

# Incident report



Template located at: Q:\MEGIS QM\02 Templates\T11 Incident Report - pdf.doc  
Template valid from: 2016-12-12

Content approved by:  
MK 2016-12-12

Released by:  
MK 2016-12-12

Valid from:  
2016-12-12

**In case of an incident due to our products, please fill in this form and return it via email ([feedback@besa.de](mailto: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):

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

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## 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.)

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### 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 does not need to be reported to Competent Authorities because:

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

\_\_\_\_\_  
Date, Signature BESA Safety Responsible