**Demonstration of conformity**

**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）* |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

1. **The requirements set out in Annex I in REGULATION (EU) 2017/745**

The requirements set out in Annex I in REGULATION (EU) 2017/745 should typically be presented in the form of a checklist.

This should list all requirements referred to in Annex I and specify:

(1) the applicability of each requirement to the device,

(2) the solution adopted by the manufacturer to comply with each applicable requirement,

(3) the reference to any possible CS or harmonized standards applied in full or in part and

(4) the reference to where to find evidence of the solution adopted in the technical

documentation.

The details can refer to Document 7 General safety and performance requirements.

1. **The relevant standards and Guidelines Name**

|  |  |
| --- | --- |
| No. | **Standard and Guidelines Name** |
|  | *{列出申报产品所需要符合的所有的法规和标准}*  *（参考示例：EN ISO 13485:2016*  *Medical devices - Quality management systems - Requirements for regulatory purposes）* |
|  | *{列出申报产品所需要符合的所有的法规和标准}*  *（参考示例：EN ISO 13485:2016*  *EN ISO 14971:2012*  *Medical device- Application of risk management to medical devices）* |
|  | *{列出申报产品所需要符合的所有的法规和标准}*  *（参考示例：EN ISO 10993-1-2009*  *Biological evaluation of medical devices-Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2009）* |
|  | *{列出申报产品所需要符合的所有的法规和标准}*  *（参考示例：EN ISO 15223-1:2016*  *Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (ISO 15223-1:2016, Corrected version 2017-03）* |
|  | *{列出申报产品所需要符合的所有的法规和标准}*  *（参考示例：EN 1041:2008*  *Terminology, Symbols and Information with Medical Devices; Information supplied by the manufacturer with medical devices）* |
|  | *{列出申报产品所需要符合的所有的法规和标准}*  *（参考示例：MEDDEV. 2.7.1 Rev. 4 June 2016*  *Clinical evaluation: A guide for manufactures and notified bodies）* |
|  | *{列出申报产品所需要符合的所有的法规和标准}*  *（参考示例：MEDDEV. 2.7.1 Rev. 4 June 2016*  *Clinical evaluation: A guide for manufactures and notified bodies）* |
|  | \*\*\*\*\*\* |
| *\*\*\** | \*\*\*\*\*\* |