**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 submitted in order to access the database of custom-made medical devices manufacturers to register the own data and the list of custom-made MDs types (non-italian manufacturer or non-italian authorized representative).
* For CE-marked medical 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 Foreign custom-made medical devices manufacturers’ database"** to the following email address: dgfdm@postacert.sanita.it
 |

#

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* **Foreign custom-made medical devices manufacturers’ database** *of the Italian Ministry of Health according to Ministerial Decree 9 June 2023.*

|  |
| --- |
| 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) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_acts as (*mark the applicable option with an X*):1. manufacturer, as defined in Article 2, paragraph 30 of Regulation (EU) 2017/745;
2. authorised representative in the EU designated by the manufacturer, pursuant to Article 11 of Regulation (EU) 2017/745.

For the purpose of entering and updating data in the database of custom-made medical devices manufacturersof 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 9 JUNE 2023**1. himself/herself
2. company employee/natural person

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

*Date*

*Signature of the legal representative*

*Signature of the appointed person*

**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*