**Product Verification and validation**

**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}**

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**Approved by:**

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{XXXX公司}

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| **Edition** | **Effective Date** | **Summary of revision** | **Drafted by** | **Checked by** | **Approved by** |
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| {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} |
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**8 Product Verification and Validation (MDR ANNEX II SECTION 6)**

**8.1 Pre-clinical and clinical data (MDR Annex II Section 6.1)**

8.1.1 Animal tests (MDR Annex II Section 6.1(a))

***(Not applicable. No Animal tests were conducted.)***

8.1.2 Simulated use test (MDR Annex II Section 6.1(a))

***(***

***We conduct a Simulated use test for the device. The details can refer to Appendix 8.1 Summary and simulated use test protocols reports.***

|  |  |  |
| --- | --- | --- |
| ***SN*** | ***Document*** | ***Refer to*** |
| ***1*** | ***Simulation test report of Reusable temperature probe*** | ***Appendix 8.1 Summary and simulated use test protocols/reports*** |

***)***

8.1.3 Biocompatibility of the device (MDR Annex II Section 6.1(b))

***(***

***We conduct a biological safety risk assessment for the device. The details can refer to Appendix 8.2.1 Biocompatibility test protocols and reports and Appendix 8.2.2 Overall biological safety assessment. Meanwhile, the Qualification of test laboratories also can refer to Appendix 8.2.4 Qualification of test laboratories. Evidence of qualification of experts can refer to Appendix 8.2.3 Evidence of qualification of experts.***

|  |  |  |
| --- | --- | --- |
| ***SN*** | ***Document*** | ***Refer to*** |
| ***1*** | ***Biocompatibility test protocols and reports*** | ***Appendix 8.2.1 Biocompatibility test protocols and reports*** |
| ***2*** | ***Overall biological safety assessment*** | ***Appendix 8.2.2 Overall biological safety assessment.*** |
| ***3*** | ***Evidence of qualification of experts*** | ***Appendix 8.2.3 Evidence of qualification of experts.*** |
| ***4*** | ***Qualification of test laboratories.*** | ***Appendix 8.2.4 Qualification of test laboratories.***  |

***)***

8.1.4 Physical, chemical and microbiological characterisation (MDR Annex II Section 6.1(b))

The Physical, chemical and microbiological characterisation are as below.

***(***

|  |  |  |
| --- | --- | --- |
| ***SN*** | ***Document*** | ***Refer to*** |
| ***1*** | ***Material characterisation test protocols and reports*** | ***Appendix 8.3.1 Material characterisation test protocols and reports*** |
| ***2*** | ***Qualification of test laboratories*** | ***Appendix 8.3.2 Qualification of test laboratories*** |

***)***

8.1.5 Electrical Safety (MDR Annex II Section 6.1(b))

***{The device is an active medical device.***

***The details of evaluation of Electrical safety are as below:***

|  |  |  |  |
| --- | --- | --- | --- |
| ***SN*** | ***Standard*** | ***Report No.*** | ***Refer to*** |
| ***1*** | ***EN 60601-1:2006+A1:2013+AC:2014+A12:2014 +A2:2020*** | ***IEC60601-1Test Report******\*\*\**** | ***Appendix 8.4.1 IEC 60601-1 Test Report*** |
| ***2*** | ***\*\*\**** | ***\*\*\**** | ***\*\*\**** |
| ***3*** | ***\*\*\**** | ***\*\*\**** | ***\*\*\**** |

***}***

8.1.6 Electromagnetic compatibility/ionising and non-ionising radiation (MDR Annex II Section 6.1(b))

***{The device is an active medical device.***

***The details of evaluation of electromagnetic compatibility (EMC) are as below:***

|  |  |  |  |
| --- | --- | --- | --- |
| ***SN*** | ***Standard*** | ***Report No.*** | ***Refer to*** |
| ***1*** | ***EN 60601-1-2:2015+A1:2020*** | ***EMC EMISSION - Test Report******(Report No.: \*\*\*)*** | ***Appendix 8.5.1 EMC EMISSION - Test Report*** |

***}***

8.1.7 MRI safety testing of the device/device system (MDR Annex II Section 6.1(b))

***(Not applicable. The device does not contain Characteristic of MRI.)***

8.1.8 Functional safety, software (MDR Annex II Section 6.1(b))

***(Not applicable. The device does not contain Software.)***

8.1.9 Cyber Security (MDR Annex II Section 6.1(b))

***(Not applicable. The device does not contain Characteristic of Cyber Security.)***

8.1.10 Software verification and validation (MDR Annex II Section 6.1(b))

***(Not applicable. The device does not contain Software.)***

8.1.11 Packaging (MDR Annex II Section 6.1(b))

***(The details can refer to section 09 Device packaging and transportation.)***

8.1.12 Stability and shelf life of the device (MDR Annex II Section 6.1(b))

***(The details can refer to Section 10 Sterilization, disinfection, and reprocessing.)***

8.1.13 Performance and safety (MDR Annex II Section 6.1(b))

***(The details of performance and safety are as below.***

|  |  |  |
| --- | --- | --- |
| ***SN*** | ***Document*** | ***Refer to*** |
| ***1*** | ***Safety and performance*** | ***Appendix 8.4 Electrical safety test and Appendix 8.5 EMC test*** |
| ***2*** | ***\*\*\**** | ***\*\*\**** |
| ***3*** | ***\*\*\**** | ***\*\*\**** |
| ***4*** | ***\*\*\**** | ***\*\*\**** |
| ***5*** | ***\*\*\**** | ***\*\*\**** |

***)***

8.1.14 Constructional and mechanical safety (MDR Annex II Section 4; 6)

***(The details of Constructional and mechanical safety can refer to Section 9 PROTECTION AGAINST MECHANICAL HAZARDS OF ME EQUIPMENT AND ME SYSTEMS of IEC 60601-1 Test Report. The details can refer to below report.***

|  |  |  |  |
| --- | --- | --- | --- |
| ***SN*** | ***Standard*** | ***Report No.*** | ***Refer to*** |
| ***1*** | ***EN 60601-1:2006+A1:2013+AC:2014+A12:2014 +A2:2020*** | ***IEC60601-1Test Report*** ***(Report No.: \*\*\*)*** | ***Appendix 8.4.1 IEC 60601-1 Test Report*** |

***The constructional and mechanical test are evaluated in IEC 60601-1 Test Report. It does not need to evaluate them individually.)***

8.1.15 Clinical data, CER, post-market clinical follow-up (PMCF) plan, and PMCF evaluation report (MDR Articles 10(3), 61; Annex II Section 6.1(c), 6.1(d); Annex III; Annex XIV)

***(The details can refer to Section 11 Clinical evaluation.)***

## 8.2 Additional information required in specific cases (MDR Annex II Section 6.2)

8.2.1 Substances considered to be medicinal products

***(Not applicable. The device does not incorporates a medicinal product.)***

8.2.2 Substances derived from human blood or human plasma (MDR Articles 1(6) lit. D and g, (8), (10); GSPR 12.1, 13.1)

***(Not applicable. The device does not incorporate medicinal substances derived from human blood or plasma derivatives.)***

8.2.3 Tissues or cells of human origin (MDR Article 1(6) lit. d and g, (8), (10); GSPR 12.1, 13.1)

***(Not applicable. The device does not utilise tissues of human origin.)***

8.2.4 Tissues of cells of animal origin (MDR Articles 1(6) lit. f; GSPR 12.1, 13.2)

***(Not applicable. The device does not utilise tissues of animal origin.)***

8.2.5 Materials of biological origin (MDR Article 1(6) lit. h; GSPR 13.3)

***(Not applicable. The device does not incorporate materials of biological origin.)***

8.2.6 Nanoparticle technology (MDR Annex II Section 1(1) lit. k)

***(Not applicable. The device does not incorporates nanoparticle technology.)***

8.2.7 Substances or combinations of substances that are absorbed by or locally dispersed in the human body (MDR Annex II Section 6.2(c))

***(Not applicable. The device is not absorbable by or intended to be locally dispersed in the human body.)***

8.2.8 CMR or endocrine-disrupting substances (MDR Annex II Section 6.2(d))

***(Not applicable. The device does not contain CMR or endocrine-disrupting substances referred to in Section 10.4.1 of Annex I.)***

8.2.9 Sterile device or devices with defined microbiological condition (MDR Annex II Section 6.2(e))

***(Not applicable. The device is not delivered in sterile condition. The device is not intended to be sterilised or delivered with defined microbiological conditions.)***

8.2.10 Infection risk and reusable device(s) (MDR Annex II Section 6.2(e); Annex VI Section 4.10)

***(The details can refer to Section 10 Sterilization, disinfection, and reprocessing.)***

8.2.11 Device with a measuring function (MDR Annex II Section 6.2(f))

***(Not applicable. The device does not contain a measuring function.)***

8.2.12 Devices connected to other device(s) (MDR Annex II Section 6.2(g))

***{***

***The device is to be connected to other device(s) in order to operate as intended. The verification can refer to Appendix 8.6 Usability engineering file.***

***The way of device connecting to the monitor is as below.***

***【加入产品连接图片】***

***The combination matrix of 【产品名称】 and compatible device is as below:***

|  |  |
| --- | --- |
| ***Product*** | ***Compatible monitor*** |
| ***\*\*\*\**** | ***\*\*\*\**** |

***}***

**8.3 Additional regulations, procedures, directives, commission decisions**

### 8.3.1 Summary of safety and clinical performance (SSCP) (MDR Article 32)

***(Not applicable. The device is not an implantable device or class III device.)***

8.3.2 Periodic safety update report (PSUR)(MDR Article 86, Annex III)/Post-market surveillance report (PMS-report)(MDR Articles 85, Annex III)

***(The details can refer to Section 12 PMS plan & PSUR & PMCF.)***

8.3.3 Environmental protection, safe disposal (GSPR 14.7)

***(Disposal Statement of the device is noted in the Instructions for use. “WEEE” label is included in Symbol Explanation of the Instructions for use.)***

### 8.3.4 Personal Protective Equipment Directive 89/686/EEC

***(Not applicable. The product does not fall under the scope of Directive 89/686/EEC.)***

### 8.3.5 Other regulatory requirements

***(Not applicable. The product does not fall under other regulatory requirements than those referenced in this document.)***