**Benefit-risk analysis and risk management**

**Product Name:** **{产品名称}**

***【本处填写产品名称，需要确保全篇技术文档及报告等的名称一致】***

**Model:** **{产品型号1}、{产品型号2}、{产品型号N}**

***【需要罗列本次认证的所有产品型号清单，如型号很多，可以采用另外附件文档的方式给出】***

**Document No.:** **{文件编号}**

***【本处填写本文件的编号】***

**Edition: {文件版本}**

***【本处填写本文件的版本】***

**Approved by:**

**Audited by:**

**Applied by：**

{XXXX公司}

**Revision records:**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Edition** | **Effective Date** | **Summary of revision** | **Drafted by** | **Checked by** | **Approved by** |
| {文件版本1} | {年-月-日} | First release | {XX名字} | {XX名字} | {XX名字} |
| {文件版本2} | {年-月-日} | {本版本相对上一版本版本更新了\*\*\*\*，主要原因是\*\*\*\*, 涉及到修改的小节是\*\*\*\*\*}  *【填写本技术文档的版本相对于上一版本更新了哪些内容？为什么更新？以及更新内容具体的地方及小节编号？】* | {XX名字} | {XX名字} | {XX名字} |
| {文件版本N} | {年-月-日} | {本版本相对上一版本版本更新了\*\*\*\*，主要原因是\*\*\*\*, 涉及到修改的小节是\*\*\*\*\*}  *【填写本技术文档的版本相对于上一版本更新了哪些内容？为什么更新？以及更新内容具体的地方及小节编号？】* | {XX名字} | {XX名字} | {XX名字} |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

**Table of Contents**

[7 Benefit-Risk Analysis and Risk Management (MDR ARTICLE 10.2; MDR ANNEX II SECTION 5) 4](#_Toc2614)

**7 Benefit-Risk Analysis and Risk Management (MDR ARTICLE 10.2; MDR ANNEX II SECTION 5)**

***(***

***A thorough design and process risk management assessment is conducted for the entire lifecycle of the device (from initial design concept up to and including device disposal). It is updated (as appropriate) with data from PMS.***

***The details can refer to Appendix 7.1 Risk management procedure, Appendix 7.2 Risk Management Plan and Appendix 7.3 Risk Management Report.***

|  |  |  |
| --- | --- | --- |
| ***SN*** | ***Document*** | ***Refer to*** |
| ***1*** | ***Risk management procedure*** | ***Appendix 7.1 Risk management procedure*** |
| ***2*** | ***Risk Management Plan*** | ***Appendix 7.2 Risk Management Plan*** |
| ***3*** | ***Risk acceptance criteria*** | ***Risk acceptance criteria in Appendix 7.2 Risk Management Plan and Appendix 7.3 Risk Management Report*** |
| ***4*** | ***Risk assessment covering the whole life cycle of the device*** | ***Risk assessment covering the whole life cycle of the device in Appendix 7.2 Risk Management Plan and Appendix 7.3 Risk Management Report*** |
| ***5*** | ***Risk Management Report*** | ***Appendix 7.3 Risk Management Report*** |
| ***6*** | ***Reference to documents including the overall benefit-risk analysis*** | ***Reference to documents including the overall benefit-risk analysis in Appendix 7.3 Risk Management Report*** |
| ***7*** | ***Usability engineering file*** | ***Appendix 8.6 Usability engineering file*** |
| ***8*** | ***Reference to documents that cover the adopted solutions*** | ***Reference to documents that cover the adopted solutions in Appendix 7.3 Risk Management Report*** |

***)***