**Description and specification**

**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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| *{填写具体的版本号}* | *{填写对应版本的有效日期}* | *{对版本进行简要描述}* | *{填写文件批准人姓名}（参考示例：张三）* | *{填写文件审核人姓名}（参考示例：李四）* | *{填写文件起草人姓名}（参考示例：王五）* |
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**1 product or trade name and a general description of the device including its intended purpose and intended users;**

1.1 Name of the Device

Product name: *{填写申报产品名称}*

1.2 Product description

*{对产品进行简要描述}【可从产品的组成，是否含附件以及所属的类别，是否需要灭菌等方面，进行简要描述】*

1.3 Intended Purpose

*{填写申报产品的预期用途}*

1.4 Intended User

*{填写申报产品的目标使用者}（参考示例：hospital staff）*

**2 The intended patient population and medical conditions to be diagnosed, treated and/or monitored and other considerations such as patient selection criteria, indications, contra-indications, warnings;**

2.1 Intended patient population

*{填写产品适用的患者人群}（参考示例：adult）*

2.2 Medical conditions

*{填写产品适用的疾病阶段或程度}(参考示例：The patient requires ventilation)*

2.3 Other considerations

2.3.1 Patient selection criteria

*{填写申报产品适用的病人的选择标准}（参考示例：the years old of patient over 18）*

2.3.2 Indications

*{填写申报产品的适应症}*

2.3.3 Contra-indications,

*{填写申报产品的禁忌症}*

2.3.4 Warnings

*{填写申报产品的警告}*

**3 Principles of operation of the device and its** **mode of action, scientifically demonstrated if necessary**

3.1 Principles of operation

*{填写申报产品的操作原理}*

3.2 Mode of action

*{填写申报产品的作用方式}*

**4 The rationale for the qualification of the product as a device**

Please refer to Document 1 “Rationale for the qualification as a medical device and the risk class attributed”.

**5 The risk class of the device and the justification for the classification rule(s) applied in accordance with Annex VIII;**

Please refer to Document 1 “Rationale for the qualification as a medical device and the risk class attributed”.

**6 An explanation of any novel features;**

*{填写申报产品是否使用新技术的描述} （参考示例：This is a traditional technology. It has been used all over the world for many years. There are no novel features.）*

**7 A description of the accessories for a device, other devices and other products that are not devices, which are intended to be used in combination with it;**

*{对申报器械是否有附件，以及预期与其他非器械联合使用的简要描述} （参考示例：The actual device do not contain accessories.* *It is not used in combination with other devices.）*

**8 A description or complete list of the** **various configurations/variants of the device that are intended to be made available on the market;**

*{详细列出申报产品的所有的型号，并描述各型号之间的差异 }*

**9 A general description of the key functional elements**

9.1 Its parts/components (including software if appropriate)

9.1.1 Parts/Components

The parts of *{填写申报产品名称}* are as below.

*{列出申报产品组件 }*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| ***SN*** | ***Part*** | ***name of material*** | ***Specification description*** | ***Suppier*** |
| *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* | *\*\*\** | *\*\*\** | *\*\*\** | *\*\*\** |

9.1.2 Software

*{此处对申报产品的软件进行描述}*

.

9.2 Formulation

It is consisted of components as section 9.1.1. It does not contain special formulation.

9.3 Its composition

Please refer to section 10.1.1.

9.4 Functionality

*{对关键原件的功能进行描述}*

9.5 qualitative and quantitative composition.

*{对关键元件的定性和定量进行描述}*

9.6 Labelled pictorial representations(e.g. diagrams, photographs, and drawings), clearly indicating key parts/components, including sufficient explanation to underst and the drawings and diagrams;

The picture of key parts/components for actual device are as below:

*{填写申报产品的关键部件的图片或图示}【提供带标记的图形指示关键部件/组件，如图表、照片、图纸等】*

**10 A description of the raw materials incorporated into key functional elements and those making either direct contact with the human body or indirect contact with the body, e.g., during extracorporeal circulation of body fluids;**

*{填写预期与人体间接接触和直接接触的材料说明}（示例见下文，包括不限于下列表格中的内容）*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| ***SN*** | ***Patient Contacting Component*** | ***name of material*** | ***Specification description*** | ***Supplier*** |
| *1* | *{接触部件名称}* | *{接触部件的材料名称}* | *{接触部件的材料规格说明}* | *{材料供应商名称}* |
| *2* | *{接触部件名称}* | *{接触部件的材料名称}* | *{接触部件的材料规格说明}* | *{材料供应商名称}* |

**11 Technical specifications**

*{对申报产品的技术规格进行描述}【包括但不限于特征、尺寸、性能属性，通常出现在用户阅读的产品规范中，例如宣传册、目录、相似出版物等】*

