Prepared By	Reviewed By	Approved By
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1. PURPOSE

To establish a documented and controlled system for initiation, evaluation, risk assessment, approval, implementation, verification/validation, regulatory assessment, effectiveness verification and closure of changes that may affect the:

- Safety of the medical device
- Performance of the medical device
- Quality of the medical device
- Intended use / indication
- Manufacturing process
- Product specifications
- Risk profile
- Regulatory compliance
- Quality Management System

The purpose is to ensure that changes are evaluated and implemented in a controlled manner without adversely affecting product conformity, safety, performance or regulatory compliance.

2. SCOPE

This SOP applies to planned, permanent, temporary and emergency changes related to:

1. Product design and specifications
2. Raw materials and components
3. Suppliers and outsourced processes
4. Manufacturing and assembly processes
5. Manufacturing equipment and machinery
6. Inspection and testing methods
7. Software / firmware
8. Packaging and labelling
9. Primary packaging materials

10. Manufacturing premises / facilities
11. Utilities and environmental conditions
12. Quality Management System processes
13. SOPs, Work Instructions and Forms
14. Product Risk Management File
15. Technical Documentation
16. Validation / Qualification
17. Customer requirements
18. Regulatory requirements
19. Post-market / PMS-related changes
20. Changes arising from CAPA, NCR, Complaint, Audit or Deviation

This SOP applies to all applicable medical devices manufactured by the organization under the Indian Medical Devices Rules, 2017.

3. REFERENCES

Sr. No.	Reference
1	ISO 13485:2016 – Medical Devices Quality Management Systems
2	ISO 14971:2019 – Application of Risk Management to Medical Devices
3	Medical Devices Rules, 2017
4	MDR 2017 – Fifth Schedule – Quality Management System Requirements
5	MDR 2017 – Sixth Schedule – Post Approval Changes
6	Applicable CDSCO / CLA requirements
7	Document Control SOP
8	Risk Management SOP
9	CAPA SOP
10	Complaint Handling SOP
11	PMS SOP
12	Validation / Qualification SOP

Indian MDR 2017's Sixth Schedule identifies certain post-approval changes as major or minor, including changes to material, design affecting quality/performance/stability, intended use, sterilization, shelf life, manufacturing site, labeling, manufacturing process/equipment/testing affecting device quality, and primary packaging material.

4. DEFINITIONS

4.1 Change

Any addition, deletion, modification, replacement or alteration to an approved product, process, equipment, document, supplier, facility or QMS activity.

4.2 Change Control

A formal documented process for evaluating, approving, implementing and verifying a proposed change.

4.3 Change Request

A formal request raised to initiate evaluation of a proposed change.

4.4 Permanent Change

A change intended to remain effective until superseded by another approved change.

4.5 Temporary Change

A change implemented for a defined period with documented expiry/review date.

4.6 Emergency Change

A change required immediately to address a significant quality, safety, regulatory or production risk.

4.7 Major Change

A change having significant potential impact on product quality, safety, performance, intended use, stability, manufacturing process or regulatory compliance.

4.8 Minor Change

A change that does not adversely affect product quality, safety, performance or regulatory compliance.

4.9 Change Owner

Person responsible for initiating, coordinating and implementing the approved change.

5. RESPONSIBILITIES

5.1 Change Initiator

- Identify the need for change.
- Raise Change Control Request.
- Provide technical justification.
- Identify affected products, processes and documents.
- Participate in impact and risk assessment.
- Implement approved actions.

5.2 Quality Assurance

QA shall:

- Assign Change Control number.
- Review the Change Control request.
- Ensure impact assessment is completed.
- Ensure risk assessment is performed where applicable.
- Review verification/validation requirements.
- Review regulatory impact.

- Ensure documents are updated.
- Verify training requirements.
- Monitor implementation.
- Verify effectiveness.
- Approve closure.

5.3 R&D / Engineering

- Evaluate technical impact.
- Review design/specification changes.
- Perform design verification/validation where applicable.
- Update drawings, BOM, specifications and technical documents.

5.4 Production

- Evaluate manufacturing impact.
- Implement approved manufacturing changes.
- Ensure affected operators are trained.
- Maintain implementation records.

5.5 QC

- Evaluate impact on inspection and testing.
- Review revised specifications/test methods.
- Perform required testing and verification.

5.6 Regulatory Affairs

Where applicable:

- Determine regulatory impact.
- Assess whether prior approval/notification is required.
- Evaluate impact on product license, technical documentation and regulatory submissions.
- Ensure applicable CDSCO/CLA requirements are fulfilled before implementation.

5.7 Purchase / Supplier Quality

- Evaluate supplier-related changes.
- Obtain supplier change notification and supporting documents.
- Evaluate component/material impact.
- Ensure supplier approval requirements are fulfilled.

5.8 QMS Head / Management

- Review significant changes.
- Approve major/critical changes as defined by the organization.
- Ensure adequate resources for implementation.

6. CHANGE INITIATION

Changes may originate from:

- CAPA
- NCR / Nonconformity
- Customer Complaint
- PMS
- Risk Management Review
- Internal Audit
- External Audit
- Regulatory requirement
- Product improvement
- Process improvement
- Supplier change
- Component obsolescence
- Equipment replacement
- Manufacturing issue
- Safety improvement
- Design improvement
- Software/Firmware update
- Validation result
- Customer requirement

The Change Initiator shall complete the **Change Control Request Form**.

7. CHANGE CONTROL NUMBER

QA shall assign a unique identification number.

Example:

INV/CC/2026/001

The same Change Control number shall be referenced in all associated records.

8. CHANGE DESCRIPTION AND JUSTIFICATION

The following shall be documented:

- Current/existing condition
- Proposed change
- Reason for change
- Technical justification
- Expected benefit
- Products affected
- Batch/Lot affected, where applicable
- Documents affected
- Proposed implementation date

Relevant supporting evidence shall be attached.

9. CHANGE IMPACT ASSESSMENT

Each proposed change shall be evaluated for its impact on:

Sr. No.	Impact Area	Yes / No / N/A	Remarks
1	Product Safety		
2	Product Performance		
3	Product Quality		
4	Intended Use		
5	Indication for Use		
6	Product Specification		
7	Design		
8	Material / Component		
9	Manufacturing Process		
10	Equipment		
11	Testing / Inspection		
12	Software / Firmware		
13	Packaging		
14	Label / IFU		
15	Primary Packaging		
16	Sterilization		
17	Shelf Life		
18	Supplier		
19	Risk Management		
20	Validation / Qualification		
21	PMS		
22	Regulatory Compliance		
23	Technical Documentation		
24	Training		
25	QMS Documents		

10. RISK MANAGEMENT ASSESSMENT

Any change having potential impact on safety, performance or product quality shall be assessed through the Risk Management process.

The assessment shall determine:

1. Whether a new hazard is introduced.
2. Whether an existing hazard is affected.
3. Whether severity changes.
4. Whether probability of occurrence changes.
5. Whether existing risk controls remain effective.
6. Whether additional risk controls are required.
7. Whether residual risk remains acceptable.

The Risk Management File shall be updated whenever required.

Risk Management activities shall be performed in accordance with the approved Risk Management SOP and ISO 14971 requirements.

11. REGULATORY IMPACT ASSESSMENT

For medical devices, every applicable product/process change shall be assessed for regulatory impact.

The assessment shall determine whether the proposed change affects:

- Device classification
- Intended use
- Indication for use
- Product design
- Safety/performance
- Manufacturing process
- Sterilization
- Shelf life
- Labeling
- Primary packaging
- Manufacturing site
- Technical documentation
- Product license
- Regulatory submissions

- PMS requirements

The applicable Indian MDR 2017 post-approval change requirements shall be assessed before implementation. CDSCO's MDR 2017 Sixth Schedule specifically categorizes certain changes as major or minor.

12. INDIAN MDR – POST-APPROVAL CHANGE CLASSIFICATION

The Regulatory/QA function shall assess changes against the applicable requirements of the **Sixth Schedule of MDR 2017**.

12.1 Major Changes

The following types of changes are identified in the Sixth Schedule as major changes, subject to the applicable regulatory requirements:

1. Change in material of construction.
2. Design change affecting specifications, indication for use, performance or stability.
3. Change in intended use / indication for use.
4. Change in sterilization method.
5. Change in approved shelf life.
6. Change in name/address of domestic manufacturer or manufacturing site, as applicable.
7. Change in label, except specified limited label changes.
8. Change in manufacturing process, equipment or testing affecting device quality.
9. Change in primary packaging material.

The organization shall assess and complete the applicable regulatory process before commercial implementation where required.

12.2 Minor Changes

Examples identified in the Sixth Schedule include:

1. Design changes that do not affect specifications, indication for use, performance or stability.
2. Manufacturing process, equipment or testing changes that do not affect device quality.
3. Packaging specification changes excluding primary packaging material.

The applicable regulatory documentation/notification requirements shall be determined by Regulatory Affairs/QA.

13. CHANGE CLASSIFICATION

Based on impact assessment, the change shall be classified as:

Level 1 – Minor

No significant impact on:

- Safety

- Performance
- Quality
- Intended use
- Risk
- Regulatory compliance

Level 2 – Major

Potential impact on:

- Product/process quality
- Validation
- Risk
- Performance
- Manufacturing process
- Regulatory documentation

Level 3 – Critical / Regulatory Significant

Potential significant impact on:

- Patient/user safety
- Essential performance
- Intended use
- Critical risk controls
- Regulatory approval
- Licensed product information

Note: Internal classification shall not replace the regulatory classification required under applicable Indian MDR provisions.

14. VERIFICATION AND VALIDATION

The Change Control team shall determine whether verification and/or validation is required.

Where applicable, activities may include:

- Design verification
- Design validation
- Process validation
- Equipment qualification
- Software validation

- Test method validation
- Performance testing
- Electrical safety testing
- Biocompatibility evaluation
- Packaging validation
- Sterilization validation
- Stability assessment
- First Article Inspection
- Trial production

The change shall not be considered complete until required verification/validation activities have demonstrated conformity with predefined acceptance criteria.

15. DOCUMENTATION IMPACT

The following documents shall be reviewed and updated where applicable:

- Product Specification
- Design Drawing
- BOM / MBOM / PBOM
- Manufacturing Specification
- SOP
- Work Instruction
- Inspection Standard
- Test Method
- QC Check Sheet
- Packaging Specification
- Label
- IFU
- Technical File / Technical Documentation
- Risk Management File
- PMS Documentation
- Validation Documents
- Device Master / Manufacturing Records

Document revisions shall be controlled through the Document Control SOP.

16. TRAINING

Where the change affects personnel activities, relevant personnel shall be trained before implementation.

Training shall include:

- Nature of change
- Reason for change
- Revised procedure
- New acceptance criteria
- Safety requirements
- Effective date

Training records shall be retained.

17. IMPLEMENTATION

The approved change shall be implemented according to the approved implementation plan.

The implementation plan shall define, where applicable:

- Effective date
- Responsible department
- Responsible person
- Affected product/model
- Affected batch/lot
- Existing stock disposition
- New material/component introduction
- Document revision
- Equipment modification
- Training
- Verification requirements

18. INVENTORY / EXISTING STOCK ASSESSMENT

Before implementation, the impact on existing:

- Raw material
- Components
- Work in Process
- Finished goods

- Packaging material
- Labels
- Printed material

shall be assessed.

The disposition shall be documented as:

☐ Use as is
☐ Rework
☐ Return to supplier
☐ Scrap
☐ Hold pending evaluation
☐ Other: _____

19. EFFECTIVENESS VERIFICATION

After implementation, effectiveness shall be evaluated using applicable objective evidence, such as:

- Inspection results
- Testing results
- Process performance
- Validation results
- NCR trend
- Complaint trend
- CAPA effectiveness
- PMS data
- Risk Management review

Acceptance criteria shall be defined before effectiveness verification wherever practicable.

20. EMERGENCY CHANGE

Emergency Change Control may be used only where immediate action is required to protect:

- Patient safety
- User safety
- Product quality
- Regulatory compliance
- Critical manufacturing continuity

The emergency change shall be documented and reviewed by QA as soon as practicable.

A retrospective assessment shall include:

- Risk assessment
- Impact assessment
- Verification/validation
- Regulatory assessment
- Documentation update
- Training, where applicable

Emergency status shall not be used to bypass regulatory requirements.

21. TEMPORARY CHANGE

Temporary changes shall include:

- Justification
- Scope
- Risk assessment
- Start date
- Expiry/review date
- Responsible person
- Required controls
- Reversion plan

Before expiry, the change shall be:

☐ Made permanent through approved Change Control
☐ Reverted to original condition
☐ Extended with documented justification and approval

22. CHANGE APPROVAL

The Change Control shall be reviewed and approved by relevant functions based on impact.

Minimum review shall include QA.

Additional approval may be required from:

- R&D / Engineering
- Production
- QC
- Regulatory Affairs
- Purchase / Supplier Quality
- Maintenance
- IT / Software

- QMS Head / Management

No permanent change shall be implemented without required approval.

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23. CHANGE IMPLEMENTATION STATUS

The following status shall be used:

Initiated → Impact Assessment → Risk Assessment → Regulatory Assessment → Review → Approval → Verification/Validation → Implementation → Effectiveness Verification → Closure

24. CHANGE CLOSURE

QA shall verify that:

☐ Change has been implemented as approved.
☐ Risk assessment is completed.
☐ Regulatory assessment is completed.
☐ Required regulatory action is completed, where applicable.
☐ Verification/validation is completed.
☐ Documents are updated.
☐ Training is completed.
☐ Existing stock disposition is completed.
☐ Risk Management File is updated, where applicable.
☐ PMS requirements are updated, where applicable.
☐ Effectiveness verification is satisfactory.
☐ All action items are closed.

Only after satisfactory completion shall the Change Control be closed.

25. CHANGE CONTROL MASTER LOG

Sr. No.	Change Control No.	Date	Change Description	Product / Model	Classification	Regulatory Impact	Status	Closure Date
1						Yes / No		
2						Yes / No		
3						Yes / No		

26. RECORD RETENTION

All Change Control records shall be maintained as controlled quality records in accordance with the organization's Document and Record Control SOP and applicable regulatory requirements.

Records shall be:

- Legible
- Identifiable
- Traceable
- Retrievable

- Protected from unauthorized alteration
- Retained for the applicable regulatory/product lifetime period

27. ANNEXURES

Annexure No.	Title
Annexure 01	Change Control Request & Impact Assessment Form
Annexure 02	Change Risk & Regulatory Impact Assessment Record
Annexure 03	Change Implementation & Verification/Validation Record
Annexure 04	Change Training Record
Annexure 05	Change Effectiveness Verification Record
Annexure 06	Change Closure Record
Annexure 07	Change Control Master Log

28. RELATED SOPs

1. Document Control SOP
2. Record Control SOP
3. Risk Management SOP
4. CAPA SOP
5. Complaint Handling SOP
6. PMS SOP
7. Non-Conformity / Deviation SOP
8. Design and Development SOP
9. Validation / Qualification SOP
10. Training SOP
11. Supplier Control SOP

29. DOCUMENT REVISION HISTORY

Revision No.	Effective Date	Description of Change	Prepared By	Reviewed By	Approved By
00	01.09.26	Initial Issue			

30. APPROVAL

Responsibility	Name	Signature	Date
Prepared By			
Reviewed By – QA			
Reviewed By – Regulatory / R&D			
Approved By – QMS Head / Management			