**1. The application**

|  |
| --- |
| Date of submission: |
| Danish Medicines Agency case number: |
| EUDAMED CIV-ID number (if known): |
| Date of previously accepted clinical investigation plan: |
| Sponsors’s reference/ID-number for changes: |

**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 |  |
| Fax 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.*

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

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

|  |  |
| --- | --- |
| Company |  |
| Contact person |  |
| Company ref. number |  |
| Address |  |
| Phone number |  |
| Fax number |  |
| E-mail |  |
| VAT number |  |

**6. Sponsor’s signature**

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

All changes/amendments shall be signed by sponsor and can only be implemented when authorised by the Danish Medicines Agency.

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

* *Safety of the subjects*
* *Interpretation of the scientific basis for the investigation*
* *Implementation or management of the investigation including a new coordinating investigator, inclusion of new Danish centres or new Danish principal investigators*
* *Quality or safety of the medical device being tested*
* *Additional significant conditions.*