



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

Please send two PDF versions of this form to med.certification.de@dekra.com:

1. By "save-as" function
2. With signature

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

Company
Contact person
Product name/product group
Classification/rule
Basic 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/IVDR 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, MDSAP and/or Taiwan TCP only

Notification of planned non-substantial changes in accordance with MDR Article 120,

which would have been classified as substantial according to MDD ²⁾

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 IIb³⁾

Products according (EU) 2017/745 (MDR)

New product variant class IIb⁴⁾, 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⁾ Please justify the classification using the decision tree from MDCG 2020-03 as well as NBOG BPG 2014-3.

³⁾ Exclusively implantable class IIb devices that are not covered by the exemption according to MDR Art. 52 section 4.

⁴⁾ 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):
<p>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.</p>	



b) Reason for the planned change(s):	Additional information given in attachment(s):
<p>Please provide a rationale for the change here (e. g., improved stability, result from CAPA, etc.).</p>	



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 Basic UDI-DI			
Technical data			
Classification			
Intended use			
Labelling			
Instruction for use			
Development and construction <ul style="list-style-type: none"> • 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	Digital ID/Signature

