**INSTRUCTIONS ON HOW FILL AND SEND FORM 2\_IDV**

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| This form is accepted by the Ministry of Health (MoH) only if fulfilled according to the directions provided below. Where found to be incomplete or wrongly filled in, the office responsible for checking form validity will ask further documentation. Directions:* this form must be sent only to access the database of medical devices to register in-vitro diagnostic medical devices. For medical devices and custom-made devices, different forms are required - please refer to the MoH website.
* where required, please specify an e-mail address and not a certified one.
* Please specify the roles of the companies.
* please send the form:
	+ in PDF format;
	+ together with documents providing proof of identity of the legal representatives, which are legible and valid;
	+ by writing an e-mail to the address dgfdm@postacert.sanita.it, specifying in the subject “Communication of mandate for access and data entry in medical devices database – In-Vitro Diagnostic Medical Devices”.
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Ministero della Salute

Direzione Generale dei Dispositivi Medici e

del Servizio Farmaceutico

Ufficio 4

PEC: 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 “Repertorio” of medical devices in Italy according to Ministerial Decree 23 December 2013.*

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| **To be completed by the DELEGATING COMPANY** |
| The company\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Tax Code or VAT Number\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_With registered place of business in (*state complete address and zip code*)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Phone number \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_e-mail \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_for devices that will be registered within the “Repertorio” of medical devices, the delegating company acts as:*(tick off the letter of interest using a X; Manufacturer with its registered place of business in one of Member States may tick off more than one letter)** a) manufacturer, as defined by article 1, paragraph 1, letter f) of legislative decree no. 332 of 8 September 2000 and by article 2, point 23) of the Regulation (UE) 2017/746;
* b) authorized representative, as defined defined by article 1, paragraph 1, letter g) of legislative decree no. 332 of 8 September 2000 and by article 2, point 25) of the Regulation (UE) 2017/746;

For the purpose of entering and updating data in “Repertorio” of medical devices of the Italian Ministry of Health, the legal representative of the delegating companyName\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_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. 10 of Legislative Decree no. 332 of 8 September 2000

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| **To be completed by the AUTHORISED AND REGITRANT COMPANY** |
| The company\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Tax Code or VAT Number \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_With registered place of business in (*state complete address and zip code*)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Phone number \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_e-mail \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_for the devices that will be registered within the “Repertorio” of medical devices, acts as:*(Tick off the letter of interest using a X; it is also possible to tick off more than one letter)** a) manufacturer, as defined by article 1, paragraph 1, letter f) of legislative decree no. 332 of 8 September 2000 and by article 2, point 23) of the Regulation (UE) 2017/746;
* b) authorized representative, as defined defined by article 1, paragraph 1, letter g) of legislative decree no. 332 of 8 September 2000 and by article 2, point 25) of the Regulation (UE) 2017/746;
* c) other individual validly delegated by the figures under letter a or b.

Therefore, for the purpose of entering data in “Repertorio” 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 AS RESPONSIBLE FOR DATA COMMUNICATION ACCORDING TO THE MINISTERIAL DECREE 23 DECEMBER 2013*** Himself / Herself
* Another employee of the delegated company *(if this option is ticked off, please provide the following data)*

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 autjorised company*

 *Signature of the appointed employee*

**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*