MODEL FILE FOR A MEDICAL DEVICE – EURO-PHARMAT

Note: Depending on the medical device (MD), this file will bear upon a <u>reference</u>, a <u>type</u> or a <u>family</u> of MD.

1. Administrative information about the company		Publishing date: Date of updating:
1.1	Name:	
1.2	Full address:	Phone number: Fax number: Email address: Website:
1.3	Contact information of the referent in charge of medical device vigilance:	Phone number: Fax number: Email address:

2. Information about the device or equipment	
2.1	**<u>Non-proprietary name:</u>** in accordance with Europharmat's classification
2.2	**<u>Trade name:</u>**
2.3	**<u>EMDN Nomenclature Code:</u>** **<u>GMDN Nomenclature Code:</u>** **<u>CLADIMED* Code:</u>** *French organisation offering a classification of medical devices
2.4	**<u>LPPR* Code (ex TIPS where applicable) :</u>** * French list of refundable medical products and services
2.5	**Class of the MD:** **EU Directive that applies:** **According to Appendix number** **Number of the notified body:** **Date when the product was first put on the market in the EU:** **Manufacturer of the MD:**
2.6	**Description of the device (photo, diagram, size, volume… included):** can be linked to 8.: according to the technical fact sheet. **Items to specify:** Standardised description based on the list of non-proprietary names when it exists in the database. Kit: Yes/No If Yes: Composition of the kit Insertion of photos: linked to 9.

2.7	**Catalogue references**: can be linked to 8.: according to the technical fact sheet
	For each reference specify:
	 REFERENCE: Number **UDI-DI code**:
	 Conditioning/packaging:
	  ● CU (Control Unit) : quantity, type
	  ● Conditioning (multiple of CU): quantity, type
	  ● Minimum quantity that can be delivered
	 Description of the reference:
	 Characteristics of the reference: Unit, Value
	 Labelling: facsimile of the labelling model of traceability label
	Insert a picture (PDF format), to be added in 9.

2.8	**Composition of the device and accessories**: for every element or component, specify:
	ELEMENTS: _____ MATERIAL: _____
	Active substances:
	For the components liable to come into contact with the patient and/or the products administered to them, additional details:
	          ✓ Presence or not of latex
	          ✓ Presence or not of phthalates (DHP)
	          ✓ Presence or not of organic products or products of animal origin (type...)
	Any statement deemed useful for the precautions of use
	Devices and accessories used in association with MD shall be listed (in case of specific medical supplies to be used in particular)

2.9	**Field - Indications:** Field of use (according to Europharmat's list) : Indications (according to Europharmat's list) : For any further information on indications, refer to PDF file titled "Storage and preservation conditions, safety of use, instructions for use and additional information"

3. Sterilization process:

	Sterile MD: YES NO **Sterilization method of the device:** Specify the sterilization of each component where applicable.

4. Storage and preservation conditions

	Normal storage and preservation conditions : Specific precautions : Period of validity of the product :co Existence of temperature gauges where appropriate :

5. Safety of use

5.1	**Technical safety:** when necessary, refer to the instructions for use or the information leaflet. For implantable MD: possibility to do a MRI, does it show on an X-ray?

5.2 Biological safety (where applicable):

6. Directions for use

6.1	**Instructions for use:** Where necessary, refer to the instructions for use (in the appendix) and the booklet (where applicable), particularly for the ancillary when necessary.
6.2	**Indications:** (purpose of use for CE marking)
6.3	**Precautions of use:** Refer to the instructions for use in the appendix (where applicable).
6.4	**Contraindications:** Both absolute and relative ones. Refer to the instructions for use in the appendix (where applicable).

7. Additional information on the product

	Bibliography, reports of clinical trials or pharmaco-economic studies, improvement of the service provided: specific recommendations for use (restrictions on care/support, technical facilities, qualifications of the user...): This space is left open for the manufacturer to add any other information deemed to be relevant and to provide elements for discussion to the user within the framework of the Committee on Drugs and Medical Devices (French body).

8. List of appendices of the file (where applicable)

	✓ Labelling and traceability labels (where necessary) ✓ Booklet ✓ Manual/Instructions for use ✓ Technical fact sheet ✓ Others

9. Pictures (where applicable)

	GIF, JPEG or PNG format