**1. Notification**

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

[ ]  Initial report

[ ]  Follow-up report

[ ]  Combined initial and final report

[ ]  Final report

**2. Clinical investigation**

|  |
| --- |
| Clinical investigation plan title / ID number:        |

**2. 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. Medical Device**

|  |  |
| --- | --- |
| Make |       |
| Name of device |       |
| Model |       |

**5. Event / near-incident**

|  |  |
| --- | --- |
| Location of event |       |
| Contact person |       |
| Subject ID number |       |
| Description of event and action taken |       |
| Type of event | [ ]  Death[ ]  Life threatening illness or injury[ ]  Permanent impairment of a body structure or body function [ ]  In-patient hospitalization or prolongation of existing hospitalization[ ]  Necessity of medical or surgical intervention to avoid above mentioned [ ]  Fetal distress, fetal death or a congenital abnormality or birth defect. [ ]  Near-incident[ ]  Congenital anomaly or malformation |
| Date of event |       |
| Assessment of relationship with the medical device under investigationInvestigator: Sponsor: [ ]  Related [ ]  Related[ ]  Probably [ ]  Probably[ ]  Possibly [ ]  Possibly[ ]  Unlikely [ ]  Unlikely [ ]  Not related [ ]  Not related |
| Patient Outcome | [ ]  Recovered[ ]  Recovering[ ]  Not recovered[ ]  Recovered with sequelae[ ]  Fatal[ ]  Unknown |
| Consequence for the subject |       |
| Consequence for the clinical investigation |       |

|  |
| --- |
| **Other findings (e.g. laboratory findings, ECG, ultrasound)**  |
|       |

|  |
| --- |
| **Relevant medication** |
|       |

|  |
| --- |
| **In case of death** |
| Cause according to investigator  |       |
| Autopsy performed | [ ]  No[ ]  Yes, findings       |

**6. Sponsor’s signature**

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

*A* ***serious event*** *is any event leading to:*

* *death*
* *life threatening illness or injury*
* *permanent impairment of a body structure or body function*
* *in-patient hospitalization or prolongation of existing hospitalization*
* *necessity of medical or surgical intervention to avoid above mentioned*
* *fetal distress, fetal death or a congenital abnormality or birth defect*

*A* ***near-incident*** *is a device deficiency that might have led to a SAE if suitable action had not been taken or if circumstances had been less fortunate.*