

Section 3: Investigational device(s)

3.1 Investigational medical device

3.1.1 Device purposes

[illegible]

3.1.2 Device type

Implantable	System
Active device	Non-medical purpose
Measuring function	Sterile
Reusable surgical instrument	Software
Intended to administer or remove medicinal substance	

3.1.3 Invasiveness

Is it an invasive medical device?	
Yes	No

3.1.4 Device Identifiers

Generic denomination:	
Device trade name:	Model:
Device name:	
European Medical Device nomenclature	
Medical device classification:	
Classification rule:	
Device description:	
Intended (clinical) purpose:	
Does the device contain or incorporate medicinal substance(s)? Yes No If yes, please provide the medicinal substance(s) name(s):	
The device incorporates, as an integral part, or it is manufactured using: Non-viable tissues of human origin or their derivatives with an ancillary action Non-viable cells of human origin or their derivatives with an ancillary action Non-viable tissues of animal origin or their derivatives with an ancillary action Non-viable cells of animal origin or their derivatives with an ancillary action Non-viable biological substance other than those referred to in the previous points None of these proposals/Not applicable	

Is the Investigational Device CE marked?

Yes No

If yes, please provide the information in the box below.

To what extent is the intended purpose of the device in the clinical investigation covered by the CE-mark?

CE marked device will be used outside the scope of its CE mark

CE marked device will be used within the scope of its CE mark and no additional procedures are foreseen in the clinical investigation

CE marked device will be used within the scope of its CE mark, but additional procedures are foreseen in the clinical investigation

Are those additional procedures considered to be burdensome and/or invasive?

Yes No

Please, comment why do you consider as such?

Information related to the Notified body involved, if applicable:

Notified body number:

Notified body name:

3.2 Previous clinical investigation

Has this device been investigated in a clinical investigation within the EU previously?

Yes No

If yes, please provide the relevant reference number(s) (such as SIN, CIV-ID, other reference(s)) of the previous clinical investigations

3.3 Scientific opinion/view

Has the investigational/study device been subject to a national scientific view/opinion from an Expert Panel

Yes No

3.4 Manufacturer of the investigational device

Is the manufacturer the same as the sponsor?

Yes No

If no, please fill in the requested information in section 3.4.1 and 3.4.2.

3.4.1 Manufacturer information

Organisation name:		
Address	Street name:	Street number:
	Postal code:	City:
	Country:	
Telephone number:		
Email:		

Contact person of the manufacturer

First name:
Last name:
Telephone number:
Email:

3.4.2 Authorised representative

Organisation name:		
Address	Street name:	Street number:
	Postal code:	City:
	Country:	
Telephone number:		
Email:		

Contact person of the authorised representative

First name:
Last name:
Telephone number:
Email:

Additional devices could be added by using a duplicated section 3, in appendix to this application form.