**1. The application**

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

*Udfyld venligst ansøgningsskemaet på engelsk eller dansk.*

Application is to be submitted as **one mail to two recipients**; [med-udstyr@dkma.dk](mailto:med-udstyr@dkma.dk) and [dketik@dketik.dk](mailto:dketik@dketik.dk) in order for both parties to assess the application within same time frame.

|  |
| --- |
| The substantial modification covers   * only a time extension of the clinical investigation    + Please specify the new clinical investigation end date   *or*   * other substantial modifications (please specify in section 4) |

|  |
| --- |
| Date of submission: |
| Danish Medicines Agency case number: |
| Medical Research Ethics Committees case number: |
| EUDAMED CIV-ID number: |
| Version of previously accepted clinical investigation plan: |
| Version for amended clinical investigation plan: |

**2. Clinical investigation**

|  |
| --- |
| Clinical investigation plan title: |
| Sponsor’s Reference/ID number: |

**3. Sponsor**

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

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

**4. Changes/amendments**

|  |
| --- |
| Description of changes/amendments: |
| Reason for changes/amendments: |
| Considerations concerning the potential consequences of the changes/amendments on the final result of the clinical investigation: |
| Number of subjects presently included in the investigation: |

**Submitted documents:**

*In the submitted documents the amended text must be clearly indicated and the rationale for the amendment must be provided.*

| Document | Version |
| --- | --- |
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**5. Invoice information**

**DKMA fee for amendment application assessment**

*According to Executive Order no. 737 of 24 May 2022 on fees for medical devices and medical devices for in vitro diagnostics, the fee for 2022 is 11,528 DKK.*

|  |  |
| --- | --- |
| Clinical investigation plan title: | |
| Company |  |
| Contact person |  |
| Company invoice ref. number |  |
| Address |  |
| Phone number |  |
| E-mail |  |
| CVR / VAT number and EAN number | CVR / VAT number  EAN number for Danish invoice recipients, if any |

**Medical Research Ethics Committees fee for amendment application assessment**

*According to Executive Order no. 713 of 24 May 2022 on “videnskabsetisk behandling af kliniske afprøvninger af medicinsk udstyr og undersøgelse af ydeevne af medicinsk udstyr til in vitro-diagnostik”, the fee for 2022 is 4,561 DKK.*

|  |  |
| --- | --- |
| Clinical investigation plan title: | |
| Company |  |
| Contact person |  |
| Company invoice ref. number |  |
| Address |  |
| Phone number |  |
| E-mail |  |
| CVR / VAT number and EAN number | CVR / VAT number  EAN number for Danish invoice recipients, if any |

**6. Sponsor’s signature**

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

All changes/amendments can only be implemented once authorized by the Danish Medicines Agency and the Medical Research Ethics Committees.

*Significant changes of a clinical investigation of a medical device are changes that can affect thet:*

* *Safety, health and rights of subjects*
* *Robustness or reliability of the clinical data generated by the investigation, e.g.*
  1. *Interpretation of the scientific documentation that serves as the foundation of the investigation,*
  2. *Conduct or management of the investigation, including the introduction of a new coordinating investigator, inclusion of a new Danish centre or new Danish principal investigators*
  3. *Quality or safety of the medical device under investigation*
  4. *Other significant aspects*