**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}***

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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. **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**

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| --- | --- |
| 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）* |
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