**Device description and specification**

**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:**

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{XXXX公司}

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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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**Table of Contents**

[1 Device Description and Specification, Including Variants and Accessories 4](#_Toc119881553)

[1.1 Device description and specification 4](#_Toc119881554)

[1.1.1 Product or trade name(MDR Annex II Section 1.1(a)) 4](#_Toc119881555)

[1.1.2 General device description, intended purpose and intended users (MDR Annex II Section 1.1(a)) 4](#_Toc119881556)

[1.1.3 Intended patient population(MDR Annex II Section 1.1(c)) 4](#_Toc119881557)

[1.1.4 Principles of operation of the device and its mode of action (MDR Annex II Section 1.1(d)) 4](#_Toc119881558)

[1.1.5 Qualification of the product as a device (MDR Annex II Section 1.1(e)) 4](#_Toc119881559)

[1.1.6 Risk class of the device (MDR Annex II Section 1.1(f); Annex VIII) 5](#_Toc119881560)

[1.1.7 Novel features/Changes to predecessor device (MDR Annex II Section 1.1(g)) 6](#_Toc119881561)

[1.1.8 Accessories and device combination (MDR Annex II Section 1.1(h) and 1.1(i)) 6](#_Toc119881562)

[1.1.9 Configurations and variants of the device (MDR Annex II Section 1.1(i)) 7](#_Toc119881563)

[1.1.10 General description of the key functional elements (MDR Annex II Section 1.1(j)) 7](#_Toc119881564)

[1.1.11 Materials incorporated into key functional elements (MDR Annex II Section 1.1(k)) 7](#_Toc119881565)

[A description of the raw materials incorporated into key functional elements and those making either direct contact with the human body or indirect contact with the body is as below. 8](#_Toc119881566)

[1.1.12 Technical specification (MDR Annex II Section 1.1(l)) 8](#_Toc119881567)

[1.2 Reference to previous and similar generations of the device (MDR Annex II Section 1.2) 8](#_Toc119881568)

[1.2.1 An overview of the previous generation or generations of the device produced by the manufacturer 8](#_Toc119881569)

[1.2.2 An overview of identified similar devices available on the Union or international markets 9](#_Toc119881570)

**1 Device Description and Specification, Including Variants and Accessories**

1.1 Device description and specification

1.1.1 Product or trade name(MDR Annex II Section 1.1(a))

Product or trade name: ***{产品名称}***

Model number:***{产品型号}***

EMDN code:***【EMDN code，可通过 https://webgate.ec.europa.eu/dyna2/emdn/ 查询】***

MDN/MDA and MDS/MDT scope: ***【MDCG 2019-14 Explanatory note on MDR codes确认产品MDN/MDA and MDS/MDT代码】{MDA 0203, MDS 1005, MDT 2010 in accordance with COMMISSION IMPLEMENTING REGULATION (EU) 2017/2185.}***

Basic UDI-DI: ***{提供产品Basic UDI-DI}***

***{The details can refer to Appendix 1.1 List of CE marked products and Appendix 1.2 EU Application Annex A/B/C}***

***[Appendix 1.2 EU Application Annex A/B/C是在TUV提供给客户的固定表格]***

1.1.2 General device description, intended purpose and intended users (MDR Annex II Section 1.1(a))

1.1.2.1 Intended purpose of the device:

***【填写产品预期用途】***

1.1.2.2 Intended users of the device:

***【填写产品预期使用者】***

The details of Design Specification can refer to Appendix 1.3 Design Specification.

1.1.3 Intended patient population(MDR Annex II Section 1.1(c))

***【填写产品预期患者人群】***

1.1.4 Principles of operation of the device and its mode of action (MDR Annex II Section 1.1(d))

***【填写产品操作原理和作用方式】***

1.1.5 Qualification of the product as a device (MDR Annex II Section 1.1(e))

***【填写产品判定为医疗器械的依据】***

***{【填写产品预期用途】***

***According to the definition of medical device in REGULATION (EU) 2017/745 as below and the application of 【填写产品名称】, we consider that 【填写产品名称】 is a medical device.***

***Define of medical device:***

***“medical device” means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:***

***— diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,***

***— diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,***

***— investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,***

***— providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations,and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.***

***The following products shall also be deemed to be medical devices:***

***— devices for the control or support of conception;***

***— products specifically intended for the cleaning, disinfection or sterilisation of devices as referred to in Article 1(4) and of those referred to in the first paragraph of this point.***

***1.1.6 Risk class of the device (MDR Annex II Section 1.1(f); Annex VIII)***

***The device belongs to Class IIa.***

***Rule 10***

***Active devices intended for diagnosis and monitoring are classified as class IIa:***

***— if they are intended to supply energy which will be absorbed by the human body, except for devices intended to illuminate the patient's body, in the visible spectrum, in which case they are classified as class I;***

***— if they are intended to image in vivo distribution of radiopharmaceuticals; or***

***— if they are intended to allow direct diagnosis or monitoring of vital physiological processes, unless they are specifically intended for monitoring of vital physiological parameters and the nature of variations of those parameters is such that it could result in immediate danger to the***

***patient, for instance variations in cardiac performance, respiration, activity of the central nervous system, or they are intended for diagnosis in clinical situations where the patient is in immediate***

***danger, in which cases they are classified as class IIb.***

***Active devices intended to emit ionizing radiation and intended for diagnostic or therapeutic radiology, including interventional radiology devices and devices which control or monitor such devices, or which directly influence their performance, are classified as class IIb.***

***【填写预期用途】 So,【填写产品名称】 belongs to Class IIb.***

***The details of Risk class of the device can refer to Appendix 1.4 Risk class of the device.***

***}***

1.1.7 Novel features/Changes to predecessor device (MDR Annex II Section 1.1(g))

***{Not applicable. The device does not contain novel features. It also does not have a predecessor device.}***

1.1.8 Accessories and device combination (MDR Annex II Section 1.1(h) and 1.1(i))

**Accessory**

***【填写与产品一起使用的附件，包括附件的信息，如CE注册证信息等】***

**Device combination**

***【填写与产品一起使用的器械，包括器械的信息，如CE注册证信息等】***

1.1.9 Configurations and variants of the device (MDR Annex II Section 1.1(i))

***{***

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| ***Model*** | ***Description*** | ***Configuration*** | ***Population*** | ***Application site*** | ***\*\*\*\**** |
| ***【产品***  ***型号】*** | ***【详细信息，罗列差异】*** | ***【详细信息，罗列差异】*** | ***【详细信息，罗列差异】*** | ***【详细信息，罗列差异】*** | ***【详细信息，罗列差异】*** |
| ***【产品***  ***型号】*** | ***【详细信息，罗列差异】*** | ***【详细信息，罗列差异】*** | ***【详细信息，罗列差异】*** | ***【详细信息，罗列差异】*** | ***【详细信息，罗列差异】*** |
| ***【产品***  ***型号】*** | ***【详细信息，罗列差异】*** | ***【详细信息，罗列差异】*** | ***【详细信息，罗列差异】*** | ***【详细信息，罗列差异】*** | ***【详细信息，罗列差异】*** |

***The details of List of all configurations variants can refer to Appendix 1.7 List of all configurations variants.***

***}***

1.1.10 General description of the key functional elements (MDR Annex II Section 1.1(j))

1.1.10.1 A general description of the key functional elements, e.g. its parts/components (including software if appropriate)

***【产品的主要功能组件：***

***BOM里面的清单；***

***软件；】***

1.1.10.2 labelled pictorial representations (e.g. diagrams, photographs, and drawings),

***【产品结构图，爆炸图等，与1.1.10.1 中内容对应】***

1.1.11 Materials incorporated into key functional elements (MDR Annex II Section 1.1(k))

***{***

***A description of the raw materials incorporated into key functional elements and those making either direct contact with the human body or indirect contact with the body is as below.***

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| ***Model*** | ***Components*** | ***Contact way*** | ***Contact position*** | ***Materials*** | ***Supplier*** |
| ***【产品型号】*** | ***【与人体接触部位组件】*** | ***【接触方式】*** | ***【接触部位】*** | ***【接触部位材质】*** | ***【供应商名称】*** |
| ***【与人体接触部位组件】*** | ***【接触方式】*** | ***【接触部位】*** | ***【接触部位材质】*** | ***【供应商名称】*** |
| ***【与人体接触部位组件】*** | ***【接触方式】*** | ***【接触部位】*** | ***【接触部位材质】*** | ***【供应商名称】*** |
| ***【产品型号】*** | ***【与人体接触部位组件】*** | ***【接触方式】*** | ***【接触部位】*** | ***【接触部位材质】*** | ***【供应商名称】*** |
| ***【与人体接触部位组件】*** | ***【接触方式】*** | ***【接触部位】*** | ***【接触部位材质】*** | ***【供应商名称】*** |

***The details of Material safety data sheets can refer to Appendix 1.8 Material safety data sheets. The details of Bill of Materials can refer to Appendix 1.9 Bill of Materials.***

***The details of Certificates of analysis of suppliers can refer to Appendix 1.10 Certificates of analysis of suppliers.***

***}***

1.1.12 Technical specification (MDR Annex II Section 1.1(l))

***【产品规格参数】***

1.2 Reference to previous and similar generations of the device (MDR Annex II Section 1.2)

1.2.1 An overview of the previous generation or generations of the device produced by the manufacturer

***{No previous generations.}***

***【如有前代产品，请描述前代产品信息】***

1.2.2 An overview of identified similar devices available on the Union or international markets

***【描述相似产品在国际市场上的情况】***

***{Many similar devices have been put on the Union or international markets. Famous 【产品名称】 manufacturers, such as Philips and \*\* , have a mature technology of design and manufacturing of 【产品名称】 for many years.***

***【产品名称】 manufactured by Philips is equivalent to the device under application. The details is as below：***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| ***No*** | ***Device name*** | ***Model*** | ***Manufacturer*** | ***NB number*** |
| ***1*** | ***【产品名称】*** | ***【产品型号】*** | ***Philips Nedical Systems*** | ***0123*** |

***【产品名称】 manufactured by \*\* is similar to the device under application. The details is as below：***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| ***No*** | ***Device name*** | ***Model*** | ***Manufacturer*** | ***NB number*** |
| ***1*** | ***【产品名称】*** | ***【产品型号】*** | ***Philips Nedical Systems*** | ***0123*** |

***The detail of Overview of generations and similar devices can refer to Appendix 1.11 Overview of generations and similar devices.***

***The detail of market analysis for the device under evaluation, equivalent device and similar device can refer to Appendix 1.12 Market analysis.***

***}***