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)**

Note 1: Submission of this report does not, in itself, represent a conclusion by the sponsor or the competent authority that the content of this report is complete or that the device(s) listed failed in any manner and/or that the device(s) caused or contributed to the alleged death or deterioration in the state of the health of any person.

Note 2: If additional columns are added to this form (for instance to include the opinion of the investigators), please add them next to the existing columns on the right. This form may be subjected to automatic analysis and addition of columns in between may interfere with automatic analysis. Widthening of columns can be applied without alteration of the order.