



Product Service



## Appendix D

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



**Manufacturer:**



**Application identification:**



### Change notice

Company name:

Address:



Contact:

Tel.:

Email:



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

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Type of change	Example	Changes related to		Minimum documentation that must be submitted
		QMS-Certificate	Product-Certificate	
<b>Changes in critical processes</b>	Changes in critical processes such development and vigilance system	<input type="checkbox"/>	–	Application Procedure / process description
<b>Change of authorized representative</b>	Change or relocation of authorized representative	<input type="checkbox"/>	<input type="checkbox"/>	Application plus Appendices B or C Excerpt from the register of companies; contract with new EC representative; transition plan for product labelling
<b>Change in the application as intended and/or indication</b>	Change of the user and/or use Additional/amended indications Change(s) influencing the clinical/ performance data	–	<input type="checkbox"/>	Application plus Appendix A Verification report <sup>1</sup> ; clinical data
<b>Change in product specifications</b>	Change in safety-related functions/ performance data/materials/ parameters listed on the certificate/ identification/instructions for use	–	<input type="checkbox"/>	Application Verification report <sup>1</sup>
<b>Change in product identification</b>	Name of product / model	–	<input type="checkbox"/>	Application plus Appendix A Verification report <sup>1</sup>
<b>Additional accessories</b>	Changes in the components in a system or set	–	<input type="checkbox"/>	Application plus Appendix A (in case of a change in the product name or identification) Verification report <sup>1</sup>
<b>Other (please describe the change)</b>		<input type="checkbox"/>	<input type="checkbox"/>	

<sup>1</sup> 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:**