

**Form**

**Change Notification  
Submission of Significant Change**



Product Service

**Identification of Change Notification:** \_\_\_\_\_ **Date:** \_\_\_\_\_

Reporting Facility: \_\_\_\_\_

Street: \_\_\_\_\_

City / ZIP code / Country: \_\_\_\_\_

Name of Contact Person: \_\_\_\_\_ Phone: \_\_\_\_\_

Fax: \_\_\_\_\_

**Scope of Change (product related):**

**Certificates acc. to following annexes:**  
MDD: II.4, III / AIMD: 2.4, 3 / IVDD: III.6, IV.4, V

- New owner\*) or new name\*)
- New product\*\*)\*\*)
- Change of intended use and/or indication\*\*)\*\*)
- Change of performance data
- Change of safety-related function(s)
- Change of materials
- Change of specifications
- Change of parameters stated on certificate\*)
- Identification of product\*)
- Additional accessories
- Labeling (including instruction for use)
- Other:

**Please list all certificates affected:**

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

**Scope of Change (system related):**

**Certificates acc. to following annexes:**  
MDD: II.3, V, VI / AIMD: 2.3, V / IVDD: IV.3, VII / ISO 13485

- New owner\*) or new name\*)
- Move of facilities to another location\*)
- Additional product category\*\*)\*\*)
- Additional design/production facilities\*)
- Transfer of design or production to another location\*)
- Change of management representative
- Change of production technology, (e.g. sterilization process)
- Change of OEM's for design and production
- Change of post market surveillance/vigilance
- Change of quality manual
- Change of European representative
- Change of harmonized QM standard
- Other:

**Please list all certificates affected:**

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

\* For these changes a new CE-application must be filled out and submitted together with this change notification form.  
\*\* For these changes the procedure Contract Review has to be followed in addition to the process of Change Notification.  
Remark: Depending on the nature of the change, additional audits, reviews, forms might be necessary.

**Additional Information** (for guidance see Notified Body Recommendations NB-MED/2.5.2/Rec2)  
Please provide either additional page(s) with your format with following information: a) brief description of the change, b) the reason for the change, c) description of the impact of the change on risk analysis and compliance of the essential requirements d) list of documents provided, or use the second page of this form.

\_\_\_\_\_  
Date

\_\_\_\_\_  
Name/ Signature / Company seal

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**Change Notification  
Submission of Significant Change**



Product Service

**Identification of Change Notification:** \_\_\_\_\_

**Date:** \_\_\_\_\_

a) Description of the change planned/comparison old-new: Additional information given on attachment:

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b) Reason for the change: Additional information given on attachment:

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c) Description of influence of the change on risk analysis and compliance with essential requirements

- Was an update of risk analysis necessary?  yes  no
- Was an update of Essential Requirements checklist necessary?  yes  no
- Has product verification/validation been changed?  yes  no

d) List of documents provided: Additional information given on attachment:

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