Form – CONFIDENTIAL

Appendix D - Plans for Substantial Change(s)

Notification of Changes to (EN) ISO 13485,
MDR (EU) 2017/745 or IVDR (EU) 2017/746

1 GENERAL

Application Identification:	Application Identification identical to Application.
Manufacturer's company name:	Manufacturer's company name

Please fill out an Appendix D to supplement your application for substantial change(s). For the definition of significant changes, please refer to NBOG-BPG 2014-3. Save this document as a pdf-version and include the filled appendix as pdf-version to the application submission.

2 CERTIFICATIONS AFFECTED BY THE CHANGE

2.1 Product (Certificate)

☐ **EU Technical Documentation Assessment Certificate (Annex IX, Chapter II)**
Change to the approved device and/or of its design, intended use, performance and/or claims made for the device.
IVDR: Changes in companion diagnostics in relation to the medicinal product concerned as outlined in Section 5.2(f) of Annex IX.
MDR: 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.

Enter affected Certificate Numbers MDR: G70, IVDR: V70 - V76

☐ **EU Type Examination Certificate (Annex X)**
Change to the approved type or of its intended purpose, design, and conditions of use.
IVDR: Changes in companion diagnostics affecting the performance or the intended use or its suitability in relation to a medicinal product as outlined in Section 5.5 of Annex X.
MDR: 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.

Enter affected Certificate Numbers MDR: G60, IVDR: V60

☐ **EU Product Verification Certificate (MDR Annex X),**
Change to the approved design of a device covered by an 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.

Enter affected Certificate Numbers MDR: G40, G42, IVDR: not applicable for IVDR

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2.2 Quality Management System and or device-range covered.

☐ **EU Quality Management System Certificate (Annex IX, Chapters I and III)**
Change to the quality management system and / or to the device-range covered.

Enter affected Certificate Numbers, MDR: G10 - G14, IVDR: V10 - V12.

☐ **EU Production Quality Assurance Certificate (Annex XI)**
Change to the quality management system and / or to the device-range covered.

Enter affected Certificate Numbers MDR: G20 - G24 & G25, IVDR: V20, V21.

☐ **(EN) ISO 13485:**
Changes to the quality management system and / or changes to the scope of certification.

Enter affected Certificate Numbers Q5, Q6, Q7, Q8, SUP..

3 DESCRIPTION OF THE CHANGE

3.1 Type of Change

Please select one of the Type of Change:

3.2 Description of the Plan(s) for Change(s)

Please Describe the planned change(s) including Comparison old / new or enter reference (via document

3.3 Reason for Change

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

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4 DOCUMENTS TO BE SUBMITTED

4.1 IVDR Overview on further applicable Documents

Affected Certificate / Applicable Documents	EU Quality Management System Certificate	EU Production Quality Assurance Certificate	EU Technical Documentation Assessment Certificate	EU Type Examination Certificate
Documents relevant for the change assessment under consideration of Annex IX 2.2 IVDR, of harmonized standards (e.g. EN ISO 13485) and of applicable Common Specifications related to the Quality Management System	**Yes**	**Yes**	N/A	N/A
Any further information relevant for the change assessment	**Yes**	**Yes**	**Yes**	**Yes**
All relevant documents for the change assessment as listed in IVDR Annex I, II, III	**Applicable if:** new generic device group of class C devices or new category of class B devices	**Applicable if:** new generic device group of class C devices or new category of class B devices	**Yes**	**Yes**

4.2 MDR Overview on further applicable Documents

Affected Certificate / Applicable Documents	EU Quality Management System Certificate	EU Production 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. EN ISO 13485). -and of applicable Common Specifications 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	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		**Yes**	**Yes**	**Yes**