Risk Management Plan

**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】***

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| {文件版本N} | {年-月-日} | {本版本相对上一版本版本更新了\*\*\*\*，主要原因是\*\*\*\*, 涉及到修改的小节是\*\*\*\*\*}  *【填写本技术文档的版本相对于上一版本更新了哪些内容？为什么更新？以及更新内容具体的地方及小节编号？】* | {XX名字} | {XX名字} | {XX名字} |
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**Risk Management Plan**

# Product description

### 1.1 Product name and model

***{产品名称及型号}***

**1.2 Working principle**

***{产品原理}***

**1.3 Product Composition**

***{产品组成}***

**1.4 Intended use**

***{预期用途}***

**1.5 Intended User**

***{预期用户}***

**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.

# Assignment of responsibilities and authorities

***(***

|  |  |  |  |
| --- | --- | --- | --- |
| ***Name*** | ***Job title*** | ***Function in team*** | ***Duty*** |
| ***\*\*\**** | ***\*\*\**** | ***\*\*\**** | ***In charge of risk management control and implementation of process*** |
| ***\*\*\**** | ***\*\*\**** | ***\*\*\**** | ***In charge of risk management control and implementation of process*** |
| ***\*\*\**** | ***\*\*\**** | ***\*\*\**** | ***Take risk into account in structure and assembly*** |
| ***\*\*\**** | ***\*\*\**** | ***\*\*\**** | ***Take risk into account in technical and software.*** |
| ***\*\*\**** | ***\*\*\**** | ***\*\*\**** | ***Take risk into account in production*** |
| ***\*\*\**** | ***\*\*\**** | ***\*\*\**** | ***Take risk into account in quality.*** |
| ***\*\*\**** | ***\*\*\**** | ***\*\*\**** | ***Take risk into account in medical field.*** |
| ***\*\*\**** | ***\*\*\**** | ***\*\*\**** | ***Take risk into account in medical field.*** |
| ***\*\*\**** | ***\*\*\**** | ***\*\*\**** | ***Take risk into account in the probability of operator’s misplay.*** |

***)***

# Reference standards and regulation

EN ISO 14971:2019 Medical devices — Application of risk management to medical devices

ISO/TR 24971 Medical devices — Guidance on the application of ISO 14971.

# Risk management schedule

***(***

***The risk management activities are 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.*** | ***\*\*\**** | ***\*\*\**** |  |

***)***

# Requirements for review of risk management activities

Participants in reviews shall include representatives of functions concerned with the design and development stage reviewed, as well as other specialist personnel. The reviewer should be responsible for the correctness and effectiveness of the review results. All departments shall cooperate with the reviewer team to review the information related to product safety, so as to provide the basis for the evaluation of overall residual risk.

a) Verification of whether the risk management plan has been properly implemented, including:

According to the following safety related information, the product shall be reviewed in the stages of design and development, engineering, trial production, production and after-sales.

1) Whether there are hazards unknown appeared;

2) Whether there is a hazard that makes the estimated risk (one or more) no longer acceptable;

3) Whether other aspects of the initial assessment have failed;

Whether the overall residual risk of the product has been reduced to an acceptable level or judged to be acceptable through risk / benefit analysis.

It is necessary to review the information collection methods of product production and post-production, and keep review records to confirm that each element of the risk management plan has been properly implemented in the specific life cycle stage of the product.

b) Effect verification of risk management activities

The evaluation team can verify the implementation effect of risk management by collecting clinical data and production and post-production information to ensure the effectiveness of risk management activities.

# Criteria for risk acceptance

### **7.1 Severity level (S)**

|  |  |  |
| --- | --- | --- |
| **Severity** | **Criteria** | **Scales** |
| Catastrophic | Results in patient death | 5 |
| Critical | Results in permanent impairment or life-threatening injury | 4 |
| Serious | Results in injury or impairment requiring professional medical intervention | 3 |
| Minor | Results in temporary injury or impairment not requiring professional medical intervention | 2 |
| Negligible | Inconvenience or temporary discomfort | 1 |

### **7.2 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).

## 7.3 Risk evaluation criteria (S)

**Three ranges of risks are defined:**

**A: acceptable risk**

**R: Reasonable and feasible risk reduction**

**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 | R | U |
| Remote | 2 | A | A | R | R | U |
| Occasional | 3 | A | R | R | U | U |
| Probable | 4 | R | R | U | U | U |
| Frequent | 5 | R | U | U | U | U |

# 

# Method to evaluate overall residual risk and criteria for acceptability

A method to evaluate the overall residual risk and criteria for acceptability of the overall residual

risk based on the manufacturer’s policy for determining acceptable risk.

The method to evaluate the overall residual risk can include gathering and reviewing data and

literature for the medical device being considered and similar medical devices on the market and can involve judgment by a cross-functional team of experts with application knowledge and clinical expertise.

This consideration takes into account the contributions of all residual risks together in relation to the benefits of the intended use of the medical device. This step is particularly important for complex medical devices and for medical devices with a large number of individual risks. The evaluation can lead to the conclusion that the medical device is safe. The criteria used to evaluate the overall residual risk are often based on additional elements, such as the benefits of the intended use of the medical device.

# Verification activities

Implementation of each risk control measure shall be verified. This verification shall be recorded in the risk management file.

The effectiveness of the risk control measures shall be verified. The results of this verification shall be recorded in the risk management file.

# Activities related to collection and review of 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.

## 10.1 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** |
| 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 |
| 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 generally  acknowledged 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 |
| Scientific  literature | —Research publications | Regularly Collection, 1 year | R&D department |
| Media  sources | —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 |

## 10.2 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?

—Are the anticipated benefits achieved?

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

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

—Is there 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?

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

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

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

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

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

## 10.3 Actions

When the collected information is reviewed and determined to be relevant to safety, several actions are conducted according to EN ISO 14971:2019.