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Receipt date of application by the Member state: / /

1 Clinical investigation identification

1.1 Sponsor identification

Name		
Address	**Street number and name:**	
	Postal code:	**City:**
	Country:	
Telephone number		
Email		
Sponsor status	☐ Private ☐ Academic	

Contact person of the sponsor

First Name	
Last Name	
Telephone number	
Email	

Sponsor's legal representative identification

Do you have a legal representative? ☐ Yes ☐ No
If yes, complete the information related to the legal representative (section 1.2)

1.2 Legal representative identification contact

Organization name		
Address	**Street number and name:**	
	Postal code:	**City:**
	Country:	
Telephone number		
Email		

Contact person of the legal representative

First Name	
Last Name	
Telephone number	
Email	

Contact person for the clinical investigation

☐ Same as contact person of sponsor
☐ Same as contact person of legal representative
☐ Other; If you selected other, please fill in the section below related to the other contact person for this clinical investigation and detail the link with the sponsor.

First name		
Last name		
Address	**Street number and name:**	
	Postal code:	**City:**
	Country:	
Telephone number		
Email		

1.3 Clinical investigation type

☐ Clinical investigation conducted to demonstrate conformity of the device (MDR Art. 62(1))

- ☐ In case of MD non-CE marked (MDR Art. 70(7))
  - ☐ Class I or non-invasive Class IIa
  - ☐ Non-invasive Class IIb, invasive Class IIa or IIb, Class III
- ☐ In case of MD CE marked and used outside the scope of its intended purpose (MDR Art. 74(2))
  - ☐ Class I or non-invasive Class IIa
  - ☐ Non-invasive Class IIb, invasive Class IIa or IIb, Class III
- ☐ PMCF investigation for MD CE marked and used in its intended purpose with invasive and/or burdensome procedure (MDR Art. 74(1))

☐ Other clinical investigation application (MDR Art. 82)

- ☐ PMCF investigation for MD CE marked and used in its intended purpose with additional procedure non-invasive or non-burdensome
- ☐ Investigation on MD CE marked used in its intended purpose without the objective of CE marking or establishing conformity and with invasive and burdensome additional procedure or additional procedure non-invasive or non-burdensome
- ☐ Investigation on MD non-CE marked without the objective of CE marking or establishing conformity
- ☐ Investigation on MD CE marked and used outside the scope of its intended purpose without the objective of CE marking or establishing conformity

1.4 Submission type

☐ First submission in the EEA

☐ First submission at the national level (clinical investigation has been already submitted in EEA). In this case, please provide the clinical investigation ID (CIV-ID) provided:

☐ Resubmission. Please provide the CIV-ID if already available:

1.5 Participating countries within the EU/EEA/UK (Northern Ireland), Turkey and Switzerland

AT	☐	BE	☐	BG	☐	CH	☐	CY	☐	CZ	☐
DE	☐	DK	☐	EE	☐	ES	☐	FI	☐	FR	☐
GB	☐	GR	☐	HR	☐	HU	☐	IE	☐	IS	☐
IT	☐	LI	☐	LT	☐	LU	☐	LV	☐	MT	☐
NL	☐	NO	☐	PL	☐	PT	☐	RO	☐	SE	☐
SI	☐	SK	☐								

In this case, has a competent authority (CA) already made a final decision on the clinical investigation (when submitting the AEC application to ANSM)? ☐ Yes ☐ No
If yes, please fill in the table below

Member state	NCA decision and date of decision	Same Protocol	Same IB	Same TD
		☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
		☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
		☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No

1.6 Participating countries outside EU/EEA/UK

List the participating countries for the clinical investigation:

1.7 Clinical investigation plan CIP

CIP Code:
CIP version:
CIP date:
Signed: ☐ Yes ☐ No

1.8 Clinical investigation identification

IDRCB number	
Full title	
Short title	
Title for lay people	

2 Clinical investigation description

2.1 Scientific opinion

Has the manufacturer consulted with an expert panel as outlined in Art. 61(2) of Regulation (EU) 2017/745: ☐ Yes ☐ No

2.2 Design of the clinical investigation

☐ Exploratory investigation

☐ Confirmatory investigation

☐ Observational investigation

☐ First in human investigation

☐ Not first in human

2.3 Design methodology

☐ Case control ☐ Controlled ☐ Cross-sectional ☐ Double blind

☐ Parallel ☐ Randomised ☐ Open

☐ Other (detailed):

2.4 Development stage

☐ Pilot stage ☐ Pivotal stage ☐ Post-marked stage

2.5 Objectives and endpoints

Primary objective(s)	
Secondary objective(s)	
Other objective(s)	
Primary endpoint(s)	

Secondary endpoint(s)	
Other endpoint(s)	

2.6 Synopsis of the clinical investigation

Overall synopsis

2.7 Planned number of subjects

In Europe	
In Asia	
In Africa	
In North America	
In South America	
In Oceania	
Total planned number of subjects:	

2.8 Duration of the clinical investigation

Estimated start date:
Estimated end date:

2.9 Population

2.9.1 Medical condition

Is there an associated medical condition? ☐ Yes ☐ No

Is the medical condition considered to be rare? ☐ Yes ☐ No

2.9.2 Therapeutic area

Select the therapeutic area that the clinical investigation falls under

☐ Circulatory system: cardiovascular/lymphatic
☐ Dermatology
☐ Endocrinology and diabetes
☐ Esthetic
☐ Gastroenterology and hepatology
☐ General and plastic surgery, dentistry
☐ Imagery/Diagnostic
☐ Nephrology and urology
☐ Neurology
☐ Obstetrics and gynecology including reproductive
☐ Oncology
☐ Ophthalmology
☐ Orthopedics, traumatology and rehabilitation
☐ Patient Help
☐ Respiratory, anesthesiology and intensive care
☐ Other :

2.9.3 Gender of subjects

☐ Female ☐ Male ☐ Other

2.9.4 Inclusion criteria

2.9.5 Exclusion criteria

2.9.6 Type of subjects that the clinical investigation plans to recruit

☐ Healthy ☐ Patients
☐ Vulnerable population ☐ Incapacited subjects ☐ Minors
☐ Pregnant women ☐ Breastfeeding women ☐ Patients in emergency situations
☐ Other (please specify):

2.9.7 Age range of the participants that the clinical investigation plans to include

☐ In utero ☐ Adults (from 18 to 84 years)
☐ New-borns (from 0 to 27 days) ☐ Elderly (from 85 years)
☐ Infants and toddlers (from 28 days to 23 months)
☐ Children (from 2 to 5 years)
☐ Adolescents (from 12 to 17 years)

2.10 Is there an independent Data Safety Monitoring Board in the investigation?

☐ Yes ☐ No
If no, justify the absence of committee for non-CE device or CE mark device used outside the scope of its intended purpose study:

2.11 Scope of the investigational device

2.11.1 Combined investigation Medical Device/In Vitro Diagnostic?

☐ Yes ☐ No
If yes, please provide the related IVD performance study identification number:

2.11.2 Is the application submitted in parallel with an application for a clinical trial on medicinal products?

☐ Yes ☐ No
If yes, please provide the EU Clinical Trial Number:

2.11.3 Coordinating investigator

First name		
Last name		
Site name		
Qualification/Specialit y		
Address	**Street number and name:**	
	Postal code:	**City:**
	Country:	
Telephone number		
Email		

2.12 Is there a laboratory or technical platform used in the investigation?

☐ Yes ☐ No
If yes

Organization name		
Address	**Street number and name:**	
	Postal code:	**City:**

	Country:	
Telephone number		
Email		

3 Investigation 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
☐ 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 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 sterilization of devices
☐ 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 process or state
☐ Treatment for an injury or disability
☐ Treatment of disease

3.1.2 Device type

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

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 devices or no other rules can be applied
☐ Rule 2 - Channeling or storing blood, body liquids, cells or tissues, liquids or gases for the purpose of eventual infusion, administration or introduction into 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 or administration into the body
☐ Rule 4 - All non-invasive devices which come into contact with injured skin or 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- <30days)
☐ Rule 8 - Implantable devices and long-term surgically invasive devices (>30days)
☐ Rule 9 - Active therapeutic devices intended to administer or exchange energy
☐ Rule 10 - Active devices for diagnosis and monitoring
☐ Rule 11 - Software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes
☐ Rule 12 - Active devices intended to administer and/or remove medicinal products, body liquids or other substances to or from the body
☐ Rule 13 - Other active devices
☐ Rule 14 - Devices incorporating, as an integral part, a substance which, if used separately, can be considered to be a medicinal product
☐ Rule 15 - Devices used for contraception or prevention of the transmission of sexually transmitted diseases
☐ Rule 16 - Specific disinfecting, sterilizing, cleaning, rinsing or, hydrating contact lenses

☐ Rule 17 - Devices intended for recording of diagnostic images generated by X-ray

☐ Rule 18 - Devices utilizing tissues or cells of human or animal origin, or their derivatives

☐ Rule 19 - Devices incorporating or consisting of nanomaterial

☐ Rule 20 - Invasive devices with respect to body orifices, other than surgically invasive devices, which are intended to administer medicinal products by inhalation

☐ Rule 21 - Devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body via a body orifice or applied to the skin and that are absorbed by or locally dispersed in the human body

☐ Rule 22 - Active therapeutic devices with an integrated or incorporated diagnostic function which significantly determines the patient management by the device

Device description	
Intended (clinical) purpose	

Does the investigation device contain or incorporate medicinal substance(s)?
☐ Yes ☐ No
If yes, please provide the medicinal substance(s) name(s):

The investigation 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 and detail the procedure?
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?

☐ Yes ☐ No

If yes, please attach a copy of the national scientific advice minutes.

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,
- attach a copy of the authorization issued by the third party to the sponsor to communicate the data relating to the device concerned and to use the investigator brochure and/or the technical file

3.4.1 Manufacturer information

Organization name		
Address	**Street number and name:**	
	Postal code:	**City:**
	Country:	
Telephone number		
Email		

Contact person of the manufacturer

First Name	
Last Name	
Telephone number	
Email	

3.4.2 Authorized representative

Organization name		
Address	**Street number and name:**	
	Postal code:	**City:**
	Country:	
Telephone number		
Email		

Contact person of the Authorized 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

4 Comparator

Is there a comparator included in the clinical investigation? ☐ Yes ☐ No
If yes, the section below needs to be completed.

4.1 Type of comparator

☐ Therapy ☐ Placebo ☐ No treatment ☐ Medical device

4.1.1 Medical device as comparator

Is the comparator medical device CE marked? ☐ Yes ☐ No

If yes, will the CE marked comparator medical device be used in the clinical investigation within the scope of its CE mark? ☐ Yes ☐ No

Generic denomination	
Device trade name	
Model	
Device name	
European Medical Device Nomenclature	
Medical device classification	☐ Class I ☐ Class IIA ☐ Class IIB ☐ Class III
Device description	
Intended (clinical) purpose	
Does the comparator device contain or incorporate medicinal substance(s)?	☐ Yes ☐ No If yes, please provide the medicinal substance(s) name(s):
The comparator 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

4.1.2 Manufacturer information

Organization name		
Address	**Street number and name:**	
	Postal code:	**City:**
	Country:	
Telephone number		
Email		

Additional comparators could be added, by using a duplicated section 4, in appendix to this application form.

5 Additional information

5.1 Special case: Use of marketed devices with the same common name in a clinical investigation where the protocol does not require the use of a device in question.

Is this particular case applicable to the concerned investigation ☐ Yes ☐ No
If yes, please complete below

	Yes	No
DM	☐	☐
DMDIV	☐	☐

If yes, please complete below

Device Name	Non CE-marked	CE marked	
		used in its destination	used in other destination than the CE
	☐	☐	☐

	☐	☐	☐
	☐	☐	☐

5.2 General research data

5.2.1 Procedures for the only research needs

Biological samples for research purposes only (i.e. samples that would not have been taken if the subject was not suitable for this research)
Example: blood, urine, saliva, tissues, cerebrospinal fluid

☐ Yes ☐ No

If yes, fill in the table below:

Type of samples	Times	Volume / unit diameter	Volume / cumulative number

5.2.2 Specific exams for research purposes only (i.e., exams that would not have been conducted if the subject did not participate to this research)

☐ Yes ☐ No

Are they radiating and/or invasive? ☐ Yes ☐ No

If yes, fill in the table below

Exams	Frequency of the exams	Usual Frequency (Yes/No)	Period between two exams	Administrated Dose per exam (if applicable)	Cumulative dose (if applicable)

if no, please indicate the other exams :

5.3 Information on non-experimental product included in the investigation

5.3.1 Is the use of a non-experimental drug (MNE) intended in this investigation?

☐ Yes ☐ No

If yes, fill in the table below:

Auxiliary medicinal product	Auxiliary medicinal product with marketing authorization (in France, Europe, USA or Japan)		If the auxiliary medicinal product has a marketing authorization, does its use in the investigation differ from the marketing authorization	
	Yes	No	Yes	No
	☐	☐	☐	☐
	☐	☐	☐	☐

If an auxiliary medicinal product does not have a marketing authorization (in France, EU, USA or Japan), please provide the rationale below or indicate where this information is located in the submitted dossier

Are there plans to import non-experimental drugs for research purposes? ☐ Yes ☐ No If yes, attach the "Attestation pour l'importation de médicaments nécessaires à la réalisation d'une recherche" form

5.3.2 Is the use of a non-experimental DM intended in this investigation?

☐ Yes ☐ No

If yes, fill in the table below

	Yes	No
MD	☐	☐
IVD	☐	☐

If yes, fill in the table below

Device name	non-CE marked	CE marked	
		use in the scope of its CE mark	used outside the scope of its CE mark
	☐	☐	☐
	☐	☐	☐
	☐	☐	☐

In case of use of a device that is non CE marked, please indicate below the justifications or specify where this information is located in the dossier submitted (a technical file is required)

Regulation (EU) 2017/745 of the European parliament and the council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

5.3.3 Is the use of a cosmetic product intended in this investigation?

☐ Yes ☐ No

If yes, specify for each of them whether they are marketed in France, EU, or other

6 National information

6.1 Study site information

Please provide the list of sites taking part in the clinical investigation

Name of institution	Site address	Investigator attached to this site	Contact information of investigators

6.2 Ethic committee information

Select the applicable option:
☐ Ethics committee opinion available

☐ Ethics committee opinion under review

☐ Ethics committee opinion is not mandatory before submission to the competent authority

If an ethics committee has to be selected by the sponsor before submission, please provide the ethics committee information's below.

Ethics committee name	
Email	

6.3 Status of the clinical investigation

Is the sponsor considered as commercial according to national legislation?
☐ Yes ☐ No

6.4 Expected number of subjects recruited within the Member State

How many subjects are expected to be recruited into the study in the Member State you are applying to?

I hereby certify that the information and documentation submitted with this notification is correct in detail and all the information requested has been supplied. The investigated (medical) device complies with the applicable general safety and performance requirements, apart from those covered by the investigation and that every precaution has been taken to protect the health and safety of the patient and/or user.
I confirm that all the clinical investigations information collected for this application, has been done in compliance with the European data protection legislation (GDPR).

Sign

Name:
Position: