Biomedical Device Quality Non-Conformance Report

Report Number

Date

Reported By

Device Information

Device Name

Model/Type

Serial/Lot No.

Manufacturer

Non-Conformance Details

Description of Non-Conformance

Detected At (Location/Department)

Date Detected

Impact/Effect

Risk Assessment

Immediate Actions Taken

Root Cause Analysis

Corrective / Preventive Actions

Follow-Up / Verification

Follow-Up By

Follow-Up Date

Verification/Comments

Approvals

Reviewed By

Date

Approved By

Date