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| Risk Management Procedure | | | | | Version | | | {此处填入文件版本} | | |
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| Modification page   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | **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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| ***1. Purpose***  *According to the requirements of ISO 14971:2019, the process and method of identification, analysis, evaluation and control of product safety related risks are specified to ensure the effectiveness of risk management, so as to ensure the safety and effectiveness of medical device products, and meet the requirements of ISO 13485:2016, ISO 14971:2019 and MDR EU 2017 / 745. This procedure provides information on how to identify, analyze, evaluate, and react to risk(s) associated with decisions made under the program, e.g. risks inherent to the program, and risks associated with recognition decisions based on program outcomes. This procedure will also assist in confirming whether or not the ISO 13485 management system effectively mitigates these risks.*  ***2. Scope***  *It is applicable to the risk control activities in the whole life cycle of all medical device products of the company.*  ***3. Definition***  *Risk: possibility of harm and comprehensive result of this harm severity.*  *Harm: injury on person or personal health, or destroy on property and environment.*  *Hazard: potential harm source.*  *Hazardous situation：circumstance in which people, property, or the environment are exposed to one or more hazard(s)*  *Residual risk: risk remaining after risk control measures have been taken*  *FTA：Failure Tree Analysis*  *FMEA：Failure Mode and Effect Analysis*  *PPM：Part Per Million ，Part Per Million means the quantity that one situation happens in one million products.*  *Review: Activity undertaken to determine the suitability, adequacy and effectiveness of the subject matter to achieve established objectives.*  *Level of Risk: magnitude of a risk or combination of risks, expressed in terms of the combination of consequences and their likelihood*  *Likelihood: chance of something happening.*  *Probability: Measure of the chance of occurrence expressed as a number between 0 and1, where 0 is impossibility and 1 is absolute certainty.*  *Risk Acceptance: Informed decision to take a particular risk.*  *Risk Analysis: Process to comprehend the nature of risk and to determine the level of risk.*  *Risk Assessment: Overall process of risk identification, risk analysis and risk evaluation.*  *Risk Criteria: Terms of reference against which the significance of the risk is evaluated.*  *Risk Evaluation: Process of comparing the result of risk analysis with risk criteria to determine whether the risk and/or its magnitude is acceptable or tolerable.*  *Risk Identification: Process of finding, recognizing and describing risks*  *Risk Management: Coordinated activities to direct and control an organization with regard to risk.*  ***4. Responsibilities***  ***4.1*** *Top management*   * *Responsible for providing appropriate resources and personnel for risk management activities;* * *Define the responsibilities and authorities of risk management;* * *Be responsible for approving <Risk management plan>, <Risk management report> and various output documents of risk management activities.*   ***4.2*** *R & D department*  *Responsible for the promotion and implementation of risk management activities in the whole product life cycle, including formulating <Risk management plan>, preparing <Risk management report> and organizing annual risk management review.*  ***4.3*** *Quality department*  *Evaluate the effectiveness of the whole risk management activities, supervise and confirm the risk management activities.*  ***4.4*** *All departments*  *participate in risk management activities, analyze all known and foreseeable hazards from the perspective of product realization, collect production and post production information, timely feedback to R & D department for risk assessment, and collect and transmit relevant information of each department to R & D department.*  ***5. Working procedure***  ***5.1 Risk management plan***  ***5.1.1****The person in charge of the R & D department formulates the product <Risk management plan> and establishes the product risk management team;*  ***5.1.2*** *The <Risk management plan> should include:*  *a) Describe and determine the applicable scope of the product life cycle in the planning stage;*  *b) Verification plan;*  *c) Distribution of responsibilities;*  *d) Risk management of activity requirements;*  *e) The acceptability criterion of risk;*  *f) Post production information.*  ***5.2 Block diagram of risk management activities according ISO 14971***  ***5.3 Risk analysis***  ***5.3.1****The R & D department is responsible for performing the risk analysis described the product planning, design and development, and the implementation and results of the risk analysis shall be recorded in the <Risk analysis report>;*  ***5.3.2****Determination of the intended use, intended purpose and safety related features of the product;*  *For the specific medical device or accessory under consideration, the intended use, intended purpose and any reasonably foreseeable misuse shall be described. All qualitative and quantitative characteristics that may affect product safety shall be listed, and limits shall be specified when appropriate. The above contents shall be recorded in the <Risk analysis report>.*  ***5.3.3****Determine the known or foreseeable hazards;*  *A list of two known malfunctions or possible hazards associated with medical devices under normal conditions. Recognized hazards should be identified. The hazards of products mentioned in international safety standards shall be identified. The above list shall be recorded in the <Risk analysis report>.*  ***5.3.4*** *Estimate one or more risks for each hazard*  ***5.3.4.1****For each identified hazard, the available information or data should be used to estimate one or more risks under normal and fault conditions. Risk estimation includes probability of occurrence and consequence analysis. The estimation of risk shall be recorded in the <Risk analysis report>.*  ***5.3.4.2****The method of risk estimation shall be recorded in the <Risk analysis report>.*  ***5.3.4.3****Information or data sources for risk assessment can be obtained from the following aspects:*  *a) Published standards;*  *b) Scientific and technological data;*  *c) Field data of similar medical devices in use (including published accident reports);*  *d) Applicability experiments conducted by typical users;*  *e) Clinical evidence;*  *f) Appropriate research results;*  *g) Expert opinion;*  *h) External quality assessment.*  ***5.4 Risk assessment***  *For each identified hazard, the acceptability criteria of risks specified in the <Risk management plan> are used to determine whether one or more of the estimated risks are too low to be further reduced. In this case, the requirements given no longer apply to this hazard. The results of risk assessment shall be recorded.*  ***5.5 Risk control***  ***5.5.1****When it is necessary to reduce the risk, one or more risks shall be controlled according to the specified procedures so that one or more residual risks related to each hazard can be judged as acceptable.*  ***5.5.2 Scheme analysis***  ***5.5.2.1****Identify risk control measures to reduce the risk to an acceptable level. One or more methods shall be used for risk control in the following order:*  *a) Inherent safety achieved by design;*  *b) Protective measures of the product itself or in the production process;*  *c) Inform safety information.*  ***5.5.2.2*** *If it is determined that further risk reduction is impractical after scheme analysis, residual risk analysis and benefit analysis shall be conducted; otherwise, the selected risk control measures shall be implemented.*  ***5.5.2.3****The selected risk control measures shall be recorded in the risk management document.*  ***5.5.3 Implementation of risk control measures***  ***5.5.3.1****The risk management group organizes relevant personnel to implement the selected risk control measures.*  ***5.5.3.2****The risk management group shall verify the effectiveness of risk control measures and record the verification results in the risk management document.*  ***5.5.3.3****The risk management group shall verify the implementation of risk control measures and record the verification results into the risk management document.*  ***5.5.4 Residual risk assessment***  ***5.5.4.1*** *Any residual risk after taking risk control measures shall be evaluated using the criteria specified in the <Risk management plan>. The evaluation results shall be recorded in the risk management document.*  ***5.5.4.2*** *If the residual risk does not meet the requirements of the standard, further risk control measures should be taken.*  ***5.5.5 Risk and benefit analysis***  *If the criteria established in the <Risk management plan> are used to judge whether the residual risk is acceptable and the further risk control is not practical, the information and literature on the intended use and medical benefits for the intended purpose shall be collected and reviewed and submitted to the risk management team for evaluation, so as to determine whether the benefit exceeds the residual risk. If this evidence does not support the conclusion that the medical benefit exceeds the residual risk, then the residual risk is unacceptable.*  ***5.5.6 Generation of other hazards***  *Analyze whether the risk reduction measures lead to new hazards, and record the analysis results into the risk management document.*  ***5.5.7 Check whether all hazards are evaluated***  *If all the identified hazards have been assessed, the <Risk management report> shall be prepared; otherwise, the returned items shall continue to assess the risk of the next hazard.*  ***5.6 <Risk management report>***  ***5.6.1*** *The risk management group is responsible for the formation of <Risk management report>s from the results of the risk management process. The <Risk management report> shall provide full traceability of risk classification, risk assessment, implementation and verification of risk control measures, and acceptability assessment of residual risk for each hazard.*  ***5.6.2*** *The general manager shall organize relevant department heads and experts to review the <Risk management report> and draw a conclusion whether the residual risk exceeds the benefit. The review results are recorded in the risk management document.*  ***5.7 Post production information***  ***5.7.1*** *In the post production stage, identification is carried out from the perspective of product safety to determine whether the feedback information violates the following aspects:*  *a) Whether the initial assessment is invalid;*  *b) Whether there is a hazard that has not been recognized in advance;*  *c) Whether one or more of the estimated risks caused by a certain hazard are no longer acceptable;*  *d) When appropriate, the risk management process of the product should be properly reviewed.*  ***5.7.2*** *Information transmission after production*  ***5.7.2.1*** *The quality department shall transfer the information related to product safety during the production process to the R & D department;*  ***5.7.2.2*** *The information fed back by customers is properly screened by the quality department, and then the information related to product safety is transmitted to the R & D department;*  ***5.7.2.3*** *The R & D department adopts new processes and technologies for products;*  ***5.7.2.4*** *The R & D Department identified that the previous risk analysis was in the failure stage.*  ***5.7.3*** *The head of R & D department shall identify the product according to the above feedback information, and then organize the risk management team to conduct risk analysis on the product again and write the <Risk analysis report>.*  ***5.8*** *All documents generated in the process of risk management shall be implemented in accordance with the* ***<****Document and data control procedure>.*  ***5.9*** *All records generated in the process of risk management shall be implemented in accordance with the* ***<****Record control procedure>.*  ***5. Related documents***  ***5.1   <****Document and data control procedure> \*\*\**  ***5.2   <****Record control procedure> \*\*\**  ***6. Relevant records***  ***6.1*** *<Risk analysis report> \*\*\**  ***6.2   <****Risk management report> \*\*\**  ***6.3*** *<Risk management plan> \*\*\** |