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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **MEDDEV 2.7/3 SAE Report Table v2** | | | | | | | | | | | | | | | | |
| **EUDAMED - ID:** | |  | | | | | | | | | | | | | | |
| **Title of Clinical Investigation:** | |  | | | | | | | | | | | | | | |
| **CIP Number:** | |  | | | | | | | | | | | | | | |
| **Contact person** (Name, Address,  E-Mail, Telephone Number) | |  |  |  |  |  |  |  |  |  | **Device type:** |  | | | | |
| **MS+NCA Reference Numbers** for all participating Countries: | |  | | | | | | | | | **Reference Member State:** |  | | | | |
| **No. of Patients enrolled to date total**: | |  |  | **No. of Patients enrolled to date** (date of report) **per country**: | |  |  |  |  |  | **No. of Invest. Devices used to date total:** |  |  | **No. of Invest. Devices used to date per country:** |  |  |
| **Date of Report:** | | dd/mm/yyyy | | | | | | | | | | | | | | |
| **Status:  A, M**, **U** | **Date Sponsor received Report of SAE (dd/mm/yyyy)** | **Countrycode** | **Study Center** | **Patient ID Code** | **SAE ID Code** | **Date of Procedure/ First Use (dd/mm/yyyy)** | **Date of Event Onset (dd/mm/yyyy)** | **SAE OR Dev. Def.** | **Description of event** | **action/ treatment/patient outcome** | **Relationship to Procedure:** not related **OR** unlikely **OR** possible **OR** probable **OR** causal relationship | **Relationship to Investigational Device:** not related **OR** unlikely **OR** possible **OR** probable **OR** causal relationship | **Unanticipated SADE:** Yes **OR** No | **Treatment Arm:** Investigational Device/ Control Group/ blinded/ n.a. | **Event Status:** Resolved/ Resolved with Sequelae/ Ongoing/Death | **Date of Event Resolution (dd/mm/yyyy)** |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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Link to the current [Medical Devices Sector Directives](https://ec.europa.eu/growth/sectors/medical-devices/current-directives/guidance_en)