1. PURPOSE

To establish, implement, maintain, and continually improve the Quality Management System (QMS) to ensure that all medical devices are consistently designed, manufactured, tested, stored, distributed, and serviced in compliance with:

- ISO 13485:2016
- Medical Devices Rules (MDR), 2017 – India
- Regulation (EU) 2017/745 (EU MDR)
- Applicable statutory and customer requirements

2. SCOPE

This SOP applies to all activities and departments involved in the lifecycle of medical devices, including:

- Management
- Regulatory Affairs
- Research & Development
- Purchase
- Stores
- Production
- Quality Control
- Quality Assurance
- Warehouse
- Service
- Human Resources

3. REFERENCES

- ISO 13485:2016 – Medical Devices – Quality Management Systems
- Medical Devices Rules, 2017 (India)
- Regulation (EU) 2017/745 (where applicable)
- ISO 14971:2019 – Risk Management
- ISO 19011:2018 – Guidelines for Auditing Management Systems
- Company Quality Manual

- SOP – Document Control
- SOP – Control of Records
- SOP – Internal Audit
- SOP – CAPA
- SOP – Complaint Handling
- SOP – Risk Management

4. DEFINITIONS

QMS – Quality Management System

CAPA – Corrective and Preventive Action

NCR – Nonconformity Report

DHR – Device History Record

DMR – Device Master Record

DHF – Design History File

PMS – Post-Market Surveillance

FSCA – Field Safety Corrective Action

MR – Management Representative

UDI – Unique Device Identification

Controlled Document – A document approved and controlled through the document control system.

Obsolete Document – A document withdrawn from use after revision or cancellation.

5. RESPONSIBILITIES

Top Management

- Establish the Quality Policy and Quality Objectives.
- Provide adequate resources.
- Conduct Management Review.
- Ensure regulatory compliance.
- Promote continual improvement of the QMS.

QA Head / Management Representative

- Establish, implement, maintain, and improve the QMS.

- Approve Quality Documents.
- Monitor regulatory compliance.
- Coordinate Internal Audits.
- Review Quality Performance Indicators.

Regulatory Affairs

- Monitor applicable regulatory requirements.
- Maintain product registrations.
- Coordinate regulatory submissions.
- Manage vigilance reporting.

Department Heads

- Implement applicable QMS procedures.
- Ensure employee competency.
- Maintain departmental records.
- Monitor department quality objectives.

QA Engineer

- Maintain controlled documents.
- Conduct Internal Audits.
- Monitor CAPA.
- Maintain Quality Records.
- Verify compliance with approved procedures.

Employees

- Follow approved procedures.
- Report nonconformities.
- Participate in required training.
- Maintain applicable records.

6. PROCEDURE

6.1 Establishment of QMS

The organization shall establish, document, implement, maintain, and continually improve an effective QMS.

The QMS shall include:

- Quality Manual
- Standard Operating Procedures
- Work Instructions
- Forms
- Records
- Risk Management Documentation
- Technical Documentation

6.2 Documentation Structure

Level 1 – Quality Manual

Level 2 – Standard Operating Procedures (SOPs)

Level 3 – Work Instructions

Level 4 – Forms and Records

Level 5 – External Documents (Standards, Regulations, Guidelines)

6.3 Document Control

QA shall ensure that:

- Documents are reviewed before approval.
- Documents are approved by authorized personnel.
- Current revisions are available at points of use.
- Obsolete documents are removed promptly.
- Revision history is maintained.
- Documents shall be periodically reviewed.
- Electronic documents shall be protected against unauthorized modification.
- Obsolete documents shall be identified as "OBSOLETE" before archiving.

6.4 Record Control

Quality records shall be:

- Legible
- Readily identifiable
- Traceable
- Protected from damage
- Retained according to the Record Retention Policy

Quality records shall remain:

- Readily retrievable
- Confidential (where applicable)
- Protected against deterioration
- Maintained for the defined retention period.

Examples include:

- Inspection Reports
- Batch Records
- Calibration Records
- Training Records
- Audit Reports
- CAPA Reports

6.5 Risk Management

Risk Management activities shall continue throughout the entire product lifecycle and shall be integrated with design, manufacturing, complaint handling, CAPA, PMS, and change control processes. Risk Management activities shall be performed throughout the product lifecycle in accordance with ISO 14971.

Activities include:

- Risk Identification
- Risk Analysis
- Risk Evaluation
- Risk Control
- Residual Risk Assessment

- Risk Review

6.6 Resource Management

The organization shall ensure:

- Qualified personnel
- Appropriate infrastructure
- Controlled environmental conditions
- Monitoring and measuring resources
- Information technology support where applicable

6.7 Training and Competency

The organization shall identify training needs and ensure personnel are competent based on education, skills, experience, and training.

Training effectiveness shall be evaluated and documented.

Training records shall be maintained.

6.8 Supplier Evaluation and Control

Suppliers shall be selected, evaluated, approved, monitored, and periodically re-evaluated.

Supplier performance shall include:

- Product Quality
- Delivery Performance
- Complaint History
- CAPA Status

Only Approved Suppliers shall be used.

6.9 Infrastructure and Work Environment

Infrastructure shall include:

- Buildings
- Utilities
- Equipment
- Software

- Environmental Controls
- ESD Controls
- Preventive Maintenance

Environmental conditions shall be monitored where product quality could be affected**.**

6.10 Equipment Calibration and Maintenance

All measuring equipment shall be calibrated against traceable national or international standards.

Calibration status shall be identified.

Out-of-calibration equipment shall not be used until evaluated.

6.11 Product Realization

- Design and Development (where applicable)
- Risk Management
- Purchasing Control
- Supplier Evaluation and Monitoring
- Incoming Material Inspection
- Manufacturing and Assembly
- In-Process Inspection
- Final Inspection and Testing
- Product Release
- Packaging and Labelling
- Storage and Distribution
- Servicing (where applicable)

6.12 Monitoring and Measurement

The effectiveness of the QMS shall be monitored through:

- Internal Audits
- Customer Feedback
- Complaint Analysis
- Supplier Performance
- Process Performance
- Product Quality Data
- CAPA Effectiveness

6.13 Internal Audit

Internal audits shall be:

- Conducted at planned intervals
- Performed by trained auditors
- Independent of the audited activity
- Documented
- Followed by corrective actions

6.14 Control of Nonconforming Product

Nonconforming products shall be:

- Identified
- Segregated
- Evaluated
- Dispositioned
- Recorded

6.15 Identification and Traceability

- Products shall be identified throughout manufacturing using Batch Number, Lot Number, Serial Number, or UDI where applicable.
- Traceability shall be maintained from raw materials through finished product release.

6.16 Corrective and Preventive Action (CAPA)

CAPA activities shall include:

- Problem Identification
- Root Cause Analysis
- Corrective Action
- Preventive Action
- Effectiveness Verification
- Closure

6.17 Complaint Handling

Customer complaints shall be:

- Logged
- Investigated
- Risk Assessed
- Reported where required
- Closed with documented evidence

6.18 Post-Market Surveillance

The organization shall collect and evaluate:

- Customer Feedback
- Service Reports
- Complaint Trends
- Vigilance Information
- Field Performance Data

6.19 Change Control

Any change affecting product, process, equipment, supplier, documents, software, or regulatory compliance shall undergo documented Change Control.

Change implementation shall include:

- Risk Assessment
- Impact Assessment
- Validation (where applicable)
- Approval prior to implementation

6.20 Data Analysis

Quality data shall be analysed periodically including:

- Complaint Trends
- NCR Trends
- CAPA Trends
- Supplier Performance

- Internal Audit Findings
- Product Quality
- Customer Satisfaction

Appropriate actions shall be initiated based on trend analysis.

6.21 Management Review

Management Review shall be conducted at least once every year.

Inputs:

- Internal Audit Results
- Customer Feedback
- Complaint Status
- CAPA Status
- Supplier Performance
- Process Performance
- Regulatory Changes
- Quality Objectives

Outputs:

Outputs:

- Improvement of the effectiveness of the QMS
- Improvement of product quality
- Changes required to the Quality Management System
- Resource Requirements
- Changes to Quality Policy
- Changes to Quality Objectives
- Regulatory Compliance Actions
- Risk Management Actions

6.22 Continual Improvement

The organization shall continually improve the effectiveness of the Quality Management System through:

- Internal Audits
- CAPA
- Management Review
- Customer Feedback
- Risk Management
- Quality Objectives
- Data Analysis

7. RECORDS (Replace)

Record	Responsibility	Retention
Quality Manual	QA	Until Superseded
Master Document List	QA	Until Superseded
SOP Register	QA	Until Superseded
Internal Audit Reports	QA	10 Years
CAPA Reports	QA	10 Years
Complaint Records	QA	Product Lifetime + Regulatory Requirement
DHR	QA	Product Lifetime + Regulatory Requirement

8. ANNEXURES (Replace)

- Annexure I– Master Document List
- Annexure II – Document Change Request
- Annexure III – QMS Process Interaction Matrix
- Annexure IV – Quality Objectives Monitoring Sheet
- Annexure V – Approved Supplier List
- Annexure VI – Training Matrix
- Annexure VII – Internal Audit Schedule
- Annexure IX – Risk Management Matrix
- Annexure X – Management Review Agenda

9. REVISION HISTORY

Rev. No.	Effective Date	Description of Change	Prepared By	Approved By
01	01.09.26	Initial Release	QA Engineer	Head – Quality

DISTRIBUTION

Controlled Copy

- Top Management
- QA
- QC
- Production
- Engineering
- Regulatory Affairs
- Purchase
- Stores
- Warehouse
- Human Resources
- Service Department

Master Copy: Quality Assurance Department.

Prepared By	Reviewed By	Approved By
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