Process of Substantial Change Notifications to DEKRA Certification GmbH

Dear Customer,

As per MDD 93/42/EEC, the Notified Body must be informed regarding any planned substantial changes to the approved quality system or the product range covered. These changes must be assessed by the Notified Body:

*"The manufacturer must inform the notified body which approved the quality system of **any plan for substantial changes** to the quality system or the product-range covered. The notified body must assess the changes proposed and verify whether after these changes the quality system still meets the requirements referred to in Section 3.2. It must notify the manufacturer of its decision. This decision must contain the conclusions of the inspection and a reasoned assessment." - MDD 93/42/EEC Annex II without Section 4 (Section 3.4) / Annex V (Section 3.4)*

*"**Changes** to the approved design must receive further approval from the notified body which issued the EC design-examination certificate wherever the changes could affect conformity with the essential requirements of the Directive or with the conditions prescribed for use of the product. The applicant shall inform the notified body which issued the EC design-examination certificate of any such changes made to the approved design. This additional approval must take the form of a supplement to the EC design-examination certificate." - MDD 93/42/EEC Annex II with Section 4 (Section 4.4)*

In order to simplify the procedure for our customers DEKRA Certification GmbH provides you with this form (either via homepage or directly from the auditor) on which you should notify us of substantial changes. Please note that the explanations are marked in italics.

As guidance regarding rating / assessment of substantial changes, please see Notified Body Operations Group NBOG 2014-3 "Guidance for manufacturers and Notified Bodies on reporting of Design Changes and Changes of the Quality System" and EK-Med 3.9 B31 respectively.

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To be completed by the manufacturer: *Please fill in the following information:*

Manufacturer:	*The complete name of your company including legal form of your company*
Contact person:	*The contact person for possible further enquiries*
Product name / Product group:	*The name of the products or product groups affected by the change*
Classification / Rule:	*The classification of the product or product group affected by the change*
MD-Code / GMDN-Code	*The MD-Code and the GMDN-Code of the product or product group affected by the change*
Article number(s):	*The article number of the product or product group affected by the change (only necessary for class III products)*
Report number (if available):	*The report number of DEKRA Certification GmbH (if available) for the product or product group affected by the change*
Certificate number:	*The certificate number (eg design examination certificate, EC-certificate for quality assurance system) in which the product or product group affected by the change is listed or shall be listed*
Date / timeframe of implementation of planned change:	*Future date or timeframe of implementation of the substantial change. Your documented planning must adequately take into account the assessment effort of the notified body*

What is the nature of the change? Please tick the relevant column according to the applicable Annex.

Scope of Change (product / product group):	**Scope of Change (QM system):**
☐ New/removed product ☐ Added or removed product category ☐ New product name ☐ New product variant class III ☐ New product variant < class III, outside of established technical specification ☐ Additional product sizes ☐ Change of intended use and/or indication ☐ Change of safety-related function(s) ☐ Change of materials ☐ Change of specifications ☐ Transfer of design or production to another location ☐ Change of production technology, (eg sterilisation process) ☐ Change of an OEM or a critical subcontractor ☐ Change of parameters stated on design examination certificate ☐ Identification of the product ☐ Additional accessories ☐ Labelling (including instructions for use) ☐ Other:	☐ Change company's name or legal form ☐ Transfer of facilities to another location ☐ Change of number of employees ☐ Additional / discontinued facilities (design / production / warehouse / technical service) ☐ Change of management representative ☐ Change of quality management system's structure ☐ Change of European representative ☐ Change of product safety or performance-relevant processes ☐ Other:

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a) Description of the planned change / comparison old/new:
Additional information given in attachment(s): ☐

Please describe the nature of the change(s) and please give (if applicable) a comparison before/after or old/new. Supporting documents (eg product description with schematic illustration of the change) can be listed here as attachment(s).

b) Reason for the planned change **Additional information given in attachment(s):** ☐

Please specify here the reason for the change (eg improved stability, result of CAPA, etc)

c) Impact of change(s) on the affected products:

Note: Wherever an impact is given, appropriate documents shall be provided (see "rationale / supporting documentation".) and an explanation of the impact shall be given (section Justification/ Evidence document). If no impact is given, please provide a rationale (see "rationale / supporting documentation").

Section	Impact		Rationale / Supporting documentation
	yes	no	
Product information	☐	☐	*For each point, please assess whether there is an impact caused by the change or not.* *If you decide there is no impact, please add a comprehensible rationale.* *If an impact is given, please list the relevant documents for verification, attach them to the change notification and give an explanation of the impact.* *If applicable, you should list when you plan to submit the documents for review.*
Technical data	☐	☐	
Classification	☐	☐	
Intended use	☐	☐	
Supplier (OEM / Subcontractor)	☐	☐	
Essential requirements	☐	☐	
Standards applied	☐	☐	
Tests performed	☐	☐	
· Shelf-life: device	☐	☐	
· Shelf-life: packaging	☐	☐	
· Biocompatibility	☐	☐	
· Bench-testing	☐	☐	
· Animal-testing	☐	☐	
Construction data, drawings, etc	☐	☐	
Risk management	☐	☐	
Clinical evaluation	☐	☐	

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Section	Impact		Rationale / Supporting documentation
	yes	no	
Verification of compatibility with accessories and/or other devices	☐	☐	
Manufacturing process / process flow	☐	☐	
Validation of sterilisation	☐	☐	
Validation of software	☐	☐	
Validation of reprocessing	☐	☐	
Labelling	☐	☐	
Instructions for use	☐	☐	
Declaration of conformity	☐	☐	
Other areas: please specify	☐	☐	

d) List of additional documents provided:
If additional documents are attached – in addition to the ones already listed above – please list them here.