**PMS plan & PSUR & PMCF**

**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:**

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| **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} |
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**12 PMS plan & PSUR & PMCF**

**12.1 PMS plan**

***(***

***The device has not been put into the market. It does not contain a Periodic safety update report. It only contains a PMS plan. The details of PMS plan can refer to Appendix 12.1 Post Market Surveillance Plan.***

|  |  |  |
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| ***SN*** | ***Document*** | ***Refer to*** |
| ***1*** | ***Post Market Surveillance Plan*** | ***Appendix 12.1 Post Market Surveillance Plan*** |

***)***

**12.2 Periodic safety update report**

***(***

***NA. The device has not been put into the market. It does not contain a Periodic safety update report.***

***)***

**12.3 Post-market clinical follow-up (PMCF) plan**

***(***

***The device has not been put into the market. It does not contain a PMCF evaluation report. The details of Post-market clinical follow-up (PMCF) plan can refer to Appendix 12.2 Post Market Clinical Follow-up Plan.***

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| ***SN*** | ***Document*** | ***Refer to*** |
| ***1*** | ***Post Market Clinical Follow-up Plan*** | ***Appendix 12.2 Post Market Clinical Follow-up Plan*** |

***)***

**12.4 Post-market clinical follow-up (PMCF) report**

***(***

***NA. The device has not been put into the market. It does not contain a PMCF evaluation report.***

***)***

**12.5 Summary of safety and clinical performance (SSCP)**

***(***

***NA. The device is not an implantable device or class III device. It does not contain a SSCP.***

***)***