**Benefit-risk analysis and Risk management**

**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. **Benefit -Risk analysis**

*{对申报产品进行风险利益分析}*

*【风险分析需要满足MDR 法规附录I的第1和8节中所述的风险利益分析】*

1. **Risk management**

*{对申报产品的风险管理结果进行描述}*

*【风险管理的方案以及结果需满足MDR 法规附录I第3节的内容，以及相应的风险管理的协调标准】（参考示例：Please refer to \*\*\* Risk management report.）*