**Clinical evaluation**

**Product Name:** **{产品名称}**

***【本处填写产品名称，需要确保全篇技术文档及报告等的名称一致】***

**Model:** **{产品型号1}、{产品型号2}、{产品型号N}**

***【需要罗列本次认证的所有产品型号清单，如型号很多，可以采用另外附件文档的方式给出】***

**Document No.:** **{文件编号}**

***【本处填写本文件的编号】***

**Edition: {文件版本}**

***【本处填写本文件的版本】***

**Approved by:**

**Audited by:**

**Applied by：**

{XXXX公司}

**Revision records:**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Edition** | **Effective Date** | **Summary of revision** | **Drafted by** | **Checked by** | **Approved by** |
| {文件版本1} | {年-月-日} | First release | {XX名字} | {XX名字} | {XX名字} |
| {文件版本2} | {年-月-日} | {本版本相对上一版本版本更新了\*\*\*\*，主要原因是\*\*\*\*, 涉及到修改的小节是\*\*\*\*\*}*【填写本技术文档的版本相对于上一版本更新了哪些内容？为什么更新？以及更新内容具体的地方及小节编号？】* | {XX名字} | {XX名字} | {XX名字} |
| {文件版本N} | {年-月-日} | {本版本相对上一版本版本更新了\*\*\*\*，主要原因是\*\*\*\*, 涉及到修改的小节是\*\*\*\*\*}*【填写本技术文档的版本相对于上一版本更新了哪些内容？为什么更新？以及更新内容具体的地方及小节编号？】* | {XX名字} | {XX名字} | {XX名字} |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

**Table of Contents**

11 Clinical evaluation 4

11.1 Clinical evaluation plan 4

11.2 Clinical evaluation report 4

11.3 Literature search protocol 4

11.4 Literature search report 4

11.5 Clinical Investigation plan 4

11.6 Clinical Investigation report 4

11.7 CV of evaluator and Annex 6 Declaration of Interests 4

11.8 Copies of clinical literature 5

**11 Clinical evaluation**

**11.1 Clinical evaluation plan**

*(The details can refer to Appendix 11.1 Clinical evaluation plan.)*

**11.2 Clinical evaluation report**

*(*

*The details of clinical evaluation can refer to below table.*

|  |  |  |
| --- | --- | --- |
| ***SN*** | ***Document*** | ***Refer to*** |
| *1* | *Clinical evaluation plan (CEP)* | *Appendix 11.1 Clinical evaluation plan* |
| *2* | *Clinical Evaluation Report* | *Appendix 11.2 Clinical evaluation report* |
| *3* | *Copies of clinical literature* | *Annex 4 The literatures used for analysis of Appendix 11.2 Clinical evaluation report* |
| *4* | *Evidence of qualification of experts involved in CER* | *Annex 1 CV of evaluator of Appendix 10.2 Clinical evaluation report* |
| *5* | *Marketing/promotional brochures* | *Annex 7 IFU of Equivalent device and Annex 8 IFU of benchmark and similar device of Appendix 11.2 Clinical evaluation report* |
| *6* | *Post Market Clinical Follow-up Plan* | *Appendix 12.2 Post Market Clinical Follow-up Plan* |

*Clinical evaluation consultation (MDR Article 54)*

*The device is a class IIb active device, not intended to administer and/or remove a medicinal product. So we considered that the device does not require observance of the procedure for clinical evaluation consultation in accordance with MDR Art.54.*

*)*

**11.3 Literature search protocol**

*(The details can refer to Annex 2.1 Literature search protocol of Appendix 11.2 Clinical evaluation report.)*

**11.4 Literature search report**

*(The details can refer to Annex 2.2 Literature search report of Appendix 11.2 Clinical evaluation report.)*

**11.5 Clinical Investigation plan**

*(NA, it does not contain a Clinical Investigation.)*

**11.6 Clinical Investigation report**

*(NA, it does not contain a Clinical Investigation.)*

**11.7 CV of evaluator and Annex 6 Declaration of Interests**

*(CV of evaluator can refer to Annex 1 of Appendix 11.2 Clinical evaluation report. Declaration of Interests can refer to Annex 6 Declaration of Interests of Appendix 11.2 Clinical evaluation report.)*

**11.8 Copies of clinical literature**

*(The details can refer to Annex 4 The literatures used for analysis of Appendix 11.2 Clinical evaluation report.)*