

## Form

### Appendix D (MDR) - Plans for Substantial Change(s) (Conformity Assessment Procedure in accordance with Regulation (EU) 2017/745 (MDR); Certification according to EN ISO 13485)



## 1 GENERAL ?

Manufacturer's / Certificate Holder's Company Name:	
Application Identification <sup>1</sup> : <span style="color: green;">?</span>	

### 1.1 Change(s) related to

#### A) Quality Management System and/or Device-Range covered

**EU Quality Management System Certificate:**

Change to the quality management system and / or to the device-range covered.

Affected Certificate(s) G10, G11, G12, G13, G14:

**EU Quality Assurance Certificate:**

Change to the quality management system and / or to the device-range covered.

Affected Certificate(s) G20, G21, G22, G23, G24, G25:

**EN ISO 13485 Certificate:**

Changes to the quality management system and / or changes to the scope of certification.

Affected Certificate(s) Q5, Q6, Q7, Q8, SUP:

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<sup>1</sup> For each conformity assessment procedure applied for, please provide a separate Appendix D.

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#### B) Product (certificate)

##### **EU Technical Documentation Assessment Certificate:**

Change to the approved design of a device or of its intended purpose or claims made for the device.

Change to any substance incorporated in or utilised for the manufacturing of a device and being subject to the specific procedures referred to in Sections 5 and 6 of Annex IX.

Affected Certificate(s) G70:

##### **EU Type Examination Certificate:**

Change to the approved design of a device or of its intended purpose or claims made for the device.

Change to any substance incorporated in or utilised for the manufacturing of a device and being subject to the specific procedures referred to Section 6 of Annex X and Section 16 of Annex XI.

Affected Certificate(s) G60:

##### **EU Product Verification Certificate:**

Change to the approved design of a device covered by a EU Product Verification Certificate or of its intended purpose or claims made for the device.

Change to any substance incorporated in or utilised for the manufacturing of a device and being subject to the specific procedures referred to Section 6 of Annex X and Section 16 of Annex XI.

Affected Certificate(s) G40, G42:

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## **2 DESCRIPTION OF THE CHANGE**

### **2.1 Type of change**

Please select one of the outlined options.

Change of supplier/subcontractor

Change of site

Change of scope

Change of design

Change of authorized representative

Change of manufacturing

Other:

### **2.2 Description of the planned Change(s)**

Please describe the planned change(s) including a comparison of the current and future situation.

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### 3 DOCUMENTS TO BE SUBMITTED

#### 3.1 Applications including Appendices

Application/ Appendix	MDR	EN ISO 13485
Main Application	Yes	Yes
Appendix A	<b>Applicable IF:</b> <ul style="list-style-type: none"> <li>Change is related to the product-range covered (i.e. devices are affected from the change) ?</li> <li>Change is related to <ul style="list-style-type: none"> <li>- EU Technical Documentation Assessment Certificate</li> <li>or</li> <li>- EU Type Examination Certificate</li> <li>or</li> <li>- EU Product Verification Certificate</li> </ul> </li> </ul>	
Appendix B	<b>Applicable IF:</b> Change is related to the site(s) covered by the quality management system	
Appendix C	<b>Applicable IF:</b> Change is related to suppliers and subcontractors	
Appendix D	<b>This document</b>	
Appendix E	<b>Applicable IF:</b> Change is combined with a renewal of EU certificates  <b>Note:</b> Only the removal of devices from a device certificates or scopes from a QM certificates may be provided in conjunction with a renewal. Other changes need to be submitted in a separate application.	
Appendix F	<b>Applicable IF:</b> Needed to submit additional information	
Appendix G	<b>Applicable IF:</b> Change is related to a change of the notified body	

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### 3.2 Overview on further applicable Documents

Applicable Documents	EU Quality Management System Certificate	EU Quality Assurance Certificate	EU Technical Documentation Assessment Certificate	EU Type Examination Certificate	EU Product Verification Certificate
Documents relevant for the change assessment under consideration  - of Annex IX, section 2.2 (MDR),  - of harmonized standards (e.g. <b>EN ISO 13485</b> ).  - and of applicable Common Specifications  related to the Quality Management System	<b>Yes</b>	<b>Yes</b>	N/A	N/A	N/A
Any further information relevant for the change assessment	<b>Yes</b>	<b>Yes</b>	<b>Yes</b>	<b>Yes</b>	<b>Yes</b>
All relevant documents for the change assessment as listed in MDR Annexes II and III	on request*	on request*	<b>Yes</b>	<b>Yes</b>	<b>Yes</b>

\* Requested if the assessment of the change results in the need of further evaluation of the technical documentation for the device or devices concerned on the basis of further representative samples