Section 3: Investigational device(s)

3.1 Investigational medical device

3.1.1 Device purposes

Alleviation of an injury or disability
Alleviation of disease
Compensation for an injury or disability
Devices for the control or support of conception
Diagnosis of an injury or disability
Diagnosis of disease
Investigation of the anatomy or of a physiological or pathological process or state
Monitoring of an injury or disability Monitoring of an injury or disability
Monitoring of disease
No medical purpose, but device belongs to a group of devices listed in MDR Annex XVI
Prediction of disease
Prevention of disease
Products specially intended for the cleaning, disinfection or sterilisation of devices
Prognosis of disease
Providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations
Replacement or modification of the anatomy or of a physiological or pathological process or state
Treatment of an injury or disability
Treatment of disease

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 Invasiness

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:
- Class I
- Class IIA
- Class IIB
- Class III

Classification rule:
- Rule 1 - non invasive device and no other rules can be applied
- Rule 2 - Channelling or storing blood, liquids, cells or tissues, liquids or gases for eventual administration or introduction in the body
- Rule 3 – Non-invasive devices that modify biological or chemical composition of human tissues or cells, blood, other body liquids or other liquids intended for implantation o
- Rule 4 - Non-invasive devices which come into contact with injured skin oe mucous membrane
- Rule 5 - Invasive devices with respect to body orifices, other than surgically invasive devices
- Rule 6 - Surgically invasive devices intended for transient use (< 60 minutes)
- Rule 7 - Surgically invasive devices intended for short-term use (>60 minutes, <30 days)
- Rule 8 - Implantable devices and long-term surgically invasive devices (> 30 days)

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 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: Belgium	
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: Belgium	
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.