**1.** **The Application**

|  |
| --- |
| Date of submission: |
| First submission |
| Re-submission  Danish Medicines Agency case number:       Date of first submission: |
| EUDAMED CIV-ID number (if known): |

**2. Sponsor**

*The Sponsor is the individual, institution or organization who or which takes responsibility for the initiation and implementation of a clinical investigation.*

|  |  |
| --- | --- |
| Company / institution |  |
| Contact person |  |
| Title |  |
| Address |  |
| Phone number |  |
| Fax number |  |
| E-mail |  |

**3. Medical Device**

*Please copy this page if there are more medical devices under investigated*

|  |  |
| --- | --- |
| Product Type |  |
| Make |  |
| Name of device |  |
| Model |  |
| Class of device | I  IIa  IIb  III  AIMD  IVD |
| Sterile medical device | Yes  No |
| CE-marked medical device | Yes  No |
| Notified Body, if relevant |  |

**NB: Please copy this page if there are more medical devices under investigation**

**4. Manufacturer**

*The manufacturer is the natural or legal person with responsibility for the design, manufacture, 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.*

|  |  |
| --- | --- |
| Company / institution |  |
| Contact person |  |
| Title |  |
| Address |  |
| Phone number |  |
| Fax number |  |
| E-mail |  |

**5. EEC representative**

*The sponsor’s legal representative in an EU/EEC county i.e., if the sponsor is not resident in an EU/EEC country.*

|  |  |
| --- | --- |
| Company |  |
| Contact person |  |
| Title |  |
| Address |  |
| Phone number |  |
| Fax number |  |
| E-mail |  |

**6. Contract Research Organisation (CRO)**

*If relevant.*

|  |  |
| --- | --- |
| Company |  |
| Contact person |  |
| Title |  |
| Address |  |
| Phone number |  |
| Fax number |  |
| E-mail |  |

**7. Clinical investigation**

|  |
| --- |
| Clinical investigation plan title: |
| Clinical investigation reference / ID number stated by Sponsor: Date: |
| Number of subjects to be included in the investigation:  DK:      Globally: |
| Total number of the device(s) to be used in the investigation:  DK:      Globally:  If more than one medical device is under investigation, please state number and name of device(s): |
| Initiation date:       Finish date: |

**8. Coordinating investigator**

*The investigator that is appointed to coordinate work in a multi-centre investigation.*

|  |  |
| --- | --- |
| Name |  |
| Institution |  |
| Title |  |
| Address |  |
| Phone number |  |
| Fax number |  |
| E-mail |  |

**9. Principal clinical investigator in Denmark**

*Every investigation centre has an investigator responsible for the investigation carried out at that particular site.*

|  |  |
| --- | --- |
| Name |  |
| Institution |  |
| Title |  |
| Address |  |
| Phone number |  |
| Fax number |  |
| E-mail |  |

**Principal clinical investigator in Denmark**

|  |  |
| --- | --- |
| Name |  |
| Institution |  |
| Title |  |
| Address |  |
| Phone number |  |
| Fax number |  |
| E-mail |  |

**Principal clinical investigator in Denmark**

|  |  |
| --- | --- |
| Name |  |
| Institution |  |
| Title |  |
| Address |  |
| Phone number |  |
| Fax number |  |
| E-mail |  |

**Please copy this page if there are more investigation centres**

**10. Investigation centres outside Denmark**

*Information concerning other countries where this investigation has been / will be notified to the competent authority, including opinions received.*

|  |  |
| --- | --- |
| **Countries where authorisation has been granted** | **Countries where authorisation is pending** |
|  |  |

Have objections, or supplementary comments, to the investigation been raised by other competent authorities:

**No**  , **Yes**

If yes, please state where and the reasons why:

**11. Attached documents**

|  |  |
| --- | --- |
| **Documents** | **Document, version, comments** |
| Clinical investigation plan |  |
| Investigator’s Brochure |  |
| Patient information sheet and informed consent form |  |
| Letter of authority, allowing the Danish Medicines Agency and the monitor to access the subject’s journal/medical records |  |
| Statement certifying that the device in question complies with the Essential Requirements, apart from those aspects covered by the investigation, and that with regard to these aspects, every precaution has been taken to protect the health and safety of the subject. The statement shall refer to the relevant medical device directive. |  |
| A description of the specified intended use of the CE-marked device, a copy of the device’s Declaration of Conformity as well as certificates from the Notified Body, if relevant |  |
| Copy of the Scientific Ethical Committee opinion(s), if available |  |
| Picture of the device or a specimen, if appropriate |  |
| Other documents, if relevant |  |

**12. Overview of information provided in the application**

*List of reference to essential information provided in the submitted documentation.*

|  |  |
| --- | --- |
| **Device under investigation** | |
| Intended purpose of the device, including indications and contraindications | Document Page |
| The device’s intended performance, mode of action, components and materials as well as identification of any features of design that are different from similar previously marketed products. | Document Page |
| Result of risk analysis and risk assessment, including potential risks and anticipated serious adverse device effects. | Document Page |
| Summary of any experience with the device and any similar devices manufactured by the company including length of time on the market and a review of safety and performance related complaints. | Document Page |
| Summary and evaluation of pre-clinical data.  Have all relevant pre-clinical test been completed:  Yes  No  Provide justification for why the investigation can be initiated. | Document Page |
| Summary of the literature and an evaluation supporting the rationale for the intended use of the device. | Document Page |
| Summary of the relevant standards applied in full or  in part, and to what extent the standards have been applied. | Document Page |
| **Design of the clinical investigation** | |
| The purpose, end points and the specific hypotheses to be accepted or rejected as well as pass/fail criteria to be applied to the results of the investigation. | Document Page |
| Justification for the statistical design, including the choice of sample size, expected drop-out rates, the level of significance to be used, the power of the investigation as well as the clinical relevance. | Document Page |
| The follow-up period in a particular subject within the investigation including follow-up procedures for subjects who have discontinued the investigation. | Document Page |
| **Quality control and quality assurance** | |
| The procedure for the management and reporting of adverse events as well as the follow-up required for each subject in the case of adverse events. | Document Page |
| Description of the monitoring plan, including the frequency of monitoring and extent of source data verification. | Document Page |

***Note*** *The application shall contain information concerning all items in the Danish executive order**on the application for the authorisation for clinical investigation of medical device[[1]](#footnote-1), as described in the guidance document “ Regulatory requirements”, available on our website www.medicaldevices.dk/clinicalinvestigation. Should a limited number of items in the executive order be considered irrelevant for a specific clinical investigation, the covering letter must contain a list of these items as well as the justification for the omissions.*

**13. Invoice information**

*To whom the invoice for the Danish Medicines Agency’s fee shall be forwarded.*

|  |  |
| --- | --- |
| Clinical investigation plan title: | |
| Company |  |
| Contact person |  |
| Company ref. number |  |
| Address |  |
| Phone number |  |
| Fax number |  |
| E-mail |  |
| VAT number |  |

**14. Sponsor’s signature**

*Sponsor declares that all information and documentation in the application are correct and that the clinical investigation will be performed according to the clinical investigation plan, national regulation and the principles for good clinical practice, i.a. described in the European standard (EN ISO 14155).*

|  |  |
| --- | --- |
| Date |  |
| Name |  |
| Signature |  |

1. Executive Order no. 292 of 19 March 2010. [↑](#footnote-ref-1)