[Medical Devices Sector - Current Directives](https://ec.europa.eu/growth/sectors/medical-devices/current-directives/guidance_en)

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **MEDDEV 2.7/3 SAE Report Table v1** | | | | | | | | | | | | | | | | | | | | | | |
| **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** (date of report): | |  | | | | | | | | | | | | | | | **No. of Invest. Devices used to date** |  | | | | |
| **Date of Report:** | |  | | | | | | | | | | | | | | | | | | | | |
| **Status:  a,** m, u | **Date Sponsor received Report of SAE** | **Country** | | **Study Center** | **Patient ID Code** | | **Date of Procedure/ First Use** | | **Date of Event Onset** | | **Event: Organ System** | | **Description of event** | **action/ treatment/patient outcome** | | **Assessment of Relationship to Procedure:** Yes No Possibly | | **Assessment of Relationship to Investigational Device:** Yes No Possibly | **Unanticipated SADE** yes/No | **Treatment Arm:** Investigational Device/ Control Group/ blinded/ n.a. | **Event Status:** Resolved/ Resolved with Sequelae/ Ongoing/Death | **Date of Event Resolution** |
|  |  |  | |  |  | |  | |  | |  | |  |  | |  | |  |  |  |  |  |
|  |  |  | |  |  | |  | |  | |  | |  |  | |  | |  |  |  |  |  |
|  |  |  | |  |  | |  | |  | |  | |  |  | |  | |  |  |  |  |  |
|  |  |  | |  |  | |  | |  | |  | |  |  | |  | |  |  |  |  |  |