**{project.name}**

{version.name}

Risk Management File

{document.id}

Generated by Ketryx Lifecycle Management on {document.date | datetime}

**{organization.name}**

**Document version control**

| **Release date** | **Document version** |
| --- | --- |
| {#documentVersions}{releaseDate|datetime} | {documentTitle} {versionName}{/} |

**Table of Contents**

{@toc}

1. **General information**
   1. **Identification and description of the medical device that was analyzed**

[Intentionally left blank; to be filled out by user]

* 1. **Identification of the person(s) and organization(s) who carried out the risk analysis**

[Intentionally left blank; to be filled out by user]

* 1. **Scope and date of risk analysis**

[Intentionally left blank; to be filled out by user]

* 1. **Intended use**

[Intentionally left blank; to be filled out by user]

* 1. **Reasonably foreseeable misuse**

[Intentionally left blank; to be filled out by user]

* 1. **Overall risk evaluation**

[Intentionally left blank; to be filled out by user]

* 1. **Completeness of risk control**

[Intentionally left blank; to be filled out by user]

* 1. **Risk management review**

[Intentionally left blank; to be filled out by user]

{#riskManagement.initialTotalProbabilityMatrix || riskManagement.initialAcceptabilityMatrix || riskManagement.residualTotalProbabilityMatrix || riskManagement.residualAcceptabilityMatrix}

1. **Risk evaluation framework**

{#riskManagement.initialTotalProbabilityMatrix}

* 1. **Initial total probability**

Initial derived total probability based on likelihood of occurrence (P1) and likelihood of harm (P2).

{~~ riskManagement.initialTotalProbabilityMatrix}

{#riskManagement.initialTotalProbabilityMatricesPerHazard}

* + 1. **Hazard type {hazardType}**

{~~ table}

{/}

{/}

{#riskManagement.initialAcceptabilityMatrix}

* 1. **Initial risk evaluation / acceptance**

Initial risk evaluation and acceptance based on total probability and severity.

{~~ riskManagement.initialAcceptabilityMatrix}

{#riskManagement.initialAcceptabilityMatricesPerHazard}

* + 1. **Hazard type {hazardType}**

{~~ table}

{/}

{/}

{#riskManagement.residualTotalProbabilityMatrix}

* 1. **Residual total probability**

Residual derived total probability based on likelihood of occurrence (P1) and likelihood of harm (P2).

{~~ riskManagement.residualTotalProbabilityMatrix}

{#riskManagement.residualTotalProbabilityMatricesPerHazard}

* + 1. **Hazard type {hazardType}**

{~~ table}

{/}

{/}

{#riskManagement.residualAcceptabilityMatrix}

* 1. **Residual risk evaluation / acceptance**

Residual risk acceptance based on total probability and severity.

{~~ riskManagement.residualAcceptabilityMatrix}

{#riskManagement.residualAcceptabilityMatricesPerHazard}

* + 1. **Hazard type {hazardType}**

{~~ table}

{/}

{/}

{/}

{@$KQL rawSafetyItems = type:RQ,SW,HW}

{@$SET safetyItems = rawSafetyItems | where:'fieldContent.Context=="Safety"'}

{@$KQL riskItems = type:RISK}

{@$KQL riskControlItems = type:RQ,SW,HW,TC,TE is:risk-control}

{#safetyItems.length > 0}

1. **Identification of characteristics related to safety**

{@$SUMMARIZE summary = itemRecords:safetyItems totalWordTarget:500 instructions:”Summarize the given safety items into a risk management summary. Do not use bullet points. Use paragraphs. End each paragraph with two newline characters. Add 2 lines between each paragraph.”}

{~~ summary}

{#safetyItems}

{~~. | itemContent}

{/}

{/}

{#riskItems.length > 0}

1. **Risks**

{@$SUMMARIZE risksummary = itemRecords:riskItems totalWordTarget:500 instructions:”Summarize the given risk items into a risk management summary. Do not use bullet points. Use paragraphs. End each paragraph with two newline characters. Add 2 lines between each paragraph.”}

{~~ risksummary}

{#riskItems}

{~~. | itemContent}

{/}

{/}