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

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| 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.
* In the fields where an email address is required, enter an email address and not a PEC (Electronic Certified E-Mail) address.
* Please send the form:
	+ in PDF format,
	+ together with a document providing proof of identity of the legal representative, which is legible and valid,
	+ by email with the following subject line "Communication of appointment for access and data entry in medical devices database" to the following email address: dgfdm@postacert.sanita.it
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Ministero della Salute

Direzione Generale dei Dispositivi Medici e

del Servizio Farmaceutico

Ufficio 3

PEC: dgfdm@postacert.sanita.it

***Subject:*** *Communication of appointment**of the person responsible 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.*

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| The company\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Tax Code or 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 companyName\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_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. company employee

*If you have selected" company employee", please provide the employee's signature and details:*Name\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Surname\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Born in\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ on\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_-Tax code (\*) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_email \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. |

*Date*

*Signature of the legal representative*

*Signature of the appointed employee*

**Attachments** – copy of an identity document, which is currently valid and contains the handwritten signatureof the legal representative

*(\*) Please indicate a unique identifier valid in the country of origin*