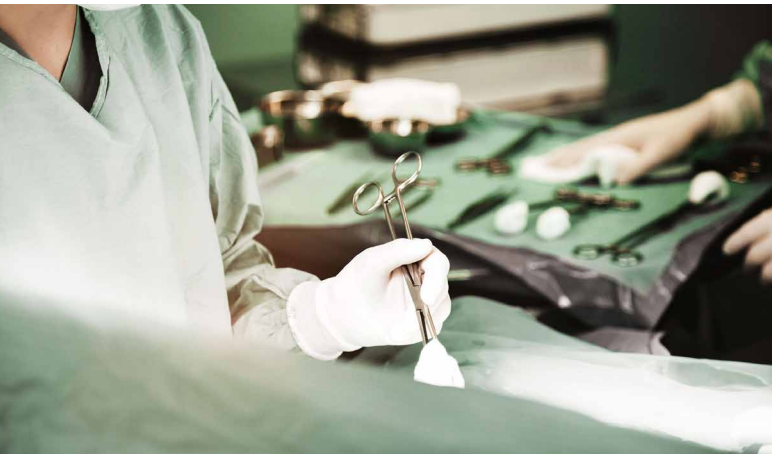

Change Notification about planned substantial changes according to the regulations (EU) 2017/745 (MDR), (EU) 2017/746 and EN ISO 13485

You are kindly asked to fill-in and return this notification once with and once without signature to med.certification.de@dekra.com.

If there are product changes, please provide us with the corresponding declaration of conformity and the current Customer Data Sheet.

Manufacturer	
Contact person	
Product name / product group	
Classification / rule	
UDI-DI	
Article number(s)	
Report number (if available)	
Certificate number:	
Date / timeframe of implementation of planned change	

What is the nature of the change? Please mark in the appropriate column according to the applicable Annex.

- ☐ Notification of planned substantial changes in accordance with MDR Annex IX, section 2.4
- ☐ Notification of planned substantial changes in accordance with MDR Article 120 [1)]
- ☐ Notification of planned substantial changes in accordance with EN ISO 13485:2016 only
- ☐ Notification of planned non-substantial changes in accordance with MDR Article 120, which would have been classified as substantial according to MDD [1)]

Scope of change (product / product group):

- ☐ New / removed product
- ☐ Additional or removed product categories
- ☐ New product name
- ☐ **Products according (EU) 2017/745 (MDR)** New product variant class III or implant class IIb[2)]
- ☐ **Products according (EU) 2017/745 (MDR)** New product variant class IIb[3)], or < class IIb; outside of established technical specification
- ☐ **Products according (EU) 2017/746 (IVDR)** New product variant class D or companion diagnostic
- ☐ **Products according (EU) 2017/746 (IVDR)** New product variant < class D and no companion diagnostic; outside of established technical specification
- ☐ **Products class D according (EU) 2017/746 (IVDR)** Changes that affect the batch release
- ☐ Addition of product sizes
- ☐ Change of intended use and/or indication
- ☐ Changes to substances contained in a product or used for the manufacture of a product and covered by the special procedures according to MDR section. 4.5.6 or IVDR section 4.5.5.
  - Substances of animal origin
  - Medicinal products
  - Tissues / cells of human origin
- ☐ Change of safety and performance related function(s)
- ☐ Change of materials
- ☐ Change of specifications
- ☐ Transfer of design or production to another location
- ☐ Change in production technology (e.g. sterilisation process)
- ☐ Change of a critical subcontractors incl. sterilisation service provider
- ☐ Change of product specific parameters stated on EU TD assessment certificate
- ☐ Identification of product (e.g. product number)
- ☐ Additional accessories
- ☐ Labelling (including instructions for use)
- ☐ Others:

Scope of change (QM System):

- ☐ Change of company's name / status
- ☐ 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 structure of quality management system
- ☐ Change of european representative
- ☐ Change of product safety or performance relevant processes
- ☐ Other:

[1)] Please justify the classification using the decision tree from MDCG 2020-03.

[2)] Exclusively implantable class IIb devices that are not covered by the exemption according to MDR Art. 52 section 4.

[3)] Implantable class IIb devices covered by the exemption under MDR Art. 52 section 4, as well as non implantable class IIb devices.

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

Please describe the type of change and eventually perform a comparison before/after or old/new. Supporting documents (e.g. product description with schematic representation of the change) can be cited here as an attachment.

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

Please provide a rationale for the change here (e.g., improved stability, result from CAPA, etc.).

c) Impact of the planned change(s) on the effected products

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

Section	Impact		Rationale / Supporting documentation
	yes	no	
Product information	☐	☐	
Article number(s) and UDI-DI	☐	☐	
Technical data	☐	☐	
Classification	☐	☐	
Intended use	☐	☐	
Labelling	☐	☐	
Instruction for use	☐	☐	
Development and construction • Construction data – drawings (for **IVDR** also assay design, kit composition, etc.)	☐	☐	
Standards applied / Common specifications (CS)	☐	☐	
Risk management	☐	☐	
Manufacturing process / process flow	☐	☐	
Subcontractor / supplier (incl. Test lab and design activities)	☐	☐	
Essential safety and performance requirements	☐	☐	
Declaration of conformity	☐	☐	

Section	Impact		Rationale / Supporting documentation
	yes	no	
Preclinical data			
Mechanical / Functional tests	☐	☐	
Electrical safety	☐	☐	
Software validation	☐	☐	
Demonstration of combinability with accessories and/or other products	☐	☐	
Biocompatibility	☐	☐	
Packaging / Shelf-life packaging	☐	☐	
Product stability	☐	☐	
Animal testing	☐	☐	
Validations			
• Sterilisation validation	☐	☐	
• Software validation	☐	☐	
• Validation of reprocessing	☐	☐	
Clinical evaluation (MDR only)	☐	☐	
Performance evaluation (IVDR only)	☐	☐	
Products containing a medicinal substance	☐	☐	
Products containing substances of human origin	☐	☐	

Section	Impact		Rationale / Supporting documentation
	yes	no	
Products containing substances of animal origin	☐	☐	
Products containing nanomaterials	☐	☐	
Products containing CMR or endocrine-disrupting substances	☐	☐	
Other areas, please specify:			
	☐	☐	
	☐	☐	

d) List of additional documents provided:

If additional documents are attached to the notification of change – besides those already listed above, they should be listed here.

Date	Name/Signature/Company seal

RESET FORM