Risk Management Report

The Risk Management Report contains the output and summary of risk management activities. The general planning and methods are described in the Risk Management plan, while the actual risks are listed and analyzed in the Risk Table.

The process and stages of risk analysis are described in the SOP Integrated Software Development.

Mapping of Standard Requirements to Document Sections

ISO 14971:2019 Section	Document Section
4.5 Risk management file	(all)
7.4 Benefit-risk analysis	6
7.6 Completeness of risk control	(by review of this document)
8 Evaluation of overall residual risk	3, 5
9 Risk management review	(all)

1. Relevant Processes and Documents

- SOP Integrated Software Development
- Risk Management Plan
- Risk Acceptance Matrix
- Risk Table

2. Risk Analysis

> The general idea about this section is that you simply summarize the amount of stuff you added to your Risk Table (a separate document).

2.1 Preliminary Hazards Analysis

<no. of hazards> hazards were identified based on the Intended Use and Usability Tests. They were further analyzed in the Risk Table.

2.2 Failure Modes

<no. of failure modes> failure modes of software systems were identified. They were further analyzed in the Risk Table.

2.3 Failure Mode and Effects Analysis (FMEA)

All preliminary hazards and potential failure modes of the software were analyzed. In total, *<no. of hazards>* were identified. The hazardous situation(s) and harm(s) which they could lead to were analyzed, including intermediate probabilities (p1 and p2).

3. Risk Control Measures

Risks were reduced as far as possible (AFAP). If a risk was classified as "unacceptable" based on the Risk Table, Risk Control Measures were implemented.

The following categories of Risk Control Measures were implemented in priority as listed below:

1. Inherent safety by design
2. Protective measures
3. Information for safety

In total, *<no. of risk control measures>* were implemented.

4. Risk Matrix

After implementation and verification of all Risk Control Measures, the count of risks in the Risk Acceptance Matrix was as follows:

Probability	S1: Negligible	S2: Marginal	S3: Critical	S4: Catastrophic	Estimated Maximum Event Count
P5: Certain	acceptable: 0	**unacceptable: 0**	**unacceptable: 0**	**unacceptable: 0**	1000000
P4: Likely	acceptable: 0	**unacceptable: 0**	**unacceptable: 0**	**unacceptable: 0**	10000
P3: Possible	acceptable: 0	acceptable: 0	**unacceptable: 0**	**unacceptable: 0**	100
P2: Unlikely	acceptable: 0	acceptable: 0	acceptable: 0	**unacceptable: 0**	1
P1: Rare	acceptable: 0	acceptable: 0	acceptable: 0	acceptable: 0	0

5. Summary of Risks and Unacceptable Risks

> If you don't have unacceptable risks (more likely), use this section:

After Risk Control Measures, no unacceptable risks remained. The software, therefore, fulfils the specifications of the defined risk policy and is safe. A Benefit-Risk Assessment is not required.

> If you still have unacceptable risks, use this section:

After Risk Control Measures, *<no. of unacceptable risks>* unacceptable risks remained. They will be further assessed in the Benefit-Risk Assessment below.

Optionally, mention here your device's software safety classification according to IEC 62304, resulting from the worst possible risks found above.

6. Benefit-Risk Assessment

Only use this whole section (Risk-Benefit Assessment) if you have unacceptable risks.

The *<no. of unacceptable risks>* remaining unacceptable risks are compared to the benefits resulting from the Clinical Evaluation Report.

The benefits are as follows:

<Copy-paste benefits from Clinical Evaluation>

Add a conclusion on whether the benefits outweigh the risks

Weighing the benefits against the risks, we conclude that. . .

7. Overall Residual Risk

Take a look at your risk mitigating measures and assess whether the combination of them could lead to a risk that has not been taken care of yet, e.g., if one mitigation serves two or more risks at once.

The overall residual risk is estimated to have a probability of *<probability of residual risk>* and a severity of *<severity of residual risk>*. According to the Risk Acceptance Matrix the overall residual risk is assessed as *<acceptable>*.