**Application form to notify a clinical investigation with a medical device**

**To be completed by FAMHP**

|  |
| --- |
| Reception date of your application form by FAMHP  FAMHP REF : 80M0\_ \_ \_ |

1. **Identification of manufacturer :**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| The manufacturer is "the natural or legal person with responsibility for the design, manufacturing, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party." (art 1, f, European directive 93/42/EEC) | | | | |
| Name |  | | | |
| Address (headquarter) | Street :  Postcode :  City :  Country : | | | |
| Contact person (First Name/Name) |  | | |  |
| Phone/fax/email |  |  |  | |

1. **Identification of promoter (if applicable) :**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| The promoter is "a person, company, institution or organization responsible for the initiation, management and/or for the financing of an experiment" (Chapter II, Article 2, 21 °, Law of 7 May 2004) | | | | |
| Name |  | | | |
| Address (headquarter) | Street :  Postcode :  City :  Country : | | | |
| Contact person (First Name/Name) |  | | |  |
| Phone/fax/email |  |  |  | |
| Sponsor’s status | Commercial  Academic[[1]](#footnote-1) | | | |

1. **Authorized representative (if applicable) :**

|  |  |  |  |
| --- | --- | --- | --- |
| Authorized representative means "any natural or legal person established in the Community who, explicitly designated by the manufacturer, acts and may be addressed by authorities and bodies in the Community instead of the manufacturer with regard to the latter's obligations under this Directive" (art 1, j, European directive 93/42/EEC). | | | |
| Name |  | | |
| Address (headquarter) | Street :  Postcode :  City :  Country : | | |
| Contact person (First Name/Name) |  | | |
| Phone/fax/email |  |  |  |

1. **Clinical Trial Identification :**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Eudamed Number |  | | | | |
| Study Title |  | | | | |
| Protocol number / date / version |  |  | |  | |
| Primary endpoints |  | | | | |
| Planned start date | Choose a date | | | | |
| Planned end date | Choose a date | | | | |
| Planned number of subjects to be enrolled in the clinical investigation | In Belgium :       In Europe (incl. Belgium) :  Outside Europe : | | | | |
| Status of clinical trial | Monocentric  Multicentric | | | | |
| If multicentric clinical trial, indicate countries participating in this study. | Austria  Belgium  Bulgaria  Cyprus  Czech Republic  Denmark  Estonia  Finland  France  Germany  Greece  Hungary | | Iceland  Ireland  Italy  Latvia  Liechtenstein  Lituania  Luxembourg  Malta  Netherlands  Norway  Poland  Portugal | | Romania  Slovakia  Slovenia  Spain  Sweden  Switzerland  Turkey  United Kingdom  Others |
| Study Design (randomized, cross-over, parallel, single-blind, double-blind, controlled, …) |  | | | | |
| Central Ethics Committee (in Belgium) | Name of institution :  Address :  Contact person :  Date of submission : choose a date  Approval date : choose a date | | | | |
| Primary Objective |  | | | | |
| Inclusion Criteria |  | | | | |
| Exclusion Criteria |  | | | | |

1. **Medical Device Identification :**

|  |  |  |
| --- | --- | --- |
| Generic denomination |  | |
| Commercial name / Model |  |  |
| GMDN code  (See on https://www.gmdnagency.com) |  | |
| Intended use |  | |
| Medical device classification | Class I  Class IIa  Class IIb  Class III  AIMD | |
| Classification rule | Choose a rule | |
| If it is a class IIa or IIb | Short term use (≤30days)    Long term use (>30days) | |
| Does the medical device bear a CE-marking?  If yes, please indicate the number and name of the notified body.  Date of the certificate issued by the notified body.  Will the medical device be used in accordance with the intended use by the manufacturer and within the scope of the CE-certificate ?  If no, indicate the intended use covered by the certificate. | YES  NO    Number :       Name of Notified Body :  Choose a date  YES  NO | |
| Does the medical device incorporate a substance which if used alone can be considered a drug?  If yes, which? | YES  NO | |
| Therapeutic area investigated | Other : | |
| Is your medical device manufactured using tissue of animal origin? (see directive 2003/32/EC) | YES  NO | |
| Does your medical device contain human blood or blood plasma component(s)? (see directive 2001/83/EC) | YES  NO | |

1. **Investigator site in Belgium**

**Investigator**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Name / First name / Title | |  | |  | |  | |
| Function | | Principal Investigator  Co-Investigator | | | | | |
| Clinical qualification, speciality | |  | | | | | |
| Clinical institution name | |  | | | | |  |
| Address | | Street :  Postcode :  City :  Country : | | | | | |
| Phone/fax/email |  | |  | |  | | |

**Investigator**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Name / First name / Title | |  | |  | |  | |
| Function | | Principal Investigator  Co-Investigator | | | | | |
| Clinical qualification, speciality | |  | | | | | |
| Clinical institution name | |  | | | | |  |
| Address | | Street :  Postcode :  City :  Country : | | | | | |
| Phone/fax/email |  | |  | |  | | |

**Investigator**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Name / First name / Title | |  | |  | |  | |
| Function | | Principal Investigator  Co-Investigator | | | | | |
| Clinical qualification, speciality | |  | | | | | |
| Clinical institution name | |  | | | | |  |
| Address | | Street :  Postcode :  City :  Country : | | | | | |
| Phone/fax/email |  | |  | |  | | |

**Investigator**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Name / First name / Title | |  | |  | |  | |
| Function | | Principal Investigator  Co-Investigator | | | | | |
| Clinical qualification, speciality | |  | | | | | |
| Clinical institution name | |  | | | | |  |
| Address | | Street :  Postcode :  City :  Country : | | | | | |
| Phone/fax/email |  | |  | |  | | |

**Statement**

For and on behalf of Name of Manufacturer or Authorized Representative

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| --- |
|  |
| 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 device complies with the Essential Requirements apart from those covered by the investigation and that with regard to these aspects, every precaution has been taken to protect the health and safety of the patient and/or user. |
| I certify that the investigation will be carried out in accordance with the Declaration of Helsinki and EN ISO 14155. |
| I undertake to keep available for the Competent Authority for a period of 5 years all the |
| documentation referred to in Annex VI Council Directive 90/385/EEC and Annex VIII Council Directive 93/42/EEC |
| **Date and signature of the manufacturer or his authorized representative**   |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | | Signed: |  |  | Date: |  |  |  |  |  | | First name/last name: |  |  |  |  |  |  |  |  | | Authority/Position : |  |  |  |  |  |  |  |  | |  |  |  |  |  |  |  |  |  | |

**Documents to be enclosed in this order in a binder and also for the electronic version :**

|  |  |
| --- | --- |
|  | 1. Cover letter |
|  | 1. Application form (original signed) |
|  | 1. Ethics committee approval or proof of application to Ethics Committee |
|  | 1. Decision from other country |
|  | 1. Agreement (only for academic study) |
|  | 1. Protocol (CIP) (following EN ISO 14155 and GCP) |
|  | 1. Investigator Brochure (following EN ISO 14155) |
|  | 1. Intended device labelling |
|  | 1. Patient informed consent |
|  | 1. Insurance certificate (National law of 7 May 2004, article 29) |
|  | 1. Notified body certificate(s) |
|  | 1. Declaration of conformity from manufacturer |
|  | 1. Proof of paiement |
|  | 1. Others (delegation form, …) |

**Account information :**

Fees have to be paid on 679-0021942-20 Federal Agency for Medicine and Health Products.

IBAN CODE: BE28 6790 0219 4220

BIC/Swift code: PCHQBEBB

Send your application to :

Federal Agency for Medicines and Health Products - R&D Division - Clinical Investigation MEDDEV  
Eurostation II   
Place Victor Horta, 40 box 40   
1060 Brussels

1. If this is an academic study (following point 15, article 2 of chapter II from the national law of 7 May 2004), provide us the clinical trial agreement between the manufacturer and the sponsor. [↑](#footnote-ref-1)