Prepared By	Reviewed By	Approved By
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(QA Engineer)	**(Manufacturing HOD)**	**(QA HOD / MR)**

1. PURPOSE

To establish a standardized system for the preparation, review, approval, issuance, revision, distribution, implementation, storage, retrieval, archival, and withdrawal of controlled documents to ensure that only current, approved, and authorized documents are available at the point of use.

This procedure ensures compliance with:

- ISO 13485:2016
- Medical Devices Rules (India), 2017
- EU MDR 2017/745 (where applicable)
- Applicable statutory and regulatory requirements

2. SCOPE

This procedure applies to all controlled documents used within the Quality Management System including:

- Quality Manual
- Standard Operating Procedures (SOP)
- Work Instructions
- Formats
- Check Sheets
- Log Books
- Specifications
- Drawings
- Validation Documents
- Quality Plans
- Technical Files
- Risk Management Files
- External Origin Documents
- Electronic Documents

Applicable to all departments including:

- QA
- QC
- Production
- Engineering
- Warehouse
- Purchase
- HR
- Regulatory Affairs
- Maintenance
- Stores
- Top Management

3. REFERENCES

- ISO 13485:2016 Clause 4.2
- ISO 13485:2016 Clause 4.2.4
- ISO 13485:2016 Clause 4.2.5
- Medical Devices Rules (India), 2017
- EU MDR 2017/745

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- Company Quality Manual
- Record Control SOP
- Change Control SOP
- Internal Audit SOP

4. DEFINITIONS

Document

Information and its supporting medium.

Controlled Document

A document approved by authorized personnel and issued through the document control system.

Uncontrolled Copy

A document issued for reference only and not automatically updated after revision.

Master Copy

The original approved copy maintained by Quality Assurance.

Obsolete Document

A document withdrawn from use following revision or cancellation.

Revision

An approved change made to a controlled document.

Document Owner

Department responsible for preparing, reviewing and maintaining the document.

MR

Management Representative.

QMS

Quality Management System.

5. RESPONSIBILITIES

5.1 Top Management

- Ensure implementation of the document control system.
- Approve company level documents.
- Provide necessary resources.

5.2 QA Head / MR

- Establish and maintain Document Control Procedure.
- Review controlled documents.
- Approve document revisions.
- Ensure compliance with ISO 13485.

5.3 QA Engineer

- Assign document numbers.
- Maintain Master Document Register.
- Issue controlled copies.
- Retrieve obsolete documents.
- Maintain revision history.
- Archive obsolete documents.

5.4 Department Heads

- Prepare departmental documents.
- Review technical accuracy.
- Ensure implementation.
- Ensure obsolete documents are removed.

5.5 Employees

- Follow only approved documents.
- Do not use obsolete documents.
- Report document discrepancies.

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6. PROCEDURE

6.1 Document Identification

Every controlled document shall contain:

- Document Title
- Document Number
- Revision Number
- Effective Date
- Page Number
- Prepared By
- Reviewed By
- Approved By

6.2 Document Numbering

Each document shall have a unique identification number.

Example

INV/SOP/QA/001

Where:

INV = Company Code

SOP = Standard Operating Procedure

QA = Department

001 = Serial Number

Other examples

INV/FRM/QA/001

INV/WI/PROD/001

INV/LOG/QA/001

INV/SPEC/QC/001

6.3 Document Preparation

The document owner shall prepare documents using the approved company template.

Documents shall be:

- Clear
- Concise
- Sequential
- Easy to understand
- Free from ambiguity

Documents shall include:

- Purpose
- Scope
- References
- Definitions
- Responsibilities
- Procedure
- Records
- Annexures
- Revision History

6.4 Document Review

All documents shall be reviewed by:

- Department Head
- QA
- Concerned Functional Department (where applicable)

The review shall ensure:

- Technical Accuracy
- Regulatory Compliance

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- Practical Applicability
- Consistency
- Completeness

6.5 Document Approval

All controlled documents shall be approved before issue and implementation.

The approval process shall ensure that:

- The document has been technically reviewed.
- The contents comply with applicable standards and regulatory requirements.
- The document is complete and suitable for its intended purpose.
- All required approvals have been obtained.

Documents shall be approved according to the following hierarchy:

Document Type	Prepared By	Reviewed By	Approved By
Quality Manual	QA	QA Head / MR	Top Management
SOP	Department Representative	Department Head	QA Head / MR
Work Instruction	Process Owner	Department Head	QA Head
Forms / Formats	Concern Department	QA	QA Head
Specifications	Concern Department	QA	QA Head

No controlled document shall be issued or implemented without approval.

6.6 Document Issuance

After approval, the QA Department shall:

- Assign the revision number.
- Assign the effective date.
- Update the Master Document Register.
- Stamp documents as **"CONTROLLED COPY"** where applicable.
- Issue controlled copies to applicable departments.
- Ensure only the latest revision is available at the point of use.
- Withdraw superseded copies.

Only QA is authorized to issue controlled documents.

6.7 Distribution of Documents

Controlled documents shall be distributed only to authorized departments.

QA shall maintain a **Document Distribution Register** indicating:

- Document Number
- Document Title
- Revision Number
- Copy Number
- Department
- Date of Issue
- Recipient Name
- Signature

Photocopying of controlled documents without QA authorization is prohibited.

Documents displayed at workstations shall always be the latest approved version.

6.8 Revision and Change Control

Documents shall be revised whenever:

- Process changes occur.
- Product design changes.
- Regulatory requirements change.
- Customer requirements change.
- Audit findings require revision.
- CAPA identifies improvements.
- Risk Management identifies changes.
- Management Review recommends improvement.

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Each revision shall include:

- Revision Number
- Effective Date
- Description of Change
- Approval

Major revisions may require employee retraining before implementation.

6.9 Change Request

Any employee may initiate a Document Change Request (DCR).
The request shall include:

- Document Number
- Document Title
- Existing Revision
- Proposed Change
- Reason for Change
- Impact Assessment
- Requested By
- Date

QA shall review all requests before implementation.

6.10 Electronic Document Control

Electronic documents shall be:

- Password protected.
- Stored on authorized company servers.
- Accessible only to authorized personnel.
- Protected against unauthorized editing.
- Regularly backed up.
- Revision controlled.

Only QA or authorized personnel shall update electronic controlled documents.

6.11 External Documents

External documents include:

- ISO Standards
- BIS Standards
- IEC Standards
- CDSCO Guidelines
- Customer Specifications
- Supplier Manuals

QA shall ensure:

- Latest revisions are available.
- Obsolete external documents are removed.
- External documents are periodically reviewed.

6.12 Obsolete Documents

Whenever a document is revised:

- Previous versions shall be withdrawn.
- Obsolete copies shall be stamped **"OBSOLETE."**
- Obsolete documents shall not be available at points of use.
- Archived copies shall be maintained only by QA.

Retention shall comply with the Record Retention Procedure.

6.13 Periodic Review

All controlled documents shall be reviewed:

- At least once every two (2) years.
- Earlier whenever significant changes occur.

The review shall verify:

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- Technical accuracy
- Regulatory compliance
- Process suitability
- Effectiveness

If no changes are required, the review shall be documented.

6.14 Training

Employees affected by a new or revised document shall receive training before implementation.

Training shall include:

- Purpose of the document
- Changes introduced
- Responsibilities
- Record requirements

Training records shall be maintained by QA and HR.

6.15 Document Archival

QA shall archive:

- Superseded SOPs
- Previous revisions
- Withdrawn documents

Archived documents shall:

- Be clearly marked as **"OBSOLETE"**.
- Be protected from deterioration.
- Be retrievable when required.
- Be retained according to the Record Retention Policy.

6.16 Monitoring and Compliance

QA shall periodically verify:

- Availability of current documents.
- Removal of obsolete documents.
- Compliance with document control procedures.
- Correct implementation during Internal Audits.

Any nonconformity shall be addressed through the CAPA process.

7. RECORDS

Record	Responsibility	Retention Period
Master Document Register	QA	Life of QMS
Controlled Copy Distribution Register	QA	10 Years
Document Change Request	QA	10 Years
Document Review Record	QA	10 Years
Obsolete Document Register	QA	10 Years
Training Records	QA / HR	Employment Period + 2 Years

8. ANNEXURES

Annexure	Description
Annexure I	Controlled Copy Distribution Register
Annexure II	Obsolete Document Register
Annexure III	Document Review Checklist

9. REVISION HISTORY

Revision No.	Effective Date	Description of Change	Prepared By	Approved By
01	01.09.26	Initial Release	QA Engineer	QA Head / MR

10. DISTRIBUTION LIST

Controlled Copies

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- Top Management
- Quality Assurance
- Quality Control
- Production
- Engineering
- Purchase
- Stores
- Warehouse
- Regulatory Affairs
- Human Resources
- Maintenance
- Service Department

Master Copy

- Quality Assurance Department

Notes

1. This SOP shall be read in conjunction with the Quality Manual and other applicable Quality Management System procedures.
2. Only the latest approved revision of this SOP shall be used.
3. Uncontrolled copies are issued for reference only and are not subject to automatic updates.
4. Any deviation from this procedure shall be documented, justified, and approved by the QA Head / Management Representative.
5. All records generated under this SOP shall be maintained in accordance with the Record Control Procedure.
6. Failure to comply with this SOP may result in corrective and preventive actions (CAPA).
7. This SOP shall be reviewed at least once every two years or earlier if required due to regulatory, process, product, or organizational changes.

This completes the remaining sections of the Document Control SOP and is suitable for inclusion after Part 1.

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