★ EXAMPLE – FOR REFERENCE ONLY ★

CORRECTIVE AND PREVENTIVE ACTION (CAPA)

Form

CAPA Number: CAPA-2025-017	**Date Initiated:** 2025-01-08
CAPA Owner: Dr. Maria Schmidt, Quality Manager	**Target Completion Date:** 2025-03-15

Source:	**Priority / Risk Level:**
☐ Internal Audit	☐ Critical (Patient Safety Impact)
☐ External Audit	☒ High (Regulatory/Major Quality)
☒ Customer Complaint	☐ Medium (Moderate Impact)
☐ Nonconformance	☐ Low (Minor / Improvement)
☐ PMS/Vigilance	
☐ Management Review	
☐ Supplier Issue	
☐ Process Deviation	
☐ Other: _____	

1. PROBLEM DESCRIPTION [ISO 13485 §8.5.2a / FDA 820.100(a)(1)]

Problem Statement	On 2025-01-06, customer complaint CC-2025-0042 was received from St. Anna Hospital. The complaint reported that 47 units of sterile urinary catheters (REF UC-200-16FR) from lot #L2024-1187 displayed an incorrect expiration date on the primary packaging. Label showed: EXP 2025-06 (incorrect) Correct date should be: EXP 2027-06 The shortened expiration date would cause premature disposal of compliant product, resulting in unnecessary waste and potential supply issues for the customer.
Affected Product(s) / Process(es)	Sterile Urinary Catheter, 16FR (REF UC-200-16FR), Lot #L2024-1187, 2,400 units produced
Reference Documents	CC-2025-0042, DHR-L2024-1187, NC-2025-0023
Impact Assessment	Patient Safety: LOW – Product sterility and function not affected, only label error Regulatory: HIGH – Mislabeling violates 21 CFR 820.120 and EU MDR Annex I §23

	Business: MEDIUM – Customer trust affected, potential recall costs Scope: 2,400 units distributed to 12 customers across EU and US markets

2. IMMEDIATE CONTAINMENT ACTIONS [FDA 820.100(a)(3)]

Containment Actions Taken	1. Production line for UC-200 series stopped immediately (2025-01-06, 14:30) 2. Remaining inventory of lot L2024-1187 quarantined (312 units in warehouse) 3. Customer notification sent to all 12 affected customers within 24 hours 4. Advisory issued: Product safe to use, apply corrective label over expiry date 5. Corrective labels printed and shipped to customers (2025-01-08) 6. No field safety corrective action (recall) required per risk assessment RA-2025-008
Containment Verified By	Thomas Weber, Production Manager – 2025-01-08

3. ROOT CAUSE INVESTIGATION [ISO 13485 §8.5.2b / FDA 820.100(a)(2)]

RCA Method Used	☒ 5-Why Analysis ☒ Fishbone / Ishikawa Diagram ☐ Fault Tree Analysis ☐ Pareto Analysis ☐ Other: _____
Investigation Team	Dr. M. Schmidt (QM), T. Weber (Prod), K. Hoffmann (Labeling), S. Braun (QC)

5-Why Analysis (Fishbone diagram attached as Appendix A)
Why 1: Why was the wrong expiration date printed? → The label template contained an incorrect shelf life parameter (24 months instead of 48 months)
Why 2: Why did the template have the wrong shelf life? → Template was copied from UC-100 series (24-month shelf life) when creating UC-200 series
Why 3: Why wasn't the shelf life parameter updated after copying? → No checklist exists for verifying all parameters when creating new label templates
Why 4: Why wasn't the error caught during label approval? → Label approval SOP focuses on text/graphics review, no explicit verification against DHF/DMR data
Why 5: Why doesn't the SOP require DHF/DMR verification? **→ SOP-LAB-002 was written in 2018 and has not been updated to include this critical check (ROOT CAUSE)**

Root Cause Statement	ROOT CAUSE: SOP-LAB-002 "Label Design and Approval" lacks a mandatory verification step requiring cross-check of critical label parameters (expiration date, shelf life,

	storage conditions) against the Device Master Record (DMR) and Design History File (DHF). CONTRIBUTING FACTOR: No standardized template creation checklist exists, allowing copy-paste errors to propagate undetected.
Evidence / Data Supporting Root Cause	• Review of SOP-LAB-002 Rev 3 confirms no DHF/DMR verification requirement • Interview with K. Hoffmann confirmed template was copied from UC-100 • Label approval record LAB-2024-0892 shows no shelf life verification performed • DMR-UC-200 clearly states 48-month shelf life based on stability study STB-2022-014 • Similar near-miss found in UC-150 template (caught before production)

4. CORRECTIVE ACTION PLAN [ISO 13485 §8.5.2c-d / FDA 820.100(a)(3-4)]

#	Corrective Action	Responsible	Due Date	Status
1	Correct UC-200 label template, update shelf life to 48 months	K. Hoffmann	2025-01-15	COMPLETE
2	Revise SOP-LAB-002 to include mandatory DHF/DMR verification step	Dr. M. Schmidt	2025-02-01	COMPLETE
3	Create Label Template Creation Checklist (FRM-LAB-015)	K. Hoffmann	2025-02-15	COMPLETE
4	Train all labeling personnel on revised SOP and checklist	S. Braun	2025-02-28	COMPLETE
5	Audit all active label templates against DMR (32 SKUs)	QC Team	2025-03-15	COMPLETE

5. PREVENTIVE ACTION [ISO 13485 §8.5.3 / FDA 820.100(a)(3)]

Preventive Actions	1. Implement automated label parameter validation in ERP system (Project IT-2025-04) - System will flag mismatches between label template and DMR before print approval - Target implementation: Q3 2025 2. Add annual label audit to internal audit schedule (AUD-PLAN-2025 updated) 3. Include labeling process in next Management Review (scheduled 2025-04-15)
Horizontal Deployment	☒ Other products reviewed for similar risk ☒ Other processes reviewed for similar risk ☐ Supplier/vendor notification required ☐ Not applicable (justify below)
Justification / Notes	All 32 active product label templates audited. One additional discrepancy found in UC-150 template (storage temperature) - corrected under NC-2025-0031.

6. VERIFICATION OF IMPLEMENTATION [ISO 13485 §8.5.2e / FDA 820.100(a)(4-5)]

Verification Activities	☒ Actions completed as planned ☒ Documentation updated (SOPs, WIs, Forms) ☒ Training completed and documented ☒ Process/Design changes implemented ☒ Actions do not adversely affect product safety/performance
Evidence of Implementation	• SOP-LAB-002 Rev 4 effective 2025-02-01 (ECO-2025-0012) • FRM-LAB-015 "Label Template Creation Checklist" approved 2025-02-15 • Training records TR-2025-0089 through TR-2025-0094 (6 employees) • Label audit report QA-RPT-2025-008 completed 2025-03-15
Verified By / Date	S. Braun, QC Supervisor – 2025-03-15

7. EFFECTIVENESS VERIFICATION [ISO 13485 §8.5.2f / FDA 820.100(a)(4)]

Effectiveness Check Date	2025-06-15 (90 days after last action completed)
Effectiveness Criteria	1. Zero label-related nonconformances in 90-day monitoring period 2. 100% compliance with new checklist (verified by audit of 10 random label approvals) 3. Zero customer complaints related to labeling errors
Effectiveness Results	Monitoring Period: 2025-03-16 to 2025-06-15 Results: • Label NCs in period: 0 (vs. 3 in prior 90-day period) ✓ • Checklist compliance audit: 10/10 approvals compliant (100%) ✓ • Customer complaints (labeling): 0 ✓ New label templates created in period: 4 (all verified against DMR per new SOP)
Effectiveness Determination	☒ EFFECTIVE - Root cause eliminated, no recurrence ☐ PARTIALLY EFFECTIVE - Improvement observed, monitoring continues ☐ NOT EFFECTIVE - New CAPA required (Reference: CAPA-____-___)

8. CAPA CLOSURE [ISO 13485 §8.5.2g / FDA 820.100(a)(6-7)]

Management Review Reference	MR-2025-Q2, Agenda Item 5.3, Meeting Date: 2025-07-10
Lessons Learned	1. Legacy SOPs require periodic review to ensure they address current risks 2. Copy-paste workflow for templates needs systematic verification controls

	3. Automated validation (ERP integration) should be prioritized for critical parameters 4. Cross-functional investigation teams improve root cause identification

APPROVALS		
CAPA Owner	*Dr. Maria Schmidt*	2025-06-20
Quality Manager	*Dr. Maria Schmidt*	2025-06-20
Management Representative	*Hans Müller, CEO*	2025-07-10

This form complies with ISO 13485:2016 §8.5.2-8.5.3, FDA 21 CFR 820.100, and EU MDR 2017/745 Annex IX requirements.