**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 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](mailto: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](mailto: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.*

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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) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  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 company  Name\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  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*