**Risk Management Report**

**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} |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

**Index**

[Chapter 1: Description 5](#_Toc911)

[1.1 Product introduction 5](#_Toc31569)

[1.1.1 Model list 5](#_Toc6781)

[1.1.2 Working principle 5](#_Toc5710)

[1.1.3 Product Composition 7](#_Toc4300)

[1.1.4 Intended use 7](#_Toc10677)

[1.1.5 Expected operator 8](#_Toc3903)

[1.1.6 Operating environment 8](#_Toc12674)

[1.2 Purpose and scope 8](#_Toc26376)

[1.3 Product expected life time 8](#_Toc29370)

[1.4 Contraindication 8](#_Toc1863)

[1.5 Side effects/complications: 8](#_Toc11622)

[1.6 Precautions and warning: 8](#_Toc12196)

[1.7 Description of risk management implementation 9](#_Toc11084)

[1.7.1 Risk Management Process 9](#_Toc20639)

[1.7.2 Risk Management implementation 9](#_Toc31087)

[1.8 Applied standard list 10](#_Toc20369)

[1.9 Risk Assessment team and responsibility 11](#_Toc19109)

[Chapter 2 Risk Analysis 13](#_Toc21356)

[2.1Risk Accept Level 13](#_Toc13248)

[2.1.1Severity level (S) 13](#_Toc10425)

[2.1.2 Probability level (P) 13](#_Toc13855)

[2.1.3 Risk evaluation criteria (S) 14](#_Toc32369)

[2.2 Intended use and reasonably foreseeable misuse 14](#_Toc29599)

[2.3 Identification of the safety related characteristic 15](#_Toc2714)

[2.3.2 Software Characteristic related to safety 47](#_Toc32582)

[2.3.3 Performance Characteristic related to safety 51](#_Toc23764)

[2.3.4 EMC related to safety 66](#_Toc6181)

[2.3.5 Usability Characteristic related to safety 70](#_Toc5684)

[2.3.6 Biological Characteristic related to safety 70](#_Toc18482)

[2.3.7 Characteristic related to safety from Production and post-production information 70](#_Toc14629)

[2.4 Identification of hazards and hazardous situations 73](#_Toc28473)

[2.4.1 Hazards and hazardous situations from Annex A of ISO/TR 24971:2020 73](#_Toc6438)

[2.4.2 Hazards and hazardous situations from software 80](#_Toc16916)

[2.4.3 Hazards and hazardous situations from Performance Characteristic 83](#_Toc29084)

[2.4.4 Hazards and hazardous situations from EMC 88](#_Toc18623)

[2.4.5Hazards and hazardous situations from Production and Post-production information 89](#_Toc9236)

[Chapter 3 Risk Evaluation and control 92](#_Toc31246)

[3.1 Risk Evaluation and Risk Control 92](#_Toc24994)

[3.1.1 Consideration of Risk analysis, Risk evaluation and Risk control 92](#_Toc18956)

[3.2 Residual risk evaluation 129](#_Toc24651)

[3.3 Benefit-risk Analysis 130](#_Toc26696)

[3.4 Risks arising from risk control measures 130](#_Toc1171)

[3.5 Completeness of Risk Control 130](#_Toc5533)

[Chapter 4 Evaluation of overall residual risk 131](#_Toc26792)

[Chapter 5 Risk Management Review 132](#_Toc30016)

[5.1 Risk management review input 132](#_Toc13763)

[5.2 Implementation of risk management plan 132](#_Toc6921)

[5.3 Overall residual risk acceptable evaluation 132](#_Toc10678)

[5.4 Reviewed document 134](#_Toc26977)

[Chapter 6 135](#_Toc12735)

[Production and post-production information 135](#_Toc9013)

[Chapter 7 Risk Management Review Conclusion 141](#_Toc3350)

# Chapter 1: Description

## Product introduction

### 1.1.1 Product name and model

***{产品名称及型号}***

### 1.1.2 Working principle

***{产品原理}***

### 1.1.3 Product Composition

***{产品组成}***

### 1.1.4 Intended use

***{预期用途}***

### 1.1.5 Intended User

***{预期用户}***

### 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

***{有效期}***

## Contraindication

***{禁忌症}***

## Side effects/complications:

***{副作用，并发症，如无，则写not applicable}***

## Precautions and warning:

Please refer to User Manual.

## Description of risk management implementation

### 1.7.1 Risk Management Process

Refer to Risk Management Plan.

### 1.7.2 Risk Management implementation

We starts the project from 项目开始时间. 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. |  |  |  |
| 2 | Identify and document the characteristics related to the safety |  |  |  |
| 3 | Identify of hazards and estimate of the risks for each hazardous situation and conduct risk evaluation. |  |  |  |
| 4 | Make risk control plan. |  |  |  |
| 5 | Implement the risk control measures |  |  |  |
| 6 | Conduct residual risk evaluation. |  |  |  |
| 7 | Evaluation of overall residual risk |  |  |  |
| 8 | Conduct risk management review. |  |  |  |
| Production and post-production phase | 1 | Actively collect and review information of the particular medical device. |  |  |  |
| 2 | Actively collect and review publicly available information about similar medical devices and similar other products on the market. |  |  |  |

## 1.8 Applied standard list

{标准清单}

## 1.9 Risk Assessment team and responsibility

|  |  |  |  |
| --- | --- | --- | --- |
| *Name* | *Job title* | *Function in team* | *Duty* |
| *\*\*\** | *R&D/Manger,*  *Team leader* | *\*\*\** | *Organize, coordinate and supervise all stages of the risk management activities* |
| *\*\*\** | *R&D/ Engineer* | *\*\*\** | *Based on the design of product to identify the potential hazards of products, leading research design phase of the risk management activities.*  *To collect all the records of risk management, comply risk management plan and report.* |
| *\*\*\** | *Quality Dept./*  *Manager* | *\*\*\** | *Based on the regulatory and quality system, to identify possible hazards. Participate in all stags of risk management activities, and feedback quality problems to the team leader.* |
| *\*\*\** | *Production Dept./*  *Manager* | *\*\*\** | *Participate in risk management activities to identify hazards in the stages of product development and production. Regularly feedback the problems in the production on to the leaders.* |
| *\*\*\** | *Sales Dept./*  *Manager* | *\*\*\** | *To collect information from users to identify the recognized and potential hazards after the products are put into the marker, and feedback to the leader.* |

# Chapter 2 Risk Analysis

## 2.1Risk Accept Level

### 2.1.1Severity level (S)

|  |  |  |
| --- | --- | --- |
| **Severity** | **Criteria** | **Scales** |
| Critical | Death. Serious deterioration in state of health (permanent damage, etc).  Significant decrease in life expectancy | 5 |
| Serious | Significant, but transient deterioration in state of health | 4 |
| Minor | Minor deterioration in state of health | 3 |
| Negligible | No medical consequences, but perception of bad quality | 2 |
| None | No effect | 1 |

### 2.1.2 Probability level (P)

The criteria for probability of occurrence are shown as follows:

Criteria for Probability of Occurrence

|  |  |  |
| --- | --- | --- |
| **Probability** | **Criteria** | **Scales** |
| Frequent | ≥10−3 | 5 |
| Probable | ＜10−3 and ≥ 10−4 | 4 |
| Occasional | ＜ 10−4 and ≥ 10−5 | 3 |
| Remote | ＜ 10−5 and ≥ 10−6 | 2 |
| Improbable | ＜ 10−6 | 1 |

NOTE: 10-n= 1/ 10n, which means the harm may happen once in 10 n testing persons (times).

### 2.1.3 Risk evaluation criteria (S)

The risk level is calculated as follows:

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | | Probability of Occurrence (P) | | | | |
| 5 | 4 | 3 | 2 | 1 |
| Severity(S) | 5 | 25 | 20 | 15 | 10 | 5 |
| 4 | 20 | 16 | 12 | 8 | 4 |
| 3 | 15 | 12 | 9 | 6 | 3 |
| 2 | 10 | 8 | 6 | 4 | 2 |
| 1 | 5 | 4 | 3 | 2 | 1 |

Risk Level= RPN (Risk Priority Number) = S × P

During the risk evaluation, in FMEA method, the RPN is calculated to evaluate the risk acceptability.

Criteria:

RPN ≥ 5: Risk is not acceptable.

RPN<5: Risk is acceptable and insignificant which is the risk reduction end point.

## 2.2 Intended use and reasonably foreseeable misuse

**2.2.1 Intended use**

It is suitable for both adult and pediatric(above 5kg).

**2.2.2 Product description**

{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? |  | 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 |  |
| 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). |  | 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. |  | 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 |  |
| 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 and  also the ISO 22442 series of standards. |  | 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 |  |
| 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 those  currently used for similar medical devices. |  | 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 |  |
| 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. |  | 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 |  |
| 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). |  | 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 |  |
| 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 |  | 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 |  |
| 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. |  | 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 |  |
| 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. |  | 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 |  |
| 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). |  | 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 |  |
| 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. |  | 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 |  |
| 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. |  | 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 |  |
| 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. |  | 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 |  |
| 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. |  | 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 |  |
| 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 |  | 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 |  |
| 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. |  | 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 |  |
| 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. |  | 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 |  |
| 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. |  | 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 |  |
| 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. |  | 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 |  |
| 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. |  | 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 |  |
| 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. |  | 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 |  |
| 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. |  | 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 |  |
| 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. |  | 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 |  |
| 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. |  | 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 |  |
| 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. |  | 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 |  |
| 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. |  | 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 |  |
| 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. |  | 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 |  |
| 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 or  re-certification of users or service personnel  would be indicated. |  | 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 |  |
| 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. |  | 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 |  |
| 31 | A.2.31 Is successful application of the medical device dependent on the usability of the user interface? |  |  |  |
| 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 of  warnings, audibility of alarms, standardisation of colour coding. See IEC 62366-1 for additional information on usability and IEC 60601-1-8 for alarms. |  | 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 |  |
| 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 the  user’s awareness or attention. |  | 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 |  |
| 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. |  | 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 |  |
| 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. |  | 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 |  |
| 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. |  | 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 |  |
| 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. |  | 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 |  |
| 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. |  | 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 |  |
| 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 and  differing cultural backgrounds and expectations that could lead to differences in what is considered appropriate application of the medical device. |  | 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 |  |
| 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. |  | 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 |  |
| 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. |  | 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 |  |
| 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. |  | 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 |  |
| 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. |  | 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 |  |
| 35 | A.2.35 Does the use of the medical device  depend 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. |  | 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 |  |
| 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 on  medical devices with a degree of autonomy. |  | 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 |  |
| 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. |  | 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 |  |
| Letters in the second column refer to ISO/ TR 24971:2020, Annex A | | | |  |

**2.3.2 Software Characteristic related to safety**

Not applicable. The device does not contain software.

**2.3.3 Performance Characteristic related to safety**

**This list lists the special safety problems related to IEC 60601-1 and ISO 80601-2-61.**

| **No.** | **Characteristic** | **Yes/No** | **Verdict** | **Hazard identification** |
| --- | --- | --- | --- | --- |
| 1 |  |  | □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 |  |
| 2 |  |  | □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 |  |  | □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 |  |
| 4 |  |  | □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 |  |
| 5 |  |  | □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 |  |
| 6 |  |  | □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 |  |
| 7 |  |  | □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 |  |
| 8 |  |  | □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 |  |
| 9 |  |  | □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 |  |
| 10 |  |  | □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 |  |
| 11 |  |  | □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 |  |
| 12 |  |  | □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 |  |
| ........ |  |  |  |  |

2.3.4 EMC related to safety

**This list lists the special safety problems related to IEC 60601-1-2.**

| **No.** | **Characteristic** | **Yes/No** | **Verdict** | **Hazard identification** |
| --- | --- | --- | --- | --- |
| 1 |  |  | □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 |  |
| 2 |  |  | □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 |  |  | □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 |  |
| ...... |  |  |  |  |

### **2.3.5 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.

### 2.3.6 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.

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

|  |  |
| --- | --- |
| **Event** | **Hazard No.** |
|  | PH1 |
|  | PH2 |
|  | PH3 |
|  | PH4 |
|  | ..... |

### **2.3.8 Characteristic related to safety from similar device in the market**

|  |  |
| --- | --- |
| **Event** | **Hazard No.** |
|  | SH1 |
|  | SH2 |
|  | ..... |

### 2**.3.9 Characteristic related to safety from IFU in the market**

|  |  |
| --- | --- |
| **Event** | **Hazard No.** |
|  | IH1 |
|  | IH2 |
|  | IH3 |
|  | IH4 |
|  | ..... |

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.** |
| \*\*\* | \*\*\* | \*\*\* | \*\*\* | H1 |
| \*\*\* | \*\*\* | \*\*\* | \*\*\* | H2 |
| \*\*\* | \*\*\* | \*\*\* | \*\*\* | H3 |
| \*\*\* | \*\*\* | \*\*\* | \*\*\* | H4 |
| \*\*\* | \*\*\* | \*\*\* | \*\*\* | H5 |
| \*\*\* | \*\*\* | \*\*\* | \*\*\* | H6 |
| \*\*\* | \*\*\* | \*\*\* | \*\*\* | H7 |
| \*\*\* | \*\*\* | \*\*\* | \*\*\* | H8 |
| \*\*\* | \*\*\* | \*\*\* | \*\*\* | \*\*\*\*\* |
| \*\*\* | \*\*\* | \*\*\* | \*\*\* | \*\*\*\*\* |
| \*\*\* | \*\*\* | \*\*\* | \*\*\* | \*\*\*\*\* |
| \*\*\* | \*\*\* | \*\*\* | \*\*\* | \*\*\*\*\* |
| \*\*\* | \*\*\* | \*\*\* | \*\*\* | \*\*\*\*\* |
| \*\*\* | \*\*\* | \*\*\* | \*\*\* | \*\*\*\*\* |
| \*\*\* | \*\*\* | \*\*\* | \*\*\* | \*\*\*\*\* |
| \*\*\* | \*\*\* | \*\*\* | \*\*\* | \*\*\*\*\* |

### 2.4.2 Hazards and hazardous situations from software

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Hazard type** | **Foreseeable sequence of events** | **Hazardous situation** | **Harm** | **Hazard No.** |
| \*\*\* | \*\*\* | \*\*\* | \*\*\* | \*\*\*\* |
| \*\*\* | \*\*\* | \*\*\* | \*\*\* | \*\*\*\* |
| \*\*\* | \*\*\* | \*\*\* | \*\*\* | \*\*\*\* |
| \*\*\* | \*\*\* | \*\*\* | \*\*\* | \*\*\*\* |
| \*\*\* | \*\*\* | \*\*\* | \*\*\* | \*\*\*\* |
| \*\*\* | \*\*\* | \*\*\* | \*\*\* | \*\*\*\* |
| \*\*\* | \*\*\* | \*\*\* | \*\*\* | \*\*\*\* |
| \*\*\* | \*\*\* | \*\*\* | \*\*\* | \*\*\*\* |

### 2.4.3 Hazards and hazardous situations from Performance Characteristic

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Hazard type | Foreseeable sequence of events | Hazardous situation | Harm | Hazard No. |
| \*\*\* | \*\*\* | \*\*\* | \*\*\* | \*\*\*\* |
| \*\*\* | \*\*\* | \*\*\* | \*\*\* | \*\*\*\* |
| \*\*\* | \*\*\* | \*\*\* | \*\*\* | \*\*\*\* |
| \*\*\* | \*\*\* | \*\*\* | \*\*\* | \*\*\*\* |
| \*\*\* | \*\*\* | \*\*\* | \*\*\* | \*\*\*\* |
| \*\*\* | \*\*\* | \*\*\* | \*\*\* | \*\*\*\* |
| \*\*\* | \*\*\* | \*\*\* | \*\*\* | \*\*\*\* |
| \*\*\* | \*\*\* | \*\*\* | \*\*\* | \*\*\*\* |
| \*\*\* | \*\*\* | \*\*\* | \*\*\* | \*\*\*\* |

### 2.4.4 Hazards and hazardous situations from EMC

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Hazard type | Foreseeable sequence of events | Hazardous situation | Harm | Hazard No. |
| \*\*\* | \*\*\* | \*\*\* | \*\*\* | \*\*\*\* |
| \*\*\* | \*\*\* | \*\*\* | \*\*\* | \*\*\*\* |
| \*\*\* | \*\*\* | \*\*\* | \*\*\* | \*\*\*\* |
| \*\*\* | \*\*\* | \*\*\* | \*\*\* | \*\*\*\* |
| \*\*\* | \*\*\* | \*\*\* | \*\*\* | \*\*\*\* |

### 2.4.5 Hazards and hazardous situations from Production and Post-production information

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Hazard type | Foreseeable sequence of events | Hazardous situation | Harm | Hazard No. |
| \*\*\* | \*\*\* | \*\*\* | \*\*\* | PH1 |
| \*\*\* | \*\*\* | \*\*\* | \*\*\* | PH2 |
| \*\*\* | \*\*\* | \*\*\* | \*\*\* | PH3 |
| \*\*\* | \*\*\* | \*\*\* | \*\*\* | PH4 |
| \*\*\* | \*\*\* | \*\*\* | \*\*\* | ..... |

### **2.4.6** Hazards and hazardous situations **from similar device in the market**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Hazard type | Foreseeable sequence of events | Hazardous situation | Harm | Hazard No. |
| \*\*\* | \*\*\* | \*\*\* | \*\*\* | SH1 |
| \*\*\* | \*\*\* | \*\*\* | \*\*\* | SH2 |
| \*\*\* | \*\*\* | \*\*\* | \*\*\* | ..... |

### 2**.4.7** Hazards and hazardous situations **from IFU in the market**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Hazard type | Foreseeable sequence of events | Hazardous situation | Harm | Hazard No. |
| \*\*\* | \*\*\* | \*\*\* | \*\*\* | IH1 |
| \*\*\* | \*\*\* | \*\*\* | \*\*\* | IH2 |
| \*\*\* | \*\*\* | \*\*\* | \*\*\* | IH3 |
| \*\*\* | \*\*\* | \*\*\* | \*\*\* | IH4 |
| \*\*\* | \*\*\* | \*\*\* | \*\*\* | ..... |

# 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

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| *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* | \*\*\* | \*\*\* | \* | \* | \*\* | \*\*\* | \*\*\* | \* | \* | \*\* | \*\*\* |
| *H2* | \*\*\* | \*\*\* | \* | \* | \*\* | \*\*\* | \*\*\* | \* | \* | \*\* | \*\*\* |
| *H3* | \*\*\* | \*\*\* | \* | \* | \*\* | \*\*\* | \*\*\* | \* | \* | \*\* | \*\*\* |
| *H4* | \*\*\* | \*\*\* | \* | \* | \*\* | \*\*\* | \*\*\* | \* | \* | \*\* | \*\*\* |
| *H5* | \*\*\* | \*\*\* | \* | \* | \*\* | \*\*\* | \*\*\* | \* | \* | \*\* | \*\*\* |
| *H6* | \*\*\* | \*\*\* | \* | \* | \*\* | \*\*\* | \*\*\* | \* | \* | \*\* | \*\*\* |
| *H7* | \*\*\* | \*\*\* | \* | \* | \*\* | \*\*\* | \*\*\* | \* | \* | \*\* | \*\*\* |
| *H8* | \*\*\* | \*\*\* | \* | \* | \*\* | \*\*\* | \*\*\* | \* | \* | \*\* | \*\*\* |
| *H9* | \*\*\* | \*\*\* | \* | \* | \*\* | \*\*\* | \*\*\* | \* | \* | \*\* | \*\*\* |
| *H10* | \*\*\* | \*\*\* | \* | \* | \*\* | \*\*\* | \*\*\* | \* | \* | \*\* | \*\*\* |
| *H11* | \*\*\* | \*\*\* | \* | \* | \*\* | \*\*\* | \*\*\* | \* | \* | \*\* | \*\*\* |
| \*\*\* | \*\*\* | \*\*\* | \* | \* | \*\* | \*\*\* | \*\*\* | \* | \* | \*\* | \*\*\* |
| \*\*\* | \*\*\* | \*\*\* | \* | \* | \*\* | \*\*\* | \*\*\* | \* | \* | \*\* | \*\*\* |
| \*\*\* | \*\*\* | \*\*\* | \* | \* | \*\* | \*\*\* | \*\*\* | \* | \* | \*\* | \*\*\* |
| \*\*\* | \*\*\* | \*\*\* | \* | \* | \*\* | \*\*\* | \*\*\* | \* | \* | \*\* | \*\*\* |

## 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 |  | \*\* | \*\* |  |  |
| Probable | 4 | \*\* | \*\* | \*\* |  |  |
| Frequent | 5 |  | \*\* | \*\* |  |  |

After taking measures

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Hazard probability | | Severity level | | | | |
| 1 | 2 | 3 | 4 | 5 |
| Negligible | Minor | Serious | Critical | Catastrophic |
| Improbable | 1 |  | \*\* | \*\* |  |  |
| Remote | 2 | \*\* | \*\* |  |  |  |
| 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, \*\* non acceptable risks (U), \*\** **Reasonable and feasible risk reduction and \*\*** *acceptable risks are found. 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(对比产品型号), all the risks posed by (对比产品型号) (including production and post-market, but no adverse event) have been considered in the subject device.

- 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** |
| ***【请填写具体识别到的风险相关内容】*** | ***【请填写对应的信息】*** | ***【请填写对应的信息】*** | ***【请填写对应的信息】*** | ***【请填写对应的信息】*** | ***【请填写对应的信息】*** |
| ***【请填写具体识别到的风险相关内容】*** | ***【请填写对应的信息】*** | ***【请填写对应的信息】*** | ***【请填写对应的信息】*** | ***【请填写对应的信息】*** | ***【请填写对应的信息】*** |
| ***【请填写具体识别到的风险相关内容】*** | ***【请填写对应的信息】*** | ***【请填写对应的信息】*** | ***【请填写对应的信息】*** | ***【请填写对应的信息】*** | ***【请填写对应的信息】*** |

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 EN 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.