**Sterilization, disinfection, and reprocessing**

**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}**

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| **Edition** | **Effective Date** | **Summary of revision** | **Drafted by** | **Checked by** | **Approved by** |
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| {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} |
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**10 Sterilization, disinfection, and reprocessing**

**10.1 Sterile device or devices with defined microbiological condition (MDR Annex II Section 6.2(e))**

***(Not applicable. The device is not delivered in sterile condition. The device is not intended to be sterilised or delivered with defined microbiological conditions.)***

**10.2 Stability and shelf life of the device (MDR Annex II Section 6.1(b))**

***(***

***The details of accelerated and real-time ageing test protocols reports can refer to Appendix 10.1 Shelf life verification protocol and report.***

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| ***SN*** | ***Document*** | ***Refer to*** |
| ***1*** | ***Shelf life verification protocol*** | ***Appendix 10.1 Shelf life verification protocol and report*** |
| ***2*** | ***Shelf life verification report*** | ***Appendix 10.1 Shelf life verification protocol and report*** |

***)***

**10.3 Infection risk and reusable device(s) (MDR Annex II Section 6.2(e); Annex VI Section 4.10)**

***(***

***The device is a reusable device. It need to clean and disinfection after use. We conduct effective life cycle verification. The details can refer to Appendix 10.2 Re-processing validation protocols and report.***

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| ***SN*** | ***Document*** | ***Refer to*** |
| ***1*** | ***Re-processing validation protocols*** | ***Appendix 10.2 Re-processing validation protocols and report.*** |
| ***2*** | ***Re-processing validation report.*** | ***Appendix 10.2 Re-processing validation protocols and report.*** |
| ***3*** | ***Instructions for use*** | ***Appendix 2.2 Instructions for use*** |

***)***

**10.4 Disinfection verification**

***(***

***The details of disinfection verification can refer to Appendix 10.3 Disinfection verification protocol and report.***

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| ***SN*** | ***Document*** | ***Refer to*** |
| ***1*** | ***Disinfection verification protocol*** | ***Appendix 10.3 Disinfection verification protocol and report.*** |
| ***2*** | ***Disinfection verification report*** | ***Appendix 10.3 Disinfection verification protocol and report.*** |

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