NONCONFORMANCE REPORT

FRM-NC-001 Rev 2.0 | QCore Consulting

Fields marked with * are mandatory. Do not leave blank.

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SECTION 1: NONCONFORMITY DESCRIPTION

→ Phase 1: NC Initiator fills at time of detection

NC Number*:	
Date Initiated*:	
Date of Discovery*:	
NC Owner*:	
Classification* (PRELIMINARY):	
Department*:	
Source*:	

Source:

☐ Incoming Inspection ☐ In-Process Inspection ☐ Final Inspection ☐ Customer Complaint

☐ Internal Audit ☐ Field Failure/Return ☐ Supplier Report ☐ Other: _____

Problem Statement*:

Affected Products:

Product Name:	
Part Number:	
Lot/Batch:	
Serial/UDI:	
Quantity Affected*:	

⚠ RELEASED PRODUCT AFFECTED?* ☐ YES (MANDATORY: Complete FSCA Assessment) ☐ NO

Reference Documents:	

SECTION 2: IMMEDIATE CONTAINMENT ACTIONS

→ Phase 1: NC Initiator fills immediately after detection

Containment Actions Taken*:

Containment Initiated (Date/Time)*:	

Scope*:

☐ Isolated (single unit/event) ☐ Systematic (recurring/batch-wide) ☐ Widespread (multiple products/sites)

FSCA Decision Gate*: Is Field Safety Corrective Action required?

☐ YES ☐ NO

Justification*:

Containment Verified By*:	
Verification Date*:	

SECTION 3: CLASSIFICATION & RISK ASSESSMENT

→ Phase 2: QA/NC Owner fills within 24–48 hours

Classification Decision*:

☐ CRITICAL (<24h) ☐ MAJOR (48h) ☐ MINOR (5 business days)

Classification Justification:

Risk Assessment Impact Check:

1. Does this NC represent a new or changed hazard? ☐ Yes ☐ No
2. Does the Risk Management File require update? ☐ Yes ☐ No
3. Is this NC related to a known risk already in the RM File? ☐ Yes ☐ No

> *NOTE: If ANY answer is YES, update the Risk Management File per ISO 14971:2019 §9.*

SECTION 4: INVESTIGATION & ROOT CAUSE

→ Phase 2: QA/NC Owner leads investigation

5-Why Analysis:

Step	Question	Finding
Why 1?		
Why 2?		
Why 3?		
Why 4?		
Why 5?		

Root Cause Statement*:

Root Cause Category:

☐ Equipment Design ☐ Material/Component ☐ Process Design ☐ Process Parameter
☐ Environmental Factor ☐ Documentation ☐ Training ☐ Supplier Quality
☐ QC Failure ☐ Other: _____

Evidence Collected:

Ref	Evidence	Key Finding
E-001		
E-002		
E-003		
E-004		
E-005		

SECTION 5: DISPOSITION DECISION

→ Phase 2: QA/NC Owner with Production/Engineering input

Disposition*:

☐ Use-as-is ☐ Rework ☐ Repair ☐ Scrap ☐ Return to Supplier

Disposition Justification*:

Disposition Approved By*:	
Disposition Date*:	

SECTION 6: CAPA ESCALATION

→ Phase 3: QA/NC Owner evaluates CAPA need

CAPA Required?*

☐ YES ☐ NO

CAPA Trigger(s):

☐ ≥3 NCs in 6 months (same root cause)
☐ Critical NC with patient safety impact
☐ Regulatory finding
☐ Customer complaint with field failure
☐ Other: _____

CAPA Number:	
CAPA Owner:	
CAPA Due Date:	

CAPA Actions:

SECTION 7: VERIFICATION & CLOSURE

→ Phase 4: QA/NC Owner completes after CAPA implementation

Closure Checklist:

☐ Root cause identified and documented
☐ Corrective action implemented
☐ Effectiveness verification completed (30-day check)
☐ Risk Management File updated (ISO 14971)
☐ Quality Agreement amended (if applicable)
☐ NC-Log updated with final disposition
☐ All affected product dispositioned
☐ Lessons learned documented and communicated

Effectiveness Verification:

Was the corrective action effective?

☐ YES ☐ NO

If NO, describe further actions required:

Closed By*:	
Closure Date*:	
Days Open:	

SECTION 8: LESSONS LEARNED

→ Optional but recommended — completed at closure

Key Learnings:

Recommended Preventive Measures:

APPROVAL & SIGN-OFF

Role	Name	Signature	Date
NC Owner			
Quality Manager			
Management Rep. (Critical only)			

This form complies with ISO 13485:2016 §8.3, FDA 21 CFR 820.90, EU MDR 2017/745 Art. 83–86. Records must be retained for product lifetime + 2 years minimum (EU MDR Art. 10(8): minimum 10 years).