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| **A separate form shall be provided for each applied product/product group.** |

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| **Product / Product Group Name** |  | | | | | | | | |
| **Models** |  | | | | | | | | |
| **Is the product a medical device, or accessory for a medical device, or an Annex XVI product?** |  | | | **Is the clinical evaluation of the product based on clinical data or Article 61.10?** | |  | | | |
| **Is the product a legacy device?** |  | | | **If the clinical evaluation is based on clinical data, which type of data that is listed in Article 2(48) has been used?** | |  | | | |
| **Is the product Well Established Technology?** |  | | | **Do you have PMS Report (for class I devices) or PSUR (for Class IIa, Class IIb, and Class III devices)?** | |  | | | |
| **Intended Use** | **(EU) 2017/2185 Codes1** | **Number of Technical Documentation** | **Consisting of human blood, plasma and its derivatives** | **Consisting Software** | **Duration Of Use for Invasive and Implantable Devices** | **Consist of Nanoparticle or Nanomaterial** | **Sterility** | **State the outsourcing company name if the design/manufacturing is completely outsourced**  **(Please add the current CE certificates of outsourcing company for the same product, if there is any)** | |
|  |  |  | Yes  No | Yes  No | <60 min.  >60 min <30 days  >30 days | Yes  Nanoparticle or Nanomaterial Type:  No | Yes  Sterilization Method:  Ethylene Oxide  Radiation  Moist Heat  Hydrogen Peroxide  Aseptic  If the applied sterilization method is an aseptic, please define other sterilization methods used during aseptic process: | Outsourcing Company Name: | |
| **EMDN Code(at least down to 4th level)** | **Invasive / Implantable** | **Consist of human/animal tissue and its derivatives** | **Consisting Drug/Medicinal Product** | **Absorbed/ Locally dispersed** | **Does your product have equivalent device in the market?** | **Did you consult to European Expert Panel for product’s clinical strategy** | **Did you perform clinical investigations for the product?** | **Does the product intended for removing- administering medicines?** |
|  |
| **UDI Code** | Non invasive  Invasive  Surgically invasive  Implantable | Yes  No | Yes  No | No  Absorbed  Locally dispersed  Systemically absorbed | Yes  Equivalent Device Brand/model:  No | Yes  No | Yes  No | Yes  No |
|  |
| **Product Class** | Class I | Class IIa | Class IIb non-implantable devices, non-rule 12, non-WET2  Class IIb implantable, non-WET2  Class IIb implantable, WET2  Class IIb Annex VIII Rule 12 | Class III  Class III implantable | Re-usable device | Measuring device | Classification Rule: | Annex XVI Listed Product  Published Common Specification: | **If your device is Annex XVI device, did you start or performed a clinical investigation for the non-medical intended use?**  Yes  No |

(1) (EU) 2017/2185 Codes can be only under the MCA’s notification scope.

(2) WET Devices: Sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips or connectors for which the clinical evaluation is based on sufficient clinical data and is in compliance with the relevant product-specific CS, where such CS is available.

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| This form has been filled as the Annex of       dated FR.MED.01 Application Form of the Company. |

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| **Company Representative** | **Name, Surname, Title** | **Signature** | **Date** |
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