In case of an incident due to our products, please fill in this form and return it via email (feedback@besa.de) or fax (+49 - 89 - 89 80 99 67).

This request for information is due to the European Directive on Medical Devices 93/42/EEC (MDD), to EN ISO 13485, and to the German Medical Product Law § 30.

Report submitted by:

Name: _____

Institution: _____

Address: _____

_____

_____

Phone/Fax/Email _____

Incident observed by (if different from above):

Name: _____

Institution: _____

Address: _____

_____

_____

Phone/Fax/Email _____

Software causing the incident:

Program: _____

Version: _____

Serial license number: _____

Hardware used with the product (if applicable):

_____

_____

_____

_____

_____

Details of the incident

Date of the incident: _____

Description of the incident: (please mention any type of technical malfunction, non-compliance of components, deterioration of health, any observation regarding influence on user or patient etc.)

_____

_____

_____

_____

Results of the incident:

Death of a person?	☐ Yes	☐ No
Permanent injury, permanent impairment, or permanent disease of person:	☐ Yes	☐ No
Surgical intervention became necessary:	☐ Yes	☐ No

If yes, please provide details: _____

Additional results of the incident: _____

Date of this incident report: _____

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

Product involved is Class I ☐ **Class IIa** ☐ **Product not classified** ☐
Other class:

(1) Incident <u>does not need to be reported</u> to Competent Authorities because:

(2) Incident <u>is subject to notification</u> to Competent Authorities because:

_____

Date, Signature BESA Safety Responsible