[Organization logo]

[Organization name]

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PROCEDURE FOR RISK MANAGEMENT

Code:	
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Commented [AES3]: This is only necessary if document is in paper form; otherwise, this table should be deleted.

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Change history

Date	Version	Created by	Description of change
	0.1	Advisera	Basic document outline

Table of contents

1. Purpose, scope, and users

The purpose of this document is to describe the process of risk management, including the identification, evaluation, and addressing of risks that arise from design and development, production and service delivery, sterilization, and post-delivery processes in [organization name].

Users of this document are members of top management of [organization name] within the scope of the Quality Management System (QMS).

2. Reference documents

- ISO 13485:2016 standard, clause 7.1
- ISO 14971:2019 standard
- ISO/TR 24971:2019 Medical devices – Guidance on the application of ISO 14971
- MDR 2017/745 article 10(9), Annex I – Chapter I, and Annex IX – Chapter I
- IVDR 2017/746
- Procedure for Data Analysis
- Procedure for Post-Market Surveillance System

3. Risk management process

3.1. Risk policy

The policy for establishing criteria for risk acceptability in [organization name] is:

- reducing risk as low as reasonably practical
- [illegible]
- [illegible]

[Job title] reviews the suitability of the risk management process at least [once per year]. [illegible]

3.2. Risk management planning

3.2.1. Risk management team

[Job title] appoints the team for risk management; the team can include customers, manufacturing engineers, test engineers, quality engineers, reliability engineers, product engineers, and sales engineers. [illegible]

[illegible]

Commented [AES4]: Adapt to organization's needs.

Commented [AES5]: Include the name of your organization.

Commented [AES6]: Include the name of your organization.

Commented [AES7]: Delete this if your organization does not need to be compliant with MDR.

You can find the full text of the MDR on the following link: https://advisera.com/13485academy/mdr/

Commented [AES8]: Delete if your medical device is not an in vitro diagnostic medical device.

Commented [AES9]: You can find a template for this document in the ISO 13485 & MDR Integrated Documentation Toolkit, folder "26_Data_Analysis".

Commented [AES10]: You can find a template for this document in the ISO 13485 & MDR Integrated Documentation Toolkit, folder "21_Post_Market_Surveillance".

Commented [AES11]: Include the name of your organization.

Commented [AES12]: E.g., Quality Manager

Commented [AES13]: This is only an example; you can adjust [illegible]

Commented [AES14]: E.g., CEO, QA Manager, Management Representative

Commented [AES15]: Adapt to the organization's needs.

Commented [AES16]: E.g., CEO, QA Manager, Management Representative

The team consists of people with competence in the following areas:

- construction of medical devices
- operation of medical devices
- production of medical devices
- [illegible]

3.2.2. *Defining the Risk Management Plan*

[Job title], with other team members, defines the plan for risk management in order to provide a structured approach to the risk management, to enable objectivity, and to avoid missing crucial elements.

[illegible]

[Job title] records the Risk Management Plan and appends it to the appropriate Risk Management File.

3.2.3. *Risk concept*

Each risk is described with the following elements:

- hazard – a potential source of harm
- hazardous situation – a circumstance in which people, property, or the environment are exposed to one or more hazards
- [illegible]

The main assignment of the risk management team is to understand how hazards progress to a hazardous situation, and under which sequence of events. [illegible]

3.2.4. *Risk criteria*

For each identified hazardous situation, the risk management team must estimate the associated risk according to the following concepts:

- severity of the harm
- [illegible]

The risk management team defines the risk severity criteria as:

Risk severity	Description

Commented [AES17]: Adapt to the organization's needs.

Commented [AES18]: For more information on the Risk [illegible]

Commented [AES19]: E.g., QA Manager, Management [illegible]

Commented [AES20]: You can find examples of the hazards, [illegible]

Commented [AES21]: This is just an example.

Depending on your organization practices, you can have different severity criteria for each medical device or medical device family.

[illegible]

1 – Negligible	No injury
[illegible]	[illegible]
[illegible]	[illegible]

The risk management team defines the risk probability as:

Risk probability	Qualitative description	Semi-quantitative description
1 – Rarely	Unlikely to happen	1:100,000
[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]

By entering the values of risk severity and risk probability in the Risk Assessment Record, the risk value is calculated automatically by multiplying the two values (risk severity x risk probability).

[illegible]

Risk acceptance criteria are defined as:

Risk value	Acceptance
1-2	Acceptable risk
[illegible]	[illegible]
[illegible]	[illegible]

Commented [AES22]: Write the criteria for risk acceptability based on your organization practices. You can choose one of the following:
- reducing risk as low as is reasonable practical
[illegible]

3.3. Executing risk management

3.3.1. Risk analysis

Before starting the risk analysis, the risk management team must define and include in the Risk Management Plan both the intended purpose of the device, and any reasonably foreseeable misuse (use of the medical device in a way that is not intended by the manufacturer, but which can result from readily predictable human behavior).

[illegible]

3.3.2. Risk estimation

For each harm identified in the Risk Assessment Record, the risk management team must estimate severity and probability as described in section 3.2.4 of this document, and in line with the defined criteria in the Risk Management Plan.

3.3.3. *Analysis of options for risk management*

Different approaches for risk mitigation can be used separately or simultaneously, and [job title] must decide how to decrease the level of risk to an acceptable level in a reasonable, practical way.

Options for risk mitigation are:

- designing for inherent safety through elimination of identified hazards and decrease of likelihood of hazard occurrence
- [illegible]
- [illegible]

The approaches listed above are in descending order with regard to their generally recognized effectiveness in reducing risk. [illegible]

3.3.4. *Implementation of risk control measures and residual risk evaluation*

Upon selection of options for risk mitigation, [job title] is responsible for implementing the risk control measures. [illegible]

The effects of the risk control measures will be reviewed by [job title] with regard to:

- the introduction of new hazards or hazardous situations
- [illegible]

Any new risks will be managed according to section 3.2.4 of this Procedure, and [job title] will record the results of the review in the Risk Management File.

[illegible]

3.3.5. *Benefit-risk analysis*

In cases when applied criteria for risk acceptance are not met after risk control measures, and no further risk controls are applicable, [job title] must gather and review all information and literature to determine whether the clinical benefits of the intended purpose of the device outweigh the residual risks. [illegible]

When the benefits outweigh the risks, [job title] makes a decision on what information will be provided to customers and distributors.

Commented [AES23]: E.g., project engineer

Commented [AES24]: Adapt to the organization's needs.

Commented [AES25]: E.g., designer, engineer

Commented [AES26]: Other factors can include financial [illegible]

Commented [AES27]: E.g., member of the team for risk assessment

Commented [AES28]: E.g., risk assessment team leader

Commented [AES29]: E.g., QA Manager, Management [illegible]

Commented [AES30]: Benefits include: clinical outcome, [illegible]

Factors that must be considered when evaluating benefits are:

- expected device performance
- expected clinical outcome at that performance level
- [illegible]
- [illegible]

The benefit-risk analysis (BRA) must be supported by objective evidence and must be based on the judgment of experienced and knowledgeable individuals. [illegible]

Commented [AES31]: E.g., Quality Manager, Risk Manager, or top management

When performing the BRA, the team for benefit-risk analysis must determine and summarize the criteria for benefits and frequency. [illegible]

Magnitude of the benefit	Description
1 – Negligible	Patient does not receive any benefit from using the medical device
[illegible]	[illegible]
[illegible]	[illegible]

Commented [AES32]: This is only an example. [illegible]

Frequency is determined based on reported complaints, adverse events, or side effects.

Frequency	Description
1 – Rarely	0-20% of patients experienced benefit
[illegible]	[illegible]
[illegible]	[illegible]

Commented [AES33]: This is only an example. [illegible]

Benefit value is calculated by multiplying magnitude and frequency:

Benefit Value = Magnitude x Frequency

[illegible]

[illegible]

3.3.6. Production and post-production activities

All relevant data are collected and analyzed in the following reports: Data Analysis Report and [Post-Market Surveillance Report / Periodic Safety Update Report].

Commented [AES34]: Choose Post-Market Surveillance Report

Commented [AES35]: E.g., QA Manager, Management

3.4. Reporting

[Job title] is responsible for the review of the execution of the Risk Management Plan and prepares the Risk Management Review. The Risk Management Review will ensure at least the following:

Commented [AES36]: E.g., Quality Manager, Head of risk management team

- that the Risk Management Plan has been implemented properly

[Job title] ensures that the Risk Management File provides traceability, and that the complete risk management process described in the previous chapters has been carried out for each risk.

Commented [AES37]: E.g., QA Manager, Management

4. Managing records kept on the basis of this document

Record name	Code	Storage		Responsibility
Risk Management Plan	PR07.1			[job title]
Risk Management File	PR07.2			[job title]
Risk Assessment Record	PR07.3			[job title]
Risk Management Review	PR07.4			[job title]
Identification of Hazards and Characteristics Related to Safety	PR07.5			[job title]

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5. Appendices

- Appendix 1 – Risk Management Plan
- Appendix 2 – Risk Management File
- Appendix 3 – Risk Assessment Record
- [illegible]
- [illegible]

[job title]
[name]

_____
[signature]

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