**Design and manufacturing information**

**Product Name:*{填写申报产品名称 }***

**Model:*{填写申报产品的具体型号}***

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

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1. **Information that allows the understanding of thedesign and manufacturing of a device**
	1. Information that allows the understanding of thedesign of a device

*{填写申报产品的设计开发程序}*

*（参考示例：The actual device are designed according to the Design and development Process as below.*

|  |  |
| --- | --- |
| ***Steps*** | ***Process*** |
| *Step 1* | *Design and development planning* |
| *Step 2* | *Design and development inputs* |
| *Step 3* | *Design and development outputs* |
| *Step 4* | *Design and development review* |
| *Step 5* | *Design and development verification* |
| *Step 6* | *Design and development validation* |
| *Step 7* | *Design and development transfer* |

*）*

* 1. Information that allows the understanding of themanufacturing of a device
		1. manufacturing processes

*{列出申报产品的生产程序}*

* + 1. Process validation

*{填写生产过程中的各种验证}.【应放入完整的测试数据或链接】(参考示例：The process validation are please refer to \* \* \* Final product test report， \* \* \* Packaging seal validation report)*

1.2.3 Continuous monitoring

*{对申报产品生产过程中的连续监测进行描述}*

*（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.）*

1.2.4 Final product testing

*{列出最终产品的所有验证测试}*

**2 Design calculations relevant to the intended use of the product**

*{填写实现申报产品预期用途的设计原理}.*

**3 Technology**

*{对申报产品的当前技术生产工艺进行简要描述}.*

*（参考示例：From the information of Section 2 of Document 5 Reference to previous generations of the device and to similar devices, the technology of actual device is mature. The design is safe and have been established for a number of years. Actual device have been performing as intended during that time such information is likely to be sufficient to cover this requirement.）*

**4 Identification of all sites**

4.1 Company address

The company registration address：*{**填写公司注册地址}*

the manufacturing address：*{填写生产地址}.*

4.2 Supplier address

The supplier addresses of critical materials are as below:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **SN** | **Critical Material** | **name of material** | **Supplier** | **Address** |
| 1 | *{主要部件名称}* | *{主要部件材料名称}* | *{主要部件材料供应商名称}* | *{主要部件材料供应商地址}* |
| 2 | *{主要部件名称}* | *{主要部件材料名称}* | *{主要部件材料供应商名称}* | *{主要部件材料供应商地址}* |
| 3 | *{主要部件名称}* | *{主要部件材料名称}* | *{主要部件材料供应商名称}* | *{主要部件材料供应商地址}* |
| 4 | \*\*\*\* | \*\*\*\* | \*\*\*\* | \*\*\*\* |

4.3 Sub-contractor address

*{填写分包商的地址}*