive attributed to DM: 10737

[Medical Device general data](#)

Differences between the current version and the version valid until 10/05/2014

Data Updated	Current value	Value until 10/05/2014
Trade name and model	name and model IVD	old name and model IVD

[Back](#)

Operations available

Action	Description	Page Name
Back	Directs the user back to the version history page	Version history



2.5.2 Menu option “Activities in progress”

Screen flow:



2.5.2.1 List of the activities in progress

To access the page containing the activities in progress list the user must click on the menu item "Activities in progress -> List of activities". The page allows Registrants having the role of Manufacturer/Authorised Representative /Other Entity mandated by the manufacturer to display the activities in progress list with respect to medical devices they themselves consolidated or validated.

To access any notifications received use the "Filter" button, set the necessary parameters for their identification and click the 'Search' button

With reference to each medical device consolidated or validated, the Registrant can receive the following notifications:

following consolidation:

- request for rectification for failure to pass the following automatic control:
lack of mandatory data with respect to General data, technical datasheet and documentation attached to the device

following Validation:

- successful publication of the medical device by the Ministry
- Ministry of Health request for data correction

By clicking on the link under the column "Error messages for the manufacturer and Notifications" the detail page with the key data of the selected activities in progress is displayed



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Home > In Vitro Diagnostic Medical Devices > Activities underway			?
Activities List			
Activities underway			Filter
Progressive system attributed to Medical Device	Error Messages for the Declarant and Communications	Communication Data	
1159637	Il Dispositivo Medico CODE 03 - MINISTERO DELLA SALUTE ha dei campi incompleti	03/06/2014	

Field detail

Field Name	Description
- Progressive system identification number assigned to the medical device	Progressive system identification number assigned to the medical device entered in the database
Error messages for the declarant and communications.	This indicates the type of notification forwarded to the entity in relation to a consolidated or validated medical device; specifically: - Request for correction for failure to pass automatic system controls (consolidation) - Successful publication of the medical device by the Ministry - Ministry of Health request for correction
Communication date	This indicates the date of communication of the notification

Operations available:

Action Name	Description	Page Called
Filters	This function opens the page where the user can set the search criteria on the basis of which the activities in progress list is filtered	Activities in progress filter.



2.5.2.2 Filter the list of the activities in progress

This page is in the form of look up and allows the user to filter the activities in progress list on the basis of the search parameters set

Worklist's Filters	
Filter by:	
System progressive attributed to Medical Device	
Error Messages for the Declarant and Communications	
Communication date	
Search Clear Filters Close	

Detail Fields

Field Name	Description
System progressive attributed to IVD	System progressive number of IVD
Error messages for the declarant and communications.	Indicates the type of notification forwarded to the entity in relation to a consolidated or validated medical device; specifically: - Request for correction for failure to pass automatic system controls (consolidation) - Successful publication of the medical device by the Ministry - Ministry of Health request for correction
Communication date	This indicates the date of communication of the notification

Operations available:

Action	Description	Page Name
Filter	Runs a search of the activities in progress based on search criteria inserted.	Activities in progress List
Clear Filters	Clears the search criteria previously put in place	Same
Close	Closes the search margin window, without running the search.	Activities in progress List



2.5.2.3 Viewing of the details of IVD activities in progress

This page allows the user to display key information of activities in progress in relation to the data consolidation and validation stages and is accessed by clicking the corresponding link in the column "Error messages for the manufacturer and Notifications"

Data consolidation: notice of request for correction for failure to pass automatic system controls – the page presents a list of errors that led to the failure of the automatic control system

Home > In Vitro Diagnostic Medical Devices > Activities underway > Error Messages for the Declarant and Communications

Error Messages for the Declarant and Communications

Data of device	
Trade name and model:	CODE REAGENT 03
Code assigned by the manufacturer (identifier catalogue):	CODE 03
Manufacturer:	MINISTERO DELLA SALUTE
Progressive System Awarded to Medical Device:	1159637

Missing Fields
Non risulta acquisito il file contenente l'etichetta del dispositivo

[Go to Device](#) [Close activity](#) [Back to list activities](#)

Medical device data can be accessed, in editable mode, by using the 'Go to device' function

Data validation: notification by the Ministry of successful publication, if the request has been accepted, the page displays the key data for the published medical device



Home > In vitro diagnostic medical device

DM DMP02M - BRISTOL Pubblicato

E' stata accettata la richiesta di pubblicazione per il dispositivo:

Dati del dispositivo

Nome commerciale e modello: name and model IVD ...

Codice attribuito dal fabbricante code 01
(identificativo catalogo):

Fabbricante: manufacturer IVD

Progressivo di Sistema
Attribuito al DM: 1833

Note di rettifica:

Close attivitie Back to the list activities

Data validation: notification of request for correction by the Ministry, if the Administration does not intend to accept the request for publication of the device - this page displays the key data of the medical device to be corrected, and the reasons for it (Correction notes)

Home > In vitro diagnostici medical device

DM DMP02M - BRISTOL non Pubblicato

Non è stata accettata la richiesta di pubblicazione per il dispositivo:

Dati del dispositivo

Nome commerciale e modello: name and model IVD ...

Codice attribuito dal fabbricante code 01
(identificativo catalogo):

Fabbricante: manufacturer IVD ...

Progressivo di Sistema
Attribuito al DM: 1833

Note di rettifica:

Close attivitie Back to the list activities

**Field detail**

Field Name	Description
Trade Name and Model	Denomination of the IVD, as given by the Manufacturer
Code assigned by the manufacturer (identifier catalogue)	Specific code attributed to the IVD by the manufacturer.
Manufacturer	Manufacturer of the IVD.
System Progressive attributed to IVD	Unique identification number assigned to each IVD by the system.
Correction notes	Indication of the reasons which led the Ministry to refuse the request for publication of the device (applicable to data validation phase)
Missing fields	The list of errors that led to the failure to pass the automatic system controls for device validation (applicable in data consolidation phase)

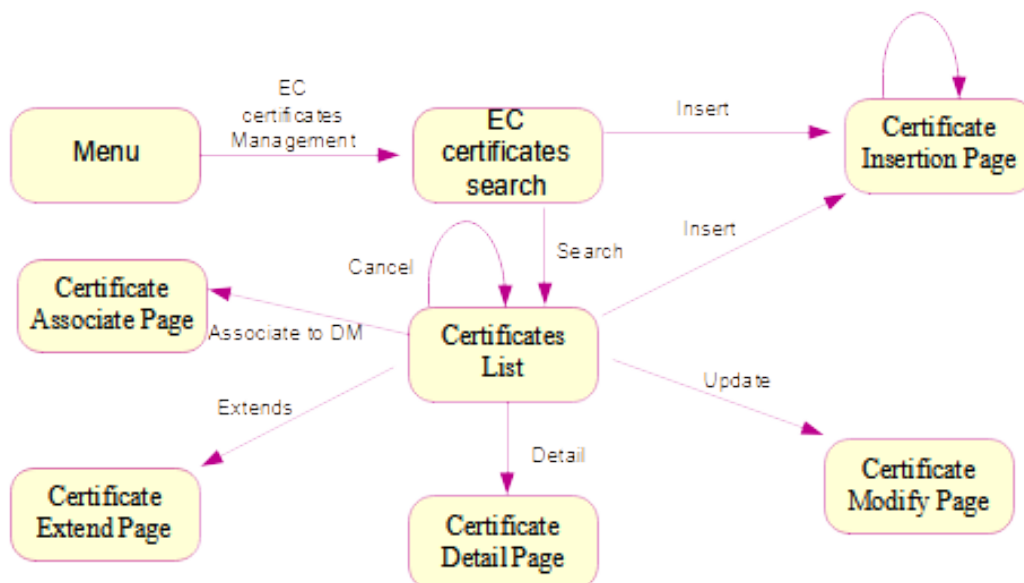
Operations available:

Action Name	Description	Page Called
Go to the device	This function provides access to the detail page of the General data of the device	General Data Page
Close Activitie	This function allows the user to return to the activities in progress list, removing previously closed tasks from the list	Activities in Progress List.
Back to list activities	This function allows the user to return to the work in progress list	Activities in Progress List.



2.5.3 Menu option “EC Certificates”

Screen flowcharts:





2.5.3.1 EC certificates search

Having clicked on “EC Certificates > EC Certificates Management” on the menu, a page appears which allows the user to define the search criteria of the EC certificates.

From this page, the user may also access the insertion page of a new certificate clicking on the “Insert” button.

Home > In Vitro Diagnostic Medical Devices > EC certificates ?

EC certificates search

Research criteria

No. of certificate of the EC marking:

Certificate Expiration Date : / /

Notified Body Code-Name:

Detail Fields

Field Name	Description
No. of certificate of the EC marking	Identification number of the EC certificate.
Certificate Expiration Date	Expiry date of the Certificate.
Notified Body Code-Name	Indication of the code and name of the organization notified. This field cannot be edited. To select the code of the organization notified it is necessary to click on the “Search” link; a look-up will open from which it will be possible to search for the organization notified by code and name.

Operations available:

Action	Description	Page Name
Search	Starts the certificates search that are consistent with the parameters that have been set.	Certificates List Page
New search	Clears the search criteria previously defined	Same
Insert	Allows access to the insertion page of a new EC certificate	Certificate Insertion Page



2.5.3.2 List of searched EC certificates

This page displays the list of the EC certificates which correspond to the criteria defined in the relative search page. For every certificate the following information is displayed

- the certificate number of the EC stamp
- the expiry date
- the organization notified which issued it
- the file attached containing the image of the certificate

As an alternative, from that page the user may:

- request the registration of a new certificate by clicking on the “Insert” button, that can always be enabled.
- select a certificate from the list and:
 - ✓ view its “Details”;
 - ✓ request the “Deletion” of the certificate only if the selected certificate is not associated to any extension/expansion nor to any in vitro medical device. When activating the “Delete” button, the system will ask the user if he/she wishes to delete the selected certificate, and in that case it will proceed with the deletion. After that, the list of remaining certificates will be displayed;
 - ✓ request its “Amendment”, in those cases where the selected certificate is not associated to an extension nor to a medical device in the validated or published status; or when it is associated to signed IVDs, but was set to be amended by an authorized office;
 - ✓ associate the selected certificate to one or more in vitro medical devices of the same manufacturer
 - ✓ replace the certificate with a new one within the IVD notification
 - ✓ access the “Extension/Expansion” page of that certificate only if the selected certificate is not associated to any extension/expansion or, even in the case in which it is, if it still appears as associated to a validated or published device.

If the user needs to amend a given certificate that has previously entered, and that is associated to validated or published medical devices, then must request to the Ministry, via e-mail, the for permission, and will have the certificate released.



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EC certificates search

Research criteria

No. of certificate of the EC marking:

Certificate Expiration Date: / /

Notified Body
Code-Name:

[Search](#) [Reset](#)

[Search](#)

[New search](#)

No. of certificate of the EC marking	Certificate Expiration Date	Notified Body	File containing the certificate	Select
IVD-01	05/05/2019	ISTITUTO SUPERIORE DI SANITÀ	Ima Certificate.pdf	☐

Select: Click on one of the squares beside the component(s) in the list depending on operations.

By means of the Edit button, the system allows the user to correct those certificate data that have not been properly entered. However, the user may be faced with two scenarios:

- Scenario 1:** The certificate is linked to a IVD in the "In progress" or "Consolidated" status. Unlike all of the other fields, here, the certificate Manufacturer cannot be edited.
- Scenario 2:** The certificate is linked to a IVD in the "Validated" or "Published" status. To edit that certificate, the user should first ask, via e-mail, the FVG Support for permission, and they will release the certificate. Once it is released, when the user selects the certificate, the 'Edit' button will be active, and they will be able to apply the changes required. Obviously, the certificate Manufacturer cannot be edited. Once such changes have been saved, the certificate will be blocked again and cannot be edited.

Page 1 of 1

[Insert](#)

[Detail](#)

[Edit](#)

[Delete](#)

[Extend / Extension](#)

[Associate to IVD](#)

[Substitution](#)

Detail Fields

Field Name	Description
No. of certificate of the EC marking	Identification number of the EC certificate.
Certificate issue date	Certificate issue date.
Certificate Expiration Date	Expiry date of the Certificate.
Notified Body	Indication of the code and name of the organization notified. This field cannot be edited. To select the code of the organization notified it is necessary to click on the "Search" link; a look-up will appear from which it will be possible to search for the organization notified by code and name

*Operations available:*

Action	Description	Page Name
Search	Starts the certificates search that are consistent with the parameters that have been set.	Page Lists Certificates
New search	Clears the search criteria previously defined.	Same
Insert	Allows access to the registration page of a new EC certificate.	Certificate Insertion Page
Detail	Allows access to a details page of the data associated to an EC certificate.	Certificate Detail Page
Edit	It allows to access the amendment page for the selected certificate, only in the case where that certificate is not associated to an extension nor to any validated or published medical device, or if it is associated to signed IVDs, but was set to be amended by an authorized office.	Certificate Modify Page
Delete	Deletes the selected certificate, only in the case where that certificate is not associated to an extension nor to any medical device.	Same
Extend/ Extensions	Allows the user to access the extension/expansion page of the selected certificate, only in the case where that certificate is not associated to an extension/expansion or, if it is, it still appears as associated to a validated or published device.	Certificate Extend Page
Associate to IVD	Allows the user to access the association page of the selected certificate to the medical devices.	Certificate Associate Page
Substitution	Allows the user to replace the selected certificate with a new one within the notification of more IVDs.	Substitution Page



2.5.3.3 New EC certificate registration

This page allows the user to insert a new EC certificate.

The page is activated by clicking on the “Insert” button, present on the pages of search and visualization of the EC certificates list.

If the user inserts a certificate having “No. of certificate of the EC marking” and “Notified Body – Code- Name” which coincide with those of a certificate already present in data base, the system will ask the user to insert such a certificate as an extension of that one which already exists (see paragraph 2.5.3.6)

Home > In Vitro Diagnostic Medical Devices > EC certificates > Certificate Data ?

Certificate Data

Certificate Data

*Manufacturer: [Search](#)
[Detail](#)

*Notified Body Code-Name: [Search](#)

*No. of certificate of the EC marking:

*Issue Date: / /

Certificate Expiration Date: / /

*Annex according to which the device was certified:

*File containing the certificate: [Sfoglia...](#)
 (max size 2MB)

It recommends to use contained file size to facilitate consultation.

[Save](#) [Back](#)

Detail Fields

Field Name	Description
Manufacturer	Indication of the manufacturer of the IVD for which the certificate has been issued. To select a manufacturer it is necessary to click on the “Search” link; there will appear a look-up from which it is possible to make a search.
Notified Body – Code- Name	Indication of the code and name of the organization notified. This field cannot be edited. To select the code of the organization notified it is necessary to click on the “Search” link ; a look-up will appear from which it will be possible to search for the organization notified by code and name.
No of certificate of the EC marking	Identification number of the EC certificate. Such number cannot contain blank spaces.
Certificate issue date	Certificate issue date.



Field Name	Description
Certificate Expiration Date	Expiry date of the Certificate. This field is always mandatory, except if the user has selected the value: Annex IV – section 6 or Annex VI or Annex VII – section 5, in the field ‘Annex according to which the device was certified.’
Annex according to which the device was certified	Reference to the Annex in Legislative Decree number 332/2000 (Directive 98/79/EC), and related procedures, according to which the device was certified.
File to attach	A .pdf file to be attached containing the image of the EC certificate. To attach this file it is necessary to use the “Browse” button. There is a limit to the dimension of the .pdf file that can be attached to the IVD; for the maximum size allowed, refer to the corresponding value shown by the application.

Operations available:

Action	Description	Page Name
Save	Memorizes the information relative to the certificate inserted in the data base and comes back to the previous page	Certificates List Page
Back	voids the insertion and comes back to the previous page	Certificates List Page

2.5.3.4 EC certificate detail

Activated by the page “Certificates List”, selecting a certificate and clicking on the “Detail” button, the page allows the user to visualize, in non editable mode, the following detailed informations concerning a certificate

- the manufacturer of the device or devices for which the certificate has been issued
- the organization notified which issued the certificate
- the certificate number of the EC stamp
- the issue date
- the expiry date of the certificate
- the annex according to which the device has been certificated
- the file attached containing the image of the certificate

Moreover, if the certificate is associated with the medical devices, the page will give evidence of it, displaying the list of the devices connected.



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Home > In Vitro Diagnostic Medical Devices > EC certificates > Certificate Data ?

Certificate Data

Certificate Data

*Manufacturer: [Detail](#)

*Notified Body Code-Name:

*No. of certificate of the EC marking:

*Issue Date: / /

Certificate Expiration Date : / /

*Annex according to which the device was certified:

*File containing the certificate: [Img Certificate.pdf](#)

Connected devices list					
System progressive attributed to IVD	Manufacturer	Code assigned by the manufacturer (catalogue identifier)	Trade name and model	CND classifications	Device status
1159637	Manufacturer IVD	CODE 03	CODE REAGENT 03	W0103010299 - TEST PER EMOGLOBINA - ALTRI	L
1153087	Manufacturer IVD	Code reagent 01	NAME AND MODEL	W0103010299 - TEST PER EMOGLOBINA - ALTRI	C

[Back](#)

Operations available:

Action	Description	Page Name
Back	Comes back to the previous page	Certificates List Page



2.5.3.5 Editing of EC certificate

This page is activated by the page “Certifications List”, selecting a certificate and clicking on button “Edit”, allows the user to modify the data of the certificate which has no extension and no medical devices associated in the validated or published status or when it is associated to signed IVDs, but was set to be amended by an authorized office (Ministry)

If the selected certificate has medical devices associated, the manufacturer is not editable.

If the selected certificate is associated with IVD already signed, the user must use the off line signature process, that allows to sign data by using any electronic signature certificate issued by one of the certification providers, according to Directive 1999/93/CE, by click on the button “Off line sign”.

Certificate Data



Certificate Data

*Manufacturer: [Search](#)
[Detail](#)

*Notified Body Code-Name: [Search](#)

*No. of certificate of the EC marking:

*Issue Date: / /

Certificate Expiration Date: / /

*Annex according to which the device was certified:

*File containing the certificate: [Annulla](#)

It recommends to use contained file size to facilitate consultation.

Detail Fields

Field Name	Description
Manufacturer	Indication of the manufacturer of the IVD for which the certificate has been issued. To select a manufacturer it is necessary to click on the “Search” link; there will appear a look-up from which it is possible to make a search.
Notified Body Code-Name	Indication of the code and name of the organization notified. This field cannot be edited. To select the code of the organization notified it is necessary to click on the “Search” link; a look-up will appear from which it will be possible to search for the organization notified by code and name.
No. of certificate of the EC marking	Identification number of the EC certificate. Such number cannot contain blank spaces.
Certificate issue date	Certificate issue date.
Certificate Expiration Date	Expiry date of the Certificate. This field is always mandatory, except if the user has selected the value: Annex IV – section 6 or Annex VI or Annex VII – section 5, in the



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Field Name	Description
	field 'Annex according to which the device was certified.
Annex according to which the device was certified	Reference to the Annex in Legislative Decree number 332/2000 (Directive 98/79/EC), and related procedures, according to which the device was certified.
File containing the certificate	A pdf file to be attached containing the image of the EC certificate. To attach another file it is necessary to use the "Cancel" button. Then it is necessary to use the button "Browse" to individuate a new pdf file which is supposed to be attached.

Operations available:

Action	Description	Page Name
Save	Memorizes any changes to the certificate in the database. Activated only if there are no validated devices associated.	Certificates List Page
Off line signature	Allows the user to access the page of download of txt file containing data. Activated only if there are validated devices associated.	Sign file download page
Back	VOIDS the insertion and comes back to the previous page.	Certificates List Page



2.5.3.6 Extension/expansion registration for an existing EC certificate

Activated by the page “Certificates List”, selecting a certificate and clicking on the “Extend/Extension” button, the page allows the user to insert an extension of validity periods to an existent certificate or an expansion of the set of IVD covered by the certificate, if it has never been extended/expanded before, or if it has already been extended/expanded, and associates it with at least one device validated or published.

The page called is divided in two sections: in the first section, “Certificate Data Existing”, informations concerning the certificate in expiry are visualized in non editable mode; the second one, “Certificate of Extension Data”, gives the same informations which can be edited to allow the user to insert the data of the certificate of extension/expansion.

Moreover, if the certificate is associated with medical devices, the page will give evidence of it visualizing the list – with elements selected – of all the devices associated. Specifically, the devices in processing will be visualized as those devices already validated and published that need a new signature.

When selecting the elements, the user is offered to extend the association for all the IVD already associated with the certificate extended to that of extension. All the same the user will be able to exclude, deselecting them, one or more IVD, expressing thus a wish to exclude the fact that certificate of extension should be associated with IVD selected.

That is why, if the user has had a wish to extend the association to device validated, user must use the off line signature process, that allows to sign data by using any electronic signature certificate issued by one of the certification providers, according to Directive 1999/93/CE, by click on the button “Off line sign”.



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Certificate Data Existing						
		*Manufacturer: Manufacturer IVD				
		*Notified Body Code-Name: 0373 - ISTITUTO SUPERIORE DI SANITÀ				
		No.of certificate of the EC marking: IVD-01				
		Issue Date: 05 / 05 / 2014				
		*Certificate Expiration Date : 05 / 05 / 2019				
		*Annex according to which the device was certified: Direttiva 98/79/CE Allegato III sezione 6				
		*File containing the certificate: Img Certificate.pdf				

Certificate of Extension Data						
		*Manufacturer: Manufacturer IVD Detail				
		*Notified Body Code-Name: 0373 - ISTITUTO SUPERIORE DI SANITÀ				
		*No.of certificate of the EC marking: IVD-02				
		Issue Date: 01 / 06 / 2014				
		Certificate Expiration Date : 05 / 05 / 2019				
		*Annex according to which the device was certified: Direttiva 98/79/CE Allegato III sezione 6				
		*File containing the certificate: Img Expansion Certifi Sfoglia... (max size 2MB)				

It recommends to use contained file size to facilitate consultation.

Connected devices list						
System progressive attributed to IVD	Manufacturer	Code assigned by the manufacturer (catalogue identifier)	Trade name and model	CND classifications	Device status	Select
1159637	Manufacturer IVD	CODE 03	CODE REAGENT 03	W0103010299 - TEST PER EMOGLOBINA - ALTRI	L	☒
1153087	Manufacturer IVD	Code reagent 01	NAME AND MODEL	W0103010299 - TEST PER EMOGLOBINA - ALTRI	C	☒

Detail Fields

Detail Fields	
Field Name	Description
Manufacturer	Indication of the manufacturer of the IVD for which the certificate has been issued. To select a manufacturer it is necessary to click on the “Search” link; there will appear a look-up from which it is possible to make a search.
Notified Body Code-Name	Indication of the code and name of the organization notified. This field cannot be edited. To select the code of the organization notified it is necessary to click on the “Search” link; a look-up will appear from which it will be possible to search for the organization notified by code and name.
No. of certificate	Identification number of the EC certificate. Such number cannot contain blank spaces.



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of the EC marking	
Certificate issue date	Certificate issue date.
Certificate Expiration Date	Expiry date of the Certificate. This field is always mandatory, except if the user has selected the value: Annex IV – section 6 or Annex VI or Annex VII – section 5, in the field ‘Annex according to which the device was certified.’ The date of expiry of the certificate of extension/expansion, when present, can be only greater or equal to that of the certificate which must be extended.
Annex according to which the device was certified	Reference to the Annex in Legislative Decree number 332/2000 (Directive 98/79/EC), and related procedures, according to which the device was certified.
File containing the certificate	A pdf file to be attached containing the image of the EC certificate. To attach another file it is necessary to use the “Cancel” button. Then it is necessary to use the button “Browse” to individuate a new pdf file which is supposed to be attached.

Operations available:

Action	Description	Page Name
Save	The extension/expansion certificate is entered in the database and the selected devices are associated to it. Activated only if there are no validated devices in association.	Certificates List Page
Off line signature	Allows the user to access the page of download of txt file containing data. Activated only if there are validated devices in association.	Sign file download page
Back	VOIDS the insertion and comes back to the previous page.	Certificates List Page



2.5.3.7 Association of an EC certificate to a IVD

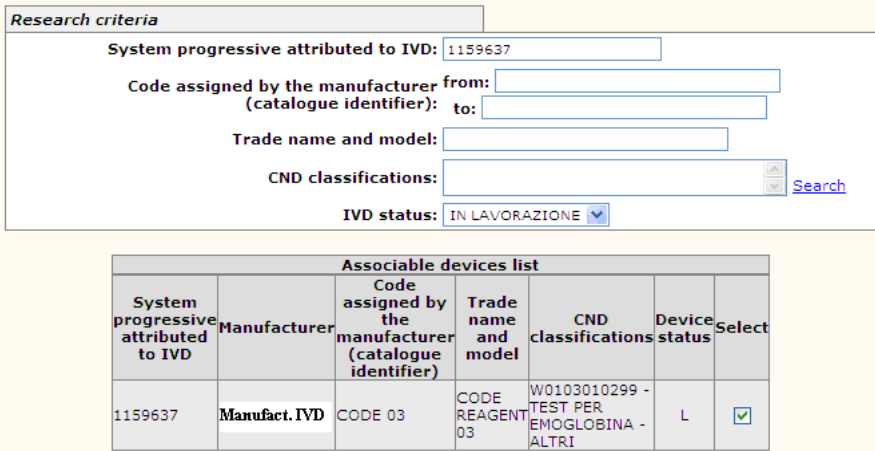
This page presents itself in the form of a lookup and allows the search and association of the medical devices to CE certificate selected. It gets activated by clicking on the button 'Associate to IVD' present on the 'certificates List' page.

It won't be possible to associate an expired certificate to a medical device

In the upper part of the page there are the search fields which should be compiled (it is necessary to define at least one search criterion) in order to get the IVD list from which the user will be able to select those that must be associated to the certificate. The medical devices that it is possible to associate are those coming from the same Manufacturer to whom the selected certificate was issued.

In the lower part of the page the list is displayed – with selectable elements – of the IVD associable coherent with the search criteria defined.

Whenever the user selects the published devices for the association, complete the operation using "Confirm" button.



Research criteria

System progressive attributed to IVD:

Code assigned by the manufacturer from: to:

Trade name and model:

CND classifications: [Search](#)

IVD status:

Associable devices list						
System progressive attributed to IVD	Manufacturer	Code assigned by the manufacturer (catalogue identifier)	Trade name and model	CND classifications	Device status	Select
1159637	Manufact. IVD	CODE 03	CODE REAGENT 03	W0103010299 - TEST PER EMOGLOBINA - ALTRI	L	☒

Page 1 of 1

Fields detail

Field Name	Description
System progressive attributed to IVD	It is possible to search on the base of the identification code (progressive of the system) attributed to the IVD
Code assigned by the manufacturer (identifier catalogue) from/to	It is possible to indicate the interval of the codes into which the univocal code attributed by the IVD manufacturer is included.
Trade Name and	It is possible to specify the commercial name (or the initial part) of the IVD.



Field Name	Description
Model	
CND Classification	It is possible to search on the base of the National classification of the IVD. This field cannot be edited. To select a CND classification the user should click on the 'Search' link; a look-up will open from which it is possible to search a CND classification by code or by description or by its part.
IVD Status	It is possible to search on the base of the status of the IVD (in progress, consolidated, published) .

Operations available

Action	Description	Page Name
Search	Activates a search with parameters set up and displays the IVD list coherent with these parameters.	Same
New search	Clears the search criteria previously defined.	Same
Confirmation	Closes the look up page, associates the device or the devices selected to the certificate. Activated only if there are no validated devices in association.	Certificates List Page
Cancel	Closes the look up page without saving the operations performed by the user.	Certificates List Page

2.5.3.8 Replacing certificates within the IVD notification

This page allows the user to replace a certificate within the notification of more IVDs simultaneously, while keeping the history of the associations in the Data Bank of Medical Device system.

The user may look for a certificate and activate the replacement feature. The "Replace" button will be active only if the certificate that has been selected is connected to at least one IVD while the action is being performed. In that case, the form that will be displayed will contain the details of the certificate that has been selected, the IVDs that are connected to it (along with their status) and a button allowing the user to look for the new certificate to be replaced within the IVD notification.

If the **new certificate selected** for the substitution is expired, it won't be possible to confirm the operation.

Once the new certificate is found, and the IVDs to be replaced have been selected, the operation needs to be signed by means of offline signing procedure, if at least one IVD amongst those that have been selected is in the Validated/Published status.



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If the user does not select all the IVDs that belong to one group of similar IVDs, the system will warn the user about the fact that the integrity of the initial group cannot be preserved if they proceed with that operation.

The function can be used to replace an EC certificate recorded in the database, even if it is still valid, which is associated with medical devices with a new certificate that has been issued by a Notified Body to which the manufacturer has decided to address a request.

Note: the extension/expansion feature (see paragraph 2.5.3.6) does not allow the user to change the ON and the MANUFACTURER within the new certificate (thus keeping those from the first certificate): as a result, the only way to replace the IVD connected to the former certificate with the new certificate is to use this feature;

Certificate reference replacement

Certificate Data

Manufacturer:

Notified Body Code-Name:

No. of certificate of the EC marking:

Issue Date: / /

Certificate Expiration Date: / /

Annex according to which the device was certified:

File to attach: [Img Certificate.pdf](#)

Search New Reference EC

List of devices associated with this certificate:

Connected devices list						
System progressive attributed to IVD	Manufacturer	Code assigned by the manufacturer (catalogue identifier)	Trade name and model	CND classifications	Device status	Select
1159637	Manufacturer IVD	CODE 03	CODE REAGENT 03	W0103010299 - TEST PER EMOGLOBINA - ALTRI	L	☒
1153087	Manufacturer IVD	Code reagent 01	NAME AND MODEL	W0103010299 - TEST PER EMOGLOBINA - ALTRI	C	☒

Operations available

Action name	Description	Recalled page name
Search New reference EC	Allows to access the search look up of the new certificate to be replaced within the IVD notification.	Certificate search look up
Confirmation	Closes the look up page, associates the device or the devices selected to the certificate. Activated only if there are no validated devices in	Certificates List Page



Action name	Description	Recalled page name
	association.	
Offline signing	Allows the user to save the information entered and redirects him to the download page of the .txt file containing the data of the new certificate and of the associated IVDs to be signed locally. Activated only if there are validated devices in association.	Signature file download
Back	Cancels the certificate replacement operation and takes the user back to the previous page.	Certificates List

2.5.3.8.1 Search look up of the new certificate replacing the previous one

This page appears as a look up and allows the user to look for the new certificate replacing the one that had been selected within the IVDs notification. It is activated by clicking the “Search New Certificate” button at the certificates replacement page within the IVD notification (see previous paragraph).

As already mentioned, If the **new certificate selected** for the substitution is expired, it won't be possible to confirm the operation.

?

Sostituzione EC marking certification

No. of certificate of the EC marking:

Certificate Expiration Date : / /

Notified Body: [Search](#)

[Reset](#)

Detail Fields

Field Name	Description
No. of certificate of the EC marking	Identification number of the EC certificate.
Certificate Expiration Date	Expiry date of the Certificate.
Notified Body	Indication of the code and name of the organization notified.



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Field Name	Description
	This field cannot be edited. To select the code of the organization notified it is necessary to click on the "Search " link; a look-up will appear from which it will be possible to search for the organization notified by code and name.

Operations available:

Action name	Description	Recalled page name
Search	Starts the certificates search that is consistent with the parameters that have been set.	Same.
New Search	Clears the search parameters previously set.	Same.
Confirmation	Closes the look up and takes the selected certificate back to the recalling replacement page. Verifies that the selected certificate isn't expired. If it's expired, the procedure will be stopped.	Certificate replacement page.
Cancel	Closes the look up page without saving the operations performed by the user.	Certificate replacement page.



2.5.4 Menu Item “Multiple Notifications of similar IVDs”

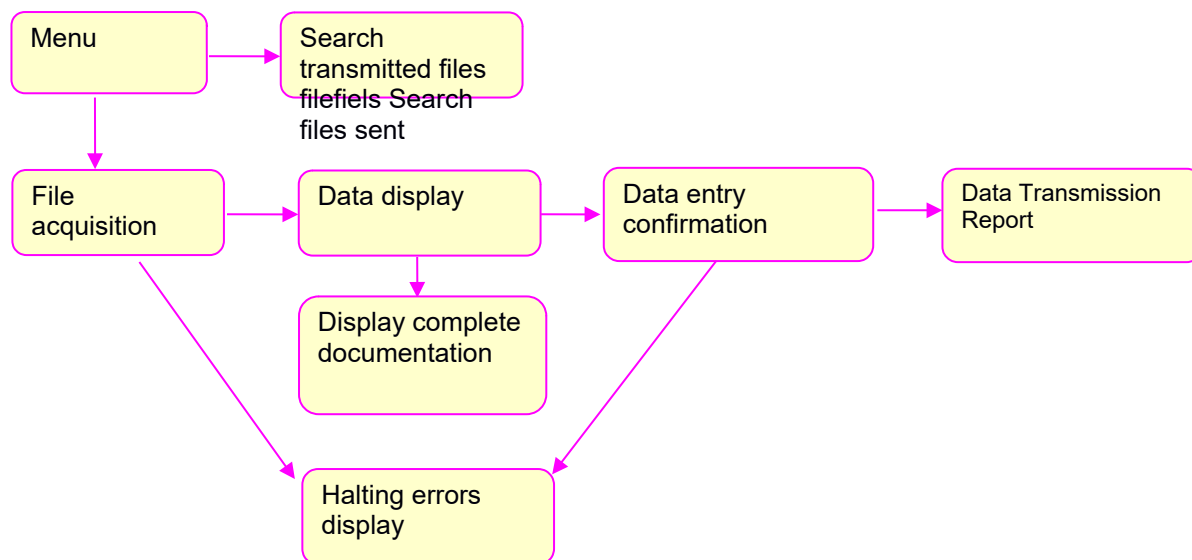
The multiple notification of similar medical devices makes the ‘similar medical devices’ registration process easier. It allows the user to transmit to the database a file – previously signed in offline mode – containing a list of catalogue identifiers, with their respective descriptions (trade name and model), related to products which need to be notified as similar to a device already registered in the database.

The file acquisition procedure consists of the following steps:

1. Upload of the signed file (CSV or XML format)
2. Display of the data which must be transmitted / errors encountered in the verification phase
3. Confirmation of the data (if no errors are present)
4. Notification report showing the progressive codes assigned by the system to the acquired medical devices

Successfully transmitted and acquired files will become searchable through database interrogation. If necessary, every file can be retrieved with its ‘notification report’ receipt.

Flow Chart:





How to set up the files in XML or CSV format:

General indications

Every file can be in one of the accepted formats: CSV (in which the “,” symbol is used as a value separator ;) or XML. The specific data that must be entered into the file refer to:

- progressive number of the medical device used as a reference to acquire similar products;
- a list of the catalogue identifiers, with their respective descriptions (trade name and model), specific to similar devices

The values of the reference medical devices already present in the system, including the label file but without the optional measurement, will be used for the remaining data.

It is allowed to enter in the same file different groups of similar devices to already notified products. In this case, the same structure must be provided for every group (reference medical device – list of similar products).

Independently from the number of the above-mentioned groups, there is a limitation on the number of rows, and consequently of devices, which can be added to each file. This limit is shown on the ‘file acquisition’ page. When processing the file, the system checks the number of rows present, halting the acquisition when the threshold is crossed.

CSV format: each row of the .csv file contains 3 data separated by the ; **symbol** (semicolon). The first information refers to the ‘progressive number of the reference device’, while the second and third respectively refer to the ‘catalogue identifier’ and ‘description’ (trade name and model) of the similar dm. Generally, it is required to add in the file a number of rows equal that are to the number of similar medical devices which are to be notified. **In each row, the first data is the ‘progressive number of the reference device’.** It is possible to add more than one list of similar devices, each one assigned to its respective reference medical device. The following example refers to the case in which 2 groups of similar devices are to be notified with reference to 2 different medical devices already present in the database with the following progressive numbers: 100 e 101

Example.csv

```
100;catalogue identifier 1;description 1
100;catalogue identifier 2;description 2
100;catalogue identifier 3;description 3
100;catalogue identifier 4;description 4
100;catalogue identifier 5;description 5
101;catalogue identifier 6;description 6
101;catalogue identifier 7;description 7
101;catalogue identifier 8;description 8
101;catalogue identifier 9;description 9
101;catalogue identifier 10;description 10
```



Excel can be used to prepare the CSV file. If this is the case, after adding the rows, the file should be saved as: "CSV (delimited by list separator)". While setting up the file, it is not required to enter column headers in the first row.

XML format: in the XML structure, which uses Tags, each medical device, and its list of similar medical devices, must be added in a structure identified by the tag pair: **<dm_collection>** , **</dm_collection>**. For example, to notify two lists of medical devices similar to reference devices already notified, it is necessary to add in the xml file two pairs of the above-mentioned tags, one representing the first list of similar devices, the other representing the second list. For each list, the 'progressive number of the reference device' (**tag: cod_dm_origine**) will have to be entered together with the catalogue identifier (**tag: dm cod**) and description (**tag: desc**) of each similar device which will be registered.

Example.xml:

```
<?xml version="1.0" encoding="ISO-8859-1" ?>
<dm_simili xmlns=http://www.eng.it/rdm/NotificheMultiple_dmSimili
  xmlns:xsi=http://www.w3.org/2001/XMLSchema-instance">
  <dm_collection>
    <cod_dm_origine>100</cod_dm_origine>
    <dm cod="catalogue identifier 1" desc="description 1" />
    <dm cod="catalogue identifier 2" desc="description 2" />
    <dm cod="catalogue identifier 3" desc="description 3" />
    <dm cod="catalogue identifier 4" desc="description 4" />
    <dm cod="catalogue identifier 5" desc="description 5" />
  </dm_collection>
  <dm_collection>
    <cod_dm_origine>101</cod_dm_origine>
    <dm cod="catalogue identifier 6" desc="description 6" />
    <dm cod="catalogue identifier 7" desc="description 7" />
    <dm cod="catalogue identifier 8" desc="description 8" />
    <dm cod="catalogue identifier 9" desc="description 9" />
    <dm cod="catalogue identifier 10" desc="description 10" />
  </dm_collection>
</dm_simili>
```



2.5.4.1 File acquisition

This page opens when clicking on the menu item “Multiple Notifications of Similar IVDs - > File transmission”. It allows to acquire specific data related to devices declared similar to products already registered into the database. To be suitable for notification, the file must be digitally signed, using qualified electronic signature, in offline mode.

Follow the steps below:

- Browse for the signed file from your computer having specified the file format (CSV, XML);
- Choose whether or not to register on the repertoire the codes of the products under acquisition;
- Click on ‘Next’ to start checking the data contained in the selected file

Home > In Vitro Diagnostic Medical Devices > Medical Device (IVD) > Multiple acquisition similar IVDs

Multiple acquisition similar IVDs

The multiple acquisition feature allows to transmit to the Ministry of Health a signed file containing the catalogue identifiers and descriptions (trade name and model) related to IVDs similar to a device already present in the database. Both text format (*.csv) and XML format (*.xml) following the [layouts](#) set by the Ministry are accepted. A single file can contain a maximum of 200 IVDs

The file acquisition procedure consists of the following steps:

1. Upload of the signed file (CSV or XML format)
2. Display of the data which must be transmitted / possible errors encountered in the verification phase
3. Confirmation of the data (if no errors are present)
4. Notification report showing the progressive codes assigned by the system to the acquired medical devices

1. Upload the file

2. Display data/errors

3. Confirmation

4. Report

1. Uploads the file with the similar IVDs

Specify the file format (CSV or XML);
 Browse for the signed file, previously signed [offline](#), containing the catalogue identifiers and descriptions of the similar IVDs which must be acquired;
 Select the checkbox "Register the codes on the repertoire" if the new catalogue identifiers are to be registered in the national Repertory;
 Click on the "Next" button to start the processing...

Specific data of similar IVDs

* File Type: CSV ⓘ

* Similar IVDs file: Caso 01 - 1 IVD 1 g Sfoglia... ⓘ

Register the codes on the repertoire: ☐ ⓘ

* Mandatory data

Next

*Fields Description*

Field Name	Description
File type (drop-down list)	Type of the file containing the codes to be acquired (xml or csv format)
Similar IVDs file (text field)	Xml/ csv file, signed offline, containing the codes to be acquired
Register the codes on the repertoire (check box)	This checkbox allows to choose whether or not to register on the repertoire the codes of the products under acquisition

Operations available:

Activity	Description	Page Opened
Browse	Browse the system folders and select the file to be processed	'File Selection' pop-up
Next	The signed file is acquired and its contents verified	Data/errors display

2.5.4.2 Display of the data

This page opens when the contents of the file to be acquired have been verified and accepted as valid for registration. The checking procedure can be started from the 'File Acquisition' window clicking on the 'Next' button.

This page shows some important data for every reference medical device present in the upload file (such as the IVD manufacturer, its catalogue identifier and description, some data pertaining to its classification, its label file). It shows also the product codes list and the descriptions of the similar devices to be acquired.

To access the contents of the label file, use the link 'show label'.

If necessary, the complete documentation (label, instruction of use...) of the reference device can be examined using the **associated link**.

The list of reference devices can be browsed using the navigation bar (previous  / next  buttons).

If a reference device is already associated with a group of similar IVDs, an (*) will be displayed next to its progressive number. In this case, the medical devices acquired from a file and associated to this reference device will be put in the already existing group.

If the uploaded file contains information already present in the database, a warning will be shown for the rows (product code, description) containing the duplicate. If product codes and descriptions already registered in the database are found during the verification phase, they will be marked with



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a red warning (▲) and will be subsequently ignored during the registration phase. Entries with the same catalogue identifier of an already registered product, but with a different description (trade name and model), will be marked with a yellow warning (▲), allowing the user to decide whether to register the product or not.

Click on 'Next' to go the 'Confirm registration' page. To quit the registration procedure and go back to the 'File acquisition' page, click on the 'Back' button

Multiple acquisition similar IVDs

1. Upload the file 2. Display data/errors 3. Confirmation 4. Report

File Name: Caso 01 - 1 IVD 1 gruppo tutti OK.csv

2. Display of the data which must be transmitted

Verify that the data to be notified are correct.
If the uploaded file contains more groups of similar medical devices, to verify the data of each group, select the progressive of the reference device using the (previous button) and (next button)

Click on "next" to proceed with the acquisition or click on "back" to cancel the operation.

Group 1/2 - Progressive of the reference IVD: 1159613

1159613 (*) 1159614 (*)

Complete documentation

Code Manufacturer: Code 00

Trade Name and Model: IVD-A code 00

Manufacturer: Manufacturer IVD

System Progressive: 1159613

33683 - A collection of reagent(s) and other associated solutions and materials used to perform an assay to measure the concentration of

GMDN Code: carbonic anhydrase protein molecules in serum and other body fluids. Measurements of carbonic anhydrase B and C aid in the diagnosis of abnormal haemoglobin metabolism.

CND Code: W01010199 - ENZIMI - ALTRI

EDMA Code: 11020105 - Cholesterol

SIMILAR IVDs UNDER ACQUISITION FOR THIS GROUP:

Code Manufacturer	Trade Name and Model
Similar IVD-A - code 01	Name and Model A01
Similar IVD-A - code 02	Name and Model A02
Similar IVD-A - code 03	Name and Model A03

Back Next



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Home > In Vitro Diagnostic Medical Devices > Medical Device (IVD) > Multiple acquisition similar IVDs

Multiple acquisition similar IVDs

1. Upload the file 2. Display data/errors 3. Confirmation 4. Report

File Name: Caso 01 - 1 IVD 1 gruppo tutti OK.csv

2. Display of the data which must be transmitted

Verify that the data to be notified are correct.

If the uploaded file contains more groups of similar medical devices, to verify the data of each group, select the progressive of the reference device using the (previous button) and .

Click on "next" to proceed with the acquisition or click on "back" to cancel the operation.

Group 2/2 - Progressive of the reference IVD: 1159614

1159613 (*) 1159614 (*)



Complete
documentation

Code Manufacturer: code 00B
Trade Name and Model: IVD-B code 00B
Manufacturer: Manufacturer IVD
System Progressive: 1159614

GMDN Code: 33683 - A collection of reagent(s) and other associated solutions and materials used to perform an assay to measure the concentration of carbonic anhydrase protein molecules in serum and other body fluids. Measurements of carbonic anhydrase B and C aid in the diagnosis of abnormal haemoglobin metabolism.

CND Code: W01010199 - ENZIMI - ALTRI

EDMA Code: 11020105 - Cholesterol

SIMILAR IVDs UNDER ACQUISITION FOR THIS GROUP:

Code Manufacturer	Trade Name and Model
Similar IVD-B - code 01	Name and Model B01
Similar IVD-B - code 02	Name and Model B02
Similar IVD-B - code 03	Name and Model B03
Similar IVD-B - code 04	Name and Model B04
Similar IVD-B - code 05	Name and Model B05

*Fields Description*

Field Name	Description
Trade name (alphanumeric)	Trade name and model of the reference IVD
Manufacturer's code	(alphanumeric) Product code assigned by the manufacturer to the reference IVD (catalogue identifier)
Manufacturer (alphanumeric)	Name of the Manufacturer of the reference IVD
System Progressive (numeric)	Unique identification number assigned to the reference IVD
GDMN code (alphanumeric)	GDMN nomenclature (code and description) assigned to the reference IVD
CND code (alphanumeric)	CND classification (description and code) assigned to the reference IVD
EDMA code (alphanumeric)	EDMA classification (code and description) assigned to the reference IVD
Label (link)	Link to the pdf label
Original IVD Group number (numeric)	List of the system progressive numbers of every IVD used as the reference IVD for groups of similar devices
Number of similar IVDs in the group	Number of IVD similar to the selected reference IVD present in the upload file
IVD to be associated with an original IVD	List of the IVD to be associated with the selected reference IVD. The following information is shown for every medical device: - Warning (optional) - Manufacturer's code (mandatory) - Trade name (mandatory)

Operations available:

Action Name	Description	Page Opened
< (previous)	Shows the previous item in the navigation bar	Same page
> (next)	Shows the following item in the navigation bar	Same page
Back	Goes back to the previous page cancelling the acquisition procedure	File acquisition
Next	Goes on with the acquisition procedure	Data entry confirmation
Label	Shows the pdf file with the label of the selected reference device	Popup
Complete	Allows to examine the complete documentation	Complete documentation



documentation	(label, instructions of use, etc), of the reference medical device.	

2.5.4.3 Data entry confirmation

Through this page it is possible to start the registration of the uploaded similar IVD in the database. For the purposes of notification, these medical devices, characterised by a specific catalogue identifier and description (trade name and model), will inherit the remaining data, including the label file, from the device chosen as a reference (with the exception of the optional measurement).

If some non-halting warnings (indicating that some of the catalogue identifiers in the file are already registered in the database, although with a different description) have been detected during the verification phase, the user can decide whether or not to enter also these codes; a decision must be taken by clicking on the corresponding radio button

Click on 'Next' to proceed with the registration process or click on the 'Back' button to cancel and go back to the 'File Acquisition' page.

The IVD which will be registered in the database will also be registered on the repertoire if the corresponding option has been selected ('File acquisition' page - check: register the codes on the repertoire)

If the medical device chosen as a reference doesn't already belong to a group of similar IVDs (in which case every similar device acquired will be included in the same group), a new group of medical devices made up of the IVD chosen as a reference and all the similar devices acquired will be created by the system.



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Home > In Vitro Diagnostic Medical Devices > Medical Device (IVD) > Multiple acquisition similar IVDs

Multiple acquisition similar IVDs

1. Upload the file 2. Display data/errors 3. Confirmation 4. Report

File Name: Caso 01 - 1 IVD 1 gruppo tutti OK.csv

3. Confirm the similar IVDs registration

The confirmation starts the registration of the IVDs in the database/repertoire.
If the medical device chosen as a reference doesn't already belong to a group of similar IVDs (in which case every similar device acquired will be included in the same group), a new group of medical devices made up of the IVD chosen as a reference and all the similar devices acquired will be created by the system.
After the operation has been completed, the system reports the identification code of each similar IVD.

Click on the "Next" button to confirm the registration
Click on "Back" to cancel the operation

[Back](#) [Next](#)

Fields Description

Field Name	Description
Acquisition of duplicate IVD (radio button)	This radio button allows to choose whether or not to enter the catalogue identifiers already present in the database with a different description. Visible <u>only</u> if the uploaded file contains information already present in the database.

Operations available:

Action Name	Description	Page Opened
Next	it goes on with the acquisition procedure, registering in the database all the similar IVD present in the file. If the corresponding option has been selected, the IVD with a duplicate product code – but with a different description (trade name and model) – will also be acquired. In any case, the IVD whose product code and description are already present in the database won't be registered. If the corresponding option has been selected, the system will register the IVD on the repertoire (step 1: 'File acquisition – check "Register the codes on the repertoire").	Data Transmission Report
Back	Goes back to the previous page cancelling the entry procedure	File acquisition



2.5.4.4 Data Transmission Report

This page opens after the acquired IVD have been registered in the database. The report shows the progressive number assigned by the system to every registered device. If the corresponding option has been selected, the devices registered on the repertoire will be shown with /R following the progressive number.

The status of these devices will be 'validated', waiting to be published.

This page allows also to export the data loading report, a CVS or XML file, containing the list of the acquired product codes and descriptions with the number of the corresponding database/repertoire. The file will also contain those catalogue identifiers not acquired due to (yellow/red) system warnings.

Click on 'Done' to complete the acquisition process.

Home > In Vitro Diagnostic Medical Devices > Medical Device (IVD) > Multiple acquisition similar IVDs

Multiple acquisition similar IVDs

1. Upload the file 2. Display data/errors 3. Confirmation 4. Report

File Name: Caso 01 - 1 IVD 1 gruppo tutti OK.csv

4. Transmission Report

The data have been successfully registered,
a progressive number has been assigned to each medical device. The progressives are shown in the table below.
Clicking on icon  it is possible to download the 'Notification Report' receipt, a CSV or XML file containing both a list of the similar devices registered with the corresponding database/repertoire numbers and a list of the catalogue identifiers not acquired (if any) due to (yellow/red) system warnings.
Click on the 'Done' button to go back to the first page of the acquisition procedure of similar IVDs

PROCESSING REPORT

SIMILAR IVDs REGISTERED FOR THE REFERENCE IVD N°: 1159613 - IVD-A code 00

Code Manufacturer	Trade Name and Model	System Progressive
Similar IVD-A - code 01	Name and Model A01	1159652
Similar IVD-A - code 02	Name and Model A02	1159653
Similar IVD-A - code 03	Name and Model A03	1159654



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SIMILAR IVDs REGISTERED FOR THE REFERENCE IVD N°: 1159614 - IVD-B code 00B		
Code Manufacturer	Trade Name and Model	System Progressive
Similar IVD-B - code 01	Name and Model B01	1159655
Similar IVD-B - code 02	Name and Model B02	1159656
Similar IVD-B - code 03	Name and Model B03	1159657
Similar IVD-B - code 04	Name and Model B04	1159658
Similar IVD-B - code 05	Name and Model B05	1159659

[Done](#)

Fields Description

Field Name	Description
Reference IVD (numeric)	Identification code of the IVD used as a reference for the group (system progressive)
Manufacturer's (alphanumeric)	Product code assigned to the medical device by the manufacturer (catalogue identifier)
Trade name and model	Trade name and model of the IVD
System Progressive (numeric)	Identification code assigned by the system to the IVD. If /R appears next to the identification number

Request download file 'Notification Report':

Select the format of the file to be downloaded:

☒ CSV Format
 ☐ XML Format

[Download](#)
[Cancel](#)



Notification Report (csv format)

A	B	C	D	E	F
reference ivd	manufacturer code	denomination	aquired	warning	system progressive
1159613	Code00	IVD-A code00			
1159613	Similar IVD-A - code 01	Name and Model A01	Y		1159652
1159613	Similar IVD-A - code 02	Name and Model A02	Y		1159653
1159613	Similar IVD-A - code 03	Name and Model A03	Y		1159654
1159614	Code 00B	IVD-B code 00B			
1159614	Similar IVD-B - code 01	Name and Model B01	Y		1159655
1159614	Similar IVD-B - code 02	Name and Model B02	Y		1159656
1159614	Similar IVD-B - code 03	Name and Model B03	Y		1159657
1159614	Similar IVD-B - code 04	Name and Model B04	Y		1159658
1159614	Similar IVD-B - code 05	Name and Model B05	Y		1159659

Fields Description

Field Name	Description
Reference IVD (numeric)	Identification code of the IVD used as a reference for the group (system progressive)
Manufacturer's code (alphanumeric)	Product code assigned to the IVD by the manufacturer (catalogue identifier)
Denomination	Trade name and model of the IVD
Acquired	Flag (Y/N) Y - the medical device has been registered in the database / repertoire N - the medical device has not been registered in the database / repertoire
Warning	Warnings shown by the system while processing the file. allowed values: not present / WG / WR not present - no alert; the medical device has been registered in the database / repertoire WG - there is a IVD with the same manufacturer's code, but different description (trade name and model), registered in the database / repertoire WR - there is a IVD with the same manufacturer's code and description registered in the database / repertoire
System Progressive (numeric)	Identification code assigned to the IVD (valid only for those devices which have been registered in the database and that are recognized by /R that appears next to the identification number)

*Operations available:*

Action Name	Description	Page Opened
Export	Downloads a CSV/XML file containing the list of the product codes and descriptions registered in the database, with the progressive number assigned by the system. The file contains also any catalogue identifier not acquired due to (yellow/red) system warnings.	Same page
Done	Completes the acquisition process	File acquisition

2.5.4.5 Halting errors display

This page opens if the system detects halting errors during the verification phase. The entire file will be discarded by the system even if some of the product codes and descriptions have got through the verification.

If possible, to facilitate reading errors will be grouped based on reference medical device.

Click on 'Back' to go back to the 'File acquisition page'

Shown below are shown all the possible halting errors

File structure verification:

- Error S01: Wrong signed file format
- Error S02: The signer certificate has expired
- Error S03: The signer certificate is not trusted
- Error S04: The structure of the file does not respect the expected layout (xml/csv)

File contents verification:

- Error B092: The medical device chosen as a reference to manage similar IVDs is not present in the database;
- Error B289: the user is not allowed to notify medical devices for registering/manufacturing company specified in the reference medical device;
- Error B172: The medical device chosen as a reference to manage similar IVDs is not in the Validated or Published status;
- Error B291: For the medical device chosen as a reference have been found invalid information

*Generic errors:*

- A system error has occurred. Couldn't complete the file acquisition procedure.

Home > In Vitro Diagnostic Medical Devices > Medical Device (IVD) > Multiple acquisition similar IVDs

Multiple acquisition similar IVDs

1. Upload the file 2. Display data/errors 3. Confirmation 4. Report

File Name: Caso 01 - 1 IVD 1 gruppo tutti OK.csv

ERROR IN THE MULTIPLE ACQUISITION OF SIMILAR IVDs

CAUTION! The following halting errors have been detected. It's not possible to proceed with the file acquisition procedure. Correct the errors and upload the signed file again.

* Reference IVD N° 1159612:
Error B092 - The medical device chosen as a reference to manage similar medical device is not present in the database;

[Back](#)

Fields Description

Field Name	Description
Reference IVD N° (numeric)	Identification code assigned to the IVD used as a reference for a group of similar devices (system progressive)
Error code (alphanumeric)	The code of the error detected during file verification
Error description (alphanumeric)	Description of the error detected during file verification
Manufacturer's (alphanumeric)	Catalogue identifier present in the duplicate row
DM description (alphanumeric)	Description (trade name and model) of the product (catalogue identifier) present in the duplicate row

Operations available:



Action Name	Description	Page Opened
Back	Quits the acquisition procedure interrupted due to halting errors	File acquisition

2.5.4.6 Search transmitted files

This page opens when clicking on the menu item “Multiple notifications of similar IVDs - > Search transmitted files”. It allows the user to search successfully transmitted and acquired files, and also to download the ‘notification report’ receipt.

It is possible to filter the search by:

transmission date of the file;

name of the transmitted file (partial text search is allowed);

When the parameters have been defined, start the search.

The system will list all the transmitted files, if any, based on the selected parameters ...

For each file, the following information will be displayed:

- Transmission date;
- Transmitted file;
- Notification report (csv / xml format).

It is possible to download both the transmitted files and the notification reports.



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Home > In Vitro Diagnostic Medical Devices > Medical Device (IVD) > Multiple acquisition similar IVDs

Search transmitted files

This feature allows to search the files containing the notifications of similar IVDs successfully transmitted and acquired by the system. It is possible to filter the search setting one or more of the following parameters: file transmission date, name of the transmitted file. When the parameters have been defined, start the search... As a result, the system will list all the transmitted files (if any), allowing the user to download both the transmitted files and the notification reports.

Search

Transmission date: from 04/06/2014 to 04/06/2014

File Name:

Search New search

Transmission date	File Name	Report file (Csv / Xml)
04/06/2014	Caso 01 - 1 IVD 1 gruppo tutti OK.csv	

Detail Fields

Field Name	Description
from - to	Time interval containing the date when the multiple notifications file has been transmitted
File name	Name of the transmitted file

Operations available

Action Name	Description	Page Opened
Search	Start searching with the selected parameters	
New search	Clears the defined parameters (if any)	Same page.
Download 'Multiple notifications file'	Downloads the multiple notifications file	File Download
Download 'Report'	Downloads the file acquisition report, available in csv / xml format	File Download



2.5.5 “Documentation” Menu option

2.5.5.1 View support's documents

This page, activated by the "Documentation > See Documentation" menu option, allows the user to view and download the support's documents

Note: for users of the features of mass uploading of class medical devices (not IVD) are also available documents *Data and flow check with annex* and *formatted XML schema*

Documentation

TECNICAL

In the section below there is the **User manual** to support the use of the System.

For users of the features of **mass uploading of data** are also available documents **Data and Flow Check** with its **annexes** and **formatted XML Schema**.

Technical		
Document	Valid from	
User Manual Manufacturer Profile	17/10/2011	Open
Data and Flow Check document	26/03/2010	Open
Attachments (Data and Flow Check document)	26/03/2010	Open
Xml schema	26/03/2010	Open

TECNICA

Nella sezione sottostante e' presente il **Manuale Utente** di supporto all'utilizzo del Sistema.

Per gli utilizzatori delle funzionalita' del **Caricamento Massivo** sono presenti inoltre i documenti inerenti a **Dati e controlli flussi** con relativi **allegati** e **Schema XML**.

Tecnica		
Document	Valid from	
Manuale Utente Profilo Fabbricante	17/10/2011	Open
Documento Dati e Controllo Flussi	26/03/2010	Open
Allegati (Documento Dati e Controlli Flussi)	26/03/2010	Open
Tracciato xml	26/03/2010	Open

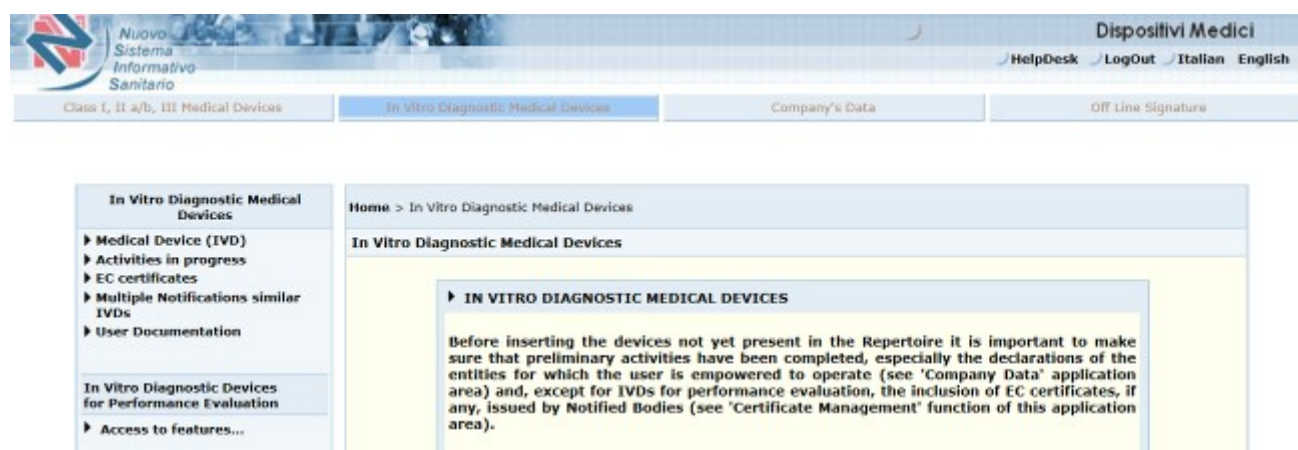
Operations available:

Action name	Description	Recalled page name
Open	Allows to open or download the corresponding file	



2.6 Detailed description of the functional Area “IVDs PE”

Access to the functional area “In vitro medical-diagnostic devices for performance evaluation” takes place via the main “In vitro medical-diagnostic devices” section and provides functions and support for first notification and searches in the archive of notifications already made, for the above type of medical devices..



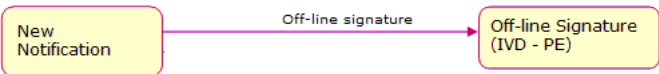
Before entering the devices, please check that preliminary activities have been completed, specifically the declarations by subjects qualified to operate (see application area “Company Data”)



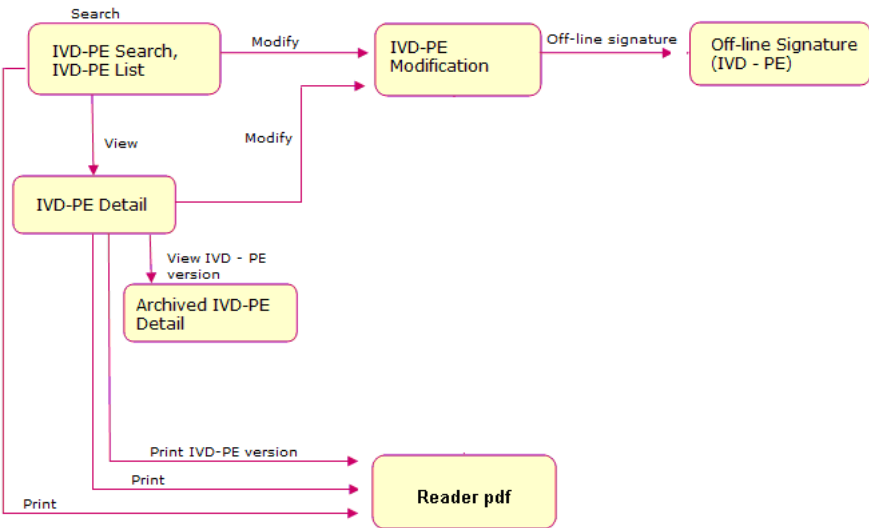
2.6.1 “In vitro medical-diagnostic devices for performance evaluation” (IVD - PE) – Planned functions

Screen shot flow:

“New Notification”



“Search (in archive)”





2.6.1.1 Notification of an IVD-PE device

To notify a new in vitro device predominantly for performance evaluation, before placing it on the market for sale, select the form “New notification”. The prepared page allows the declaring party to provide the Ministry of Health with the relative information; specifically, it allows specific information about the device and information about the performance evaluation to be acquired. Before entering, it may be useful to check that the information has not already been notified, by using the “search” form.

On completing entering the data provided, they must be signed in offline mode (“off-line signature”)



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New Notification
Search

first you need to proceed with the initial declaration of the persons who in various ways are used in the notification of In vitro medical-diagnostic device for performance evaluation

To communicate the data regarding the performance evaluation of an in vitro device, carry out the fields below. On completion, digitally sign the data using one of the modes foreseen

INFORMATION ABOUT DEVICE

Trade name and model:*

User role:*

Company that entered the Medical devices:*

MINISTERO DELLA SALUTE

Manufacturer:*

Agent

EC Classification (D.L.vo n. 332/2000):*

EDMA Classification:*

Label:*

CARRYING OUT OF EVALUATION

Period:*

FROM:

TO:

Territorial environment:*

☐ Italy

☐ ABRUZZO
☐ BASILICATA
☐ CALABRIA
☐ CAMPANIA
☐ EMILIA ROMAGNA
☐ FRIULI VENEZIA GIULIA
☐ LAZIO

☐ LIGURIA
☐ LOMBARDIA
☐ MARCHE
☐ MOLISE
☐ PIEMONTE
☐ PROV. AUTON. BOLZANO
☐ PROV. AUTON. TRENTO

☐ PUGLIA
☐ SARDEGNA
☐ SICILIA
☐ TOSCANA
☐ UMBRIA
☐ VALLE D'AOSTA
☐ VENETO

☐ Overseas

Sign Off Line
Cancel

*Field Details*

Name of Field	Description
INFORMATION ABOUT THE DEVICE	
Commercial name and model	Device name and model allocated by the manufacturer (Mandatory data)
Name of Field	Description
Role of declarant with regard to the device	Indication of the role carried out by the declarant with regard to the device. The declarant can take on the following roles: • Manufacturer • Agent • Other subject appointed by manufacturer. (Mandatory data)
Company that has entered the device	Declarant company registered in the list of companies – general data of declarant (field cannot be edited, Mandatory)
Manufacturer	Name of device manufacturer (field cannot be edited, Mandatory). If the item “manufacturer” has been selected as the declaring company’s role with regard to the device, the system sets the company entered by the user in “Declarant’s General Data” as the manufacturer company. By selecting a role different from the “manufacturer”, the user can indicate the manufacturer by searching among the companies associated with it (“magnifying glass function”)
Agent	Name of Agent (field cannot be edited) If the item “agent” has been selected as the role filled by the declarant company with regard to the device, the system sets the company entered by the user in “Declarant’s General Data” as the agent company.” By selecting a role other than “agent”, the user can indicate the manufacturer by searching among the companies associated with it (“magnifying glass function”) The agent is: - Mandatory: if the manufacturer has its registered offices in a non-EU member country, with the exception of EEA/Turkey, - Optional: if the manufacturer has its registered offices in an EEA country/Turkey.



Name of Field	Description
	- Cannot be given a value: if the manufacturer has its registered offices in an EU Member State. The agent's nation must be in the EU/EEA/Turkey
Name of field	Description
EC Classification (Leg- Decree no. 332/2000)	Indication of the device classification as set out in Leg. Decree 332/2000. Choice of one of the following four options: - Annex II – List A - Annex II – List B - Self-diagnostic tests (not included in Annex II) - Other type of IVD (Mandatory field)
EDMA Classification	Classification of the device according to the European Diagnostic Manufacturers Association (EDMA) – Field cannot be edited, Mandatory To select an EDMA classification, it is necessary to click on “magnifying glass”; a look-up will open, from where it is possible to search for this classification by code and description (or part of it), by obtaining the list of items corresponding to the set search criteria. Each item is expandable if it is not terminal, that can only be selected if it is a terminal item.
Label (file)	Pdf file containing the device label. Mandatory field During the file upload phase, the system reports if the file is larger than the maximum size allowed: pdf to attach to device.
CARRYING OUT THE EVALUATION :	
Period: From - to	Time period (from – to) in which the performance evaluation takes place. Mandatory field
Territorial Environment	Place in which the evaluation took place: Italy, and relative regions/overseas. Mandatory. By selecting the check box: ‘Italy’ it is necessary to indicate (check box) at least one of the Italian regions where the evaluation took place. Both places can be selected (check box): Italy and Overseas

*Operations that can be activated*

Name of Action	Description	Page Called
Search for subject (manufacturer/agent) 	This allows access to the search page for companies listed in the relative register (Company Data) to be associated for various reasons (manufacturer/agent) to the medical device	Company Search
Company Details 	Allows viewing of detailed data about a company referred to for various reasons in the device notification (company that has entered the medical device, manufacturer, agent, other subject appointed by manufacturer)	Lookup Company data
Remove EDMA classification 	Allows removal of selected EDMA classification	itself
Search for EDMA classification 	Allows access to the search page for EDMA codes that can be associated with the medical device	Lookup EDMA
Browse 	Allows access to the list of files in the user's local workstation for selecting the label file to be associated with the device	Pop up of 'file selection'
Off-line signature	Allows the qualified electronic signature, offline, of device data that the declarant intends to communicate. Specifically, it produces a txt file containing the entered data, which is then downloaded and signed using qualified electronic signature, using the software available.	Off-line signature



2.6.1.2 Signing IVD-PE device data offline

This allows the subject to complete device data notification by signing the communicated information digitally (*'Offline Signature'* button). The data must be signed both to complete a first notification (ref. "notification of an IVD-PE device"), and to complete subsequent notifications regarding the communication of variations ("Modifying an IVD-PE device").

Once the *'off-line signature'* process is completed, the system produces a text file (.txt format) containing the data entered and permits the download. The generated file must then be signed, using qualified electronic signature, locally, using the software available.

To sign the data in offline mode, it is not necessary to be connected to the databank.

(N.B.) Files signed in offline mode must then be scanned into the system, using the relative file upload functions that can be accessed from the "offline signature" item on the menu. Completed communications will be considered valid, therefore will be registered in the databank, only after the above 'file upload' procedure.'



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Download Off Line Signature

Off Line Validation .

- This process allows the signing of the data stored in the "Data Bank and Repertoire of Medical Devices" as an alternative to the on-line signature using:
 - Any electronic signature certificate issued by one of the certification providers, according to Directive 1999/93/CE.
 - The software already owned by the user in order to use the signature device (smart card or other device). Format of signed data must be **PKCS #7** standard compliant.
 - The 'Off line signature' consists of three steps:
 - 1.** The user downloads the file in txt format on his computer (download); this file, automatically generated by the system, contains all the information previously entered. It is possible to simultaneously sign multiple medical devices; to activate the download it is enough to click on the link below.
 - 2.** the user then proceeds to sign the above mentioned files by using the software he already owns in order to use their signature device (smart card or other device). For the realization of this step it is not necessary to be connected to the "Data Bank and Repertoire of Medical Devices" system.
 - 3.** the user uploads the signed file on "Data Bank and Repertoire of Medical Devices" system through the appropriate upload function accessible from the menu item "Off line Signature".
 - For a successful completion of the Off line Validation process it is necessary that:
 - the user (or users of the same company for those accessing through "Impresa.gov") who uploads the file is the same who downloaded it.
 - the petitioner of the data must be the same person delegated to the data notification.
 - the name (except for the extension) of the signed file, acquired by the system during the upload phase, must be the same that is automatically assigned by the system in the download phase.
 - The data subject to signature (*) are not modified in the "Data Bank and Repertoire of Medical Devices" between the time of the download and the subsequent upload.
- (*) Please note that in case of signature of Medical Devices and Systems /Assembled Kits, the data subject to signature include the name of the Manufacturer / Agent / Marketing Responsible/ Other deputed subject, the EC certificate, the Medical Devices necessary to the operation and the components of the systems / Kits.

[DatiPE08022016122713536784](#)

Operations that can be activated

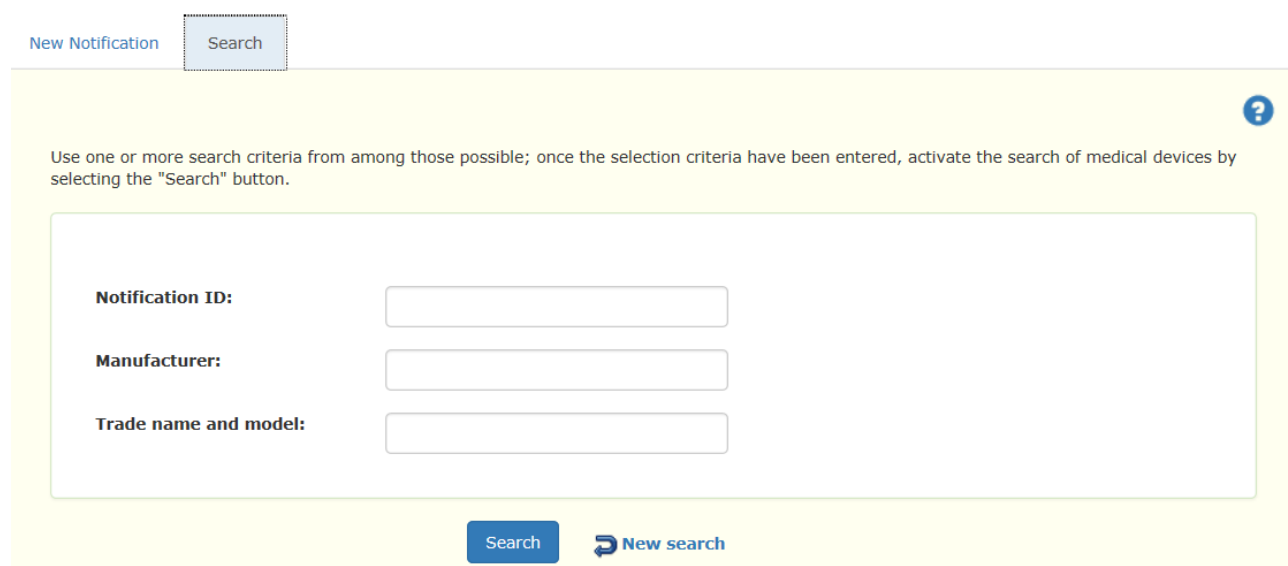
Name of action	Description	Page called
Download file	Downloads the txt file to be signed, using qualified electronic signature, locally	Dialogue window 'Saving window'



2.6.1.3 Searching for a notified IVD-PE device in the archive

To search for devices notified to the Ministry of Health in the databank, select the page “Search”. It is possible to use one or more search criteria from among the ones provided for; once the selection criteria has been entered, it is possible to activate the medical device search by selecting the “Search” button. Wherever found, the system returns the list of notifications made with regard to the entered criteria; otherwise it will report that no notification have been found.

In the presence of completed notifications, the declaring subject can ask to view data details, any variations and a printout (in pdf format) of a receipt, with declaration of the completed notification. The above will carry the summary of the signed data.



Medical Device Search – Field Details

Name of field	Description
DEVICE SEARCH	
Notification ID	Notification identification number allocated to the medical device by the system on completion of communication of data entered, with signature
Manufacturer	Name of device manufacturer
Commercial name and model	Name and model of device allocated by the manufacturer (Mandatory data)

**Medical Device Search – Operations that can be activated:**

Name of action	Description	Page called
Search 	Starts up the search of notified PE devices in the databank, using the selection criteria typed in. Where present, it returns the list of PE found	List of devices searched for
New Search 	Cleans the search parameters previously set and cancels the results of a previous search, where available	Search

In the section reserved for in vitro medical-diagnostic devices subjected beforehand to a performance evaluation before being marketed it is possible:

- Communicate the medical device data to the Ministry of Health by selecting the form **New Notification**;
- **Search**, in archive, a notification carried out to view communicated data, modify them, where necessary, and print for the receipt of signature to certify the completed communication

New Notification Search

You searched for **Notification ID:** PE-IT-2015-0001 [New search](#)

It is possible to view , modify  or print  a notification by using the corresponding functions that can be activated for each line in the list

Notification ID	Manufacturer	Trade name and model	Actions
PE-IT-2015-0001		strumento per monitoraggio glicemia	  

Page 1 of 1

List of Medical Devices searched for – Field details

Name of field	Description
LIST OF MEDICAL DEVICES SEARCHED FOR	
Notification ID	Notification identification number allocated to the medical device by the system on completion of communication of data entered, with signature
Manufacturer	Name of device manufacturer.
Commercial	Name and model of device allocated by the manufacturer



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Name of field	Description
name and model	

List of Medical Devices searched for – Operations that can be activated:

Name of action	Description	Page called
New search 	Cleans the search parameters previously set and cancels the results of a previous search, where available	Search
Detail 	Allows access to notified device data, in non-editable mode	Device details
Printout 	Allows the printing of a receipt containing the information communicated to the Ministry on signing, in pdf format	Reader pdf
Modify 	Allows the data from a previously completed notification to be modified. The variations made, and duly signed, are placed in chronological order, for later consultations	Device modification

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2.6.1.4 Consultation of an IVD-PE Device

The page allows consultation, in non-editable mode, of the data details of a device identified after a databank search. Where available, it also allows consultation, and printing, of the historical version of device data, following variations that have been made.

Detail

Details of Notification ID - Id : PE-IT-2015-0001

[Back](#)

INFORMATION ABOUT DEVICE

Trade name and model: strumento per monitoraggio glicemia

User role: ALTRO SOGGETTO DELEGATO DAL FABBRICANTE

Company that entered the Medical devices:

Manufacturer:

EC Classification (D.L.vo n. 332/2000): Allegato II - elenco A

EDMA Classification: 21071001 - RT_BGM Hardware + accessories + consumables + software

Label: [Etichetta.pdf](#)

CARRYING OUT OF EVALUATION

Period: Dal: 10/06/2015 - Al: 30/07/2015

Territorial environment: Estero - Italia

Regions: Abruzzo, Basilicata, Calabria, Campania, Emilia Romagna, Friuli Venezia Giulia, Lazio, Prov. Auton. Trento, Valle D'Aosta

Edit

Print

Previous versions of the device are present in the system

Valid notification dal 13/01/2016 11:26:16 al 13/01/2016 13:08:42

*Detail of Field*

Name of field	Description
INFORMATION ABOUT DEVICE	
Commercial name and model	Device name and model allocated by the manufacturer (Mandatory data)
Declarant's role	Indication of the role carried out by the declarant with regard to the device. The declarant may take on one of the following roles: • Manufacturer • Agent • Other subject appointed by manufacturer. (Mandatory data)
Company that has entered the device	Declaring company registered in the company list – declarant's general data (Mandatory)
Manufacturer	Name of device manufacturer (Mandatory).
Agent	Name of agent, where foreseen The agent is: - Mandatory: if the manufacturer has its registered offices in a non-EU member country, with the exception of EEA/Turkey - Optional: if the manufacturer has its registered offices in an EEA country/Turkey - Cannot be given a value: if the manufacturer has its registered offices in an EU Member State. The agent's nation must be in the EU/EEA/Turkey
EC Classification (Leg. Decree no. 332/2000)	Indication of the device classification as set out in Leg. Decree 332/2000. Choice of one of the following four options: • Annex II – List A • Annex II – List B • Self-diagnostic tests (not included in Annex II) • Other type of IVD (Mandatory)
EDMA Classification	Classification of the device according to the European Diagnostic Manufacturers Association (EDMA) – Mandatory



Name of field	Description
Name of field	Description
Label (file)	Pdf file containing the device label. (Mandatory)
CARRYING OUT OF EVALUATION:	
Period: From-To	Time period (from: – to:) in which the performance evaluation takes place. (Mandatory)
Territorial Environment	Place in which the evaluation took place: Italy/overseas. Mandatory.
Regions	List of Regions in which the evaluation took place. The data is available if “Italy” has been indicated as the place of evaluation

Operations that can be activated

Name of action	Description	Page called
Company Details 	Allows viewing of detailed data about a company referred to for various reasons in the device notification (company that has entered the medical device, manufacturer, agent, other subject appointed by manufacturer)	Company Data
Label file link	Allows access to the pdf file content, containing the label associated with the device being consulted	Pdf Reader
Modification	Allows modification of the data about a notification previously made. The variations introduced and duly signed, are placed in chronological order for later consultations	Modification to device
Print	Allows the printing of a receipt containing the information communicated to the Ministry on signing, in pdf format	Reader pdf
Back 	Closes the device data details page and repropose the previously searched for list of devices	List of devices searched for



Consultation of data – historical list of versions

Operations that can be activated

Name of action	Description	Page called
Detail 	Allows access, in non-editable mode, to the historical version of device data following variations made	Device details
Print 	Allows the printing of a receipt containing the information communicated to the Ministry on signing, in pdf format	Pdf Reader

2.6.1.5 Printout of signature receipt for an IVD-PE device

Allows the printing of a receipt, in pdf format, containing the device data, with signature, communicated to the Ministry of Health. The printout may be requested of both the current version and the previous versions generated following variations to the device data.

** Declaration pursuant to art. 10 of the Leg. Decree 332/2000

The undersigned on behalf of
 ,delegated by the Manufacturer or by the Agent to register data
 pertaining in vitro medical-diagnostic device data for performance evaluation
 before being placed on the market, validates the following information on the
 date 08/02/2016:

INFORMATION ABOUT DEVICE

Trade name and model: man

Manufacturer:

Company that entered the Medical devices:

User role: FABBRICANTE

Classification (D.L.vo n. 332/2000): Allegato II - elenco B

EDMA Classification: 11010113 - Creatine Kinase - Total

Label: CEATOS.pdf

INFORMATION ABOUT PERFORMANCE EVALUATION

Period in which evaluation is carried out From: 13/01/2016 To: 29/01/2016

Territorial environment: Estero - Italia (Abruzzo, Basilicata, Calabria,
 Campania, Emilia Romagna, Prov. Auton. Bolzano)

The information was successfully acquired by the Ministry of Health issued the
 following id notification to use for subsequent communications: PE-IT-2016-
 0008

The undersigned states he/she is aware of the sanctions provided for in case
 of false statement (art.76 of the D.P.R. n. 445 dated 28.12.2000).



2.6.1.6 Modification to an IVD-PE device

Allows a declaring subject to modify the data of a previously notified device. This function ("Modify" button) can be activated by selecting the device for which the associated information is to be changed from the list of devices searched for. Once the modification page has been recalled, the user must indicate the reason for the variation: to correct errors or mistakes / to update the information, in addition to providing a short description of the modifications requested. Proceed by modifying the device data according to needs. Specifically, both the reference to the manufacturer and, where necessary, the modification to the EDMA code to be used to classify the device, is permitted. In both cases, it will be necessary to access the relative lists.

Once the device data has been modified, complete the operation signing them by using offline mode ('Off-line signature' mode). The variations made, acquired by the system only after completing the signature process, are placed in a historical list and made available for consultation

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MOTIVATION

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Attention! You have chosen to **modify a notification** identified by the id: PE-IT-2015-0001

State reason for modification below:*

☐ to correct errors or mistakes
☐ to update information

Brief description of modifications:*

INFORMATION ABOUT DEVICE

Trade name and model:*

User role:*

Company that entered the Medical devices:*

Manufacturer:*

Agent:

EC Classification (D.L.vo n. 332/2000):*

EDMA Classification:*

Label:*

CARRYING OUT OF EVALUATION

Period:* FROM: TO:

Territorial environment:*

☒ Italy

☒ Abruzzo	☐ Liguria	☐ Puglia
☒ Basilicata	☐ Lombardia	☐ Sardegna
☒ Calabria	☐ Marche	☐ Sicilia
☒ Campania	☐ Molise	☐ Toscana
☒ Emilia Romagna	☐ Piemonte	☐ Umbria
☒ Friuli Venezia Giulia	☐ Prov. Auton. Bolzano	☒ Valle D'Aosta
☒ Lazio	☒ Prov. Auton. Trento	☐ Veneto

☒ Overseas

Sign Off Line

Cancel

*Detail of Fields*

Name of field	Description
MOTIVATIONS FOR MODIFICATION REQUEST	
Reason for modification	Indication of reason for modification: - to correct errors or mistakes; - to update information (Mandatory)
Brief description of modification	Brief description, free text, of modifications to be made to the device (Mandatory)
INFORMATION ABOUT DEVICE	
Commercial name and model	Device name and model allocated by the manufacturer (Mandatory)
Declarant's role	Indication of the role carried out by the declarant with regard to the device. The declarant may take on one of the following roles: • Manufacturer • Agent • Other subject appointed by manufacturer. (Mandatory)
Company that entered the device	Declaring company registered in the company list – general details of declarant (field cannot be edited, Mandatory)
Manufacturer	Name of device manufacturer (field cannot be edited, Mandatory). If the item “manufacturer” has been selected as the declaring company's role with regard to the device, the system sets the company entered by the user in “Declarant's General Data” as the manufacturer company. By selecting a role different from the “manufacturer”, the user can indicate the manufacturer by searching among the companies associated with it (“magnifying glass function”)

Name of field	Description



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Name of field	Description
Agent	Name of the Agent (field cannot be edited) If the item “manufacturer” has been selected as the declaring company’s role with regard to the device, the system sets the company entered by the user in “Declarant’s General Data” as the manufacturer company. By selecting a role different from the “manufacturer”, the user can indicate the manufacturer by searching among the companies associated with it (“magnifying glass function”) The agent is: - Mandatory: if the manufacturer has its registered offices in a non-EU member country, with the exception of EEA/Turkey - Optional: if the manufacturer has its registered offices in an EEA country/Turkey - Cannot be given a value: if the manufacturer has its registered offices in an EU Member State. The agent’s nation must be in the EU/EEA/Turkey
EC Classification (Leg. Decree no. 332/2000)	Indication of the device classification as set out in Leg. Decree 332/2000. Choice of one of the following four options: • Annex II – List A • Annex II – List B • Self-diagnostic tests (not included in Annex II) • Other type of IVD (Mandatory field)
EDMA Classification	Classification of the device according to the European Diagnostic Manufacturers Association (EDMA) – Field cannot be edited, Mandatory To select an EDMA classification, it is necessary to click on “magnifying glass”; a look-up will open, from where it is possible to search for this classification by code and description (or part of it), by obtaining the list of items corresponding to the set search criteria. Each item is expandable if it is not terminal, that can only be selected if it is a terminal item.



Name of field	Description
Name of field	Description
Label (file)	File pdf containing the device label. Mandatory field During the file upload phase, the system reports if the file is larger than the maximum size allowed: pdf to attach to device.
CARRYING OUT THE EVALUATION:	
Period: From-to	Time period (from: – to:) in which the performance evaluation takes place. Mandatory field
Place	Place in which the evaluation took place: Italy, and relative regions/ overseas. Mandatory. By selecting the check box: 'Italy' it is necessary to indicate (check box) at least one of the Italian regions where the evaluation took place. Both places can be selected (check box): Italy and Overseas

Operations that can be activated

Name of action	Description	Page called
Subject search (manufacturer/ agent) 	Allows access to the search page of the companies registered in the relative list (Company Data) to be associated with the medical device (manufacturer/agent) for various reasons.	Company Search
Company Details 	Allows viewing of the detailed information of the company referred to for various reasons in the device notification (company that entered the medical device, manufacturer, agent, other subject appointed by manufacturer)	Company Data LookUp
EDMA classification search 	Allows access to the search page for the EDMA codes that can be associated with the medical device	EDMA Search
Remove EDMA classification 	Allows the selected EDMA classification to be removed	Same page
Browse 	Allows the list of files present in the user's to be accessed to select the label file to associate with the device.	'File selection' pop-up
Off-line	Allows the qualified electronic signature in offline	Firma off-line

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Name of action	Description	Page called
signature	mode, of the modified device data. Specifically, it produces a .txt file containing the new device data, and downloads the file, on which the signature can be placed digitally. The variations made will be acquired only after the returning of the signed file (use of the 'Upload off-line' signature function).	



2.6.1.7 Consultation of historical list of versions of an IVD-PE device

Allows access, in non-editable mode, to the historical version of the device data following the variations made.

Version Detail

Details of Notification ID - Id : PE-IT-2015-0001 (validate from 13/01/2016 11:26:16 to 13/01/2016 13:08:42) [Back](#)

INFORMATION ABOUT DEVICE

Trade name and model: strumento per monitoraggio glicemia

User role: ALTRO SOGGETTO DELEGATO DAL FABBRICANTE

Company that entered the Medical devices:

Manufacturer:

EC Classification (D.L.vo n. 332/2000): Allegato II - elenco A

EDMA Classification: 21071001 - RT_BGM Hardware + accessories + consumables + software

Label: [Etichetta.pdf](#)

CARRYING OUT OF EVALUATION

Period: Dal: 10/06/2015 - Al: 30/07/2015

Territorial environment: Estero - Italia

Regions: Abruzzo, Basilicata, Calabria, Campania, Emilia Romagna, Friuli Venezia Giulia, Prov. Auton. Trento, Valle D'Aosta

EC Classification (D.L.vo n. 332/2000): Allegato II - elenco A

EDMA Classification: 21071001 - RT_BGM Hardware + accessories + consumables + software

Label: [Etichetta.pdf](#)

*Detail of fields*

Name of field	Description
INFORMATION ABOUT DEVICE	
Commercial name and model	Device name and model allocated by the manufacturer (Mandatory data)
Declarant role	Indication of the role carried out by the declarant with regard to the device. The declarant may take on one of the following roles: • Manufacturer • Agent • Other subject appointed by manufacturer. (Mandatory data)
Name of field	Description
Company that entered the device	Declaring company registered in the list of companies – declarant's general details (Mandatory)
Manufacturer	Name of device Manufacturer (Mandatory).
Agent	Name of Agent , where foreseen The agent is: - Mandatory: if the manufacturer has its registered offices in a non-EU member country, with the exception of EEA/Turkey - Optional: if the manufacturer has its registered offices in an EEA country/Turkey - Cannot be given a value: if the manufacturer has its registered offices in an EU Member State. The agent's nation must be in the EU/EEA/Turkey
EC Classification (Leg. Decree no. 332/2000)	Indication of the device classification as set out in Leg. Decree 332/2000. Choice of one of the following four options: • Annex II – List A • Annex II – List B • Self-diagnostic tests (not included in Annex II) • Other type of IVD (Mandatory field)



Name of field	Description
EDMA Classification	Classification of the device according to the European Diagnostic Manufacturers Association (EDMA) – Field cannot be edited, Mandatory
Label (file)	Pdf file containing the device label. (Mandatory)
CARRYING OUT THE EVALUATION:	
Period: From -To	Time period (from: – to:) in which the performance evaluation takes place. Mandatory field
Territorial context	Place in which the evaluation took place: Italy/Overseas. (Mandatory).
Regioni	List of Regions where the evaluation took place. The data is available if “Italy” is indicated as the place of evaluation

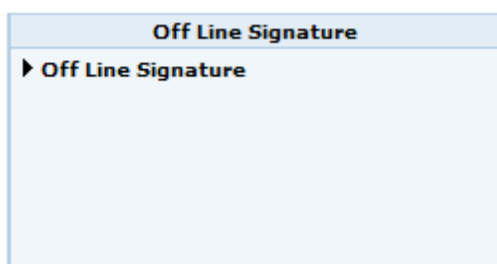
Operations that can be activated

Name of action	Description	Page called
Company details 	Allows viewing of detailed data about a company referred to for various reasons in the device notification (company that has entered the medical device, manufacturer, agent, other subject appointed by manufacturer)	Company data LookUp



2.7 Detailed description of the “Off line Signature” functional area

Having gained access to the “off line signature” functional area, the features available are displayed on the left-hand menu.



This area contains function that allows the user to complete the data off line signature process.

The off line signature allows the signing of the data stored in the “Data Bank and Repertoire of Medical Devices” using any electronic signature certificate issued by one of the certification providers, according to Directive 1999/93/CE and consists of three steps:

- The user **downloads** the file in txt format on his computer; this file, automatically generated by the system, contains all the information previously entered.
- The user then proceeds to sign the above mentioned files by using the software he already owns in order to use their signature device (smart card or other device). For the realization of this step it is not necessary to be connected to the “Data Bank and Repertoire of Medical Devices” system;
- The user uploads the signed file on “Data Bank and Repertoire of Medical Devices” system through the browse button of this **upload function**.



2.7.1 “Off line signature” Menu option

2.7.1.1 Upload signed files

This page is activated by clicking the menu option “Off line signature > Upload signed files” and allows to upload the signed file.

For a successful completion of the Off line Validation process it is necessary that:

- the user (or users of the same Italian company for those accessing through "Impresa.gov") who uploads the file is the same who downloaded it;
- the petitioner of the data is the same person delegated to the data notification;
- the name (except for the extension) of the signed file, acquired by the system during the upload phase, is the same that is automatically assigned by the system in the download phase.
- The data subject to signature (*) is not modified in the “Data Bank and Repertoire of Medical Devices” between the time of the download and the subsequent upload.



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Upload Off Line Signature

Upload Off Line Signature

Signed file

Off Line Validation .

- This process allows the signing of the data stored in the "Data Bank and Repertoire of Medical Devices" as an alternative to the on-line signature using:
 - Any electronic signature certificate issued by an accredited Certification Authority (CA) in compliance with Directive 1999/93/EC.
 - The software already owned by the user in order to use the signature device (smart card or other device).
- The 'Off line signature' consists of three steps:
 1. The user downloads the file in txt format on his computer (download); this file, automatically generated by the system, contains all the information previously entered. It is possible to simultaneously sign multiple medical devices.
 2. the user then proceeds to sign the above mentioned files by using the software he already owns in order to use their signature device (smart card or other device). For the realization of this step it is not necessary to be connected to the "Data Bank and Repertoire of Medical Devices" system.
 3. the user upload the signed file on "Data Bank and Repertoire of Medical Devices" system through the browse button of this upload function.
- For a successful completion of the Off line Validation process it is necessary that:
 - the user (or users of the same company for those accessing through "Impresa.gov") who uploads the file is the same who downloaded it.
 - the petitioner of the data must be the same person delegated to the data notification.
 - the name (except for the extension) of the signed file, acquired by the system during the upload phase, must be the same that is automatically assigned by the system in the download phase.
 - The data subject to signature (*) are not modified in the "Data Bank and Repertoire of Medical Devices" between the time of the download and the subsequent upload.

(*) Please note that in case of signature of Medical Devices and Systems /Assembled Kits, the data subject to signature include the name of the Manufacturer / Agent / Marketing Responsible/ Other deputed subject, the EC certificate, the Medical Devices necessary to the operation and the components of the systems / Kits.

Operations available:

Action	Description	Page Name
Save	Upload the signed file.	Same