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

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| **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 Patientsenrolled to date** (date of report): |  | **No. of Invest.Devicesused 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:OrganSystem** | **Description of event** | **action/ treatment/patient outcome** | **Assessment of Relationshipto Procedure:**YesNoPossibly | **Assessment of Relationship to Investigational Device:**YesNoPossibly  | **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** |
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