# General

|  |  |
| --- | --- |
| **Manufacturer’s company name:** | Manufacturer’s company name |
| **Application Identification:** | Application Identification |

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

# Description of the change

## 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) | Please enter keyword(s) | | |

## Description of the planned Changes

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

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

### Reason for Change1

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. [↑](#footnote-ref-1)