T11 Incident Report - pdf

Document ID	Revision Number	Edited by	Reviewed by:	Released by / Date
80846	003/08.2018	Kornwebel, Michael 2018-08-08	Vogel, Anne 2018-08-09	Kornwebel, Michael 2018-08-10

In case of an incident due to our products, please fill in this form and return it via Email (incident@besa.de) or fax (+49 - 89 - 89 80 99 67) to Dr. Tobias Scherg, Safety Responsible or to the Deputy Safety Responsible Michael Kornwebel, Quality Manager.

Note:
Incident "Any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labeling or the instructions for use which, directly or indirectly, might lead to or might have led to the death of a patient, or USER or of other persons or to a serious deterioration in their state of health." (MEDDEV 2.12-1 Rev.8, 4.10)

Report submitted by:

Name: _____

Title: _____

Institution: _____

Working Department _____

Address: _____

_____

_____

Phone/Fax/Email _____

Mobile (voluntary) _____

Incident observed by (if different from above):

Name: _____

Institution: _____

Working Department _____

Address: _____

_____

_____

Phone/Fax/Email _____

Mobile (voluntary) _____

Software causing the incident:

Program: _____

Version: _____

Serial license number: _____

Hardware used with the product (if applicable):

_____

Details of the incident

Date of the incident yyyy-mm-dd: _____

Description of the incident: (please indicate any malfunction or deterioration in the characteristics and/or performance of our device, as well as any inadequacy in the labelling or the instructions for use):

_____

_____

_____

_____

_____

_____

Result of the Incident (also indicate if death or deterioration of health might have been provoked)

Death of a person - patient, user, third person? ☐ Yes ☐ No

Deterioration of health ☐ Yes ☐ No

Permanent injury, permanent impairment, or permanent disease of person: ☐ Yes ☐ No

If yes or probable, please provide details:

_____

Additional event/remark on the incident:

_____

Submitted to BESA GMBH on yyyy-mm-dd: _____

by: Fax☐ Email☐ Mobile☐ other: _____

Section hereafter for internal use by BESA GMBH ONLY.

Evaluation of the seriousness of the incident (to be filled in by Safety Responsible)

Product involved is: Class I ☐ Class IIa ☐ Other class: ☐

Product not classified ☐

Note: *) for rationale refer to MOI Incident Reporting

1) Incident is subject to submission to German Authorities (BfArM, Notified Body, DIMDI) because.

2) Incident does not need to be reported to German BfArM and the Notified Body because:

3) Incident has to be reported to other National Competent Authorities NCA because:

4) Incident does not need to be reported to other National Competent Authorities NCA because:

Date: yyyy-mm-dd

_____

Signature

BESA Safety Responsible
CEO Dr. Tobias Scherg

***) Rationale for reporting/non-reporting stored in QM/08 Medical Registration+Incident Reporting**

****) Original document filed in Incident Folder (paper) : _____**
and in QM / 08 Medical Registration + Incident Reporting
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