**Rationale for the qualification as a medical device and the risk class attributed**

**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}***

**Edition: *{填写本文档版本号}***

Drafted by: Date: ***{填写本文档编写日期}***

Checked by: Date: ***{填写本文档审核日期}***

Approved by: Date: ***{填写本文档批准日期}***

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

**Revision records:**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Edition** | **Effective Date** | **Summary of revision** | **Approved by** | **Checked by** | **Drafted by** |
| *{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：San Zhan）* | *{填写文件审核人姓名}（参考示例：Si Li）* | *{填写文件起草人姓名}（参考示例：Wu Wang）* |
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1. **Rationale for the qualification as a medical device**

*{填写申报产品可作为器械的合理的理由}*

*【可从产品的预期用途，适应症方面考虑】*

*（参考示例：*

*According to the definition of medical device in REGULATION (EU) 2017/745 as below and the application of**{填写申报产品名称}（参考示例：CRP mask）, we consider that{填写申报产品名称}（参考示例：CRP mask） is a medical device.*

*Define of medical device:*

*“medical device” means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:*

*— diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,*

*—* *diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,*

*— investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,*

*— providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations,and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.*

*The following products shall also be deemed to be medical devices:*

*—* *devices for the control or support of conception;*

*— products specifically intended for the cleaning, disinfection or sterilisation of devices as referred to in Article 1(4) and of those referred to in the first paragraph of this point.）*

1. **Rationale for the risk class attributed**

*{填写申报产品风险分类的基本原理}*

*（参考示例：*

*The risk class is attributed according to Annex VIII CLASSIFICATION RULES in REGULATION (EU) 2017/745.*

*{填写申报产品名称}（参考示例：CPR mask）is a{填写申报产品的类别}【根据产品实际情况填写申报产品所属类别如是属于非侵入、侵入还是有源】（参考示例：non-invasive）device. The rules of classification for{填写申报产品的类别}【根据产品实际情况填写申报产品所属类别如是属于非侵入、侵入还是有源】（参考示例：non-invasive） devices is in{填写申报产品分类所适用的分类法规}（参考示例：Rule1-Rule4）, the details are as below.*

*{填写申报产品分类所适用的分类法规原文}（4. NON-INVASIVE DEVICES*

*4.1. Rule 1*

*All non-invasive devices are classified as class I, unless one ofthe rules set out hereinafter applies.*

*4.2. Rule 2*

*All non-invasive devices intended for channelling or storingblood, body liquids, cells or tissues, liquids or gases for thepurpose of eventual infusion, administration or introduction intothe body are classified as class IIa:*

*— if they may be connected to a class IIa, class IIb or class IIIactive device; or*

*— if they are intended for use for channelling or storing blood or other body liquids or for storing organs, parts of organs or body cells and tissues, except for blood bags; blood bags are classified as class IIb.*

*In all other cases, such devices are classified as class I.*

*4.3. Rule 3*

*All non-invasive devices intended for modifying the biological or chemical composition of human tissues or cells, blood, otherbody liquids or other liquids intended for implantation or administration into the body are classified as class IIb, unless thetreatment for which the device is used consists of filtration,centrifugation or exchanges of gas, heat, in which case they areclassified as class IIa.*

*All non-invasive devices consisting of a substance or a mixtureof substances intended to be used in vitro in direct contact withhuman cells, tissues or organs taken from the human body orused in vitro with human embryos before their implantation oradministration into the body are classified as class III.*

*4.4. Rule 4*

*All non-invasive devices which come into contact with injuredskin or mucous membrane are classified as:*

*— class I if they are intended to be used as a mechanical barrier,for compression or for absorption of exudates;*

*— class IIb if they are intended to be used principally for injuriesto skin which have breached the dermis or mucous membraneand can only heal by secondary intent;*

*— class IIa if they are principally intended to manage themicro-environment of injured skin or mucous membrane; and*

*— class IIa in all other cases.*

*This rule applies also to the invasive devices that come intocontact with injured mucous membrane.）*

*According to above rules, {填写申报产品名称}（参考示例：CPR mask）is classified as Class I according to{填写产品适用的分类规则}（参考示例：rule 1）.）*

