Risk Management Report

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

1.1. Purpose

The purpose of this Risk Management Report is to document the risk management activities for [Device Name] as per EU MDR requirements and ISO 14971.

1.2. Scope

This report covers risk identification, analysis, evaluation, and control for the device's lifecycle, including post-market considerations.

2. Device Description

2.1. General Overview

Provide a brief description of the device, its components, and configuration.

2.2. Intended Use

Describe the intended purpose of the device, target patient population, and environment of use.

2.3. Device classification

Device Class: [Class I/IIa/IIb/III]

Rationale for Classification: [Brief rationale based on EU MDR Annex VIII rules.]

3. Risk Management Process Overview

3.1. Risk Management Plan Summary

Summarizes the Risk Management Plan, including objectives, team responsibilities, and resources.

3.2. Risk Analysis Approach

Outlines the methodology used to identify and assess risks (e.g., FMEA, FTA, HAZOP).

4. Risk Identification

4.1. Hazard Identification

Identify and list all potential hazards associated with the device, including those related to intended use and foreseeable misuse.

4.2. Foreseeable Misuse

List potential misuse scenarios that could impact the safety or effectiveness of the device.

5. Risk Analysis

5.1. Hazard and Hazardous situation Analysis

Hazard	Hazardous Situation	Possible Harm	Severity	Occurrence
Example Hazard	Example Situation	Example Harm	[Rating]	[Rating]

5.2. Risk Estimation

Provide a qualitative or quantitative risk estimation for each hazardous situation.

6. Risk Evaluation and Control

6.1. Risk Control Measures

Outline specific measures to control each identified risk, such as protective measures, alarms, or procedural safeguards.

6.2. Residual Risk Assessment

Hazard	Control measure	Residual Risk level	Acceptability
Example Hazard	Example Control	[Level]	[Yes/ No]

7. Benefit-Risk Analysis

7.1. Justification of Residual Risks

Provide a justification for any residual risks that remain after control measures, demonstrating that the device's benefits outweigh the risks.

7.2. Benefit-Risk Determination

Summarize the benefit-risk profile of the device, including references to clinical data, where applicable.

8. Risk Management Report Conclusion

Confirm that the risk management process is complete, that residual risks are acceptable, and that the device meets safety and performance requirements as per EU MDR.

9. Appendices

9.1. Risk Assessment Matrix

Define criteria for risk assessment (e.g., severity and occurrence scales).

9.2. Supporting Documents List

Reference any related documents, such as the Risk Management Plan, FMEA, or Clinical Evaluation Report.