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1. PURPOSE

To establish a systematic and documented process for **Quality Risk Management (QRM)** throughout the lifecycle of medical devices.

This SOP defines the administration, planning, review, approval, maintenance, and monitoring of risk management activities to ensure that risks associated with medical devices are identified, evaluated, controlled, and monitored throughout the product lifecycle.

2. SCOPE

This SOP applies to all medical devices manufactured, developed, distributed, or maintained by the organization, as applicable.

Risk management activities shall cover, as applicable:

- Design and Development
- Raw Materials and Components
- Manufacturing Processes
- Software / Firmware
- Electrical and Mechanical Safety
- Packaging and Labelling
- Storage and Transportation
- Installation and Servicing
- Use-related risks
- Clinical / Performance-related risks
- Supplier-related risks
- Post-Market Surveillance
- Complaints and Feedback
- Changes to product or process

- CAPA and Nonconforming Products

3. REFERENCES

Sr. No.	Reference
1	ISO 14971:2019 – Medical devices – Application of risk management to medical devices
2	ISO 13485:2016 – Quality Management System for Medical Devices
3	Medical Devices Rules, 2017 – India
4	Regulation (EU) 2017/745 – EU MDR
5	Applicable product-specific standards
6	Applicable Quality Manual
7	Design and Development Procedure
8	CAPA Procedure
9	Change Control Procedure
10	Complaint and PMS Procedure

4. DEFINITIONS

Risk: Combination of the probability of occurrence of harm and the severity of that harm.

Hazard: Potential source of harm.

Harm: Injury or damage to the health of people, or damage to property or the environment.

Risk Analysis: Systematic use of available information to identify hazards and estimate risks.

Risk Evaluation: Process of comparing estimated risk against defined risk acceptability criteria.

Risk Control: Process through which risks are reduced to an acceptable level.

Residual Risk: Risk remaining after risk control measures have been implemented.

Risk Management File (RMF): Set of records and documents produced by the risk management process.

5. RESPONSIBILITIES

Function	Responsibility
Top Management	Provide resources and ensure risk management is integrated into the QMS.
QA / QRM Coordinator	Administer the risk management programme and maintain required records.
R&D / Design Team	Identify design-related hazards and implement risk control measures.
Production / Process Engineering	Identify and control manufacturing and process risks.
QC / QA	Provide quality data, inspection results, NC trends and verification of controls.
RA	Identify applicable regulatory requirements and review regulatory risk implications.

PMS / Complaint Team	Provide post-market, complaint and vigilance information for risk review.
Risk Management Team	Conduct risk analysis, evaluation, control and review.
Management	Review significant risks and provide required resources.

6. RISK MANAGEMENT TEAM

A cross-functional Risk Management Team shall be established based on the product and risk.

The team may include:

- QA / Quality Engineer
- R&D / Design Engineer
- Production Engineer
- QC Engineer
- Regulatory Affairs
- Clinical / Medical representative, where applicable
- Service / Technical representative, where applicable

Team members shall have appropriate knowledge and experience relevant to the product and risk management activity.

7. RISK MANAGEMENT PROCESS

The risk management process shall include:

Risk Management Planning
↓
Risk Analysis
↓
Risk Evaluation
↓
Risk Control
↓
Evaluation of Residual Risk
↓
Benefit-Risk Analysis, if required
↓
Risk Management Report
↓
Production & Post-Production Information Monitoring

8. RISK MANAGEMENT PLANNING

Before or during product development, a Risk Management Plan shall be prepared.

The plan shall define:

- Product / device name
- Model / variant
- Intended use
- Intended users
- Intended patient population, where applicable
- Intended environment of use
- Applicable regulatory requirements
- Risk acceptance criteria
- Risk analysis method
- Risk control approach
- Verification requirements
- Residual risk evaluation
- Production and post-production monitoring
- Responsibilities and authorities
- Review requirements

9. RISK ANALYSIS

Risk analysis shall identify reasonably foreseeable hazards and hazardous situations associated with the medical device.

The analysis shall consider, as applicable:

9.1 Biological Risks

- Infection
- Contamination
- Toxicity
- Biocompatibility
- Allergic reaction

9.2 Electrical Risks

- Electric shock
- Leakage current
- Short circuit
- Overheating
- Battery failure
- Charging failure

9.3 Mechanical Risks

- Sharp edges
- Breakage
- Crushing
- Pinching
- Component detachment

9.4 Thermal Risks

- Excessive temperature
- Burns
- Overheating

9.5 Software Risks

- Incorrect software operation
- Data corruption
- Incorrect measurement
- Software failure
- Unauthorized modification

9.6 Usability Risks

- Incorrect user operation
- Misinterpretation of instructions
- Incorrect assembly
- Incorrect display / indication

9.7 Manufacturing Risks

- Incorrect assembly
- Wrong component
- Process variation
- Inspection failure
- Labelling error
- Packaging failure

10. RISK ESTIMATION

Risk shall be estimated using the approved risk assessment methodology.

A risk matrix may be used based on:

Risk = Severity × Probability of Occurrence

Example:

Severity	Description	Score
Negligible	No significant harm	1
Minor	Temporary minor injury	2
Moderate	Injury requiring medical attention	3
Major	Serious injury	4
Critical	Death / life-threatening harm	5

Probability	Description	Score
Rare	Highly unlikely	1
Unlikely	Unlikely to occur	2
Possible	May occur	3
Likely	Expected to occur	4
Frequent	Frequently occurs	5

The organization's approved risk matrix and acceptance criteria shall be defined in the applicable **Risk Management Plan / Risk Management Procedure**.

11. RISK EVALUATION

The estimated risk shall be compared with predefined risk acceptance criteria.

Example:

Risk Score	Risk Level	Action
1–4	Low	Accept / Monitor
5–9	Medium	Risk control required where applicable
10–16	High	Risk reduction required
17–25	Critical	Immediate risk reduction required

Note: The actual acceptance criteria shall be approved by the organization and justified based on product risk.

12. RISK CONTROL

Risk control shall follow the hierarchy:

1. Inherently safe design
2. Protective measures
3. Information for safety

Risk control measures may include:

- Design modification
- Protective enclosure
- Alarm / indication
- Software control
- Process control
- Inspection / testing
- Warning labels
- IFU / User Manual
- Training
- Packaging controls

13. VERIFICATION OF RISK CONTROLS

Each implemented risk control shall be verified to confirm that it is effective.

Verification may include:

- Testing
- Inspection
- Design verification
- Design validation
- Process validation
- Software verification
- Usability evaluation
- Electrical safety testing

- Performance testing

Objective evidence shall be maintained.

14. RESIDUAL RISK

After implementation of risk controls:

1. Residual risk shall be estimated.
2. Residual risk shall be evaluated against the approved acceptance criteria.
3. Residual risks shall be documented.
4. Risks requiring disclosure shall be communicated through:
    - Labels
    - Warnings
    - Precautions
    - IFU / User Manual
    - Training information

15. BENEFIT-RISK ANALYSIS

Where a residual risk is not acceptable and further risk reduction is not practicable, a documented **Benefit-Risk Analysis** shall be performed.

The analysis shall consider:

- Clinical / intended benefits
- Severity of residual risk
- Probability of harm
- Available alternative solutions
- State of the art
- Available clinical / performance information

The justification shall be approved by authorized personnel.

16. RISK MANAGEMENT FILE

A Risk Management File shall be maintained for each applicable medical device.

The file may include:

- Risk Management Plan
- Intended Use

- Risk Analysis
- Hazard Identification
- Risk Evaluation
- Risk Control Measures
- Risk Control Verification
- Residual Risk Evaluation
- Benefit-Risk Analysis
- Risk Management Report
- Production / Post-Production Monitoring Records
- Relevant complaints
- CAPA
- Change control records
- PMS information

17. PRODUCTION AND POST-PRODUCTION INFORMATION

Risk management shall not end after product release.

The organization shall monitor:

- Customer complaints
- Product returns
- Nonconforming products
- CAPA
- Service reports
- Adverse events
- Vigilance information
- PMS data
- Supplier issues
- Process deviations
- Field performance
- New hazards

- Changes in applicable standards and regulations

New information shall be assessed to determine whether the Risk Management File requires updating.

18. RISK MANAGEMENT REVIEW

Risk Management shall be reviewed:

- Before product release
- During design changes
- During significant process changes
- After major NC / CAPA
- After significant complaints
- During PMS review
- When new hazards are identified
- When applicable standards or regulations change
- At defined periodic intervals based on product risk

19. RISK MANAGEMENT REPORT

At completion of the risk management process, a Risk Management Report shall confirm that:

- Risk Management Plan was implemented.
- Risk analysis was completed.
- Risk controls were implemented.
- Risk control measures were verified.
- Residual risks were evaluated.
- Benefit-risk analysis was completed where applicable.
- Production and post-production monitoring arrangements are established.
- Overall residual risk is acceptable or appropriately justified.

20. CHANGE CONTROL AND RISK MANAGEMENT

Any change that may affect product safety or performance shall be evaluated for risk impact.

Examples:

- Component change
- Material change

- Supplier change
- Software change
- PCB change
- Design change
- Manufacturing process change
- Packaging change
- Labelling change
- Intended-use change

Risk Management File shall be updated where the change affects identified risks or introduces new risks.

21. RECORD CONTROL

All Risk Management records shall be controlled according to the Document and Record Control SOP.

Records shall be:

- Legible
- Identifiable
- Traceable
- Protected from unauthorized changes
- Readily retrievable
- Securely maintained
- Retained for the defined retention period

22. TRAINING

Personnel involved in risk management shall receive appropriate training on:

- ISO 14971
- Risk analysis and evaluation
- Risk control
- Risk acceptance criteria
- Medical device hazards
- Applicable regulatory requirements
- Risk Management File

- PMS and post-production risk monitoring

Training records shall be maintained.

23. REQUIRED FORMS / RECORDS

Sr. No.	Record / Form	Responsibility
1	Risk Management Plan	QA / R&D
2	Risk Analysis / Risk Assessment	Risk Management Team
3	Risk Control Verification Record	R&D / QA
4	Residual Risk Evaluation	QA / Risk Team
5	Benefit-Risk Analysis	Risk Management Team
6	Risk Management Report	QA / R&D
7	Risk Management Review Record	QA
8	Risk Management File	QA / R&D
9	Risk Review due to CAPA / Complaint / PMS	QA / RA
10	Risk Management Training Record	QA / HR

24. ANNEXURES

The following Annexures / controlled formats shall be used for implementation and documentation of the Quality Risk Management process:

Sr. No.	Annexure No.	Annexure / Record Name	Form / Record No.	Responsibility
1	Annexure-01	Risk Management Plan	As per Document Control System	QA / R&D
2	Annexure-02	Risk Analysis / Risk Assessment Form	As per Document Control System	Risk Management Team
3	Annexure-03	Risk Control Verification Record	As per Document Control System	R&D / QA
4	Annexure-04	Residual Risk Evaluation Form	As per Document Control System	QA / Risk Management Team
5	Annexure-05	Benefit-Risk Analysis Form	As per Document Control System	Risk Management Team
6	Annexure-06	Risk Management Report	As per Document Control System	QA / R&D
7	Annexure-07	Risk Management Review Record	As per Document Control System	QA

8	Annexure-08	Risk Management File Index / Checklist	As per Document Control System	QA / R&D
9	Annexure-09	Risk Review due to CAPA / Complaint / PMS	As per Document Control System	QA / RA
10	Annexure-10	Risk Management Training Record	As per Document Control System	QA / HR

24.1 Control of Annexures

1. All Annexures shall be controlled documents and shall be issued, revised, approved and maintained in accordance with the Document and Record Control SOP.
2. Only the latest approved revision of the applicable Annexure shall be used.
3. Completed Annexures shall be reviewed and approved by authorized personnel, wherever applicable.
4. Completed records shall be retained as objective evidence of implementation of the Quality Risk Management process.
5. Any revision to an Annexure shall be evaluated for its impact on the applicable Risk Management process and Risk Management File.
6. Obsolete Annexures shall be withdrawn from point of use and controlled in accordance with the Document Control Procedure.
7. The applicable Annexure number, form number, revision number and effective date shall be identified on each controlled format.

24.2 Applicability

Not all Annexures may be applicable to every product or risk management activity. The applicable records shall be selected based on the product, risk, lifecycle stage and regulatory requirements. Where an Annexure is not applicable, the reason for non-applicability shall be documented and justified.