**Manufacturing Information**

**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} |
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**5 Manufacturing Information (MDR Art. 10.1)**

**5.1 Manufacturing process and process validation (MDR Annex II Section 3(b))**

**5.1.1 Manufacturing information, manufacturing flow chart：**

***(The manufacturing flow chart of 【产品名称】 production process can refer to Appendix 5.1 Manufacturing information, manufacturing flow chart.***

***There is no special process during the production. The critical process is test. The details can refer to Appendix 5.1 Manufacturing information, manufacturing flow chart.)***

**5.1.2 Manufacturing process validations and test method validations：**

***(There is no special process during the production. The critical process test has been verified.***

***The details can refer to Appendix 5.2 Summary list with references to manufacturing process validations and test method validations.)***

**5.1.3 Adjuvants**

|  |  |
| --- | --- |
| **Production process** | **Adjuvants** |
| \*\*\* | No adjuvants |
| \*\*\* | No adjuvants |
| \*\*\* | No adjuvants |
| \*\*\* | No adjuvants |
| \*\*\* | No adjuvants |
| \*\*\* | No adjuvants |
| \*\*\* | No adjuvants |

**5.1.4 The continuous monitoring and the final product testing**

#### **5.1.4.1 Incoming inspections and acceptance criteria & results from a sample batch**

***(The incoming inspection records of key materials can refer to Appendix 5.8 The Incoming Inspection Record.)***

#### **5.1.4.2 In-process inspections and acceptance criteria & results from a sample batch**

***(The In-process inspection records of the production process can refer to Appendix 5.9 The In-process Inspection Record.)***

#### **5.1.4.3 Final inspections and acceptance criteria & results from a sample batch**

***(The Final inspection records can refer to Appendix 5.10 The Final Inspection Record.)***

**5.1.5 Description of subcontracted processes:**

***(NA. The device does not contain subcontracted processes.***

***The details can refer to Appendix 5.3 Description of subcontracted processes.)***

**5.1.6 Certificates of critical suppliers**

***{***

***The details of certificates of critical suppliers are as below. It can refer to Appendix 5.4 Certificates of critical suppliers.***

|  |  |  |  |
| --- | --- | --- | --- |
| ***Component*** | ***Model*** | ***Supplier*** | ***Certificate*** |
| ***\*\*\**** | ***\*\*\**** | ***\*\*\**** | ***\*\*\**** |
| ***\*\*\**** | ***\*\*\**** | ***\*\*\**** | ***\*\*\**** |
| ***\*\*\**** | ***\*\*\**** | ***\*\*\**** | ***\*\*\**** |

***}***

**5.2 Design and manufacturing sites (MDR Annex II Section 3(c))**

**5.2.1 Design facility/-ies**

***{***

***Name: \*\*\****

***Address:\*\*\****

***SRN: \*\*\****

***}***

***【研发中心信息】***

**5.2.2 Manufacturing facility/-ies**

***{***

***Name: \*\*\****

***Address:\*\*\****

***SRN: \*\*\****

***}***

***【制造中心信息】***

**5.2.3 Critical subcontractors and Suppliers sites**

**{**

|  |  |  |  |
| --- | --- | --- | --- |
| **Component** | **Model** | **Supplier** | **Address** |
| ***\*\*\**** | ***\*\*\**** | ***\*\*\**** | ***\*\*\**** |
| ***\*\*\**** | ***\*\*\**** | ***\*\*\**** | ***\*\*\**** |
| ***\*\*\**** | ***\*\*\**** | ***\*\*\**** | ***\*\*\**** |
| ***\*\*\**** | ***\*\*\**** | ***\*\*\**** | ***\*\*\**** |

}

**5.2.4 Sterilization Site**

***{NA. It is a non-sterile device.***

***The details of Valid supplier certificates as mentioned in TÜV SÜD EU Application Appendix ABC can refer to Appendix 5.5 Valid supplier certificates as mentioned in TÜV SÜD EU Application Appendix ABC.***

***The details of Information on critical suppliers and subcontractors can refer to Appendix 5.6 Information on critical suppliers and subcontractors***

***The details of Information on supplier control can refer to Appendix 5.7 Information on supplier control.}***