**Clinical** **Evaluation Plan**

**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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Summary

## 1.1 General details

Device name: *{填入申报产品名称}*

Device model: *{填入申报产品型号}*

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

Address:*{填入生产地址}*

Tel: *{填入申请者的联系方式}*

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Website:*{填入申请者公司网址}*

## 1.2 Introduce of Clinical evaluation plan

*{对临床评价计划进行介绍}*

*（参考示例：This plan applies to actual device produced by \*\*\*. It’s evaluated according to MEDDEV.2.7.1 Rev.4 and MDR Regulation (EU) 2017/745 Annex XIV PART A. The clinical evaluation plan is one stage of clinical evaluation, depending on the stage in the life-cycle of the product, clinical evaluation plan include different aspects.）*

# Content of clinical evaluation plan under actual device

## 2.1 An Identification of the general safety and performance requirements that require support from relevant clinical data

*{临床评价计划中对申报产品的一般安全和性能要求所需要的临床数据的支持证据的识别}*

*【参考示例：Obtain the clinical data about general safety and performance required of \*\*\*, the data, which can from*

*Obtain the clinical data. Scope of the literature search are follow:*

*Intended purpose and application of the device;*

*Manufacturer’s specific claims about clinical performance and safety of device;*

*The significance of any risks that remain;*

*The data source and type of data to be used in the clinical evaluation.*

*The details of search strategy refer to the literature search protocol. Search result refer to search protocol and clinical evaluation report. 】*

## 2.2 Device description

### 2.2.1 product name

*{填入申报产品名称}*

### 2.2.2 Components

*{对申报产品的组件进行描述}*

### 2.2.3 Intend user

*{填写申报产品预期用户}*

### 2.2.4 Intended purpose

*{填写申报产品的预期用途}*

### 2.2.5 Intended target groups

*{填写申报产品的目标群体} 【参考示例：Adult】*

### 2.2.6 Indications

*{填写申报产品的适应症}*

### 2.2.7 Contraindications

*{填写申报产品的禁忌症}*

## 2.3 Intend clinical benefits to patients with relevant and specified clinical outcome parameters;

*{对患者预期临床益处的详细说明以及相关和制定的临床结果参数的说明}*

*【参考示例：The clinical outcome parameters come from the clinical data. the benefit summary can refer to part \*\*\* summary of advantages and disadvantages of the different options, benefit/risk profiles of clinical evaluation report.】*

## 2.4 Methods to be used for examination of qualitative and quantitative aspects of clinical safety with clear reference to the determination of residual risks and side-effects

*{计划用于检验临床安全性的定性和定量的方法说明，需要明确说明剩余风险和副作用的确定方法}*

## 2.5 Indicative list and specification of parameters to be used to determine , based on the state of the art in medicine, the acceptability of the benefit-risk ratio for the various indications and for the intended purpose or purposes of the device

*{填入医学中最先进的技术确定器械各种适应症和预期用途的收益风险比的可接受性所使用的参数的指示性清单和说明}*

## 2.6 An indication how benefit-risk issues relating to specific components such as use of pharmaceutical, nonviable animal or human tissues, are to be addressed; and

*{说明如何解决特定方面（如药物、非活性动物或人体组织的使用）相关的风险利益问题的指示；}*

**2.7 clinical development plan indicating progression from exploratory investigations, such as first-in-man studies, feasibility and pilot studies, to confirmatory investigations, such as pivotal clinical investigations, and a PMCF as referred to in Part B of this Annex with an indication of milestones and a description of potential acceptance criteria;**

*{填入用于指示从探索性研究（如首次人体研究、可行性研究、先导研究）到验证性研究（如关键的临床研究）进展过程的临床研发计划，以及符合本附录第 B 部分所述的 PMCF， 此 PMCF 需列出里程碑并说明潜在验收标准；}*