



In case of an incident or near-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 / near-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 MEGIS Software GmbH)

Product involved is Class I **Class IIa** **Product not classified**

Other class:

(1) Incident does not need to be reported to Competent Authorities because:

(2) Incident is near-incident because:

(3) Incident is subject to notification to Competent Authorities because:

Date, Signature MEGIS Safety Responsible