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1. PURPOSE

To establish a documented and controlled procedure for identifying, reporting, evaluating, investigating, documenting, approving, and closing **deviations** from approved procedures, specifications, processes, work instructions, manufacturing conditions, or other established requirements.

The procedure ensures that deviations are assessed for their potential impact on **product quality, safety, performance, regulatory compliance, and patient safety**.

2. SCOPE

This SOP applies to deviations occurring in:

- Raw material / component receipt
- Incoming inspection
- Production and assembly
- In-process inspection
- Final inspection and testing
- Packaging and labelling
- Storage and handling
- Equipment and utilities
- Calibration and maintenance
- Environmental conditions
- Software / computerized systems
- Documentation and records
- Supplier / outsourced processes
- Validated processes
- Product specifications

- Approved procedures / work instructions

3. REFERENCES

Sr. No.	Reference
1	ISO 13485:2016 – Control of Nonconforming Product / CAPA requirements
2	ISO 14971:2019 – Risk Management
3	Medical Devices Rules, 2017 – India
4	Regulation (EU) 2017/745 – EU MDR
5	Nonconforming Product Control SOP
6	CAPA SOP
7	Risk Management SOP
8	Change Control SOP
9	Document and Record Control SOP

4. DEFINITIONS

Deviation: A temporary or unplanned departure from an approved procedure, specification, process, instruction, or established requirement.

Planned Deviation: A deviation that is identified and approved before the activity is performed.

Unplanned Deviation: An unexpected departure from an approved requirement that has already occurred.

Critical Deviation: A deviation that may have a significant impact on patient safety, product safety, product performance, or regulatory compliance.

Major Deviation: A deviation that may affect product quality, process performance, or QMS effectiveness.

Minor Deviation: A deviation with limited or negligible impact that does not affect product safety or essential performance.

5. RESPONSIBILITIES

Function	Responsibility
Person Identifying Deviation	Immediately report and document the deviation.
Department Head	Assess the situation and ensure containment.
QA	Review, classify, investigate, approve disposition, and monitor closure.
QC	Perform required testing / inspection and provide objective evidence.
R&D / Engineering	Evaluate technical and product impact.
RA	Assess regulatory impact where applicable.
Risk Management Team	Evaluate impact on product risk and update risk records where required.
Process Owner	Identify root cause and implement corrective action.
Quality Head	Review significant deviations and approve closure.

6. DEVIATION MANAGEMENT PROCESS

Deviation Identified

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Immediate Notification to QA

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Containment / Immediate Action

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Deviation Record Initiation

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Initial Impact & Risk Assessment

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Classification

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Investigation / Root Cause Analysis

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Product / Process Disposition

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Corrective Action / CAPA, if Required

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Effectiveness Verification

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QA Review & Closure

7. IDENTIFICATION AND REPORTING

Any employee who identifies a deviation shall immediately inform the concerned supervisor / department head and QA.

The deviation shall be recorded with:

- Deviation number
- Date and time
- Department / process
- Product / model
- Batch / lot number, where applicable
- Description of deviation
- Requirement that was not followed
- Immediate action taken
- Person reporting the deviation

8. IMMEDIATE CONTAINMENT

Where required, immediate containment shall be taken to prevent further impact.

Examples:

- Stop the affected process.
- Segregate affected material / product.
- Identify and hold affected batches.
- Prevent further use or release.
- Inform relevant departments.
- Preserve relevant records and evidence.
- Conduct additional inspection / testing where justified.

No affected product shall be released until QA has completed the required assessment and approved the disposition.

9. INITIAL IMPACT ASSESSMENT

The deviation shall be assessed for its potential impact on:

- Product safety
- Product performance
- Patient / user safety
- Regulatory compliance
- Product specifications
- Risk Management File
- Validated process
- Manufacturing process
- Traceability
- Labelling / packaging
- Technical documentation
- PMS / vigilance
- Previously released products

10. DEVIATION CLASSIFICATION

Classification	Criteria	Typical Action

Critical	Potential significant impact on patient safety, product safety, essential performance, or regulatory compliance	Immediate containment + investigation + CAPA / escalation
Major	Potential impact on product quality, process performance, or QMS effectiveness	Investigation + corrective action
Minor	Limited deviation with no significant impact on safety or essential performance	Document + correction / appropriate action

The final classification shall be based on documented risk assessment.

11. INVESTIGATION

The investigation shall determine:

- What happened?
- When did it happen?
- Where did it happen?
- Who identified / performed the activity?
- Which product / batch / lot is affected?
- Which requirement was not met?
- Why did the deviation occur?
- Whether similar products / batches are affected?
- Whether the deviation has occurred previously?

Objective evidence shall be collected and documented.

12. ROOT CAUSE ANALYSIS

For significant deviations, an appropriate root cause analysis method shall be used, such as:

- 5 Why Analysis
- Fishbone / Ishikawa Analysis
- Fault Tree Analysis
- Process Analysis
- Data / Trend Analysis

The identified root cause shall be supported by objective evidence.

13. PRODUCT / PROCESS DISPOSITION

Based on the investigation and risk assessment, QA shall determine the appropriate disposition.

Possible dispositions include:

- Accept as-is with documented justification
- Rework
- Repair
- Re-inspection / re-testing
- Return to supplier
- Reject / scrap
- Additional monitoring
- Hold pending further investigation

Where a deviation affects a released product, QA / RA shall assess whether complaint, PMS, vigilance, recall, or regulatory action is required.

14. RISK MANAGEMENT ASSESSMENT

The deviation shall be evaluated against the applicable **ISO 14971 Risk Management File**.

The assessment shall determine whether:

- Existing hazards are affected.
- A new hazard is introduced.
- Existing risk controls remain effective.
- Residual risk changes.
- Risk Management File requires updating.
- Benefit-risk assessment is required.

15. CAPA

CAPA shall be initiated where the deviation indicates:

- Systemic failure
- Repeated deviation
- Major / critical issue
- Significant product or patient safety risk
- Regulatory noncompliance
- Ineffective existing controls

CAPA shall be managed according to the approved CAPA procedure.

16. CHANGE CONTROL

If permanent modification of an approved product, process, specification, equipment, document, or procedure is required as a result of the deviation, a **Change Control** shall be initiated.

Deviation approval shall not be used as a substitute for permanent change control.

17. REGULATORY ASSESSMENT

QA / RA shall evaluate whether the deviation has regulatory significance.

Assessment shall consider, as applicable:

Indian MDR 2017

- Product safety and performance
- Manufacturing requirements
- Product release
- Labelling
- Complaint / adverse event reporting
- Recall / field action requirements

EU MDR 2017/745

- Safety and performance requirements
- Risk management
- Technical documentation
- PMS
- Vigilance
- Field Safety Corrective Action
- Regulatory / Notified Body communication, where applicable

18. EFFECTIVENESS VERIFICATION

For applicable deviations and CAPA, effectiveness shall be verified using:

- Subsequent batch review
- Process monitoring
- Inspection / testing
- Internal audit
- Trend analysis
- Complaint review

- Repeat deviation monitoring

The deviation shall not be considered fully closed until required effectiveness verification is completed.

19. DEVIATION CLOSURE

QA shall close the deviation after verifying:

- Investigation completed.
- Root cause identified where required.
- Containment completed.
- Product disposition approved.
- Corrective action completed.
- Risk assessment completed.
- Regulatory assessment completed where applicable.
- Change Control initiated where required.
- CAPA initiated / closed where required.
- Effectiveness verified where applicable.
- All supporting records attached.

20. DEVIATION RECORD

Sr. No.	Particular	Details
1	Deviation No.	
2	Date / Time	
3	Department	
4	Product / Model	
5	Batch / Lot No.	
6	Deviation Type	Planned / Unplanned
7	Description	
8	Requirement / Specification	
9	Immediate Containment	
10	Risk Classification	Critical / Major / Minor
11	Impact Assessment	
12	Root Cause	
13	Corrective Action	
14	Product Disposition	
15	Risk Management Impact	
16	CAPA Required	Yes / No
17	Change Control Required	Yes / No
18	Regulatory Assessment	Required / Not Required

19	Effectiveness Verification	
20	Closure Date	

21. RECORD CONTROL

Deviation records shall be controlled according to the applicable Document and Record Control procedure.

Records shall be:

- Legible
- Complete
- Accurate
- Traceable
- Protected from unauthorized modification
- Readily retrievable
- Retained for the defined retention period

22. TRAINING

Personnel involved in deviation management shall be trained on:

- Deviation identification and reporting
- Containment
- Risk assessment
- Root cause analysis
- CAPA
- Change Control
- Documentation and Data Integrity
- Applicable regulatory requirements

Training records shall be maintained.

23. RECORDS

Sr. No.	Record	Responsible
1	Deviation Report	QA
2	Investigation Record	Concerned Department / QA
3	Risk Assessment	QA / Risk Team
4	Product Disposition Record	QA
5	CAPA Record	QA
6	Change Control Record	QA

7	Effectiveness Verification Record	QA
8	Regulatory Assessment Record	QA / RA

24. ANNEXURES

Annexure No.	Title
Annexure I	Deviation Report / Deviation Form
Annexure II	Deviation Impact & Risk Assessment Form
Annexure III	Deviation Investigation & Root Cause Analysis Record
Annexure IV	Product / Batch Disposition Record
Annexure V	Deviation Corrective Action & Effectiveness Verification Record
Annexure VI	Deviation Closure Record
Annexure VII	Deviation Log / Register