NONCONFORMANCE REPORT (NCR)

SECTION 1: IDENTIFICATION

NCR Number:	NC-	**Date Issued:**	
Initiated By:		**Department:**	

SECTION 2: PRODUCT/PROCESS IDENTIFICATION

Product Name:		**Part Number:**	
Lot/Batch No.:		**Quantity Affected:**	
Supplier (if appl.):		**PO Number:**	
Source of NC:	☐ Incoming Inspection ☐ In-Process ☐ Final Inspection ☐ Customer Complaint ☐ Audit ☐ Other		
Released product affected? ☐ YES ☐ NO		**Serial/UDI (if appl.):**	

SECTION 3: DESCRIPTION OF NONCONFORMITY

Specification/Requirement Not Met:

Description of Nonconformity (include actual vs. expected results):

Evidence Attached: ☐ Photos ☐ Test Results ☐ Inspection Records ☐ Other: _____

SECTION 4: CLASSIFICATION (QA to complete)

☐ **CRITICAL** Safety/Regulatory	☐ **MAJOR** Quality Impact	☐ **MINOR** Cosmetic/Documentation

Classification Justification:

Classified By:		Date:

SECTION 5: DISPOSITION

☐ **USE-AS-IS (Concession)** *Requires documented justification*	☐ **REWORK** *Re-inspection required after rework*
☐ **SCRAP/DESTROY** *Document disposal method*	☐ **RETURN TO SUPPLIER** *Initiate SCAR if applicable*

Disposition Justification / Rework Instructions:	
Disposition Decision By:	Name: _____ Signature: _____ Date: _____
Management Approval:	Name: _____ Signature: _____ Date: _____

SECTION 6: CAPA EVALUATION

Does this NC require a CAPA?

☐ YES → CAPA Number: _____ ☐ NO → Justification below

CAPA Escalation Criteria Evaluation:

☐ NC Classification is Critical
☐ Same/similar NC occurred 3+ times in 12 months
☐ Resulted in or could result in customer complaint
☐ Root cause indicates systemic issue
☐ Regulatory notification may be required

If NO CAPA, provide justification:

Evaluated By:	Name: _____ Signature: _____ Date: _____

SECTION 7: VERIFICATION & CLOSURE

Verification of Disposition Completion:

☐ Disposition action completed as documented
☐ Product re-inspected and meets specifications (if rework)
☐ NC Tracking Log updated

Verification Notes:

Verified By:	Name: _____ Signature: _____ Date: _____
NCR CLOSED:	QA Signature: _____ Date: _____

Compliant with ISO 13485:2016 Clause 8.3 and FDA 21 CFR 820.90
Template provided by QCore Consulting