**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 investigation  Investigator: 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.*