Appendix D

Plans for substantial change(s) to the quality management system/product

Product Service

Manufacturer:

Application identification:

Change notice

Company name:

Address:

Contact:

Tel.:

Email:

Type of change	Example	Changes related to QMS-Certificate	Changes related to Product-Certificate	Minimum documentation that must be submitted
New owner / new name / new address	Change of certificate holder	☐	☐	Application plus Appendix B Excerpt from the register of companies Transition plan for product labelling
Site-related changes	Relocation or new site; Closure of site	☐	☐	Application plus Appendix B Audit report or site certificate
Additional product category / product / variant	Product category: applicable to "QMS"; Product/variant: applicable to "product"	☐	☐	Application plus Appendix A Audit report (product category) Design dossier (product) or design verification (variant)
Transfer of processes to other sites	Transfer of development or production processes to another site; Outsourcing of a production process to a critical supplier	☐	☐	Application plus Appendix B (where appropriate Appendix C) Audit report or site certificate
Change in production technology	Changes in production technology or application to another product family; Changes in special production processes (e.g. new sterilization method, changes in sterilization method)	☐	☐	Application Depending on the change, e.g. validation reports
Changes of suppliers	OEM suppliers; Critical suppliers	☐	☐	Application plus Appendix C EC certificate and contract with OEM supplier Action list for supplier control

Appendix D

Plans for substantial change(s) to the quality management system/product

Product Service

Manufacturer:

Application identification:

		Changes related to		
Type of change	**Example**	**QMS-Certificate**	**Product-Certificate**	**Minimum documentation that must be submitted**
Changes in critical processes	Changes in critical processes such development and vigilance system	☐	–	Application Procedure / process description
Change of authorized representative	Change or relocation of authorized representative	☐	☐	Application plus Appendices B or 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	–	☐	Application plus Appendix A Verification report[1]; clinical data
Change in product specifications	Change in safety-related functions/ performance data/materials/ parameters listed on the certificate/ identification/instructions for use	–	☐	Application Verification report[1]
Change in product identification	Name of product / model	–	☐	Application plus Appendix A Verification report[1]
Additional accessories	Changes in the components in a system or set	–	☐	Application plus Appendix A (in case of a change in the product name or identification) Verification report[1]
Other (please describe the change)		☐	☐	

[1] The required verification report depends on the type of change and may include for example: risk management file, Essential Requirements checklist, test reports etc.

Appendix D

Plans for substantial change(s) to the quality management system/product

Product Service

Manufacturer:

Application identification:

a) Description of the plans for changes/old/new comparison: **Additional information in Appendix F:** ☐

b) Reason for change: **Additional information in Appendix F:** ☐

c) List of submitted documents: **Additional information in Appendix F:** ☐