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| **Please send to: Bundesamt für Sicherheit im Gesundheitswesen**Institut ÜberwachungTraisengasse 51200 ViennaAustria |  |
| **Study identifier:**  |
|  |
| 1. Title/short title and version (number and/or date) of the Clinical Investigation Plan/Performance Evaluation Plan:
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| 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:
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| 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:
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| 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:

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| 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:

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| 1. Details on what measures were taken to treat the study participant:

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| 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) |