UDecide

MANAGEMENT OF RMS  
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SCOPE: This document contains the projects interpretation and management of the Risk Management standard (ISO 14971:2019)

REFERENCES:

REVISION HISTORY:

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| **Revision** | **Revised by** | **Revision date** | **Description of changes** |
| 1.0 | Sigrid Stang & Sofie Bjørn | 17-03-2021 | First version of interpretation and management of the Risk Management standard (ISO 14971:2019) |
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APPROVAL:

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| *Author:* |  | | |
| *Reviewer:* |  | | |
| *Independent reviewer:* |  | | |

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| **Where in**  **ISO 14971: 2019** | **What the chapter/article is about** | **Our interpretation and management of the regulation** | **Reference to other standards/documents/annexes** |
| Chapter 1: | Scope | The requirements of this standard are applicable in all phases of the life cycle of a medical device. For us it can be risks such as data and systems security. |  |
| Chapter 3: | Definitions | 3.2 Benefit: positive or desirable outcome of the use of our medical device.  This can include clinical outcome and QoL etc.  Other relevant definitions (that do not need extra attention at this point) can for us include reasonably foreseeable misuse and use error. |  |
| Chapter 4: | General requierements for risk management system |  |  |
|  | 4.1 Risk management process | As manufacturers we shall establish, implement, document and maintain an ongoing process for   1. identifying hazards 2. evaluate the associated risks 3. control the risks 4. monitor the effectiveness of the risk control measures.   This process shall include analysis, evaluation, control and post-production activities. It must be a process throughout the entire life-cycle of the medical device. | “A schematic representation of the risk management process” |
|  | 4.4 Risk management plan | For our medical device we shall establish and document a risk management plan in accordance with the risk management process. This plan shall be a part of the risk management file. The plan shall at least contain:  a) Scope of activities, medical device description and life cycle phases (relating to the plan)  b) ...  c) Requirements for review of risk management activities  d) Criteria for risk acceptability.  e) Method for evaluating residual risk  f) Activities for verification of the implementation  g) …  If we change something in the plan, we must keep record of the changes in the risk management file. |  |
|  | 4.5 Risk management file | We shall have a risk management file, wherein traceability for each idnetifyed hazard must be evident. The traceability is in regards to the risk analysis, the risk evaluation, the implementation and verification of the risk control measures and the results of the evaluation of the residual risk.  OBS! Some files may overlap with files required by the QMS. In this case a reference to the documentation is sufficient. |  |
| Chapter 5 | Risk analysis |  |  |
|  | 5.1 Risk analysis process | The manufacturer shall perform a risk analysis. The plan, activities and results of this analysis shall be recorded in the risk management file. Remember to include identification of the device, identification of who performed the analysis and scope and date of the risk analysis. |  |
|  | 5.2 Intended use and reasonably foreseeable misuse | Included in the risk management file the manufacturer shall include the intended use and a documentation of the reasonable foreseeable misuse. |  |
|  | 5.3 Identification of characteristics related to safety | In the risk management file the manufacturer shall include a documentation of both qualitative and quantitative characteristics that could affect the safety of the device. Limits shall be defined where appropriate. |  |
|  | 5.4 Identification of hazards and hazardous situations | In the risk management file the manufacturer shall include documentation of every foreseeable hazard of the device. This must be based upon the intended use and include any sequence or comination of events that may result in hazardous situations. Everything shall be documented. |  |
|  | 5.5 Risk estimation | In the management file every hazardous situation shall be associated with a risk. |  |
| Chapter 6 | Risk control | This is the part of the risk evaluation where risks are quantified or defined in a  qualitative manner. This shall be done to evaluate the risks. If a risk is not deemed acceptable, the manufacturer shall perform risk control activities. | 7.1-7.6 is about risk control |
| Chapter 7 | Risk control |  |  |
|  | 7.1 Risk control option analysis | The manufacturer shall determined different measures for reducing the risk to an acceptable level. This can be done by lowering the probability of harm, the severity of harm or both. This risk control consists of safe design, protective measures/processes and/or information for safety. |  |
|  | 7.2 Implementation of risk control measures | The measures identified in 7.1 must be implemented. |  |
|  | 7.3 Residual risk evaluation | An evaluation of the residual risk after implementation of the risk control measures, must be performed. If the residual risk is deemed unacceptable the manufacturer will have to determining additional risk control measures. |  |
|  | 7.4 Benefit-risk analysis | If the residual risk is not deemed acceptable the manufacturer may use literature to document if the possible benefits of the device outweighs the risks. An alternative will be to modify the device or its intended use. |  |
|  | 7.5 Risks arising from risk control measures | The effects of the risk control measures shall be reviewed in order to determine if any new hazards have emerged from the measure. Any new or increased risk shall be manage as the original risks. This goes in the risk management file as well. |  |
| Chapter 8 | Evaluation of overall residual risk | Any residual risk shall be evaluated in relation to the device and its intended purpose. If the risk is judged acceptable the manufacturer shall inform users of significant residual risks and include documentation to disclose the risks. If the risk is not acceptable the manufacturer has to modify the device or its intended use. This shall be part of the risk management file. |  |
| Chapter 9 | Risk management review | In order to release the device for commercial distribution the manufacturer shall make a risk management report stating how the risk management plan has been executed. The minimum content is to ensure that the plan has been appropriately implemented, that the overall residual risk is acceptable, and that appropriate methods for reviewing information from the production and post-production phases. |  |
| **Chapter 10** | Production and post production | Not relevant for this project. |  |
| **Annex A** | Rationale for requirements | Not really relevant for this project. It contains the reasons why this standard is made with arguments for approximately every part. Good knowledge, but not need to know at this point. |  |
| **Annex B** | Risk management process for medical devices | Table with differences in definitions from earlier issues.  Contains flowchart for processes in the risk management |  |
| **Annex C** | Fundamental risk concepts | Flowchart of hazards vs risks.  Examples of hazards and events. |  |