**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)**

Product Service

# 1 GENERAL

| | |
|---|---|
| Manufacturer's / Certificate Holder's Company Name: | |
| Application Identification[1]: | |

## 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:

Please enter the affected certificate numbers

☐ **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:

Please enter the affected certificate numbers

☐ **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:

Please enter the affected certificate numbers

[1] For each conformity assessment procedure applied for, please provide a separate Appendix D.

## 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:

Please enter the affected certificate numbers

☐ **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:

Please enter the affected certificate numbers

☐ **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:

Please enter the affected certificate numbers

# 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.

Please enter text or reference (via document code/revision) to a different document within your submission.

# 3 DOCUMENTS TO BE SUBMITTED

## 3.1 Applications including Appendices

| Application/ Appendix | MDR | EN ISO 13485 |
|---|---|---|
| Main Application | **Yes** | **Yes** |
| Appendix A | **Applicable IF:**<br>• Change is related to the product-range covered (i.e. devices are affected from the change)<br>• Change is related to<br>- EU Technical Documentation Assessment Certificate<br>or<br>- EU Type Examination Certificate<br>or<br>- EU Product Verification Certificate | |
| Appendix B | **Applicable IF:**<br>Change is related to the site(s) covered by the quality management system | |
| Appendix C | **Applicable IF:**<br>Change is related to suppliers and subcontractors | |
| Appendix D | **This document** | |
| Appendix E | **Applicable IF:**<br>Change is combined with a renewal of EU certificates<br><br>**Note:** Only the removal of devices from a device certificates or scopes from a QM certificates may be provided in conjunction with a renewal.<br>Other changes need to be submitted in a separate application. | |
| Appendix F | **Applicable IF:**<br>Needed to submit additional information | |
| Appendix G | **Applicable IF:**<br>Change is related to a change of the notified body | |

## 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<br><br>- of Annex IX, section 2.2 (MDR),<br><br>- of harmonized standards (e.g. EN ISO 13485:2016),<br><br>- and of applicable Common Specifications<br><br>related to the Quality Management System | **Yes** | **Yes** | N/A | N/A | N/A |
| Any further information relevant for the change assessment | **Yes** | **Yes** | **Yes** | **Yes** | **Yes** |
| All relevant documents for the change assessment as listed in MDR Annexes II and III | on request* | on request* | **Yes** | **Yes** | **Yes** |

* 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