

	EPIL	Document Code: CBF-702-04 Document version: 00
	INFORMATION FORM – Regulation (EU) no. 2017/745 related to medical devices	Revision Date: 2020 June 30 Page 1 of 4

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)		<input type="checkbox"/> 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	
<input type="checkbox"/>	EU Initial Certification
<input type="checkbox"/>	EU Certification with transfer from other Notified Body: <ul style="list-style-type: none"> <input type="checkbox"/> Voluntary transfer <input type="checkbox"/> 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.

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Site no. 1:	[Site address]
Performed process/es:	[Specify]
Work shifts:	<input type="checkbox"/> No <input type="checkbox"/> Yes [if Yes, Specify]
No. of Employees:	[Specify]

Site no. 2:	[Site address]
Performed process/es:	[Specify]
Work shifts:	<input type="checkbox"/> No <input type="checkbox"/> Yes [if Yes, Specify]
No. of Employees:	[Specify]

Site no. 3:	[Site address]
Performed process/es:	[Specify]
Work shifts:	<input type="checkbox"/> No <input type="checkbox"/> Yes [if Yes, Specify]
No. of Employees:	[Specify]

If necessary, duplicate the table to add further sites

5 – SUBCONTRACTORS	
Are any processes being outsourced?	<input type="checkbox"/> No <input type="checkbox"/> Yes If Yes, please provide the following required information for each subcontractor.



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Subcontractor no. 1:	[Name]
Address:	[Specify]
Performed process/es:	<input type="checkbox"/> Design and development <input type="checkbox"/> Purchasing <input type="checkbox"/> Production and service provision <input type="checkbox"/> Sterilization <input type="checkbox"/> Cleanliness of product <input type="checkbox"/> Assembly <input type="checkbox"/> Packaging and labeling <input type="checkbox"/> Servicing activities <input type="checkbox"/> Warehouse <input type="checkbox"/> Other: [Specify]
Third part certification:	<input type="checkbox"/> No <input type="checkbox"/> 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?	<input type="checkbox"/> No <input type="checkbox"/> 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:	<input type="checkbox"/> No <input type="checkbox"/> Yes
If necessary, duplicate the table to add further critical suppliers	



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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	<input type="checkbox"/> I Sterile <input type="checkbox"/> I with measuring function <input type="checkbox"/> I Reusable surgical instrument		<input type="checkbox"/> IIA <input type="checkbox"/> IIB <input type="checkbox"/> III
Procedure for the conformity assessment	Regulation (UE) 2017/745 according to: <input type="checkbox"/> Full Annex IX (Annex IX chapter II and Annex IX chapter I) <input type="checkbox"/> Annex IX, chapter I <input type="checkbox"/> Annex X <input type="checkbox"/> Annex XI-Part A <input type="checkbox"/> Annex XI-Part B Device No.: [Specify]		
Device specific characteristics	<input type="checkbox"/> Device incorporating medicinal substances <input type="checkbox"/> Device manufactured using tissues or cells of human or animal origin, or their derivatives <input type="checkbox"/> Device is also machinery as regarding the Directive 2006/42/EC <input type="checkbox"/> Device in sterile condition: / Method: [Specify] <input type="checkbox"/> Reusable surgical instrument <input type="checkbox"/> Device using nanomaterials <input type="checkbox"/> 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 <input type="checkbox"/> Device incorporating software / using software / controlled by software <input type="checkbox"/> Device with a measuring function <input type="checkbox"/> Device in systems or procedure packs <input type="checkbox"/> Product without an intended medical purpose listed in Annex XVI of the MDR <input type="checkbox"/> Class III custom-made implantable devices <input type="checkbox"/> Device incorporating, as an integral part, an in vitro diagnostic device		

Date

Stamp and Signature of the
Manufacturer or the Authorized representative

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