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Receipt date of application by the Member state:      /     /

# Clinical investigation identification

## 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)

## 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 |  | |

## 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 CE marked and used outside the scope of its intended purpose without the objective of CE marking or establishing conformity

Investigation on MD non-CE marked without the objective of CE marking or establishing conformity

## 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:

## 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 |

## Participating countries outside EU/EEA/UK

List the participating countries for the clinical investigation:

## Clinical investigation plan CIP

CIP Code:

CIP version:

CIP date:

Signed:  Yes  No

## Clinical investigation identification

|  |  |
| --- | --- |
| IDRCB number |  |
| Full title |  |
| Short title |  |
| Title for lay people |  |

# Clinical investigation description

## Scientific opinion

Has the manufacturer consulted with an expert panel as outlined in Art. 61(2) of Regulation

(EU) 2017/745:  Yes  No

## Design of the clinical investigation

Exploratory investigation

Confirmatory investigation

Observational investigation

First in human investigation

Not first in human

## Design methodology

Case control  Controlled  Cross-sectional  Double blind

Parallel  Randomised  Open

Other (detailed):

## Development stage

Pilot stage  Pivotal stage  Post-marked stage

## Objectives and endpoints

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

## Synopsis of the clinical investigation

|  |
| --- |
| Overall synopsis |

## Planned number of subjects

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

## Duration of the clinical investigation

Estimated start date:

Estimated end date:

## Population

### Medical condition

Is there an associated medical condition?  Yes  No

Is the medical condition considered to be rare?  Yes  No

### 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 : |

### Gender of subjects

Female  Male  Other

### Inclusion criteria

|  |
| --- |
|  |

### Exclusion criteria

|  |
| --- |
|  |

### 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):

### 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)

## 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:

## Scope of the investigational device

### Combined investigation Medical Device/In Vitro Diagnostic?

Yes  No

If yes, please provide the related IVD performance study identification number:

### 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:

### Coordinating investigator

|  |  |  |
| --- | --- | --- |
| First name |  | |
| Last name |  | |
| Site name |  | |
| Qualification/Speciality |  | |
| Address | **Street number and name:** | |
| **Postal code:** | **City:** |
| **Country:** |  |
| Telephone number |  | |
| Email |  | |

## 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 |  | |

# Investigation device(s)

## Investigational medical device

### 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

### Device type

Implantable  System

Active device  Non-medical purpose

Measuring function  Sterile

Reusable surgical instrument  Software

Intended to administer or remove medicinal substance

### Invasiness

Is it an invasive medical device?  Yes  No

### 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: | |

## 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:

## 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.

## 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

### 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 |  |

### 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*

# Comparator

Is there a comparator included in the clinical investigation?  Yes  No

If yes, the section below needs to be completed.

## Type of comparator

Therapy  Placebo  No treatment  Medical device

### 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 | |

### 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.

# Additional information

## 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 | |
|  |  |  | |  | |
|  |  |  | |  | |
|  |  |  | |  | |

## General research data

### 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 |
|  |  |  |  |
|  |  |  |  |

### 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 :

|  |
| --- |
|  |

## Information on non-experimental product included in the investigation

### 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 |

### 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) |
|  |

### 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

|  |
| --- |
|  |

# National information

## 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** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

## 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 |  |

## Status of the clinical investigation

Is the sponsor considered as commercial according to national legislation?

Yes  No

## 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: