Risk Management Procedure

风险管理控制程序

发布时间：　　生效时间：

Written by/编者:		**Date/日期:**	
Reviewed by/审核:		**Date/日期:**	
Approved by/批准:		**Date/日期:**	

History/修改履历

Nr. 序号	Version 版本号	Change description 修改内容概述	**Written by** 编制 /**Date** 日期	**Reviewed by** 审核 /**Date** 日期	**Approved by** 批准 /**Date** 日期

1. Purpose / 目的

In order to ensure the safety and effectiveness of the Company's products in the whole life cycle, this procedure is formulated according to the requirements of GB/T 42062-2022 Application of Risk Management to Medical Devices, ISO 14971:2019 Application of Risk Management to Medical Devices, MDR Regulation (EU) 2017-745 and Medical Device Production Quality Management Specification.

为确保本公司产品在整个寿命周期中的安全性和有效性，依据 GB/T 42062-2022《医疗器械 风险管理对医疗器械的应用》、ISO 14971:2019《 Application of risk management to medical devices》、MDR-Regulation (EU) 2017-745、《医疗器械生产质量管理规范》要求规范风险管理过程，制定本程序。

2. Scope / 适用范围

It is applicable to the Company's medical devices. For all stages of the product life cycle, including the whole process of product realization and the risk management of the marketing service process, other non medical products shall refer to the implementation.
The risk management related to network security shall refer to the Control Procedure for Network Security Risk Management.
The risks described in this procedure are those related to product safety.

适用于本公司医疗器械产品。针对产品全生命周期的所有阶段包括产品实现全过程，以及上市服务过程的风险管理，其他非医疗产品参考执行。
网络安全相关风险管理参照《网络安全风险管理控制程序》执行。
本程序所述的风险是与产品安全相关的风险。

3. Responsibility / 职责

Executive director
As a comprehensive guide to the risk management process, it specifically includes:

a. Determine the company's risk management policy according to regulations, standards, existing technical level and stakeholders' concerns to determine the risk acceptability criteria;
b. Review the suitability of the risk management process, ensure the continuous effectiveness of the risk management process, and take it as a part of the company's quality management system review;
c. Provide necessary resources, including personnel, facilities and places, and designate the risk management team leader.

执行董事
作为风险管理过程的全面指导，具体包括：

a. 依据法规、标准、现有技术水平和利益相关方关注点，确定公司的风险管理方针，用以确定风险可接受准则；
b. 评审风险管理过程的适宜性，确保风险管理过程的持续有效，将其作为公司质量管理体系评审的一部分；
c. 提供必要的资源，包括人员、设施和场所，并指定风险管理小组组长。

Management representative

a. Organize the formulation of risk control procedures and timely revise them according to the development of new technologies and changes in laws and regulations;
b. Be responsible for organizing training related to risk management, and maintaining consistency in understanding risks and regulations.

管理者代表

a. 负责组织制定风险控制程序并依据新技术的发展和法律法规的变化及时修订；
b. 负责组织风险管理相关的培训，保持对于风险和法规理解的一致性。

Risk Management Team
The head of the risk management team shall establish a risk management team to be responsible for the risk management of the whole life cycle of product realization and marketing, including the development of

风险管理小组
由风险管理小组组长建立风险管理小组，负责产品实现及上市后整个生命周期的风险管理，包括制定风险管理计划、风险分析、评价、控

risk management plans, risk analysis, evaluation, control, residual risk estimation, etc., and maintain the integrity and traceability of the documents.
The risk team members shall include the following personnel:
a. Personnel familiar with product design and development process, production process and quality control requirements;
b. Clinical experts familiar with product use;
c. Personnel skilled in applying risk analysis tools;
d. Professionals familiar with regulations and standards.

制、剩余风险估计等，并保持文档的完整性、可追溯性。
风险小组成员应包括以下方面人员：
a. 熟知产品的设计开发过程、生产过程及质量控制要求的人员；
b. 熟悉产品使用的临床专家；
c. 能够熟练应用风险分析工具的人员；
d. 熟悉法规和标准的专业人员。

4. Definitions / 定义

Hazard (source): potential source of injury (ISO 14971).

危险（源）：可能导致伤害的潜在根源(ISO 14971)。

Hazardous situation: the situation where people, property or environment are in one or more hazard sources (ISO 14971).

危险情况：人员、财产或环境处于一个或多个危险源之中的情形 (ISO 14971) 。

Injury: physical injury or damage to human health, or damage to property or the environment (ISO 14971).

伤害：身体上的损伤或对人员健康的损害，或者对财产或环境的损害(ISO 14971)。

Probability of injury occurrence: the probability of danger (patient, user or third party).

伤害发生概率：发生危险 (病人、用户或第三方) 的概率。

Severity: a measure of the possible consequences of a hazard (source).

严重度：危险（源）可能造成后果的度量。

Risk: the combination of the probability of injury occurrence and the severity of the injury (ISO 14,971).

风险：伤害发生的概率和该伤害严重度损的组合(ISO 14971)。

Residual risk: the risk still exists after the implementation of risk control measures (ISO 14971).

剩余风险：实施风险控制措施后还存在的风险 (ISO 14971)。

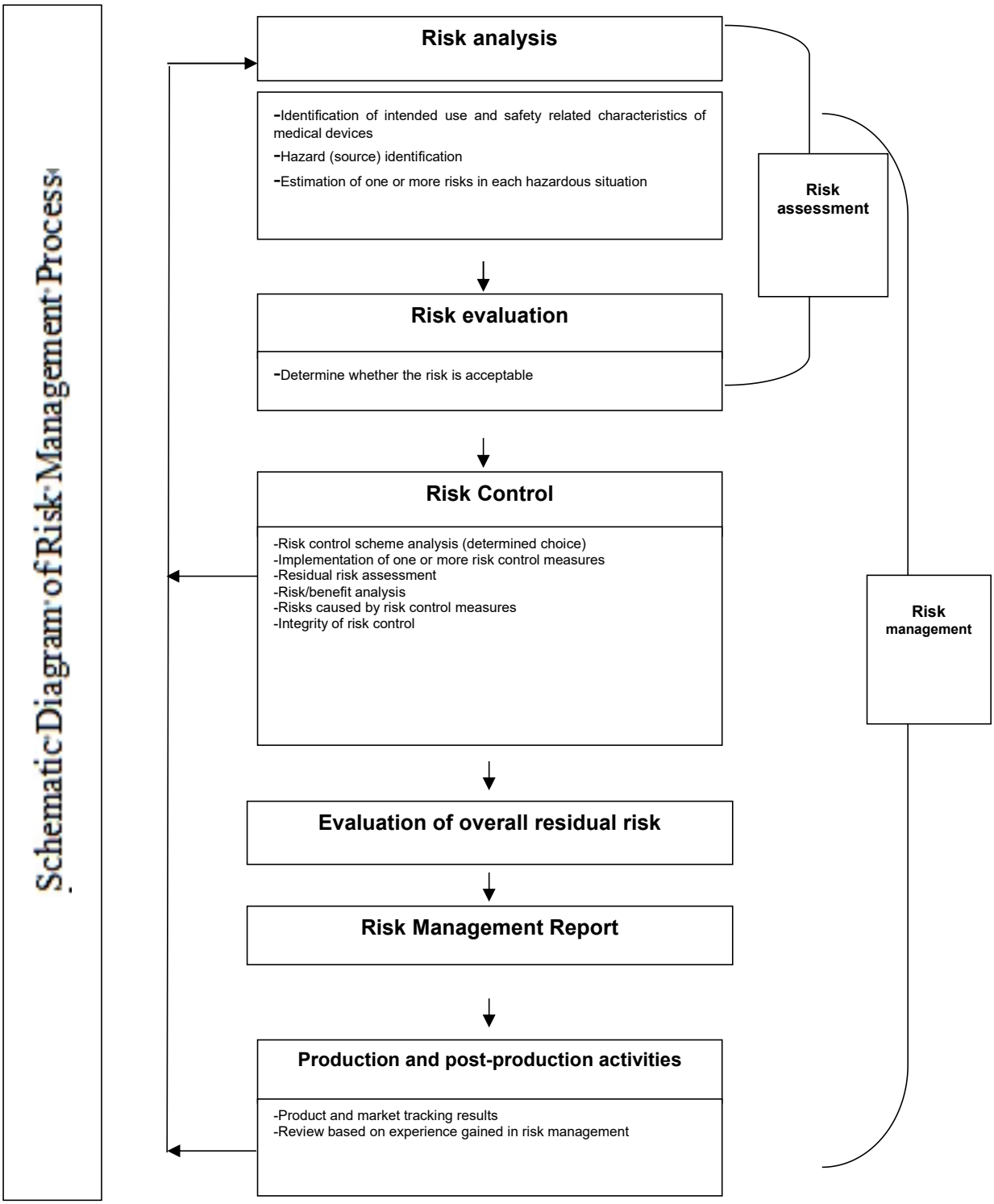
Risk management: systematic application of management policies, procedures and practices for risk analysis, evaluation, control and monitoring. (ISO 14971)。

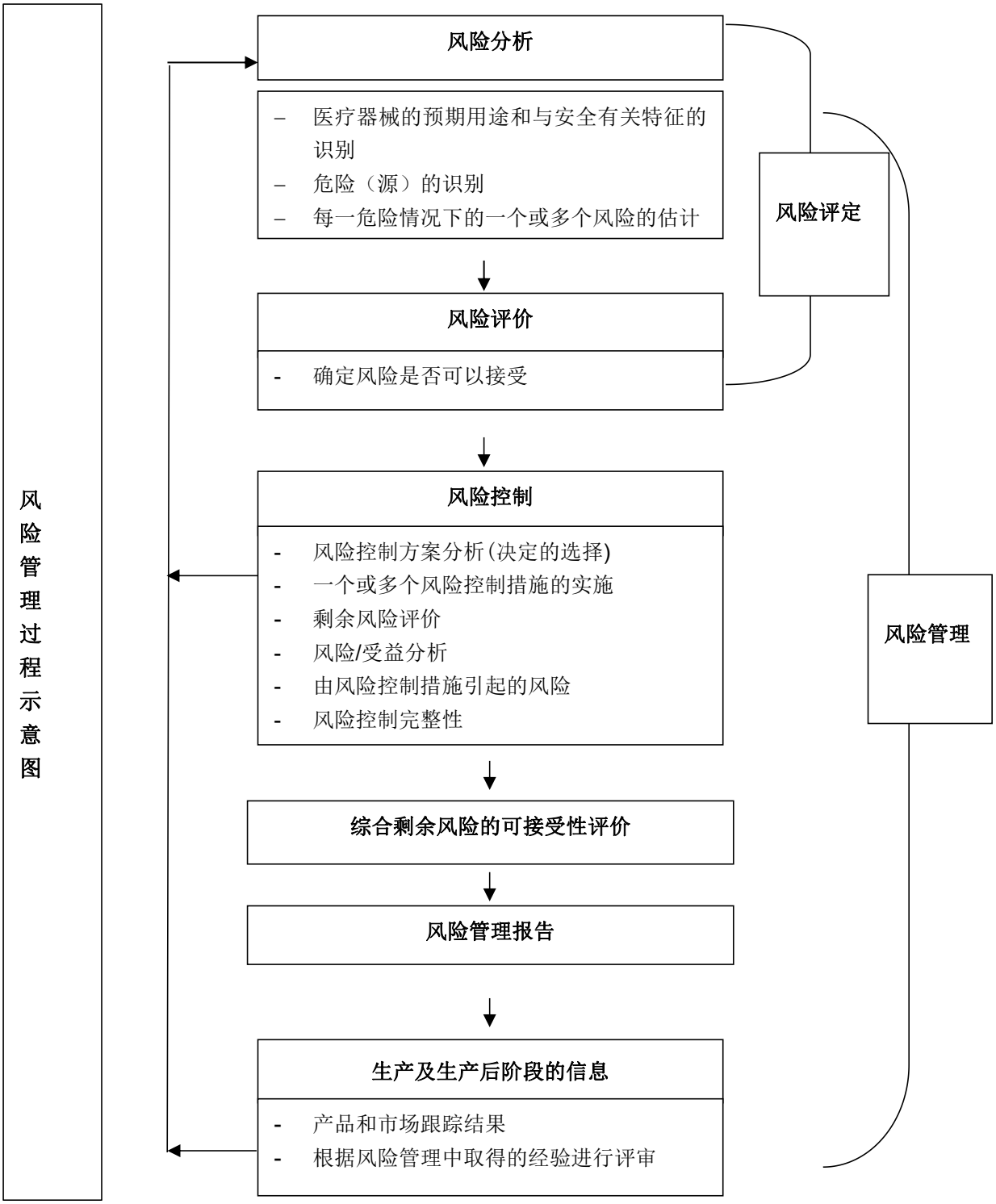
风险管理：用于风险分析、评价、控制和监视工作的管理方针、程序及其实践的系统运用。(ISO 14971)。

Risk management file: a set of records and other documents generated by the risk management process (ISO 14971).

风险管理文档：由风险管理过程产生的一组记录和其他文件 (ISO 14971) 。

5. Flowchart / 过程流程图




风险管理过程示意图
风险分析
– 医疗器械的预期用途和与安全有关特征的识别
– 危险（源）的识别
– 每一危险情况下的一个或多个风险的估计
风险评定
风险评价
- 确定风险是否可以接受
风险控制
- 风险控制方案分析(决定的选择)
- 一个或多个风险控制措施的实施
- 剩余风险评价
- 风险/受益分析
- 由风险控制措施引起的风险
- 风险控制完整性
综合剩余风险的可接受性评价
风险管理报告
生产及生产后阶段的信息
- 产品和市场跟踪结果
- 根据风险管理中取得的经验进行评审
风险管理

6. Process & requirement/程序和要求

6.1. Risk management policy/风险管理方针

The risk management policy is to provide guidance for the establishment of risk acceptability criteria, and the requirements are as follows:
a. The executive director shall fully evaluate the external and internal information and formulate risk management policies;
b. The executive director shall organize a review of risk management activities at least once a year, which can be conducted separately or in combination with management review or other relevant quality activities. If necessary, the number of reviews can be increased;
c. The risk management team shall review and approve the Risk Management Report formed by the risk management review activities before the launch of new products;
d. The risk acceptability criteria shall be implemented in accordance with the requirements of the Risk Management Policy.

风险管理方针是为建立风险可接受性准则提供指导，要求如下：

a. 执行董事应充分评价外部及内部相关信息，制定风险管理方针；
b. 执行董事应组织每年最少一次对风险管理活动进行评审，该评审可单独进行也可与管理评审或其他相关质量活动结合进行。必要时可增加评审的次数；
c. 风险管理小组对新产品上市前风险管理评审活动形成的结果《风险管理报告》进行审批；
d. 风险可接受性准则应按照《风险管理方针》的要求执行。

6.2. Personnel qualification/人员资质

Risk management personnel shall have the knowledge and experience appropriate to the task, including specific medical devices (or similar medical devices) and the knowledge and experience used, relevant technology or risk management technology when appropriate. Table 1 gives examples of personnel who can undertake risk management tasks and relevant knowledge and experience to support effective completion of tasks. Before the start of each risk management task, the risk management team leader is responsible for confirming the qualification of the personnel performing risk management.

风险管理人员应具备与任务相适应的知识和经验，适当时包括特定医疗器械（或类似医疗器械）及使用的知识和经验、有关的技术或风险管理技术。表 1 给出了可承担风险管理任务人员示例及支持有效完成任务的相关知识和经验。在每一风险管理任务开始前，风险管理组长负责确认执行风险管理的人员资格。

Table 1 Examples of Personnel Qualification and Related Knowledge and Experience

Personnel or functions	Knowledge and experience
Risk management team leader	Medical device risk management process
engineer	Medical device technology, design and working principle
Medical or clinical experts	Clinical evaluation methods and requirements Application of medical practice, including benefits, hazards and possible injuries

Personnel or functions	Knowledge and experience
Production management	Sources of materials and services, including outsourcing processes Hazard and risk control during storage and transportation
Manufacturing	Manufacturing process
after-sale service	Hazard and risk control during installation, maintenance, repair, service and support
Regulations and quality assurance	Security and risk control measures of countries/regions to be listed Quality management system and quality practice
All personnel involved in the review and approval of records	Functional experts related to review and approval

表 1 人员资格及相关知识和经验示例

人员或职能	知识和经验
风险管理组长	医疗器械风险管理过程
工程师	医疗器械技术、设计、工作原理
医学或临床专家	临床评价方法和要求 医疗实践的应用，包括受益、危害情况和可能的伤害
生产管理	物料和服务的来源，包括外包过程 储存和运输过程的危险和风险控制
生产制造	生产制造过程
售后服务	安装、维护、维修、服务和支持过程的危险和风险控制
法规及质量保证	拟上市国家/地区的安全和风险控制措施 质量管理体系和质量实践
参与审核和批准记录的所有人员	与评审和批准相关职能专家

6.3. Risk management at all stages of design and development/设计和开发各阶段风险管理

The risk management of product design and development, production and post production stages is combined with the Company's Design and Development Control Procedure. See Table 2 for the risk management activities and relevant records to be carried out at each stage.

产品设计开发、生产和生产后阶段的风险管理结合本公司《设计和开发控制程序》，各阶段应开展的风险管理活动和相关记录见表 2。

Table 2 Risk Management Activities and Records

stage	Risk management activities	Activity output and record
S1 - Design and development planning	Develop risk management plan	Risk Management Plan
S1 - Design and development input	Conduct safety feature judgment and initial hazard analysis according to the intended use, structural composition and technical characteristics of the product	List of Safety Feature Problems Initial Hazard (Source) Analysis Report
S2 - Design and Development	Develop risk control measures for the identified risk points and implement them into the design. At the same time, identify and evaluate the new risk points or the increase of the original risk brought by the control plan, and control again	Risk Control Plan
S2-R&D prototype verification/confirmation	Verify the effectiveness of risk control plan, re identify new risk points or increase of original risks, and take control measures.	Risk Control Verification Report

stage	Risk management activities	Activity output and record
S3 -Design and development transformation, verification and confirmation (production prototype)	Identify the risks that may be introduced in the trial production process and after-sales installation process, and take control measures and verify. Summarize all for comprehensive residual risk assessment.	Risk Analysis and Control Report at the production prototype stage Summary of Comprehensive Residual Risk Assessment Form
S3 -Design and development verification confirmation (product registration/certification)	Identify, control and verify new risks or increased risks during product registration. Summarize the risk management process in the design, development and prototype stages and form a report	Risk Analysis and Control Report at the product registration stage Updated Comprehensive Residual Risk Assessment Form Risk Management Report
S4 - Feedback and improvement (continuous production)	Regularly collect risk related information in the production and post production stages, conduct regular evaluation, identify risk points, take control measures and verify, update the comprehensive residual risk evaluation form, and conduct annual risk management review	Production and Post production Information Risk Assessment Form Risk Analysis and Control Report for production and post production information Updated Comprehensive Residual Risk Assessment Form Annual Risk Management Report

stage	Risk management activities	Activity output and record
Design change	Identify the risk points caused by design changes, take control measures and verify, and update the comprehensive residual risk assessment table	Risk Analysis and Control Report for design changes Updated Comprehensive Residual Risk Assessment Form

表 2 风险管理活动和记录

阶段	风险管理活动	活动输出和记录
S1-设计和开发策划	制定风险管理计划	《风险管理计划》
S1-设计和开发输入	根据产品预期用途、结构组成、技术特点进行安全特征判定和初始危害分析	《安全特征问题清单》 《初始危险（源）分析报告》
S2-设计和开发	针对已识别的风险点制定风险控制措施，并将其落实到设计中，同时识别和评价控制方案带来的新风险点或原有风险的增加，并再次控制	《风险控制方案》
S2-研发样机验证/确认	验证风险控制方案有效性，再次识别新风险点或原有风险的增加，并采取控制措施。	《风险控制验证报告》
S3-设计和开发转换、验证确认（生产样机）	对试生产过程和售后安装过程可能引入的风险进行识别，并采取控制措施并验证。汇总所有进行综合剩余风险评价。	生产样机阶段的《风险分析与控制报告》 汇总的《综合剩余风险评价表》

阶段	风险管理活动	活动输出和记录
S3-设计和开发验证确认（产品注册/认证）	对产品注册过程中新发现的风险或增加的风险进行识别、控制和验证。总结设计开发和样机阶段的风险管理过程并形成报告	产品注册阶段的《风险分析与控制报告》 更新的《综合剩余风险评价表》 《风险管理报告》
S4-反馈、改进（持续生产）	定期收集生产和生产后阶段与风险有关的信息，定期进行评价，识别风险点，采取控制措施并验证，更新综合剩余风险评价表，年度风险管理评审	《生产和生产后信息风险评价表》 针对生产和生产后信息的《风险分析与控制报告》 更新的《综合剩余风险评价表》 年度《风险管理报告》
设计变更	识别设计变更带来的风险点，采取控制措施并验证，更新综合剩余风险评价表	针对设计变更的《风险分析与控制报告》 更新的《综合剩余风险评价表》

6.4. Risk Management Plan/风险管理计划

The product risk management plan shall be prepared by the members of the product risk management team and approved by the risk management team leader, including the following contents:
a. Define the scope of risk management activities and describe the life cycle stages of products;
b. Determine the assignment of responsibilities and authorities of risk management members;
c. Specify the review requirements for risk management activities;
d. Formulate risk acceptability criteria;
E. Arrange risk verification activities;
f. Arrange the collection and review of production and post production information.
Among them, the risk acceptability criteria shall be determined according to the company's risk management policy, relevant international and domestic standards, the latest technical level, the beneficiaries' concerns and other factors.

产品的风险管理计划由该产品的风险管理小组成员编制，由风险管理组长批准，包括以下内容：

a. 明确风险管理活动的范围，描述产品的生命周期阶段；
b. 确定风险管理成员的职责和权限的分配；
c. 明确风险管理活动的评审要求；
d. 制定风险的可接受性准则；
e. 安排风险的验证活动；
f. 安排生产和生产后信息的收集和评审活动。

其中，风险可接受准则应根据公司的风险管理方针、相关的国际国内标准、最新技术水平和受益者关注等因素确定。

6.5. Risk management process/风险管理过程

6.5.1. Risk analysis and evaluation/风险分析和评价

The risk management team leader shall organize risk analysis and evaluation of products, including:
a. Determine the intended use and reasonably predictable misuse, including the expected indication, patient group, body part or the type of organization interacting with it, user identity, use environment, and working principle, so as to possibly involve misuse, intentional uselessness, and intentional use of the product for other than the intended use;
b. Identify safety related features, refer to Appendix A of ISO 14971:2019 and review existing information and literature (including adverse event reports);

c. To identify hazards (sources) and hazardous situations, refer to ISO14971:2019 Appendix C and relevant product regulations and registration guidelines;

d. Risk assessment to determine the probability and severity of injury of each hazard (source), including:
1) Severity definition
The more serious the failure effect is, the higher the severity of injury caused by this hazard source. Indirect hazard sources are also considered in the evaluation stage (such as incorrect treatment due to misdiagnosis caused by the failure of medical devices).

由风险管理组长组织，对产品进行风险分析和评价，内容包括：
a. 确定预期用途和合理可预计的误用，包括预期的适应症、患者群体、身体部分或与之相互作用的组织类型、使用者身份、使用环境、工作原理，以可能涉及使用错误、故意无用以及故意将产品用于预期用途外的其他应有；
b. 识别与安全有关的特征，参考 ISO 14971:2019 附录 A 以及评审现有的信息和文献（包括不良事件报告）；

c. 识别危险（源）和危险情况，参考 ISO14971:2019 附录 C 及相关产品法规和注册指导原则；

d. 风险评估，确定每个危险（源）发生伤害的概率和严重程度，其中：
1) 严重性定义
失效效应越严重，这种危险源发生伤害的严重度越高。在评估阶段也考虑到间接危险源(如由于医疗器械的故障引起的误诊最终导致治疗的不正确)。

Table 3 Severity of hazard sources

Severity level	Code	Possible description
Catastrophic	5	Cause patient death
Critical	4	Cause permanent damage or life threatening injury
Serious	3	Injuries or injuries that require professional medical intervention
Minor	2	Cause temporary injury or injury that does not require professional medical intervention
Negligible	1	Inconvenience or temporary discomfort