# Appendix 1

# DATA ABOUT THE PRODUCT:

Please fill in the following table for the following information about your products **for each product category** (medical devices with the same use / for the same purpose). If the company would like to submit more than one medical device (cathegory of the devices) please fill in the chart below for each device separately.

|  |  |
| --- | --- |
| Medical device type: | *click and type:* |
| Medical device trade name: | *click and type:* |
| Type/ model/ product version | Designation of type/model/version (if applicable) *click and type:* |
| Basic UDI-DI | *click and type:* |
| Medical purpose declared by the producer | *click and type:* |
| Description of the device and mechanism of action of submitted devices (types, versions) | *click and type:* |
| Does submitted devices have common technical documentation?  If yes, please specify for which. | yes,  no  *click and type:* |
| Classification  \*Procedure pack in accordance with Article 22 MDR 2017/745 | **Is sterile,**  **Ir reusable,**  **Im with measuring function**  **II a,**  **II b,**  **III, \*** **not applicable** |
| Classification rule according to MDR 2017/745Annex VIII, point and paragraph  \*Procedure pack in accordance with Article 22 MDR 2017/745 | **\*** **not applicable** |
| *click and type:* |
| Classification code EMDN with the definition | *click and type:* |
| Duration of product use: | transient – use for less than 60 minutes  short term – use for not more than 30 days  long term – use for more than 30 days |
| Type of a medical device | single use  reusable  invasive device  non-invasive device  reusable surgical instrument  surgically invasive device  implantable device  active device |
| Conformity assessment procedure according to Annex: | MDR 2017/745, Annex IX for clases Is, Im, Ir, IIa, IIb, III |
| MDR 2017/745, Annex XI p. 10 for clases IIa |
| MDR 2017/745, Annex XI part A for clases Is, Im, Ir |
| MDR 2017/745 Article 16 a) translating information provided by producer |
| MDR 2017/745 Article 16 b) changes in outer packaging |
| Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product within the meaning of point 2 of Article 1 of Directive 2001/83/EC, including a medicinal product derived from human blood or human plasma, as referred to in the first subparagraph of Article 1(8) ? | yes,  no |
| Where a device is manufactured utilising tissues or cells of human or animal origin, or their derivatives, and is covered by this Regulation in accordance with points (f) and (g) of Article 1(6, and where a device incorporates, as an integral part, tissues or cells of human origin or their derivatives that have an action ancillary to that of the device and is covered by this Regulation in accordance with the first subparagraph of Article 1(10) ? | yes,  no |
| In the case of devices that are composed of substances or combinations of substances that are intended to be introduced into the human body and that are absorbed by or locally dispersed in the human body ? | yes,  no |
| In the case of devices containing CMR or endocrine-disrupting substances referred to in Section 10.4.1 of Annex I ? | yes,  no |
| Does the medical device contain software? | yes,  no |
| Accessories for use with the product: | *click and type:* |
| Is the product in a sterile condition? | yes,  no |
| In case of sterile medical device – sterilization method | ethylene oxide gas sterilisation  moist heat sterilisation  radiation sterilisation  aseptic processing  filtration  Others (need to be specified) *click and type:* |
| Is the product sell in a non sterile condition but designed for sterilization? | No  Yes (please identyfy sterilization method)  ethylene oxide gas sterilisation  moist heat sterilisation  radiation sterilisation  aseptic processing  filtration  Others (need to be specified) *click and type:* |
| Other information about the product e.g. photo, brochure | *click and type:* |
| What is the language of technical file ? | Polish,  English *note:* |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Group to which the product belongs to, according to the classification MD  :( [Commission Implementing Regulation](https://context.reverso.net/t%C5%82umaczenie/angielski-polski/Commission+Implementing+Regulation) (UE) 2017/2185 | | **MDA 0100 Active implantable devices** | *Click and type.* | |
| **MDA 0200 Active non-implantable devices for imaging, monitoring and/or diagnosis** | *Click and type.* | |
| **MDA 0300 Active non-implantable therapeutic devices and general active non-implantable devices** | *Click and type.* | |
| **MDN 1100 Non-active implants and long term surgically invasive devices** | *Click and type.* | |
| **MDN 1200 Non-active non-implantable devices** | *Click and type.* | |
| **MDS 1000 Devices with specific characteristics** | *Click and type.*  *Click and type.*  *Click and type.* | |
| **MDT 2000 Devices for which specific technologies or processes have been used** | *Click and type.*  *Click and type.*  *Click and type.*  *Click and type.*  *Click and type.* | |
| Was the article submitted for evaluation by another notified body? | | | yes | Did other unit refuse to assess the compatibility of the proposed product? The reason for the refusal of the conformity assessment:*click and type:* |
| no |
| OBL producer | In the case of OBL producer certification, Notified Body requires the customer to provide a complete technical product documentation. | | | |

Hereby I declare that the personal data included in this inquiry have been gathered and transmitted in accordance with the applicable rules on the protection of personal data.

|  |  |  |
| --- | --- | --- |
| *click and type*  Name of a manufacturer | *click and type date*  Date | Signature |

***NOTE:*** In case of medical devices certification, the inquiry form and appendices should be signed and submitted to the notified body in non-editable form (pdf, scan, fax)