**Technical Specifications**

**Product Name:*{填写申报产品名称 }***

**Model:*{填写申报产品的具体型号}***

**Document No.: *{填写本文档编号}***

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***{填写申请者的企业名称}（参考示例：Shenzhen Hlongmed Biotech Co.,Ltd.）***

**Revision records:**

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1. **Raw materials**

*{填写原材料信息}*

*（参考示例：*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| *SN* | *Patient Contacting Component* | *name of material* | *Specification description* | *Supplier* |
| *1* | *{填写组件名称}* | *{填写组件的材料名称}* | *{填写组件的规格描述}* | *{填写供应商名称}* |
| *2* | *\*\*\** | *\*\*\** | *\*\*\** | *\*\*\** |
| *3* | *\*\*\** | *\*\*\** | *\*\*\** | *\*\*\** |
| *4* | *\*\*\** | *\*\*\** | *\*\*\** | *\*\*\** |

*）*

1. **Drawings of components**

*{请详细列出各种组件的图片或图纸}*

*【若有多个组件图片，请依次列出】*

**3. Quality control procedures**

*{对申报产品的质量控制进行简要描述 }*

*（参考示例：Our company has established EN ISO 13485 quality system. The manufacture process is continuously monitored.*

*Firstly, the materials are monitored. All incoming suppliers shall be selected by the company in accordance with the requirements of the Supplier management control procedures. When incoming materials of the supplier are delivered to the factory, the quality department shall formulate incoming inspection specifications and conduct incoming inspection in accordance with the inspection requirements. The defective incoming materials shall be handled in accordance with the company's procedure document control procedure for nonconforming products.*

*Secondly, final product is monitored. Before product delivery, the final inspection should be conducted. Meanwhile, deal with the unqualified products according to the control procedure of unqualified products.*

*Thirdly, ex-factory process is monitored.*

*According to the inspection specification, the inspector shall carry out factory inspection on the products, make inspection records and mark the quality status as required, and deal with the unqualified products according to the control procedure of unqualified products.）*

