*Please fill in the application form in English or Danish.*

*Udfyld venligst ansøgningsskemaet på engelsk eller dansk.*

*Submit the application form when submitting the necessary documentation as listed in the MREC checklist (in Danish):* [*https://nationaltcenterforetik.dk/ansoegerguide/ansoegninger-til-vmk/kliniske-afproevninger-af-medicinsk-udstyr-under-mdr/tjekliste-til-ansoegninger-om-kliniske-afproevninger-med-medicinsk-udstyr*](https://nationaltcenterforetik.dk/ansoegerguide/ansoegninger-til-vmk/kliniske-afproevninger-af-medicinsk-udstyr-under-mdr/tjekliste-til-ansoegninger-om-kliniske-afproevninger-med-medicinsk-udstyr)

**1.** **Scope of Application**

|  |
| --- |
| Application for authorisation of a clinical investigation of   * a CE marked medical device to generate clinical data within the scope of its intended purpose (art.74 (1))   *or*   * a medical device investigated for other purposes than those listed in MDR art. 62(1) (art. 82) |
| Date of submission: |
| First submission |
| Re-submission |
| EUDAMED CIV-ID number (if known): |

|  |
| --- |
| Is the clinical investigation of the medical device also submitted to Danish Medicines Agency as an application for authorisation as a clinical trial of a *medicinal product*? Yes  No  If yes, state EudraCT number  and DKMA case number |

|  |
| --- |
| Application is to be submitted to VMK by e-mail: [dketik@dketik.dk](mailto:dketik@dketik.dk)  Or via secure mail (<https://nationaltcenterforetik.dk/om-nationalt-center-for-etik/kontakt>) |

**2. Sponsor**

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

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

**3. Sponsors EEC representative, if any**

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

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

**4. Monitor (only for art. 74 (1) investigations))**

*Sponsor shall appoint a monitor, independent of the investigation site, to ensure that the investigation is conducted in accordance with the CIP, GCP and legislation. (Annex XV, Chapter III, 4). Please note that internal monitoring procedures should be described in the Clinical Investigation Plan for article 82 investigations.*

|  |  |
| --- | --- |
| Company/ individual/ organisation with the responsibility of the monitoring activities |  |
| Contact person |  |
| Title |  |
| Address |  |
| Phone number |  |
| E-mail |  |

**5. Contract Research Organisation (CRO), if any**

*If a CRO is used in the clinical investigation for another purpose than monitoring (e.g. submission of application, data management etc.) the CRO and the related activities can be identified here*

|  |  |
| --- | --- |
| Company |  |
| Contact person |  |
| Title |  |
| Address |  |
| Phone number |  |
| E-mail |  |
| Role of the CRO in the clinical investigation |  |

**6. Manufacturer of the medical device in clinical investigation**

*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. The manufacturer in this section refers to the manufacturer responsible for the IB/ statement of compliance for the investigational medical device.*

*Identification of the manufacturer’s Person Responsible for Regulatory Compliance at the time when statement of compliance is signed. Please note that MDR in article 15 has specific qualification criteria for this person.*

|  |  |
| --- | --- |
| Company / institution |  |
| Address |  |
| Contact person |  |
| Phone number |  |
| E-mail |  |
| Person responsible for regulatory compliance |  |
| Phone number |  |
| E-mail |  |

**7. Manufacturers EU representative, if any**

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

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

**8. Coordinating investigator**

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

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

**Principal clinical investigator in Denmark**

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

**Principal clinical investigator in Denmark**

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

**10. Investigation centres outside Denmark**

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

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

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

**No** , **Yes**

If yes, please state where and the reasons why:

**11. Medical Device**

*Please copy this page if there are more medical devices under investigation.   
All fields are obligatory and must be filled in.*

|  |  |
| --- | --- |
| Product type and generic name of device |  |
| Name of device |  |
| Model |  |
| CE-marked medical device | Yes  No |
| Proposed class of device (according to MDR) | I  IIa  IIb  III |
| Sterile medical device | Yes  No |
| Medical device with measuring function | Yes  No |
| Reusable surgical medical device | Yes  No |
| Is the device an *invasive* device (according to rule 5 in Chapter III of Annex VIII in MDR)? | Yes  No |
| Is the device implantable? | Yes  No |
| Does the device incorporate a medicinal substance or a human blood or plasma derivate? | Yes  No  If yes, specify the component |
| Does the device incorporate any non-viable tissues or cells of human or animal origin or their derivates? | Yes  No  If yes, specify the component |
| Notified Body, if relevant |  |

**NB: Please copy this page if there are more medical devices under investigation (i.e. a comparator device)**

**12. Clinical investigation**

|  |
| --- |
| Clinical investigation plan title in English (if any): |
| Clinical investigation plan title in Danish: |
| Clinical investigation plan   * reference number / code given by Sponsor: * version number * date |
| Number of subjects to be included in the investigation:  DK:      Globally: |
| Total number of device(s) to be used in the investigation:  DK:      Globally: |
| Expected Initiation date (patient recruitment start): Global (if any)       / Denmark  Expected end date (last patient last visit): Global (if any)       / Denmark |
| **Short** summary of the design (controlled/randomised) and objective of the clinical investigation, including information on population gender/age of subjects (e.g. inclusion of subjects under 18 years) and *main* eligibility criteria for subjects: |

**13. Submission of documents and fees**

VMK charges a fee for processing applications under MDR art. 74 (1). 1 and MDR art. 82.

Therefore applicants shall fill out an invoicing form, which must be attached to the application and sent in simultaneously with submission of the application.

Further information on MREC guidelines, fees and a link to invoicing forms can be found on this website: <https://nationaltcenterforetik.dk/ansoegerguide/ansoegninger-til-vmk/kliniske-afproevninger-af-medicinsk-udstyr-under-mdr>

*I have read, numbered and attached documents according to the MREC guideline*

**14. Sponsor’s Declaration and Signature**

*I/We are aware of the obligations in Annex XV of MDR to*

* *Conduct the study according to ethical principles (declaration of Helsinki), the principles for good clinical practice in clinical investigation of medical devices ISO 14155 and according to national legislation*
* *Make the clinical investigation report and a summary of the clinical investigation report (in lay man terms) publicly available in EU commissions EUDAMED database when this is made available*
* *Keep available for the Danish Medicines Agency for a period of 10 years (15 years for implantable devices) after the end of the clinical investigation all documentation referred to in Annex XV of MDR.*

*We are aware that the Danish Medicines Agency and Medical Research Ethics Committees may contact each other and share information in relation to the assessment of this specific clinical investigation.*

|  |  |
| --- | --- |
| Date |  |
| Name |  |
| Sponsor’s signature |  |