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| **Please send to:  Bundesamt für Sicherheit im Gesundheitswesen** Institut Überwachung Traisengasse 5  1200 Vienna  Austria |  | | | |
| **Study identifier:** | | | | |
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| 1. Title/short title and version (number and/or date) of the Clinical Investigation Plan/Performance Evaluation Plan: | | | | |
| 1. Date of registration of the clinical investigation/performance evaluation (dd.mm.yyyy):   Reference number: INS- | | | | |
| 1. Name/description of the medical device/in vitro diagnostic medical device: | | | | |
| 1. Sponsor:   Company:  Contact:  Street:  ZIP code/place:  Country:  Phone/Fax:  Email: | | 1. Representative of the sponsor in Austria or in the EEA:   Company:  Contact:  Street:  ZIP code/place:  Country:  Phone/Fax:  Email: | | |
| 1. Hospital, department, office, or outpatient clinic at which the study is being carried out: | | 1. Name of the responsible investigator: | | |
| 1. Study participant in whom the serious adverse event occurred:   Patient ID: Year of birth (yyyy):  female  male | | | |  |
| 1. Description of the event, time, duration (from–to): | | | | |
| 1. Relationship to the medical device/in vitro diagnostic medical device:   certain  probable  unlikely  not assessed  not assessable | | | | |
| 1. Statement/assessment of the clinical investigator: | | | | |
| 1. Consequences of the serious adverse event:   death  life-threatening event  persistent disability  hospitalisation  prolongation of hospitalisation  malignant tumour | | | | |
| 1. Outcome/state of the study participant after intervention:   recovered  not yet recovered  persistent disability  unknown  death; cause: | | | | |
| 1. Details on how the medical device/in vitro diagnostic medical device was used in the study participant: | | | | |
| 1. Details on what measures were taken to treat the study participant: | | | | |
| 1. Was the use of the medical device/in vitro diagnostic medical device discontinued as a result of the event?   no  yes, on (dd.mm.yyyy):  interrupted and resumed, on (dd.mm.yyyy): | | | | |
| 1. Details, in case the comparative treatment (or concomitant medication) caused a serious adverse event: | | | | |
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| Place, date and signature of the investigator or stamp or signature of the sponsor (including names in capital letters) | | | | |