**ADVERSE EVENT REPORT – ELECTRO MEDICAL DEVICES**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **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| Was the subject withdrawn due to this event?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)* | | | | | | | | | | | | | | | | | | | | | |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **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:** | | | | | | | | | | |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Name of Device** | **Indication for use** | | **Route of administration / use** | | | | **Date of first use** | | | | | **Date of last use** | | | |
|  |  | |  | | | |  | | | | |  | | | |
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|  |  | |  | | | |  | | | | |  | | | |
|  |  | |  | | | |  | | | | |  | | | |
| **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)*