# **UrDiary**

# Risk Management Plan - Controlled document

**References:**

* ISO14971 - Medical devices - Application of risk management to medical devices
* ISO/TR 24971 - Medical devices - Guidance on the application of ISO 14971
* IEC 62304:2006 - Medical Device Software - Software life cycle processes

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| **Revision Control** | | | |
| Revision | Revised by | Revision date | Change Description |
| 0.1 | Ellen Ritterbusch | 21/03/2024 | First Version of risk management plan |
| 0.2 | Maja Husum |  | Second Version of risk management plan |
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Authorized by: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

# Purpose

The purpose of this document is to form a plan for the risk management of the application “name”. The risk management will contribute to safety requirements for “name”. The safety requirements will along with other relevant regulatory requirements and system requirements form the foundation of the implementation of “name”.

The scope of this risk management is to identify possible hazards associated with the use of “name”. This includes usability specific risks and software specific risks. The hazards will be evaluated and controlled.

# Methodologies

The risk management will comply with the relevant points from ISO 14971:2019. We are intended to follow the steps described below. A plan of six steps have been formed and will be followed. A description of the six steps can be found under the section “Description of each step”. This plan and the report will not be centered around marked implementation, post-marked evaluation, and control due to time constraints.

|  |  |
| --- | --- |
| **Step nr.** | **Steps in plan** |
| 1 | Intended purpose and device description |
| 2 | Identifying hazards and hazardous situations |
| 3 | Risk evaluation |
| 4 | Risk control |
| 5 | Evaluation of overall residual risk |
| 6 | Risk management review |

The steps are formed based on figure 1 in ISO 14971

## Criteria for risk acceptability

Risk factor will be assessed in severity and occurrence of harm from 1-5.

|  |  |  |
| --- | --- | --- |
| **Value** | **Occurrence** | **Description** |
| 1 | Very unlikely | The hazardous situation will never occur but are theoretical possible |
| 2 | Unlikely | The hazardous situation is not likely to occur, but may happen over the lifetime of the system |
| 3 | Possible | The hazardous situation is likely to occur at least one time over the lifetime of the system |
| 4 | Likely | The hazardous situation is likely to happen multiple times over the lifetime of the system |
| 5 | Very likely | The hazardous situation is likely to occur on almost or every use |

|  |  |  |
| --- | --- | --- |
| **Value** | **Severity** | **Description** |
| 1 | Insignificant | The harm is negligible and will only in worst case lead to inconvenience and/or an unpleasant environment for the patient |
| 2 | Minor | The harm result in temporary injuries not requiring medical treatment |
| 3 | Moderate | The harm result in temporary injury requiring medical treatment |
| 4 | Major | The harm result in permanent injury and require medical treatment |
| 5 | Catastrophic | The harm is death or serious injury, and the patient will need medical help to survive |

The risk factor will be calculated by multiplying occurrence and severity factor.

The acceptable risk factor is 6, represented with green. Risk factors between 8 and 12 are acceptable with mitigation. This is visualized with yellow. Risk factors between 15-25 are not acceptable.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Severity** | | | | | |
| **Occurrence** |  | 1 | 2 | 3 | 4 | 5 |
| 5 | 5 | 10 | 15 | 20 | 25 |
| 4 | 4 | 8 | 12 | 16 | 20 |
| 3 | 3 | 6 | 9 | 12 | 15 |
| 2 | 2 | 4 | 6 | 8 | 10 |
| 1 | 1 | 2 | 3 | 4 | 5 |

# Activities for verification

The verification of the implementation of risk control mitigations will be conducted in the system testing documented in the project report.

# Description of steps in the Risk Management Plan

## Intended purpose and device description

Start by describing the intended purpose of the medical device or refer to appropriate documentation. If any, reasonably foreseeable misuse must also be documented. The medical device must be classified according to MDR 2017/745 and if the device contains software components, these must be classified according to IEC 62304:2006. The classification must be documented in the project report

## Identifying hazards and hazardous situation

Use table C.1 from Annex C.2 in ISO 14971:2019 to identify hazards. The identified hazards must be documented in the risk management report. For every identified hazard a table as shown below must be filled out.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Hazard** | **Cause of hazardous situation** | **Sequence of events** | **Hazardous situation** | **Harm** |
|  |  |  |  |  |

## Estimate the risk factor for each hazardous situation

See section 5.5 in the ISO 14971:2019. If the occurrence and severity of the harm in hazardous situations cannot be estimated, the consequences must be identified in risk evaluation and risk control. The results must be documented in the risk management file.

## Risk evaluation

See section 6 in ISO14971:2019. Compare the evaluated risk factor, with the predetermined acceptable factor. The evaluation of the risks must be documented in the risk management file.

## Risk control

See section 7 in ISO14971:2019.

### 5.1. Risk control option analysis

See section 7.1 in ISO14971:2019. Other relevant standards must be recorded in the risk control option analysis. The selected measures must be documented in the risk management file. Compliance is thorough controlled of the risk management file.

### 5.2. Implementation of risk control measures

See section 7.2 in ISO14971:2019. The verification of each risk control measures must be documented in the risk management file. The verification of the effectiveness of the risk control measures must also be documented in the risk management file. Compliance is thorough controlled of the risk management file.

### 5.2. Residual risk evaluation

See section 7.3 in ISO14971:2019. The results of the evaluated residual risk must be documented in the risk management file. Compliance is thorough controlled of the risk management file.

### 5.4. Benefit-risk analysis

See section 7.4 in ISO14971:2019. The results of the benefit-risk analysis must be documented in the risk management file. Compliance is thorough controlled of the risk management file.

### 5.5. Risks arising from risk control measures

See section 7.5 in ISO14971:2019. The result of the review must be documented in the risk management file. Compliance is thorough controlled of the risk management file.

### 5.6. Completeness of risk control

See section 7.6 in ISO14971:2019. The result of the review must be documented in the risk management file. Compliance is thorough controlled of the risk management file.

## Evaluation of overall residual risk

See section 8 in ISO14971:2019. The results of the evaluation of the overall residual risks must be documented in the risk management file. Compliance is thorough controlled of the risk management file and the appertaining documentation.

## Risk management review

See section 9 in ISO14971:2019. The result of the risk management review must be maintained as the risk management report, and must be documented in the risk management file. Compliance is thorough controlled of the risk management file.