Form

Appendix D - Plans for substancial change(s) to the quality management system/product

(Conformity Assessment Procedure in Accordance with Directive (EC) 98/79/EC (IVDD); Certification according to EN ISO 13485)

Product Service

1 GENERAL

Manufacturer's company name:	
Application Identification:	

Please include the filled appendix as pdf-version to the application submission.

2 DESCRIPTION OF THE CHANGE

2.1 Change Category

Change to	Type of change	Example	Minimum Documentation to be submitted
☐	New name / new address	Change of certificate holder	Appendix A/B/C Excerpt from the register of companies Transition plan for product labelling
☐	Site-related changes	Relocation or new site; Closure of site	Appendix A/B/C Audit report or site certificate
☐	Additional or removal of product category / product / variant	Product category: or Product/variant: applicable	Appendix A/B/C Audit report (product category) Design Dossier or design verification (variant)
☐	Transfer of process(es) to other site(s)	Transfer of development or production processes to another site; Outsourcing of a production process to a (critical) supplier	Appendix A/B/C Audit report or site certificate Validation data in case of transfer of production; Risk Management
☐	Change in production technology	Changes in production technology or application to another product family; Changes in critical production processes (e.g. new sterilization method, changes in sterilization method)	Appendix A/B/C Depending on the Change, e.g. validation report; Risk Management
☐	Changes of suppliers	OEM suppliers; Critical suppliers	Appendix A/B/C EC certificate and contract with OEM supplier; action list for supplier control
☐	Changes in critical QM processes	Changes in critical processes such as development and vigilance system	Procedure/ process description
☐	Change of authorized representative	Change or relocation of authorized representative	Appendix A/B/C Excerpt from the register of companies; contract with new EC representative; transition plan for product labelling
☐	Change in the application as intended and/or indication	Change of the user and/or use; Additional/amended indications Change(s) influencing the clinical/performance data	Appendix A/B/C Verification report(s); Clinical data; Risk Management
☐	Change in product specifications and/or design	Change in safety-related functions/performance data/materials/shelf life/parameters listed on the certificate /identification/instruction for use	Verification report(s); Risk Management
☐	Change in product identification	Name of product/model	Appendix A/B/C; Labelling documents
☐	Additional accessories	Changes in the components in a system or set	Appendix A/B/C Verification report(s); Risk Management
☐	Other (please describe the change)		

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Product Service

2.2 Description of the planned Changes

2.2.1 Description of the current and planned situation (old/new comparison)[1]

Please enter text or reference (via document code/revision) to a different document within your submission. Include internal Change Request Number when applicable.

2.2.2 Reason for Change[1]

Please enter text or reference (via document code/revision) to a different document within your submission. Include CAPA, Complaint, Field Action identification when applicable.

[1] Please refer to Appendix F for further information.