**ADVERSE EVENT REPORT – ELECTRO MEDICAL DEVICES**

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| --- |
| **What are you reporting?** |
| **SAE / SADE** |  | **USADE** |  |
| **\* If the event is related and unanticipated it is an Unexpected Serious Adverse Device Event (USADE) and requires expedited reporting. Inform the Sponsor immediately.** |
| Is the Study Device Blinded or Unblinded? | Blinded |  | Unblinded |  |
| Has the subject been unblended? | Yes |  | No |  | N/A |  |
| Was the event related to a protocol violation? | Yes |  | No |  |
| Was the subject withdrawn due to this event? | Yes |  | No |  |
| **Report Type:** | Initial Report |  | Follow-up Report |  | Final Report |  |
| **Study Information:-** |
| **Study Title:** |  |
| **NBC Number:** |  |
| **Sponsor:** | Chief Investigator Name: |  |
| Email: |  |
| **Clinical Investigation Plan title & version number** |
| **Site Number***(For multicenter studies only)* | **Site Name:** |  |
| **Principal Investigator**  | **Name:** |  |
| **PI Institution Address:** |  |
| **Email:** |  |
| **Contact Number:** |  |
| **Date of site becoming aware of the event**  | *(dd/mm/yyyy):* |
| **Participant Information:** |
| **Participant Date of Birth (DOB)** | **Participant Initials:** | **Participant Gender:** |
| dd | mm | yyyy |  | Male |  | Female |  |
| **Participant Randomisation No:** |
| **Evaluation of Event:** |
| **Event/Reaction:** *(keywords: e.g. body site, symptoms, severity, treatment)* |

|  |  |  |  |
| --- | --- | --- | --- |
| **Date of onset:** | *(dd/mm/yyyy)* | **Date person completing form became aware of event** | *(dd/mm/yyyy)* |
| **Criteria for definition as SAE:** | Congenital abnormality / birth defect |  |
| Resulted in death |  |
| Life threatening |  |
| In patient hospitalization / prolongation of hospitalization |  |
| Persistent or significant disability |  |
| Other e.g. is otherwise considered medically significant by the investigator |  |
| ***\**** *If there is more than one criterion, choose the more / most significant one.* |
| **Describe the event:** *(A summary of signs and symptoms, diagnosis, treatment of event, concurrent treatment, other relevant medical history, including re-challenge details if applicable. Please include the point in the study at which the event occurred.)* |
|  |
| **In the investigators opinion was the event related to a research procedure?** | Definitely |  |
| Likely |  |
| Possibly |  |
| Unlikely |  |
| Not related |  |
| **Please specify which procedure if applicable** |  |
| **Study Medical Device Information:** If more than one device is being used, please complete for each device: |
| **Subject has been fitted / used / treated with the devices?** | **Yes** |  | **No** |  |
| **If No – Give Reason** (i.e. screening) |  |
| **If Yes – Provide details in the table below:** |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Name of Device** | **Indication for use** | **Route of administration / use** | **Date of first use** | **Date of last use** |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
| **In the investigators opinion was the event related to the device?** | Definitely |  |
| Likely |  |
| Possibly |  |
| Unlikely |  |
| Not related |  |
| **Action taken with Device** | None |  |
| Device schedule adjusted |  |
| Device permanently removed / discontinued Date | *(dd/mm/yyyy)* |
| Other – provide details |  |
| Detail treatment given |  |
| Unknown at time of report |  |
| Not applicable |  |
| **If related to the device was this reaction unexpected (Unexpected Serious Adverse Device Event – USADE)?** | Yes |  | No |  | Not Applicable |  |
| **Outcome of event** |
| **What is the outcome of the SAE?** |  |
| **Date of event resolved:** | *(dd/mm/yyyy)* |
| **Date of patient died:** | *(dd/mm/yyyy)* |
| **Recovered** |  |  |
| **Recovered with Sequalae** |  |  |
| **Continuing** |  |  |
| **Resulted in death** |  |  |
| **Unknown** |  |  |
| **Cause of death obtained from:** | Coroner’s inquest |  |
| Death certificate |  |
| Working diagnosis |  |
| ***Contact and signatures*** |
| **Please supply contact details where further information may be obtained:** | *Person to contact* |  |
| *Contact number* |  |
| *Email Address* |  |

***Signature*** *(Person completing report)* Date: *(dd/mm/yyyy)*

***PI Signature*** *(if multicentre trial)* Date: *(dd/mm/yyyy)*

***CI Signature*** *(If not completing report)* Date: *(dd/mm/yyyy)*