Please fill in this Form and send it to cb@eepil.com

1 - MANUFACTURER (MDR - art. 2 p. 30)	
Registered Name:	
National Registration Number and VAT Code:	[Specify]
Registered office address:	[Specify]
No. Employees of Registered office:	[Specify]
Contact person:	[Specify]
Contact e-mail:	[Specify]

2- AUTHORISED REPRESENTATIVE (MDR - art. 2 p. 32)	**☐ Not applicable**
Registered Name:	[if applicable- Specify]
National Registration Number and VAT Code:	[if applicable- Specify]
Registered office address:	[if applicable- Specify]
Contact person:	[if applicable- Specify]
Contact e-mail:	[if applicable- Specify]

3 – TYPE OF ACTIVITY

☐ EU Initial Certification

☐ EU Certification with transfer from other Notified Body:

- ☐ Voluntary transfer
- ☐ Forced transfer due to the suspension / withdrawal / renunciation of the outgoing Notified Body's designation

Please submit the EU Certificate issued by the outgoing Notified Body.

4 – MANUFACTURER'S SITES

Please list all sites of the Manufacturer, specifying the processes carried out in each one, for example: Management, Quality management, Measurement, Analysis and improvement, Purchasing, Design and development, Planning of product manufacturing, Production and service provision, Sterilization, Cleanliness of product, Assembly, Packaging and labeling, Servicing activities, Warehouse and Control of monitoring and measuring devices.

Site no. 1:	[Site address]
Performed process/es:	[Specify]
Work shifts:	☐ No ☐ Yes [if Yes, Specify]
No. of Employees:	[Specify]

Site no. 2:	[Site address]
Performed process/es:	[Specify]
Work shifts:	☐ No ☐ Yes [if Yes, Specify]
No. of Employees:	[Specify]

Site no. 3:	[Site address]
Performed process/es:	[Specify]
Work shifts:	☐ No ☐ Yes [if Yes, Specify]
No. of Employees:	[Specify]

If necessary, duplicate the table to add further sites

5 – SUBCONTRACTORS	
Are any processes being outsourced?	☐ No ☐ Yes If Yes, please provide the following required information for each subcontractor.

Subcontractor no. 1:	[Name]
Address:	[Specify]
Performed process/es:	☐ Design and development ☐Purchasing ☐ Production and service provision ☐ Sterilization ☐ Cleanliness of product ☐ Assembly ☐ Packaging and labeling ☐ Servicing activities ☐ Warehouse ☐ Other: [Specify]
Third part certification**:**	☐ No ☐ Yes
If necessary, duplicate the table to add further subcontractors	

6 – CRITICAL SUPPLIERS	
Are there any suppliers of raw materials, materials, components or sub-assemblies that may affect the safety and performance of the device?	☐ **No** ☐ Yes If Yes, please provide the following required information for each critical supplier.

Critical supplier no. 1:	[Name]
Address:	[Specify]
Supplied Product:	[Specify]
Third part certification**:**	☐ No ☐ Yes
If necessary, duplicate the table to add further critical suppliers	

.Please fill the Annex 1 for each device category and provide the technical sheet of the product.

Annex 1			
Device description	[Specify]	Technical documentation reference	[Specify]
Risk Class	☐ **I Sterile** ☐ **I with measuring function** ☐ **I Reusable surgical instrument**		☐ **IIA** ☐ **IIB** ☐ **III**
Procedure for the conformity assessment	Regulation (UE) 2017/745 according to: ☐ Full Annex IX (Annex IX chapter II and Annex IX chapter I) ☐ Annex IX, chapter I ☐ Annex X ☐ Annex XI-Part A ☐ Annex XI-Part B Device No.: [Specify]		
Device specific characteristics	☐ Device incorporating medicinal substances ☐ Device manufactured using tissues or cells of human or animal origin, or their derivatives ☐ Device is also machinery as regarding the Directive 2006/42/EC ☐ Device in sterile condition: / Method**:** [Specify] ☐ Reusable surgical instrument ☐ Device using nanomaterials ☐ Device using biologically active coatings and/or materials or being wholly or mainly absorbed or locally dispersed in the human body or are intended to undergo a chemical change in the body ☐ Device incorporating software / using software / controlled by software ☐ Device with a measuring function ☐ Device in systems or procedure packs ☐ Product without an intended medical purpose listed in Annex XVI of the MDR ☐ Class III custom-made implantable devices ☐ Device incorporating, as an integral part, an in vitro diagnostic device		

Date

Stamp and Signature of the
Manufacturer or the Authorized representative