**Risk Management Report**

**Product Name:** **【产品名称】**

**Model: 【产品型号】**

**Document No.: 【文件编号】**

**Edition: 【版本】**

Prepared by : Date：

Reviewed by: Date：

Approved by:  Date：

【公司名称】

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# Chapter 1: Description

## **Product introduction**

1.1.1 Model list

*【产品型号】*

1.1.2 Working principle

*【填写工作原理】*

1.1.3 Product Composition

*【填写产品组成】*

1.1.4 Intended use

*【填写产品预期用途】*

1.1.5 Expected operator

*【预期操作者】*

1.1.6 Operating environment

*【操作环境】*

##  Purpose and scope

This article is a plan for the risk management of the *【产品名称】.*

The scope identifies and describes the medical device and the life cycle phases for which each element of the plan is applicable.

## Product expected life time

*【填写产品效期】*

## Contraindication

*【填写禁忌症】*

##  Side effects/complications:

*【填写副作用】*

##  Precautions and warning:

*【填写注意事项和警告】*

## Description of risk management implementation

**1.7.1 Risk Management Process**

Refer to Risk Management Plan.

**1.7.2 Risk Management implementation**

*【公司名称】* starts the project from ***{September in 2021}***. At the same time, the risk management plan is build up.

The plan determined the acceptable risk level. Assign the responsibility of related person. And establish the method of collecting post-production information.

The company formed a risk management team and determined the project's risk management leader. The project's risk management activities are implemented as below.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Phase** | **Task** | **Planning complete date** | **Responsible person** | **Remark** |
| product realization process | 1 | Define the risk management plan. | ***{2021-09}*** | ***【负责人姓名】*** | NA |
| 2 | Identify and document the characteristics related to the safety | ***{2021-10}*** | ***【负责人姓名】*** | NA |
| 3 | Identify of hazards and estimate of the risks for each hazardous situation and conduct risk evaluation. | ***{2021-10}*** | ***【负责人姓名】*** | NA |
| 4 | Make risk control plan. | ***{2021-12}*** | ***【负责人姓名】*** | NA |
| 5 | Implement the risk control measures | ***{2021.12～2022.09}*** | ***【负责人姓名】*** | NA |
| 6 | Conduct residual risk evaluation. | ***{2022.10～2023.01}*** | ***【负责人姓名】*** | NA |
| 7 | Evaluation of overall residual risk | ***{2023.01～2023.03}*** | ***【负责人姓名】*** |  |
| 8 | Conduct Risk management review. | ***{2023.03}*** | ***【负责人姓名】*** | NA |
| Production and post-production phase | 1 | Actively collect and review information of the particular medical device. | / | ***【负责人姓名】*** | NA |
| 2 | Actively collect and review publicly available information about similar medical devices and similar other products on the market. | / | ***【负责人姓名】*** | NA |

## 1.8 Applied standard list

1. ISO 10993-1: 2018 Biological evaluation of medical devices - Part 1: Evaluation and testing
2. ISO 13485:2016 Medical devices – Quality management systems – Requirements for regulatory purposed
3. ISO 14155-1: 2020 Clinical investigation of medical devices for human subjects - Part 1: General requirements
4. ISO 14971:2019 Medical devices - Application of risk management to medical devices

......

## 1.9 Risk Assessment team and responsibility

|  |  |  |  |
| --- | --- | --- | --- |
| **Name** | **Job title** | **Function in team** | **Duty** |
| ***【负责人姓名】*** | Director | Risk management owner | In charge of risk management control and implementation of process |
| ***【负责人姓名】*** | Director | Engineer | In charge of risk management control and implementation of process |
| ***【负责人姓名】*** | engineer | Structure engineer | Take risk into account in structure and assembly |
| ***【负责人姓名】*** | engineer | Electric engineer | Take risk into account in technical and software. |
| ***【负责人姓名】*** | engineer | Production engineer | Take risk into account in production |
| ***【负责人姓名】*** | engineer | Quality engineer | Take risk into account in quality. |
| ***【负责人姓名】*** | engineer | Sales engineer(abroad)  | Take risk into account in medical field. |
| ***【负责人姓名】*** | engineer | Sales Department | Take risk into account in medical field. |
| ***【负责人姓名】*** | engineer | Customer service manager | Take risk into account in the probability of operator’s misplay. |

# Chapter 2 Risk Analysis

## 2.1Risk Accept Level

**2.1.1Severity level (S)**

|  |  |  |
| --- | --- | --- |
| **Common term** | **Code** | **Description** |
| Negligible  | 1 | Results in inconvenience or temporary discomfort |
| Minor | 2 | Results in temporary injury or impairment not requiring medical or surgical intervention |
| Serious  | 3 | Results in injury or impairment requiring medical or surgical intervention |
| Critical | 4 | Results in permanent impairment or irreversible injury |
| Catastrophic | 5 | Results in death |

**2.1.2 Probability level (P)**

|  |  |  |
| --- | --- | --- |
| **Code** | **Type** | **Probability** **(events / unit product life period)** |
| **1** | Improbable | <10-6 |
| **2** | Remote | ＜10-5 and ≥10-6 |
| **3** | Occasional | ＜10-4 and ≥10-5  |
| **4** | Probable | ＜10-3and ≥10-4 |
| **5** | Frequent | ≥10-3 |

**2.1.3 Risk evaluation criteria (S)**

**Three ranges of risks are defined:**

**A: acceptable risk**

**U: Unacceptable risk without risk or benefit analysis**

|  |  |  |  |
| --- | --- | --- | --- |
| Hazard probability |  Severity level |  |  |
| 1 | 2 | 3 | 4 | 5 |
| Negligible  | Minor | Serious  | Critical | Catastrophic |
| Improbable | 1 | A | A | A | A | R |
| Remote | 2 | A | A | A | R | R |
| Occasional | 3 | A | A | R | R | R |
| Probable | 4 | A | R | R | R | R |
| Frequent | 5 | R | R | R | R | R |

## 2.2 Intended use and reasonably foreseeable misuse

**2.2.1 Clinical use**

【描述预期使用者的信息，包括operator和patient，如用户简历，病人类型等】

**2.2.2 Product description**

【请添加产品描述】

## 2.3 Identification of the safety related characteristic

**2.3.1 Characteristic from Annex A of ISO/TR 24971:2020 related to safety**

According to Annex A of ISO/TR 24971:2020, answer the following question to identify the safety related characteristic

| **No.** | **Characteristic**  | Yes/No | **Verdict**  | Hazard identification |
| --- | --- | --- | --- | --- |
| 1 | A2.1 What is the intended use and how is the medical device to be used?Factors that should be considered include:—what is the medical device's role relative to—diagnosis, prevention, monitoring, treatment or alleviation of disease,—diagnosis, monitoring, treatment or alleviation of or compensation for an injury,—investigation, replacement, modification or support of anatomy or a physiological process, or—control of conception?—What are the indications for use (e.g. patient population, user profile, use environment)?—What are the contra-indications?—does the medical device sustain or support life?—is special intervention necessary in the case of failure of the medical device?—can the performance of the medical device be impacted in the event of a security breach (performance degradation or loss of availability)?—can unauthorized access, unauthorized activities, or loss of data affect the medical device safety? | {Intended use: The device is used to monitor vital signs. Operator: Trained and qualified medical staffs.} | Hazards :☑1.Energy hazard □2 biological hazards □3. Operation hazards □4. Software hazards □5. Environment hazards □6. Information hazards□7. Hazards from Inappropriate or over-complicated interface (man/machine communication)□8.hazards from function failure, maintenance or aging  | H1 |
| 2 | A.2.2 Is the medical device intended to be implanted?Factors that should be considered include the location of implantation, the characteristics of the patient population, age, weight, physical activity, the effect of ageing on implant performance, the expected lifetime of the implant, the reversibility of the implantation, whether the implant can be modified or configured while implanted and the access connection to perform this modification or configuration (e.g. physical access point or wireless connection to the implanted medical device). | No | Hazards :□1.Energy hazard □2 biological hazards □3. Operation hazards □4. Software hazards □5. Environment hazards □6. Information hazards□7. Hazards from Inappropriate or over-complicated interface (man/machine communication)□8.hazards from function failure, maintenance or aging  | / |
| 3 | A.2.3 Is the medical device intended to be in contact with the patient or other persons? Factors that should be considered include the nature of the intended contact, i.e. surface contact, invasive contact, or implantation and, for each, the period and frequency of contact. | 【根据实际情况填写】 | Hazards :□1.Energy hazard □2 biological hazards □3. Operation hazards □4. Software hazards □5. Environment hazards □6. Information hazards□7. Hazards from Inappropriate or over-complicated interface (man/machine communication)□8.hazards from function failure, maintenance or aging  | 【根据实际情况填写，如有识别到风险，则填写相应的风险识别号】 |
| 4 | A2.4 What materials or components are utilized in the medical device or are used with, or are in contact with, the medical device?Factors that should be considered include:—compatibility with relevant substances;—compatibility with tissues or body fluids;—whether characteristics relevant to safety are known;—is the device manufactured utilizing materials of animal origin?NOTE See Annex B of ISO 10993-1:2018 andalso the ISO 22442 series of standards. | 【根据实际情况填写】 | Hazards :□1.Energy hazard □2 biological hazards □3. Operation hazards □4. Software hazards □5. Environment hazards □6. Information hazards□7. Hazards from Inappropriate or over-complicated interface (man/machine communication)□8.hazards from function failure, maintenance or aging  | 【根据实际情况填写，如有识别到风险，则填写相应的风险识别号】 |
| 5 | A.2.5 Is energy delivered to or extracted from the patient?Factors that should be considered include:—the type of energy transferred;—its control, quality, quantity, intensity and duration;—whether energy levels are higher than thosecurrently used for similar medical devices. | 【根据实际情况填写】 | Hazards :□1.Energy hazard □2 biological hazards □3. Operation hazards □4. Software hazards □5. Environment hazards □6. Information hazards□7. Hazards from Inappropriate or over-complicated interface (man/machine communication)□8.hazards from function failure, maintenance or aging  | 【根据实际情况填写，如有识别到风险，则填写相应的风险识别号】 |
| 6 | A2.6 Are substances delivered to or extracted from the patient?Factors that should be considered include:—whether the substance is delivered or extracted;—whether it is a single substance or range of substances;—The maximum and minimum transfer rates and control thereof. | 【根据实际情况填写】 | Hazards :□1.Energy hazard □2 biological hazards □3. Operation hazards □4. Software hazards □5. Environment hazards □6. Information hazards□7. Hazards from Inappropriate or over-complicated interface (man/machine communication)□8.hazards from function failure, maintenance or aging  | 【根据实际情况填写，如有识别到风险，则填写相应的风险识别号】 |
| 7 | A.2.7 Are biological materials processed by the medical device for subsequent reuse, transfusion or transplantation?Factors that should be considered include the type of process and substance(s) processed (e.g. auto-transfusion, dialysis, blood component or cell therapy processing). | 【根据实际情况填写】 | Hazards :□1.Energy hazard □2 biological hazards □3. Operation hazards □4. Software hazards □5. Environment hazards □6. Information hazards□7. Hazards from Inappropriate or over-complicated interface (man/machine communication)□8.hazards from function failure, maintenance or aging  | 【根据实际情况填写，如有识别到风险，则填写相应的风险识别号】 |
| 8 | A.2.8 Is the medical device supplied sterile or intended to be sterilized by the user, or are other microbiological controls applicable?Factors that should be considered include:—whether the medical device is intended for single use or re-use packaging;—shelf-life issues;—limitation on the number of reuse cycles;—method of product sterilization;—the impact of other sterilization methods not intended by the manufacturer | 【根据实际情况填写】 | Hazards :□1.Energy hazard □2 biological hazards □3. Operation hazards □4. Software hazards □5. Environment hazards □6. Information hazards□7. Hazards from Inappropriate or over-complicated interface (man/machine communication)□8.hazards from function failure, maintenance or aging  | 【根据实际情况填写，如有识别到风险，则填写相应的风险识别号】 |
| 9 | A.2.9 Is the medical device intended to be routinely cleaned and disinfected by the user?Factors that should be considered include the types of cleaning or disinfecting agents to be used and any limitations on the number of cleaning cycles. The design of the medical device can influence the effectiveness of routine cleaning and disinfection. In addition, consideration should be given to the effect of cleaning and disinfecting agents on the safety or performance of the medical device. | 【根据实际情况填写】 | Hazards :□1.Energy hazard □2 biological hazards □3. Operation hazards □4. Software hazards □5. Environment hazards □6. Information hazards□7. Hazards from Inappropriate or over-complicated interface (man/machine communication)□8.hazards from function failure, maintenance or aging  | 【根据实际情况填写，如有识别到风险，则填写相应的风险识别号】 |
| 10 | A.2.10 Does the medical device modify the patient environment?Factors that should be considered include:—temperature;—humidity;—atmospheric gas composition;—pressure;—light. | 【根据实际情况填写】 | Hazards :□1.Energy hazard □2 biological hazards □3. Operation hazards □4. Software hazards □5. Environment hazards □6. Information hazards□7. Hazards from Inappropriate or over-complicated interface (man/machine communication)□8.hazards from function failure, maintenance or aging  | 【根据实际情况填写，如有识别到风险，则填写相应的风险识别号】 |
| 11 | A.2.11 Are measurements taken?Factors that should be considered include the variables measured and the accuracy and the precision of the measurement results, as well as whether the measurement apparatus or data can be compromised. In addition, the need for calibration and maintenance should be considered (see A.2.18). | 【根据实际情况填写】 | Hazards :□1.Energy hazard □2 biological hazards □3. Operation hazards □4. Software hazards □5. Environment hazards □6. Information hazards□7. Hazards from Inappropriate or over-complicated interface (man/machine communication)□8.hazards from function failure, maintenance or aging  | 【根据实际情况填写，如有识别到风险，则填写相应的风险识别号】 |
| 12 | A.2.12 Is the medical device interpretative? Factors that should be considered include whether conclusions are presented by the medical device from input or acquired data, the algorithms used, and confidence limits. Special attention should be given to unintended applications of the data or algorithm, as well as unauthorized manipulation or changes to algorithms and data. | 【根据实际情况填写】 | Hazards :□1.Energy hazard □2 biological hazards □3. Operation hazards □4. Software hazards □5. Environment hazards □6. Information hazards□7. Hazards from Inappropriate or over-complicated interface (man/machine communication)□8.hazards from function failure, maintenance or aging  | 【根据实际情况填写，如有识别到风险，则填写相应的风险识别号】 |
| 13 | A.2.13 Is the medical device intended for use in conjunction with other medical devices, medicines or other medical technologies?Factors that should be considered include:—identifying any other medical devices, medicines or other medical technologies that can be involved;—the potential problems associated with such interactions(such as the medical device impacting the performance of other medical devices); and—whether the patient follows the instructions for the therapy. | 【根据实际情况填写】 | Hazards :□1.Energy hazard □2 biological hazards □3. Operation hazards □4. Software hazards □5. Environment hazards □6. Information hazards□7. Hazards from Inappropriate or over-complicated interface (man/machine communication)□8.hazards from function failure, maintenance or aging  | 【根据实际情况填写，如有识别到风险，则填写相应的风险识别号】 |
| 14 | A.2.14 Are there unwanted outputs of energy or substances?Energy-related factors that should be considered include noise and vibration, heat, radiation (including ionizing, non-ionizing, and ultraviolet/visible/infrared radiation), contact temperatures, leakage currents, and electric or magnetic fields.Substance-related factors that should be considered include substances used in manufacturing, cleaning or testing having unwanted physiological effects if they remain in the product.Other substance-related factors that should be considered include discharge of chemicals, waste products, and body fluids. | 【根据实际情况填写】 | Hazards :□1.Energy hazard □2 biological hazards □3. Operation hazards □4. Software hazards □5. Environment hazards □6. Information hazards□7. Hazards from Inappropriate or over-complicated interface (man/machine communication)□8.hazards from function failure, maintenance or aging  | 【根据实际情况填写，如有识别到风险，则填写相应的风险识别号】 |
| 15 | A.2.15 Is the medical device susceptible to environmental influences?Factors that should be considered include the operational, transport and storage environments. These include light, temperature, humidity, vibrations, spillage, and susceptibility to variations in power and cooling supplies, and electromagnetic interference. | 【根据实际情况填写】 | Hazards :□1.Energy hazard □2 biological hazards □3. Operation hazards □4. Software hazards □5. Environment hazards □6. Information hazards□7. Hazards from Inappropriate or over-complicated interface (man/machine communication)□8.hazards from function failure, maintenance or aging  | 【根据实际情况填写，如有识别到风险，则填写相应的风险识别号】 |
| 16 | A.2.16 Does the medical device influence the environment?Factors that should be considered include:—the effects on power and cooling supplies;—emission of toxic materials;—the generation of electromagnetic disturbance | 【根据实际情况填写】 | Hazards :□1.Energy hazard □2 biological hazards □3. Operation hazards □4. Software hazards □5. Environment hazards □6. Information hazards□7. Hazards from Inappropriate or over-complicated interface (man/machine communication)□8.hazards from function failure, maintenance or aging  | 【根据实际情况填写，如有识别到风险，则填写相应的风险识别号】 |
| 17 | A.2.17 Does the medical device require consumables or accessories?Factors that should be considered include specifications for such consumables or accessories and any restrictions placed upon users in their selection of these. | 【根据实际情况填写】 | Hazards :□1.Energy hazard □2 biological hazards □3. Operation hazards □4. Software hazards □5. Environment hazards □6. Information hazards□7. Hazards from Inappropriate or over-complicated interface (man/machine communication)□8.hazards from function failure, maintenance or aging  | 【根据实际情况填写，如有识别到风险，则填写相应的风险识别号】 |
| 18 | A.2.18 Is maintenance or calibration necessary? Factors that should be considered include:—whether maintenance or calibration are to be carried out by the user or by a specialist;—whether special substances or equipment are needed for proper maintenance or calibration;—traceability of the calibrator values to a higher order reference;—how to determine when maintenance or recalibration is needed;—how to verify that calibration is (still) acceptable. | 【根据实际情况填写】 | Hazards :□1.Energy hazard □2 biological hazards □3. Operation hazards □4. Software hazards □5. Environment hazards □6. Information hazards□7. Hazards from Inappropriate or over-complicated interface (man/machine communication)□8.hazards from function failure, maintenance or aging  | 【根据实际情况填写，如有识别到风险，则填写相应的风险识别号】 |
| 19 | A.2.19 Does the medical device contain software?Factors that should be considered include whether software is intended to be installed, verified, modified or exchanged by the user or by a specialist, and the authenticity of a software update. | 【根据实际情况填写】 | Hazards :□1.Energy hazard □2 biological hazards □3. Operation hazards □4. Software hazards □5. Environment hazards □6. Information hazards□7. Hazards from Inappropriate or over-complicated interface (man/machine communication)□8.hazards from function failure, maintenance or aging  | 【根据实际情况填写，如有识别到风险，则填写相应的风险识别号】 |
| 20 | A.2.20 Does the medical device allow access to information?Factors that should be considered include accessible Ethernet ports, USB ports, serial ports, and removable hard drives. | 【根据实际情况填写】 | Hazards :□1.Energy hazard □2 biological hazards □3. Operation hazards □4. Software hazards □5. Environment hazards □6. Information hazards□7. Hazards from Inappropriate or over-complicated interface (man/machine communication)□8.hazards from function failure, maintenance or aging  | 【根据实际情况填写，如有识别到风险，则填写相应的风险识别号】 |
| 21 | A.2.21 Does the medical device store data critical to patient care?Factors that should be considered include the possibility of the data being modified or corrupted, unauthorized access to the data, and the consequences for the patients. | 【根据实际情况填写】 | Hazards :□1.Energy hazard □2 biological hazards □3. Operation hazards □4. Software hazards □5. Environment hazards □6. Information hazards□7. Hazards from Inappropriate or over-complicated interface (man/machine communication)□8.hazards from function failure, maintenance or aging  | 【根据实际情况填写，如有识别到风险，则填写相应的风险识别号】 |
| 22 | A.2.22 Does the medical device have a restricted shelf-life?Factors that should be considered include whether the medical device can deteriorate over time, the impact of storage conditions and primary packaging, the communication of the expiry data (by labelling or an indicator), possibility of use after the expiry data, and the disposal of expired medical devices. | 【根据实际情况填写】 | Hazards :□1.Energy hazard □2 biological hazards □3. Operation hazards □4. Software hazards □5. Environment hazards □6. Information hazards□7. Hazards from Inappropriate or over-complicated interface (man/machine communication)□8.hazards from function failure, maintenance or aging  | 【根据实际情况填写，如有识别到风险，则填写相应的风险识别号】 |
| 23 | A.2.23 Are there any delayed or long-term use effects?Factors that should be considered include ergonomic and cumulative effects. Examples could include pumps for saline that corrode over time, mechanical fatigue, loosening of straps and attachments, vibration effects, labels that wear or fall off, long term material degradation. | 【根据实际情况填写】 | Hazards :□1.Energy hazard □2 biological hazards □3. Operation hazards □4. Software hazards □5. Environment hazards □6. Information hazards□7. Hazards from Inappropriate or over-complicated interface (man/machine communication)□8.hazards from function failure, maintenance or aging  | 【根据实际情况填写，如有识别到风险，则填写相应的风险识别号】 |
| 24 | A.2.24 To what mechanical forces will the medical device be subjected?Factors that should be considered include whether the forces to which the medical device will be subjected are under the control of the user or controlled by interaction with other persons. | 【根据实际情况填写】 | Hazards :□1.Energy hazard □2 biological hazards □3. Operation hazards □4. Software hazards □5. Environment hazards □6. Information hazards□7. Hazards from Inappropriate or over-complicated interface (man/machine communication)□8.hazards from function failure, maintenance or aging  | 【根据实际情况填写，如有识别到风险，则填写相应的风险识别号】 |
| 25 | What determines the lifetime of the medical device?Factors that should be considered include battery depletion, deterioration of materials and failure of components due to ageing, wear, fatigue or repeated use. The availability of spare parts should be considered as well. | 【根据实际情况填写】 | Hazards :□1.Energy hazard □2 biological hazards □3. Operation hazards □4. Software hazards □5. Environment hazards □6. Information hazards□7. Hazards from Inappropriate or over-complicated interface (man/machine communication)□8.hazards from function failure, maintenance or aging  | 【根据实际情况填写，如有识别到风险，则填写相应的风险识别号】 |
| 26 | A.2.26 Is the medical device intended for single use?Factors that should be considered include:—whether the medical device self-destruct after use;—whether it is obvious to the user that the medical device has been used. | 【根据实际情况填写】 | Hazards :□1.Energy hazard □2 biological hazards □3. Operation hazards □4. Software hazards □5. Environment hazards □6. Information hazards□7. Hazards from Inappropriate or over-complicated interface (man/machine communication)□8.hazards from function failure, maintenance or aging  | 【根据实际情况填写，如有识别到风险，则填写相应的风险识别号】 |
| 27 | A.2.27 Is safe decommissioning or disposal of the medical device necessary?Factors that should be considered include the waste products that are generated during the disposal of the medical device itself, and the proper sanitization (removal) of all sensitive data on the medical device. For example, does it contain hazardous material (e.g. toxic chemical or biological agent), or is the material recyclable? If the medical device stores data, proper handling and security of the stored data should be considered, including data removal and retention. | 【根据实际情况填写】 | Hazards :□1.Energy hazard □2 biological hazards □3. Operation hazards □4. Software hazards □5. Environment hazards □6. Information hazards□7. Hazards from Inappropriate or over-complicated interface (man/machine communication)□8.hazards from function failure, maintenance or aging  | 【根据实际情况填写，如有识别到风险，则填写相应的风险识别号】 |
| 28 | A.2.28 Does installation or use of the medical device require special training or special skills?Factors that should be considered include the complexity and novelty of the medical device and the knowledge, skills and ability of the persons installing, maintaining or using the medical device. This can include training, education, competence assessment, certification or qualification. | 【根据实际情况填写】 | Hazards :□1.Energy hazard □2 biological hazards □3. Operation hazards □4. Software hazards □5. Environment hazards □6. Information hazards□7. Hazards from Inappropriate or over-complicated interface (man/machine communication)□8.hazards from function failure, maintenance or aging  | 【根据实际情况填写，如有识别到风险，则填写相应的风险识别号】 |
| 29 | A.2.29 How will information for safety be provided?Factors that should be considered include:—whether information will be provided directly to the end user by the manufacturer or will it involve the participation of third parties such as installers, care providers, health care professionals, laboratory directors or pharmacists and whether this will have implications for training;—commissioning and transferring to the end user and whether it is likely/possible that installation can be carried out by people without the necessary skills;—based on the type and expected lifetime of the medical device, whether re-training orre-certification of users or service personnelwould be indicated. | 【根据实际情况填写】 | Hazards :□1.Energy hazard □2 biological hazards □3. Operation hazards □4. Software hazards □5. Environment hazards □6. Information hazards□7. Hazards from Inappropriate or over-complicated interface (man/machine communication)□8.hazards from function failure, maintenance or aging  | 【根据实际情况填写，如有识别到风险，则填写相应的风险识别号】 |
| 30 | A.2.30 Are new manufacturing process established or introduced?Factors that should be considered include the application of new or innovative technology and changes in the scale of production. This can also involve changes in contract manufacturing, suppliers and vendors. | 【根据实际情况填写】 | Hazards :□1.Energy hazard □2 biological hazards □3. Operation hazards □4. Software hazards □5. Environment hazards □6. Information hazards□7. Hazards from Inappropriate or over-complicated interface (man/machine communication)□8.hazards from function failure, maintenance or aging  | 【根据实际情况填写，如有识别到风险，则填写相应的风险识别号】 |
| 31 | A.2.31 Is successful application of the medical device dependent on the usability of the user interface? | 【根据实际情况填写】 | Hazards :□1.Energy hazard □2 biological hazards □3. Operation hazards □4. Software hazards □5. Environment hazards □6. Information hazards□7. Hazards from Inappropriate or over-complicated interface (man/machine communication)□8.hazards from function failure, maintenance or aging  | 【根据实际情况填写，如有识别到风险，则填写相应的风险识别号】 |
| 31.1 | A.2.31.1 Can the user interface design features contribute to use error? Factors that should be considered include: control and indicators, symbols used, ergonomic features, physical design and layout, hierarchy of operation, menus for software-driven medical devices, visibility ofwarnings, audibility of alarms, standardisation of colour coding. See IEC 62366-1 for additional information on usability and IEC 60601-1-8 for alarms. | 【根据实际情况填写】 | Hazards :□1.Energy hazard □2 biological hazards □3. Operation hazards □4. Software hazards □5. Environment hazards □6. Information hazards□7. Hazards from Inappropriate or over-complicated interface (man/machine communication)□8.hazards from function failure, maintenance or aging  | 【根据实际情况填写，如有识别到风险，则填写相应的风险识别号】 |
| 31.2 | A.2.31.2 Is the medical device used in an environment where distractions can use error?Factors that should be considered include:—the consequence of use error;—whether the distractions are commonplace;—whether the user can be disturbed by an infrequent distraction;—whether repetitive stress can reduce theuser’s awareness or attention. | 【根据实际情况填写】 | Hazards :□1.Energy hazard □2 biological hazards □3. Operation hazards □4. Software hazards □5. Environment hazards □6. Information hazards□7. Hazards from Inappropriate or over-complicated interface (man/machine communication)□8.hazards from function failure, maintenance or aging  | 【根据实际情况填写，如有识别到风险，则填写相应的风险识别号】 |
| 31.3 | A.2.31.3 Does the medical device have connecting parts or accessories?Factors that should be considered include the possibility of wrong connection, similarity to other products’ connections, connection force, feedback on connection integrity, and over-and under-tightening. | 【根据实际情况填写】 | Hazards :□1.Energy hazard □2 biological hazards □3. Operation hazards □4. Software hazards □5. Environment hazards □6. Information hazards□7. Hazards from Inappropriate or over-complicated interface (man/machine communication)□8.hazards from function failure, maintenance or aging  | 【根据实际情况填写，如有识别到风险，则填写相应的风险识别号】 |
| 31.4 | A.2.31.4 Does the medical device have a control interface?Factors that should be considered include spacing, coding, grouping, mapping, modes of feedback, blunders, slips, control differentiation, visibility, direction of activation or change, whether the controls are continuous or discrete, and the reversibility of settings or actions. | 【根据实际情况填写】 | Hazards :□1.Energy hazard □2 biological hazards □3. Operation hazards □4. Software hazards □5. Environment hazards □6. Information hazards□7. Hazards from Inappropriate or over-complicated interface (man/machine communication)□8.hazards from function failure, maintenance or aging  | 【根据实际情况填写，如有识别到风险，则填写相应的风险识别号】 |
| 31.5 | A.2.31.5 Does the medical device display information?Factors that should be considered include spacing, coding, grouping, mapping, modes of feedback, blunders, slips, control differentiation, visibility, direction of activation or change, whether the controls are continuous or discrete, and the reversibility of settings or actions. | 【根据实际情况填写】 | Hazards :□1.Energy hazard □2 biological hazards □3. Operation hazards □4. Software hazards □5. Environment hazards □6. Information hazards□7. Hazards from Inappropriate or over-complicated interface (man/machine communication)□8.hazards from function failure, maintenance or aging  | 【根据实际情况填写，如有识别到风险，则填写相应的风险识别号】 |
| 31.6 | A.2.31.6 Is the medical device controlled by a menu?Factors that should be considered include complexity and number of layers, awareness of state, location of settings, navigation method, number of steps per action, sequence clarity and memorization problems, and importance of control function relative to its accessibility and the impact of deviating from specified operating procedures. | 【根据实际情况填写】 | Hazards :□1.Energy hazard □2 biological hazards □3. Operation hazards □4. Software hazards □5. Environment hazards □6. Information hazards□7. Hazards from Inappropriate or over-complicated interface (man/machine communication)□8.hazards from function failure, maintenance or aging  | 【根据实际情况填写，如有识别到风险，则填写相应的风险识别号】 |
| 31.7 | A.2.31.7 Is the successful use of the medical device dependent on a user’s knowledge, skills and abilities?Factors that should be considered include:—the (intended) users, their mental and physical abilities, skill and training;—the use environment, ergonomic aspects, installation requirements;—the capability of intended users to control or influence the use of the medical device; and—the personal characteristics of intended users that can affect their ability to successfully interact with the medical device. See IEC TR 62366-2. | 【根据实际情况填写】 | Hazards :□1.Energy hazard □2 biological hazards □3. Operation hazards □4. Software hazards □5. Environment hazards □6. Information hazards□7. Hazards from Inappropriate or over-complicated interface (man/machine communication)□8.hazards from function failure, maintenance or aging  | 【根据实际情况填写，如有识别到风险，则填写相应的风险识别号】 |
| 31.8 | A.2.31.8 Will the medical device be used by persons with specific needs?Factors that should be considered include:—users with special characteristics, such as disabled persons, the elderly and children, who might need assistance by another person to enable the use of a medical device;—users having wide-ranging skill levels anddiffering cultural backgrounds and expectations that could lead to differences in what is considered appropriate application of the medical device. | 【根据实际情况填写】 | Hazards :□1.Energy hazard □2 biological hazards □3. Operation hazards □4. Software hazards □5. Environment hazards □6. Information hazards□7. Hazards from Inappropriate or over-complicated interface (man/machine communication)□8.hazards from function failure, maintenance or aging  | 【根据实际情况填写，如有识别到风险，则填写相应的风险识别号】 |
| 31.9 | A.2.31.9 Can the user interface be used to initiate unauthorised actions?Factors that should be considered include whether the user interface allows the user to enter an operation mode with restricted access (e.g. for maintenance or special use), which increase the possibility of use error and thereby the associated risks, and whether the user becomes aware of having entered such operation mode. | 【根据实际情况填写】 | Hazards :□1.Energy hazard □2 biological hazards □3. Operation hazards □4. Software hazards □5. Environment hazards □6. Information hazards□7. Hazards from Inappropriate or over-complicated interface (man/machine communication)□8.hazards from function failure, maintenance or aging  | 【根据实际情况填写，如有识别到风险，则填写相应的风险识别号】 |
| 32 | A.2.32 Does the medical device include an alarm system?Factors that should be considered are the risk of false alarms, missing alarms, disconnected alarm systems, unreliable remote alarm systems, and the user’s ability of understanding how the alarm system works. Guidance for alarm systems is given in IEC 60601-1-8. | 【根据实际情况填写】 | Hazards :□1.Energy hazard □2 biological hazards □3. Operation hazards □4. Software hazards □5. Environment hazards □6. Information hazards□7. Hazards from Inappropriate or over-complicated interface (man/machine communication)□8.hazards from function failure, maintenance or aging  | 【根据实际情况填写，如有识别到风险，则填写相应的风险识别号】 |
| 33 | A.2.33 In what ways might the medical device be misused (deliberately or not)? Factors that should be considered are incorrect use of connectors, disabling safety features or alarms, neglect of manufacturer’s recommended maintenance, unauthorized access to the medical device or to medical device functions. | 【根据实际情况填写】 | Hazards :□1.Energy hazard □2 biological hazards □3. Operation hazards □4. Software hazards □5. Environment hazards □6. Information hazards□7. Hazards from Inappropriate or over-complicated interface (man/machine communication)□8.hazards from function failure, maintenance or aging  | 【根据实际情况填写，如有识别到风险，则填写相应的风险识别号】 |
| 34 | A.2.34 Is the medical device intended to be mobile or portable?Factors that should be considered are the need for grips, handles, wheels or brakes, and the need for mechanical stability and durability. | 【根据实际情况填写】 | Hazards :□1.Energy hazard □2 biological hazards □3. Operation hazards □4. Software hazards □5. Environment hazards □6. Information hazards□7. Hazards from Inappropriate or over-complicated interface (man/machine communication)□8.hazards from function failure, maintenance or aging  | 【根据实际情况填写，如有识别到风险，则填写相应的风险识别号】 |
| 35 | A.2.35 Does the use of the medical devicedepend on essential performance?Factors that should be considered are, for example, the characteristics of the output of life supporting medical devices or the operation of an alarm. See IEC 60601-1 for a discussion of essential performance of medical electrical equipment and medical electrical systems. | 【根据实际情况填写】 | Hazards :□1.Energy hazard □2 biological hazards □3. Operation hazards □4. Software hazards □5. Environment hazards □6. Information hazards□7. Hazards from Inappropriate or over-complicated interface (man/machine communication)□8.hazards from function failure, maintenance or aging  | 【根据实际情况填写，如有识别到风险，则填写相应的风险识别号】 |
| 36 | A.2.36 Does the medical device have a degree of autonomy?Factors that should be considered include:—awareness of the user when the medical device with a degree of autonomy generates an error, alarm or failure;—awareness of the user when intervention in an autonomously performed action is required;—the ability of the user to intervene in or abort an action that is performed autonomously; and—the ability of the user to select and perform proper corrective actions.See IEC TR 60601-4-1 for further guidance onmedical devices with a degree of autonomy. | 【根据实际情况填写】 | Hazards :□1.Energy hazard □2 biological hazards □3. Operation hazards □4. Software hazards □5. Environment hazards □6. Information hazards□7. Hazards from Inappropriate or over-complicated interface (man/machine communication)□8.hazards from function failure, maintenance or aging  | 【根据实际情况填写，如有识别到风险，则填写相应的风险识别号】 |
| 37 | A.2.37 Does the medical device produce an output that is used as an input in determining clinical action ?Factors that should be considered include whether incorrect or delayed outputs can result in direct or indirect risks to patients, e.g. an incorrect diagnosis resulting in delayed or omitted therapy for a patient. See Annex H for guidance on in vitro diagnostic medical devices. | 【根据实际情况填写】 | Hazards :□1.Energy hazard □2 biological hazards □3. Operation hazards □4. Software hazards □5. Environment hazards □6. Information hazards□7. Hazards from Inappropriate or over-complicated interface (man/machine communication)□8.hazards from function failure, maintenance or aging  | 【根据实际情况填写，如有识别到风险，则填写相应的风险识别号】 |
| Letters in the second column refer to ISO/ TR 24971:2020, Annex A |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 2 | 4.6Whether parts that can come into contact with the patient but fall outside of the definition of the applied parts need to be subject to the requirement for applied part? | Yes | Hazards :☑1.Energy hazard □2 biological hazards □3. Operation hazards □4. Software hazards □5. Environment hazards □6. Information hazards□7. Hazards from Inappropriate or over-complicated interface (man/machine communication)□8.hazards from function failure, maintenance or aging  | H44 |
| 9 | 9.6.1ME EQUIPMENT shall be designed so that human exposure to acoustic energy and vibration shall not result in an unacceptable RISK | Yes | Hazards :□1.Energy hazard □2 biological hazards ☑3. Operation hazards □4. Software hazards □5. Environment hazards □6. Information hazards□7. Hazards from Inappropriate or over-complicated interface (man/machine communication)□8.hazards from function failure, maintenance or aging  | H51 |

**2.3.2 Usability Characteristic related to safety**

*{The details of identified usability characteristic can refer to section 2.3.1 and section 2.4. No new usability characteristic related to safety has been identified. }*

**2.3.3 Biological Characteristic related to safety**

*{The details of identified biological characteristic can refer to section 2.3.1 and section 2.4. No new biological characteristic related to safety has been identified.}*

**2.3.4 Characteristic related to safety from Production and post-production information**

|  |  |
| --- | --- |
| **Event**  | **Hazard No.** |
|  |  |
|  |  |
|  |  |
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|  |  |

***【实际公司内部产品生产和上市后的收集的与安全相关的信息，按实际情况填写，如无，则写无相关内容】***

**2.3.7 Characteristic related to safety from recalling of foreign products in Chinese market**

|  |  |
| --- | --- |
| **Event**  | **Hazard No.** |
|  |  |
|  |  |

***【在国际及国内药监局网站搜索的公开的产品相关的不良事件和召回信息，按实际情况填写，如无，则写无相关内容】***

**2.4 Identification of hazards and hazardous situations**

**2.4.1 Hazards and hazardous situations from Annex A of ISO/TR 24971:2020**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Hazard type** | **Foreseeable sequence of events** | **Hazardous situation** | **Harm** | **Hazard No.** |
| *【根据实际情况填写，内容需要与2.3部分的内容相互呼应】* | *【根据实际情况填写，内容需要与2.3部分的内容相互呼应】* | *【根据实际情况填写，内容需要与2.3部分的内容相互呼应】* | *【根据实际情况填写，内容需要与2.3部分的内容相互呼应】* | H1 |
| *【根据实际情况填写，内容需要与2.3部分的内容相互呼应】* | *【根据实际情况填写，内容需要与2.3部分的内容相互呼应】* | *【根据实际情况填写，内容需要与2.3部分的内容相互呼应】* | *【根据实际情况填写，内容需要与2.3部分的内容相互呼应】* | H2 |
| *【根据实际情况填写，内容需要与2.3部分的内容相互呼应】* | *【根据实际情况填写，内容需要与2.3部分的内容相互呼应】* | *【根据实际情况填写，内容需要与2.3部分的内容相互呼应】* | *【根据实际情况填写，内容需要与2.3部分的内容相互呼应】* | H3 |
| *【根据实际情况填写，内容需要与2.3部分的内容相互呼应】* | *【根据实际情况填写，内容需要与2.3部分的内容相互呼应】* | *【根据实际情况填写，内容需要与2.3部分的内容相互呼应】* | *【根据实际情况填写，内容需要与2.3部分的内容相互呼应】* | H4 |
| ..... |  |  |  |  |

**2.4.2Hazards and hazardous situations from Production and Post-production information**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Hazard type | Foreseeable sequence of events | Hazardous situation | Harm | Hazard No. |
| *【根据实际情况填写，内容需要与2.3部分的内容相互呼应】* | *【根据实际情况填写，内容需要与2.3部分的内容相互呼应】* | *【根据实际情况填写，内容需要与2.3部分的内容相互呼应】* | *【根据实际情况填写，内容需要与2.3部分的内容相互呼应】* | PH1 |
| *【根据实际情况填写，内容需要与2.3部分的内容相互呼应】* | *【根据实际情况填写，内容需要与2.3部分的内容相互呼应】* | *【根据实际情况填写，内容需要与2.3部分的内容相互呼应】* | *【根据实际情况填写，内容需要与2.3部分的内容相互呼应】* | PH2 |
| *【根据实际情况填写，内容需要与2.3部分的内容相互呼应】* | *【根据实际情况填写，内容需要与2.3部分的内容相互呼应】* | *【根据实际情况填写，内容需要与2.3部分的内容相互呼应】* | *【根据实际情况填写，内容需要与2.3部分的内容相互呼应】* | PH3 |
| *【根据实际情况填写，内容需要与2.3部分的内容相互呼应】* | *【根据实际情况填写，内容需要与2.3部分的内容相互呼应】* | *【根据实际情况填写，内容需要与2.3部分的内容相互呼应】* | *【根据实际情况填写，内容需要与2.3部分的内容相互呼应】* | PH4 |
| ....... |  |  |  |  |
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# Chapter 3 Risk Evaluation and control

## 3.1 Risk Evaluation and Risk Control

**3.1.1** **Consideration of Risk analysis, Risk evaluation and Risk control**

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| --- | --- | --- | --- | --- | --- | --- |
| *No.* | *Foreseeable sequence of events* | *Harm* | *Risk evaluation* | *Risk control measure* | *Risk evaluation after risk control measures are applied* | *Risk/Benefit Analysis* |
| *P* | *S* | *R* | *Control measure*  | *Measure verify* | *P* | *S* | *R* |
| *H1* | *【根据实际情况填写，内容需要与2.3部分的内容相互呼应】* | *【根据实际情况填写，内容需要与2.3部分的内容相互呼应】* | 4 | 2 | U | *【根据实际情况填写，内容需要与2.3部分的内容相互呼应】* | *【根据实际情况填写，内容需要与2.3部分的内容相互呼应】* | *1* | 2 | A |  |
| *H2* | *【根据实际情况填写，内容需要与2.3部分的内容相互呼应】* | *【根据实际情况填写，内容需要与2.3部分的内容相互呼应】* | 4 | 2 | U | *【根据实际情况填写，内容需要与2.3部分的内容相互呼应】* | *【根据实际情况填写，内容需要与2.3部分的内容相互呼应】* | *1* | 2 | A |  |
|  | ...... |  |  |  |  |  |  |  |  |  |  |

## 3.2 Residual risk evaluation

**The statistics of before/after risk control measurement**

Before taking measures

|  |  |  |  |
| --- | --- | --- | --- |
| Hazard probability |  Severity level |  |  |
| 1 | 2 | 3 | 4 | 5 |
| Negligible  | Minor | Serious  | Critical | Catastrophic |
| Improbable | 1 |  |  |  |  |  |
| Remote | 2 |  |  |  |  |  |
| Occasional | 3 |  |  |  | 5 |  |
| Probable | 4 |  | 4 | 5 | 12 |  |
| Frequent | 5 |  |  |  |  |  |

After taking measures

|  |  |  |  |
| --- | --- | --- | --- |
| Hazard probability |  Severity level |  |  |
| 1 | 2 | 3 | 4 | 5 |
| Negligible  | Minor | Serious  | Critical | Catastrophic |
| Improbable | 1 |  |  |  | 17 |  |
| Remote | 2 |  | 4 | 5 |  |  |
| Occasional | 3 |  |  |  |  |  |
| Probable | 4 |  |  |  |  |  |
| Frequent | 5 |  |  |  |  |  |

From the tables we can see that the risk of each hazard is reduced to an acceptable level.

After take control measures, all the risks do not exist non-acceptable risk. All potential risk and mis-operation are indicated in the user manual and let the operator know.

After risk evaluation, all risks can be accepted.

## 3.3 Benefit-risk Analysis

*Before risk evaluation, 26 non acceptable risks (U). And after risk measurement and validation, all known risks are controlled at acceptable level (A).*

## 3.4 Risks arising from risk control measures

The manufacturer review the effects of the risk control measures with regard to whether:

— new hazards or hazardous situations are introduced; or

— the estimated risks for previously identified hazardous situations are affected by the introduction of the risk control measures.

No new or increased risks were arisen.

## 3.5 Completeness of Risk Control

The manufacturer review the risk control activities to ensure that the risks from all identified hazardous situations have been considered and all risk control activities are completed.

# Chapter 4 Evaluation of overall residual risk

After all risk control measures have been implemented and verified, the manufacturer evaluates the overall residual risk posed by the medical device, taking into account the contributions of all residual risks, in relation to the benefits of the intended use, using the method and the criteria for acceptability of the overall residual risk defined in the risk management plan.

The overall residual risk is judged acceptable. The manufacturer informs users of significant residual risks and includes the necessary information in the accompanying documentation in order to disclose those residual risks.

# Chapter 5 Risk Management Review

## 5.1 Risk Management review input

1. Risk accept level
2. Document of risk management
3. Risk management plan
4. Safety characteristic
5. Risk evaluation, risk control implementation and validation
6. Residual risk evaluation
7. Related standard

## 5.2 Implementation of risk management plan

The risk assessment team checked the management plan and considered all the risks are well implemented.

## 5.3 Overall residual risk acceptable evaluation

The review team has performed a comprehensive analysis for all the residual risks, combined effects of all the residual risks have been considered. The overall residual risk of the device is acceptable. Details of the conclusion are listed below:

1) Are there any conflicting requirements in risk control measures for individual risks?

Conclusion: no conflicting requirements in risk control measures have been found.

2) Review of warnings (Are there too many warnings?)

Conclusion: The warnings are clear and comply with the standards.

3) Review of operating instructions (Inconsistent information and instructions too difficult to follow.)

Conclusion: The instructions for use of the device comply with the requirements of the general safety standard; information related to safety is clear and easy to follow.

4) Comparison with the products which has similar specifications

Conclusion: The device has been compared with the similar product on the market through clinical applications and the aspects of features and performance; it has been concluded that the device and the similar product on the market have similar features and performance.

5) Clinical expert's conclusion

Conclusion: The risk management review team performed the above analysis and -together with the clinical experts - made the conclusion that the overall residual risk of the device is acceptable.

- By checking the evaluation of the residual risks and the results, all residual risks are acceptable.

Using event tree analysis, consider all the individual residual risks all together, the overall residual risk is acceptable.

- By review, all risk control measures that are appropriate for individual risks cannot result in conflicting requirements. Using a fault tree analysis, the combined probability of harm is based on a combination of the individual probabilities, but not the sum, the overall residual risk is acceptable.

- By review of warning, find that there is not an over-reliance on warnings, and each warning is also effective and can provide adequate risk reduction.

- By review of the User Manual, consider all the operating instructions for the device, all the information provided in the User Manual are clear and easy to follow.

- By comparison with the similar existing device, all the risks posed by similar existing device (including production and post-market, but no adverse event) have been considered in actual.

- By performing the clinical evaluation, the safeness and the effectiveness of the device have been verified to meet the doctors' requirements.

In conclusion, the overall residual risk of the Product Name is acceptable.

## 5.4 Reviewed document

Risk management plan

Safety related characteristic

Risk evaluation, control implementation and validation

Residual risk evaluation record

# Chapter 6 Production and post-production information

Company has established, documented and maintained a systematic procedure, including Vigilance System Procedure, Corrective Action Procedure and Post-market Surveillance Procedure to actively collect and review information relevant to the medical device in the production and post-production phases.

**6.1 Information collect**

When establishing this system, the manufacturer shall consider appropriate methods for the collection and processing of information as below.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Data sources** | **Information** | **Information acquisition method** | **Responsible department** | **Collected information** | **Hazard** |
| Production | —Data from monitor supplier ---performance/controls—Process monitoring—In-Process inspection/testing—Internal/external audits | Regularly Collection, 1 year | QC department | / | / |
| Compliant handling | —Quantity—By medical device family—By customer (physician, healthcare facility, patient, etc.)—Reason for complaint—Compliant codes—Severity of any harm—Component involved | Regularly Collection, 1 year | QC department | 【如有，请按实际编写】 | PH1 |
| 【如有，请按实际编写】 | PH2 |
| ... |  |
| Service reports | —Installation—First use of medical device—Frequency of maintenance visits—Types of repairs—Frequency of repaires—Usage frequency—Parts replaced—Service personnel | Regularly Collection, 1 year | Sales department | / | / |
| Risk management | —Published adverse event reports for similar medical devices—Stakeholder concerns and generallyacknowledged state of the art | Regularly Collection, 1 year | R&D department | / | / |
| Clinical activities | —Post-Market Clinical Follow-up(PMCF)studies | Regularly Collection, 1 year | R&D department | / | / |
| Market/patient surveys | —Service response time —Solicited information on new or modified medical devices | Regularly Collection, 1 year | Sales department | / | / |
| Scientificliterature | —Research publications | Regularly Collection, 1 year | R&D department | / | / |
| Mediasources | —Online newsletters—Medical information websites—Article in trade journals, scientific journals and other literature | Regularly Collection, 1 year | R&D department | / | / |
| Security data sources | —Independent security researchers—In-house testing—Suppliers of software or hardware technology—Health care facilities—Published events for devices sharing similar technologies as the medical device—Information Sharing and Analysis Center(ISAC) | Regularly Collection, 1 year | R&D department | / | / |

The hazards identified from the Production and post-production information can refer to Section 2.3.6.

**6.2 Information review**

The collected information is reviewed to determine if the information is relevant to safety. The following questions are considered in this review:

—Is the intended use still valid?

Conclusion: Yes, the intended use is still valid.

—Are the anticipated benefits achieved?

Conclusion: Yes, the anticipated benefits are achieved.

—Is there evidence of hazards or hazards situations not previously identified ? For example, did any unforeseen harm occur?

Conclusion: Yes, the information can refer to section 6.1 and no unforeseen harm occur.

—Are there occurrences of misuse which were previously not foreseen?

Conclusion: No, there are no occurrences of misuse which were previously foreseen.

—Is there an increasing trend of use for applications other than the intended use?

Conclusion: No, there is not an increasing trend of use for applications other than the intended use.

—Does the frequency of occurrence of a particular hazardous situation or harm suggest that the probability of occurrence of harm was underestimated?

Conclusion: Yes, the frequency of occurrence of a particular hazardous situation or harm suggest that the probability of occurrence of harm was underestimated.

—Does the reported harm indicate that the severity of harm was underestimated?

Conclusion: Yes, the reported harm indicates that the severity of harm was underestimated.

—Is there evidence that the risk control measures are not effective?

Conclusion: No, the evidence that the risk control measures is effective.

—Does the evaluation of the overall residual risk accurately represent the actual market experience?

Conclusion: Yes, the evaluation of the overall residual risk accurately represent the actual market experience.

—Are there changes in the generally acknowledged state of the art?

Conclusion: No, there are not changes in the generally acknowledged state of the art.

—Are there indications that the criteria for risk acceptability should be adjusted?

Conclusion: No, there are not indications that the criteria for risk acceptability should be adjusted.

**6.3 Actions**

When the collected information is reviewed and determined to be relevant to safety, several actions are conducted according to ISO 14971:2019. The details can refer to Chapter 3 Risk Evaluation and control.

# Chapter 7 Risk Management Review Conclusion

Prior to release for commercial distribution of the medical device, the manufacturer shall review the execution of the risk management plan.

This review ensure that:

— the risk management plan has been appropriately implemented;

— the overall residual risk is acceptable; and

— appropriate methods are in place to collect and review information in the production and post production phases.

The results of this review are recorded and maintained as the risk management report and are included in the risk management file.