**INSTRUCTIONS FOR FILLING OUT AND SENDING THE FORM**

|  |
| --- |
| The office of the Italian Ministry of Health (MoH) responsible for checking forms cannot consider valid any documentation that is not completed in accordance with the indications listed below; if the form is incomplete, MoH will request further information.  Directions:   * This form must be sent in order to access the database of medical devices to register data relating to medical devices. For in vitro diagnostic medical devices and custom-made devices, different forms are required - please refer to the MoH website. * Please specify the roles of the companies. * Please attach to this form the document providing proof of identity of both legal representatives, which is legible and valid.   + In case of italian authorised company, it is required to upload this form in PDF format into the database of medical devices according to the directions laid down in the MoH website   + In case of foreign authorised company, it is required to send the form in PDF format, by email with the following subject line "Communication of authorisation for access and data entry in the medical devices database" to the following email address: [dgfdm@postacert.sanita.it](mailto:dgfdm@postacert.sanita.it) |

# 

Ministero della Salute

Direzione Generale dei Dispositivi Medici e

del Servizio Farmaceutico

Ufficio 3

PEC: [dgfdm@postacert.sanita.it](mailto:dgfdm@postacert.sanita.it)

***Subject:*** *Communication of authorisation from the delegating company to the authorised company and appointment of the responsible person for entering and updating data in the database of the Ministry of Health and in the “Repertorio” of medical devices in Italy according to Ministerial Decree 21 December 2009.*

|  |  |
| --- | --- |
| ***Fields to be filled in by the DELEGATING company*** | The company\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  VAT Number \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  with registered office in (please indicate the full address)  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Phone number \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  e-mail \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  PEC-Electronic Certified E-mail (optional field) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  for devices which will be registered in the database and possibly included in the medical device list called “Repertorio”, acts as (*mark the applicable option with an X; more than one option can be selected*):   1. manufacturer, as defined in Article 1, paragraph 2, letter f) of Legislative Decree No 46 of 24 February 1997; 2. subject referred to in Article 12, paragraph 2 of Legislative Decree No 46 of 24 February 1997 (subjects who place systems or procedure packs on the market); 3. authorised representative in the EU designated by the manufacturer, referred to in Article 13, paragraph 2 of Legislative Decree No 46 of 24 February 1997.   For the purpose of entering and updating data in the database of medical devices of the Italian Ministry of Health, the legal representative of the delegating company  Name\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Surname\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Born in\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ on\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Tax code (\*) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  email \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

**AUTHORISES**

the following company to carry out the registration and communication of information within the database of medical devices of the Italian Ministry of Health according to the obligations set out in art. 13 of Legislative Decree No 46 of 24 February 1997

|  |  |
| --- | --- |
| ***Fields for AUTHORISED and REGISTRANT company registering information within the database*** | the company \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Tax Code or VAT Number \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  with registered office in (indicate the full address)  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Phone number \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  e-mail \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  PEC-Electronic Certified E-mail (optional field) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  which, for the devices that will be registered in the database and possibly included in the medical device list called “Repertorio”, acts as (*mark the applicable option with an X; more than one option can be selected*):   1. manufacturer, as defined in Article 1, paragraph 2, letter f) of Legislative Decree No 46 of 24 February 1997; 2. subject referred to in Article 12, paragraph 2 of Legislative Decree No 46 of 24 February 1997 (subjects who place systems or procedure packs on the market); 3. authorised representative in the EU designated by the manufacturer, referred to in Article 13, paragraph 2 of Legislative Decree No 46 of 24 February 1997. 4. company validly authorised by the subjects referred to in letters a, b or c.   Therefore, for the purpose of entering data in the database of medical devices of the Ministry of Health, the legal representative of the authorised and registrant company  Name\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Surname\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Born in\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ on\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Tax code (\*) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  email \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **APPOINTS THE FOLLOWING AS RESPONSIBLE FOR DATA COMMUNICATION ACCORDING TO THE MINISTERIAL DECREE 21 DECEMBER 2009**   1. himself/herself 2. employee of the authorised and registrant company   *If you have selected "employee of the authorised and registrant company", please provide the employee's signature and details:*  Name\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Surname\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Born in\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ on\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_-  Tax code (\*) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  email \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. |

*Date*

*Signature of the legal representative of the delegating company*

*Signature of the legal representative of the authorised company*

*Signature of the employee of the authorised company*

**Attachments** – copy of identity documents which are currently valid and contain the handwritten signaturesof the legal representatives of both companies

*(\*) If the subject does not have an Italian tax code, please indicate a unique identifier valid in the country of origin*