Risk Management Plan

Device Name/ Model Name

Confidentiality Statement

This document contains trade secrets and commercial information that are privileged or confidential and may not be disclosed unless such disclosure is required by applicable law or regulations. In any event, persons to whom the information is disclosed must be informed that the information is privileged or confidential and may not be further disclosed by them. These restrictions on disclosure will apply equally to all future information supplied to you which is indicated as privileged or confidential.

Document Authorisation

Task	Name	Signature	Date
Document Prepared By	Enter the In-charge Person's Name	Insert Signature	DD-MM-YYYY
Document Reviewed By	Enter the In-charge Person's Name	Insert Signature	DD-MM-YYYY
Document Approved By	Enter the In-charge Person's Name	Insert Signature	DD-MM-YYYY

Revision History

Version	Release Date	Change History
Version Number	DD-MM-YYYY	Changes made on the particular release date mentioned in previous column.

Table of Contents

1. Introduction

The purpose of this Risk Management Plan (RMP) is to define the procedures and methodologies for identifying, assessing, controlling, and monitoring risks associated with [Device Name] in compliance with **EU Medical Device Regulation (MDR) 2017/745** and **ISO 14971:2019**. This RMP will ensure that the risks associated with the use of [Device Name] are reduced to an acceptable level and are monitored throughout the product's lifecycle.

2. Scope

This RMP applies to the entire lifecycle of [Device Name], covering risk management activities related to the design, development, manufacturing, post-production, and use of the device. It applies to all personnel involved in the risk management process.

3. Objectives

The objectives of this plan are:

- To identify and analyze potential hazards related to [Device Name].
- To estimate and evaluate the associated risks.
- To implement measures to control risks and verify the effectiveness of these measures.
- To monitor risks throughout the lifecycle of [Device Name].

4. Risk Management Process Overview

The risk management process for [Device Name] follows the principles of ISO 14971:2019, which include:

4.1. Risk Analysis

Identifying and assessing hazards and associated risks.

4.2. Risk evaluation

Comparing risks against predetermined acceptance criteria.

4.3. Risk Control

Implementing measures to reduce risks and verifying their effectiveness.

4.4. Residual Risk evaluation

Assessing the overall residual risk and conducting a risk-benefit analysis.

4.5. Post-Market Surveillance

Monitoring risk once the device is on the market and applying any necessary adjustments.

5. Roles and Responsibilities

Hazard	Hazardous Situation
Project Manager	Oversees risk management activities and ensures compliance.
Risk Management Team	Identifies, evaluates, and controls risks as per this RMP.
Quality Assurance	Reviews risk management activities for regulatory compliance.
Clinical Expert	Provides input on clinical risks and benefit assessments.
Regulatory Affairs	Ensures the plan aligns with EU MDR requirements.

6. Risk Analysis and Hazard Identification

The following steps outline the risk analysis and hazard identification process:

6.1. Hazard Identification

Identify hazards associated with intended use, foreseeable misuse, and device characteristics.

6.2. Risk Estimation

Estimate the probability of occurrence and the severity of harm associated with each identified hazard.

6.3. Documentation

Document each identified hazard and associated risk for traceability and assessment.

Hazard ID	Hazardous Description	Risk source	Severity	Probability	Risk Level

7. Risk Evaluation criteria

Risks will be evaluated based on a risk matrix that considers **severity** and **probability**. A risk level will be assigned to each identified hazard, categorized as **Low, Medium, or High**.

8. Risk Control measures

Control measures will be identified for all unacceptable risks. These may include:

- **Inherent safety by design**: Modification of device design to eliminate hazards.
- **Protective measures**: Adding protective barriers.
- **Information for safety**: Adding warnings or instructions.

9. Residual Risk Evaluation and Acceptance

All residual risks will be evaluated and accepted based on the benefit-risk analysis, ensuring that the residual risk level aligns with acceptance criteria.

10. Post-Market Surveillance and Risk Management Review

Post-market data will be continuously gathered, analyzed, and reviewed as part of ongoing risk management activities. This includes monitoring adverse events, feedback, and clinical performance data.