# **UrDiary**

# Risk Management File - 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 | Maja Husum | xx/xx/2024 | First Version of risk management file |
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# Documentation of steps from the Risk Management Plan

## Intended purpose and device description

## Identifying hazards and hazardous situation

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

## Estimate the risk factor for each hazardous situation

## Risk evaluation

## Risk control

### 5.1. Risk control option analysis

### 5.2. Implementation of risk control measures

### 5.2. Residual risk evaluation

### 5.4. Benefit-risk analysis

### 5.5. Risks arising from risk control measures

### 5.6. Completeness of risk control

## Evaluation of overall residual risk

## Risk management review