**Applied standards list and GSPR checklist**

**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:**

|  |  |  |  |  |  |
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| **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} |
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**6 General safety and performance requirements**

6.1 Applicable General Safety and Performance Requirements (MDR Annex II Section 4(a))

***(***

***The details of GSPR checklist can refer to Appendix 6.1 Checklist for GSPR Compliance Analysis.***

|  |  |  |
| --- | --- | --- |
| ***SN*** | ***Document*** | ***Refer to*** |
| ***1*** | ***Checklist for General Safety and Performance Requirements Compliance Analysis*** | ***Appendix 6.1 Checklist for GSPR Compliance Analysis.*** |

***)***

6.2 Method or methods used to demonstrate conformity (MDR Annex II Section 4(b)

***(The details can refer to Appendix 6.1 Checklist for GSPR Compliance Analysis.)***

6.3 Harmonised standards, common specifications, or other solutions applied (MDR Articles 8, 9; MDR Annex II Section 4(c))

***{***

***Harmonised standards***

|  |  |  |
| --- | --- | --- |
| ***SN*** | ***Standard No.*** | ***Standard*** |
| ***1*** | ***EN ISO 13485:2016/A11:2021*** | ***Medical devices - Quality management systems - Requirements for regulatory purposes*** |
| ***2*** | ***EN 60601-1:2006+A1:2013+AC:2014+A12:2014 +A2:2020*** | ***Medical electrical equipment - Part 1: General***  ***requirements for basic safety and essential performance*** |
| ***3*** | ***EN 60601-1-2:2015+A1:2020*** | ***Medical electrical equipment - Part 1-2: General***  ***requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests*** |
| ***4*** | ***EN ISO 15223-1:2021*** | ***Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements (ISO 15223-1:2021)*** |
| ***5*** | ***EN ISO 14971:2019/A11:2021*** | ***Medical devices - Application of risk management to medical devices*** |
| ***6*** | ***EN62366-1:2015+AC:2015+AC:2016+A1:2020*** | ***Medical devices -Part 1: Application of usability engineering to medical devices to medical devices*** |
| ***7*** | ***EN ISO 10993-1:2020*** | ***Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process*** |
| ***8*** | ***EN ISO 10993-5:2009*** | ***Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity*** |
| ***9*** | ***EN ISO 10993-10:2013*** | ***Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization*** |
|
| ***10*** | ***EN ISO 14155:2020*** | ***Clinical investigation of medical devices for human subjects - Good clinical practice*** |
| ***11*** | ***\*\*\**** | ***\*\*\**** |

***Common specifications***

***The device does not contain any Common specifications.***

***Other solutions***

|  |  |  |
| --- | --- | --- |
| ***SN*** | ***Solution*** | ***Title*** |
| ***1*** | ***Regulation(EU) 2017/745*** | ***Medical devices regulations*** |
| ***2*** | ***MEDDEV 2.12/1 rev 8***  ***(January 2013)+(July 2019)*** | ***Guidelines on a medical devices vigilance system＋***  ***[Additional guidance on MEDDEV 2.12/1 rev.8](https://ec.europa.eu/docsroom/documents/36292)*** |
| ***3*** | ***MEDDEV 2.7.1 Rev.4***  ***(June 2016)*** | ***Guidelines On Medical Devices-Clinical evaluation: A Guide for manufacturers and notified bodies*** |
| ***4*** | ***MEDDEV 2.12/2 rev. 2***  ***(January 2012)*** | ***Guidelines on medical devices:Post market clinical follow-up studies - A guide for manufacturers and notified bodies*** |
| ***5*** | ***[MDCG 2020-7](https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_mdcg_2020_7_guidance_pmcf_plan_template_en.pdf)*** | ***Post-market clinical follow-up (PMCF) plan template - A guide for manufacturers and notified bodies*** |
| ***6*** | ***MDCG 2020-5*** | ***A guide for manufacturers and notified bodies: Clinical Evaluation - Equivalence*** |
| ***7*** | ***MDCG 2020-13*** | ***Clinical evaluation assessment report template*** |

***There is no gap analysis between Harmonised standards, common specifications, and other solutions applied.***

***The details can refer to Appendix 6.2 List of Harmonised Standards, Appendix 6.3 Common Specifications, Appendix 6.4 Other solutions and Appendix 6.5 Gap analysis.***

***}***

6.4 Controlled documents offering evidence of conformity (MDR Annex II Section 4(d))

***(The details can refer to Appendix 6.1 Checklist for GSPR Compliance Analysis.)***

6.5 Declaration of conformity (MDR Art. 19; Annex IV)

***(The details can refer to Appendix 13.1 Declaration of conformity.)***