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1. PURPOSE

To establish a documented procedure for identification, documentation, evaluation, segregation, disposition and control of nonconforming products to prevent their unintended use, release or delivery.

This SOP ensures that nonconforming products are appropriately controlled throughout manufacturing, inspection, storage and, where applicable, after delivery.

2. SCOPE

This SOP applies to:

- Incoming materials and components
- In-process products
- Finished products
- Packaging and labelling materials
- Products identified during inspection and testing
- Products returned by customers
- Products identified after delivery
- Products affected by deviations, complaints or process failures
- Reworked / repaired products
- Products requiring concession or use-as-is disposition

3. REFERENCES

1. **ISO 13485:2016 – Clause 8.3 – Control of Nonconforming Product**
2. ISO 13485:2016 – Clause 7.5.9 – Traceability of Product
3. ISO 13485:2016 – Clause 7.5.1 – Control of Production and Service Provision
4. ISO 13485:2016 – Clause 8.2 – Monitoring and Measurement
5. ISO 13485:2016 – Clause 8.5 – Improvement

6. Medical Devices Rules, 2017 – applicable requirements for quality management, device control, complaints and post-market activities
7. Applicable product-specific standards and specifications
8. Good Documentation Practices & Data Integrity SOP
9. Record Control SOP
10. Deviation Management SOP
11. CAPA SOP
12. Change Control SOP
13. Complaint Handling / PMS SOP

4. DEFINITIONS

4.1 Nonconforming Product

A product, component, material or output that does not meet specified requirements, approved specifications, drawings, acceptance criteria, regulatory requirements or applicable quality standards.

4.2 Rework

Action taken on a nonconforming product to make it conform to the specified requirements.

4.3 Repair

Action taken on a nonconforming product to make it acceptable for intended use, although it may not fully meet the original specified requirement.

4.4 Use-As-Is / Concession

A documented authorization to use or release a product that does not fully conform to specified requirements, where permitted and where safety, performance and regulatory requirements are not adversely affected.

4.5 Scrap

Disposition in which the nonconforming product is permanently prevented from unintended use.

4.6 Segregation

Physical or electronic separation of nonconforming product from conforming product to prevent unintended use or release.

4.7 Nonconformity

Failure to meet a specified requirement.

5. RESPONSIBILITIES

5.1 Quality Assurance

QA shall:

- Establish and maintain this procedure.
- Review identified nonconforming products.
- Ensure proper identification and segregation.
- Evaluate the nonconformity and its impact.
- Review and approve disposition.
- Ensure rework / repair is properly documented and verified.
- Maintain nonconforming product records.
- Monitor recurring nonconformities.
- Initiate CAPA where required.
- Ensure post-delivery nonconformities are appropriately evaluated.

5.2 Quality Control

QC shall:

- Identify nonconforming products during inspection and testing.
- Record inspection results.
- Inform QA / concerned department.
- Identify and segregate affected products.
- Perform re-inspection after rework where applicable.

5.3 Production

Production shall:

- Stop further processing when required.
- Segregate identified nonconforming products.
- Prevent mixing with accepted products.
- Perform approved rework / repair.
- Maintain rework records.

5.4 Stores / Warehouse

Stores shall:

- Maintain physical segregation of nonconforming material.
- Control access to rejected / quarantined material.
- Maintain identification and traceability.
- Prevent accidental issue or dispatch.

5.5 Regulatory / QA

Where applicable, QA / Regulatory shall evaluate regulatory reporting, field action, recall or other regulatory requirements for nonconformities identified after delivery.

6. PROCEDURE

6.1 Identification of Nonconforming Product

Nonconforming product may be identified through:

- Incoming inspection
- In-process inspection
- Final inspection
- Functional testing
- Product testing
- Process monitoring
- Internal audit
- Supplier evaluation
- Customer complaint
- Returned product
- Post-market surveillance
- Deviation
- CAPA
- Field failure
- Regulatory inspection
- Any other quality-related activity

The person identifying the nonconformity shall immediately inform the concerned supervisor and QA.

6.2 Identification and Labelling

Nonconforming product shall be clearly identified using an appropriate status identification such as:

"NONCONFORMING / REJECTED / HOLD / QUARANTINE"

The identification shall include, where applicable:

- Product name
- Part / component name
- Product code
- Batch / Lot No.
- Quantity
- Date
- Nonconformity / rejection reference
- Status
- Identified by

Identification shall remain with the product until final disposition.

7. SEGREGATION AND CONTROL

Nonconforming products shall be physically segregated or otherwise controlled to prevent unintended use, processing, release or delivery.

Where physical segregation is not practical, electronic / system controls or other effective methods shall be used.

Status shall be clearly identified as applicable:

- Quarantine
- Hold
- Rejected
- Awaiting Inspection
- Awaiting Disposition
- Rework
- Scrap

8. NONCONFORMING PRODUCT RECORD

Each significant nonconformity shall be documented in the **Nonconforming Product Report / Record**.

The record shall include, as applicable:

- Nonconformance No.
- Date
- Product / component
- Batch / Lot No.
- Quantity affected
- Requirement
- Actual observation
- Source of detection
- Description of nonconformity
- Initial assessment
- Risk / impact assessment
- Investigation
- Root cause, where required
- Proposed disposition
- Approval
- Rework / repair details
- Re-inspection / testing results
- Final disposition
- Closure

9. EVALUATION OF NONCONFORMITY

QA shall evaluate the nonconforming product to determine:

1. Nature of nonconformity.
2. Quantity affected.
3. Batch / lot impact.
4. Product safety impact.
5. Product performance impact.
6. Regulatory impact.

7. Traceability impact.
8. Impact on previously released products.
9. Need for additional investigation.
10. Need for CAPA.
11. Need for risk assessment update.
12. Need for complaint / PMS evaluation.
13. Need for field action or recall, where applicable.

10. RISK AND IMPACT ASSESSMENT

Where the nonconformity may affect product safety, performance or regulatory compliance, a documented risk assessment shall be performed.

The assessment shall consider:

- Severity of potential harm
- Probability of occurrence
- Affected products / batches
- Existing risk controls
- Residual risk
- Regulatory requirements

If required, the **Risk Management File** shall be reviewed and updated.

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11. DISPOSITION OF NONCONFORMING PRODUCT

Nonconforming product may be disposed of by one or more of the following methods, as applicable:

11.1 Rework

The product may be reworked according to an approved documented instruction.

Reworked products shall be re-inspected / re-tested to verify conformity.

11.2 Repair

Repair shall be performed only where technically justified and approved.

The repaired product shall undergo defined verification / testing.

11.3 Regrade / Alternative Use

Where permitted, the product may be regraded or diverted for an approved alternative use after appropriate evaluation and authorization.

11.4 Use-As-Is / Concession

Use-as-is shall be permitted only after documented evaluation and approval by authorized personnel.

The concession shall not compromise:

- Patient / user safety
- Product performance
- Regulatory compliance
- Intended use
- Applicable statutory requirements

Where regulatory or customer approval is required, it shall be obtained before disposition.

11.5 Scrap / Destruction

Products that cannot be safely or economically brought into conformity shall be scrapped or destroyed in a controlled manner.

Destruction shall prevent unintended use.

12. DISPOSITION AUTHORITY

Disposition	Responsible / Approval
Rework	Production + QA
Repair	Production / Engineering + QA
Re-inspection	QC / QA
Use-As-Is / Concession	QA + Authorized Function
Scrap	QA + Stores / Authorized Function
Regulatory / Field Action	QA / Regulatory / Authorized Management

13. REWORK CONTROL

Where rework is performed:

1. Rework instructions shall be documented.
2. Rework shall be approved before implementation.
3. Only trained personnel shall perform rework.
4. Required tools and equipment shall be identified.
5. Reworked quantity shall be recorded.
6. Rework shall be traceable to the original batch / lot.

7. Re-inspection / testing shall be performed.
8. Rework results shall be documented.
9. Repeated rework shall be evaluated for potential quality or process issues.

14. RE-INSPECTION / RE-TESTING

After rework or repair, the product shall be subjected to appropriate inspection / testing.

The acceptance criteria shall be based on approved:

- Product specification
- Drawing
- Inspection standard
- Test method
- Work instruction
- Applicable standard

The result shall be recorded in the applicable record.

15. RELEASE AFTER DISPOSITION

Only authorized personnel shall release a nonconforming product after satisfactory completion of the approved disposition.

The product status shall be changed from:

NONCONFORMING / HOLD / REJECTED

to the appropriate status only after objective evidence confirms conformity.

16. PRODUCTS IDENTIFIED AFTER DELIVERY

Where a nonconformity is identified after product delivery, QA shall evaluate:

- Product identification and traceability
- Affected batch / lot
- Quantity distributed
- Customer / user impact
- Safety and performance impact
- Regulatory impact
- Complaint requirements
- PMS impact

- Field correction requirements
- Recall requirements, where applicable

Appropriate action shall be initiated based on documented evaluation.

17. CUSTOMER RETURNED PRODUCT

Returned products shall be:

1. Identified and segregated.
2. Recorded with return details.
3. Evaluated by QA / QC.
4. Investigated where required.
5. Tested where applicable.
6. Dispositioned based on documented evaluation.
7. Linked with complaint / CAPA records where applicable.

Returned product shall not be returned to saleable stock without documented authorization and verification of conformity.

18. CAPA REQUIREMENT

CAPA shall be initiated where the nonconformity:

- Is recurring.
- Has significant product / process impact.
- Indicates a systemic failure.
- Has potential safety impact.
- Has regulatory significance.
- Requires systemic corrective action.
- Indicates failure of existing controls.

CAPA shall be managed according to the applicable CAPA SOP.

19. TRENDING AND MONITORING

QA shall periodically review nonconforming product records to identify:

- Recurring nonconformities
- High-frequency defects
- Supplier-related issues

- Process-related issues
- Product-related issues
- Critical / major trends
- Rework trends
- Scrap trends
- Customer / field-related trends

Significant trends shall be evaluated for CAPA or other appropriate action.

20. RECORDS

The following records shall be maintained, as applicable:

Sr. No.	Record	Reference
1	Nonconforming Product Report / Record	Annexure-01
2	Nonconforming Product Evaluation & Disposition Record	Annexure-02
3	Rework / Repair Record	Annexure-03
4	Nonconforming Product Re-inspection / Re-test Record	Annexure-04
5	Nonconforming Product Closure Record	Annexure-05
6	Nonconforming Product Log / Register	Annexure-06

Records shall be controlled as per the applicable Record Control SOP.

21. RECORD RETENTION

Records generated under this SOP shall be retained for the period defined in the applicable **Record Control SOP**, regulatory requirements, customer requirements and product-specific requirements, whichever is applicable.

Records shall remain legible, identifiable, traceable and readily retrievable.

22. TRAINING

Personnel involved in identification, segregation, evaluation, disposition, rework, inspection and release of nonconforming products shall be trained on this SOP and applicable work instructions.

Training records shall be maintained.

23. FLOW CHART

Nonconformity Identified
↓
Inform QA / Concerned Department
↓
Identify & Segregate Product
↓
Record Nonconformity

↓

Evaluate Nonconformity & Impact

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Risk Assessment – If Applicable

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Disposition Decision

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Rework / Repair / Use-As-Is / Scrap / Other Approved Disposition

↓

Re-inspection / Re-testing – If Applicable

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Conformity Verified?

↓

YES → Release / Appropriate Status

NO → Further Action / Re-evaluation

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CAPA / Risk / Complaint / PMS Evaluation – If Required

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Closure & Record Retention

24. ANNEXURES

Annexure No.	Title
Annexure-01	Nonconforming Product Report / Record
Annexure-02	Nonconforming Product Evaluation & Disposition Record
Annexure-03	Rework / Repair Record
Annexure-04	Nonconforming Product Re-inspection / Re-test Record
Annexure-05	Nonconforming Product Closure Record
Annexure-06	Nonconforming Product Log / Register

25. REVISION HISTORY

Rev. No.	Effective Date	Description of Change	Prepared By	Approved By
01	01.09.26	Initial Issue		