**Clinical Evaluation Report**

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

**Content**

[1. Summary 5](#_Toc37839520)

[2. Scope of the clinical evaluation 5](#_Toc37839521)

[2.1 Company Introduction 5](#_Toc37839522)

[2.2 Product Introduction 6](#_Toc37839523)

[2.2.1 Product name 6](#_Toc37839524)

[2.2.2 Classification of the device 6](#_Toc37839525)

[2.2.3 Specification, model and article numbers 6](#_Toc37839526)

[2.2.4 Chosen conformity assessment path 6](#_Toc37839527)

[2.2.5 Intended use 6](#_Toc37839528)

[2.2.6 Diagram of products 7](#_Toc37839529)

[3. Clinical background, current knowledge, state of the art 7](#_Toc37839530)

[3.1 Scope of the literature search 7](#_Toc37839531)

[3.2 Objective of the literature review 8](#_Toc37839532)

[4. Device under evaluation 8](#_Toc37839533)

[4.1. Type of evaluation 8](#_Toc37839534)

[4.2. Demonstration of equivalence 8](#_Toc37839535)

[4.3. Clinical data generated and held by the manufacturer 9](#_Toc37839536)

[4.3.1 All pre-market clinical investigations 9](#_Toc37839537)

[4.3.2 Clinical data generated from risk management activities and PMS programmes 9](#_Toc37839539)

[4.3.2.1 PMCF studies 10](#_Toc37839540)

[4.3.2.2 The clinical data search and evaluation reports for PMS 10](#_Toc37839541)

[4.3.3 Relevant pre-clinical studies 12](#_Toc37839542)

[4.4. Clinical data from literature 13](#_Toc37839543)

[4.5. Summary and appraisal of clinical data 13](#_Toc37839544)

[4.5.1 Summary of the clinical data 13](#_Toc37839545)

[4.5.2 Data set analysis from clinical literature 15](#_Toc37839546)

[4.5.3 Clinical data analysis from Clinical experience 16](#_Toc37839547)

[4.6. Analysis of the clinical data 17](#_Toc37839548)

[4.6.1. Requirement on safety 17](#_Toc37839549)

[4.6.2. Requirement on acceptable benefit/risk profile 17](#_Toc37839550)

[4.6.3. Requirement on performance 18](#_Toc37839551)

[4.6.4. Requirement on acceptability of side-effects 18](#_Toc37839552)

[5. Conclusions 19](#_Toc37839553)

[6. Date of the next clinical evaluation 19](#_Toc37839554)

[6.1 Suggested date 19](#_Toc37839555)

[6.2 Justification of the date 20](#_Toc37839556)

[7. Dates and signatures 21](#_Toc37839557)

[8. Qualification of the responsible evaluators 21](#_Toc37839558)

[9. References 21](#_Toc37839559)

1. **Summary**

*{填入临床评价的概述}*

*（参考示例:The purpose of this document is to specify and justify the level of clinical evidence necessary to demonstrate conformity with the relevant general safety and performance requirements described in Annex I of MDR regulation EU 2017/745 and plan, conduct and document a clinical evaluation in accordance with Article 61 and Part A of Annex XIV of MDR regulation EU 2017/745.*

*Based upon the output of the risk management process, we can conclude that our device is enough safety and effectiveness, and the benefits outweigh the risks.*

*Based on the equivalence analysis performed in this report, the equivalent device and other similar devices can be applied to the use of our evaluating device.*

*In conclusion, the actual device when used under the conditions and for the purposes intended by the manufacturer, performed as intended, comply with Article 61 and Part A of Annex XIV of MDR regulation EU 2017/745, conform to the Annex I of MDR regulation EU 2017/745 and conform to MEDDEV. 2.7.1 Rev.4.）*

1. **Scope of the clinical evaluation**

2.1 Company Introduction

*{填写申报企业的简介}*

2.2 Product Introduction

2.2.1 Product name

*{填写申报产品名称}*

2.2.2 Classification of the device

*{填写申报产品的类别}*

*（参考示例：According to the intended use and requirement in MDR regulation EU 2017/745 Annex VIII, the classification and definition are as followings:*

*Rule 1*

*All non-invasive devices are in Class I, unless one of the rules set out hereinafter applies.*

*So,the actual device \*\*\* is classified class I.）*

2.2.3 Specification, model and article numbers

*{填写申报产品的规格、型号、和货号}*

2.2.4 Chosen conformity assessment path

*{填入申报产品选择的符合性评价路径}*

*（参考示例：Declare the conformity of their products by issuing the EU declaration of conformity referred to in Article 19(MDR regulation EU 2017/745) after drawing up the technical documentation set out in Annexes II and III.）*

2.2.5 Intended use

*{填写申报产品的预期用途}*

2.2.6 Diagram of products

*{填写申报产品的产品图}*

**3. Clinical background, current knowledge, state of the art**

**3.1 Scope of the literature search**

1) Intended purpose and application of the device;

2) Manufacturer’s specific claims about clinical performance and safety of device;

3) The significance of any risks that remain;

4) The data source and type of data to be used in the clinical evaluation.

**3.2 Objective of the literature review**

*{填写文献综述的目的}*

1. **Device under evaluation**

**4.1. Type of evaluation**

*{填写临床评价的类型} （参考示例：The clinical evaluation is based on scientific literature and clinical experience data. ）*

**4.2. Demonstration of equivalence**

*{从产品的技术参数、生物、临床三个方面证明产品等同}*

**4.3. Clinical data generated and held by the manufacturer**

**4.3.1 All pre-market clinical investigations**

*{填写申报产品的所有临床前研究}*

**4.3.2 Clinical data generated from risk management activities and PMS programmes**

*{填写来自与风险管理活动和PMS产生的临床数据}*

**4.3.2.1 PMCF studies**

*{填写PMCF研究}*

**4.3.2.2 The** **clinical data search and evaluation reports for PMS**

*{填写收集到的临床数据和PMS的评估报告}*

**4.3.2.2.1 NMPA**

NMPA Adverse event

*{收集申报产品在NMPA的不良事件，并截图}*

**4.3.2.2.2 Gov.UK**

*{收集申报产品在英国的不良事件，并截图}*

**4.3.3 Relevant pre-clinical studies**

*{请列出申报产品所有的上市前研究}*

**4.4. Clinical data from literature**

*{列出文献中的临床数据}*

**4.5. Summary and appraisal of clinical data**

*{对临床数据进行总结概述和评价}*

**4.5.1 Summary of the clinical data**

*{对临床数据进行总结}*

*（参考示例：*

 ***Tabulation of the clinical data and Evaluation of Data Contribution Rate and Suitability***

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| ***No.*** | ***Categories according to Intended Evaluation*** | ***Citable Data*** | ***Suitability Description*** | ***Suitability Appraisal*** | ***Data Contribution Appraisal*** |
| ***Data generated and held by the manufacturer (including clinical experience data)*** |
| *1* | *{临床前的测试名称}（参考示例：Performance Test）* | *{临床前测试所满足的标准以及对应的报告}（参考示例：EN166:2001 test report number：\*\*\*）* | *{对数据的适用性进行描述}（参考示例：The data is from intended evaluating device）* | */* | */* |
| *\*\*\** | *\*\*\*\** | *\*\*\*\** | *\*\*\*\** | */* | */* |
| ***Clinical literature data*** |
| *{文献编号}* | *{填写文献数据涉及到产品的哪一方面} 【可以是产品的性能、安全、临床应用的一种或多种】（参考示例：Evaluation of safety performance and clinical application）* | *{填文献名称}* | *{判断数据是来源是申报产品、等同、还是相似产品} （参考示例：The data is from similar device）* | *{对文献质量打分}**（参考示例：D3**A1**P1**R1）* | *{对数据贡献进行打分} （参考示例：T101F1S1C1）* |
| *{文献编号}* | *{填写文献数据涉及到产品的哪一方面} 【可以是产品的性能、安全、临床应用的一种或多种】（参考示例：Evaluation of safety performance and clinical application）* | *{填文献名称}* | *{判断数据是来源是申报产品、等同、还是相似产品} （参考示例：The data is from similar device）* | *{对文献质量打分}**（参考示例：D3**A1**P1**R1）* | *{对数据贡献进行打分} （参考示例：T101F1S1C1）* |
| *\*\*\*\** | *\*\*\*\** | *\*\*\*\*\** | *\*\*\*\** | *\*\*\** | *\*\*\** |
| *\*\*\*\** | *\*\*\*\** | *\*\*\*\*\** | *\*\*\*\** | *\*\*\** | *\*\*\** |

*）*

**4.5.2 Data set analysis from clinical literature**

*{对来自于临床文献的临床数据进行分析}*

**4.5.3 Clinical data analysis from Clinical experience**

*{从临床经验进行临床数据分析}*

**4.6. Analysis of the clinical data**

**4.6.1. Requirement on safety**

*{从临床数据角度分析产品的安全要求}*

**4.6.2. Requirement on acceptable benefit/risk profile**

*{从临床数据角度对申报产品的可接受利益/风险的要求进行分析}*

**4.6.3. Requirement on performance**

*{从临床数据角度对申报产品性能要求进行分析}*

1. **Conclusions**

*{对上述分析的内容进行总结}*

*（参考示例：Analysis of the contribution of literatures and clinical experience data show that the actual device \*\*\*\* are safe and effective. They are consistent with the proposed evaluating device in intended use, specification and parameters.*

*Besides, the safety and performance of the proposed evaluating device also meet the requirements of clinical research literature and clinical application, and the proposed evaluating device had passed and conform to the relevant standard, proving the device is safety and effectiveness.*

*In additional, collect the clinical experience data including literature and clinical experience data to analysis as a key part and evidence to support the safety and effectiveness of proposed evaluating device.*

*All the above proved the proposed evaluating device is safe and effective.*

*The clinical evaluation report conforms to MEDDEV. 2.7.1 Rev.4.）*

1. **Date of the next clinical evaluation**

**6.1 Suggested date**

*{填写下次临床评价的建议日期 }*

*（参考示例：The clinical evaluation is actively updated:*

*when the manufacturer receives new information from PMS that has the potential to change the current evaluation;*

*if no such information is received, then every 2 to 5 years, because the device is not expected to carry significant risks and is well established. ）*

**6.2** **Justification of the date**

*{填写建议临床评价日期的依据 }*

*（参考示例：The manufacturer defines and justifies the frequency at which the clinical evaluation needs to be actively updated, the main justification is that the device is not expected to carry significant risks and is well established. The detailed justification is following:*

*The device negligibly carries significant risks because the design, materials, components, clinical procedures of the device under evaluation are very common in many similar mature Medical Isolation Goggles in the market, which are clinical used for several decades of years, eg: equivalent devices.*

*the device under evaluation is well established because:*

*1) the device under evaluation is not innovation;*

*2) and there are no relevant changes in clinical sciences, materials sciences or other sciences related to the device under evaluation;*

*3) In additional, the current level of confidence in the evaluation of clinical performance and clinical safety of the device is high enough, because the data available from pre-clinical study on the device under evaluation had proved that the device well conform to the relevant specifications, the data available from clinical literatures, PMS, registries or other systematic studies related to the similar devices had proved that the device is safety and effectiveness and no risk residual after risk analysis and controlled which identify from these clinical experiences data. Moreover, similar device is been used in the market for many years and is very widely used, include the EU etc, and there is no relevant adverse events and recalls reported related to the equivalent device after searching the database.*

*After the risk analysis, so far there are no risks and uncertainties or unanswered questions, in the medium or long term, that would influence the frequency of updates.*

*In the change plan, there is no design changes or changes to manufacturing procedures related to the device under evaluation ）*

1. **Dates and signatures**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Members | Major | Degree | Depart | Position | Signature | Date |
| *{填写参与临床评价报告的人员名称}* | *{填写参与临床评价报告的人员专业背景} （参考示例：Electrical engineering and automation）* | *{填写参与临床评价报告的人员专业背景} （参考示例：Bachelor）* | *{填写参与临床评价报告的人员所属部门} （参考示例：RA Deparment）* | *{填写参与临床评价报告的人员职位} （参考示例：Manager）*  | *{填写参与临床评价报告的人员签字}* | *{签日期}* |
| *{填写参与临床评价报告的人员名称}* | *{填写参与临床评价报告的人员专业背景} （参考示例：Electrical engineering and automation）* | *{填写参与临床评价报告的人员专业背景} （参考示例：Bachelor）* | *{填写参与临床评价报告的人员所属部门} （参考示例：RA Deparment）* | *{填写参与临床评价报告的人员职位} （参考示例：Manager）*  | *{填写参与临床评价报告的人员签字}* | *{签日期}* |
|  | \*\*\*\* | \*\*\*\* | \*\*\*\* | \*\*\*\* | *\*\*\*\** | *\*\*\*\** |

1. **Qualification of the responsible evaluators**

*{请填入临床评价人员的资质证明}*

1. **References**

*{列出临床评价报告所参考的法规、指南等}*

*（参考示例：MEDDEV 2.7/1 revision 4 CLINICAL EVALUATION: A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES UNDER DIRECTIVES 93/42/EEC and 90/385/EEC*

*REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL*

*of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC）*