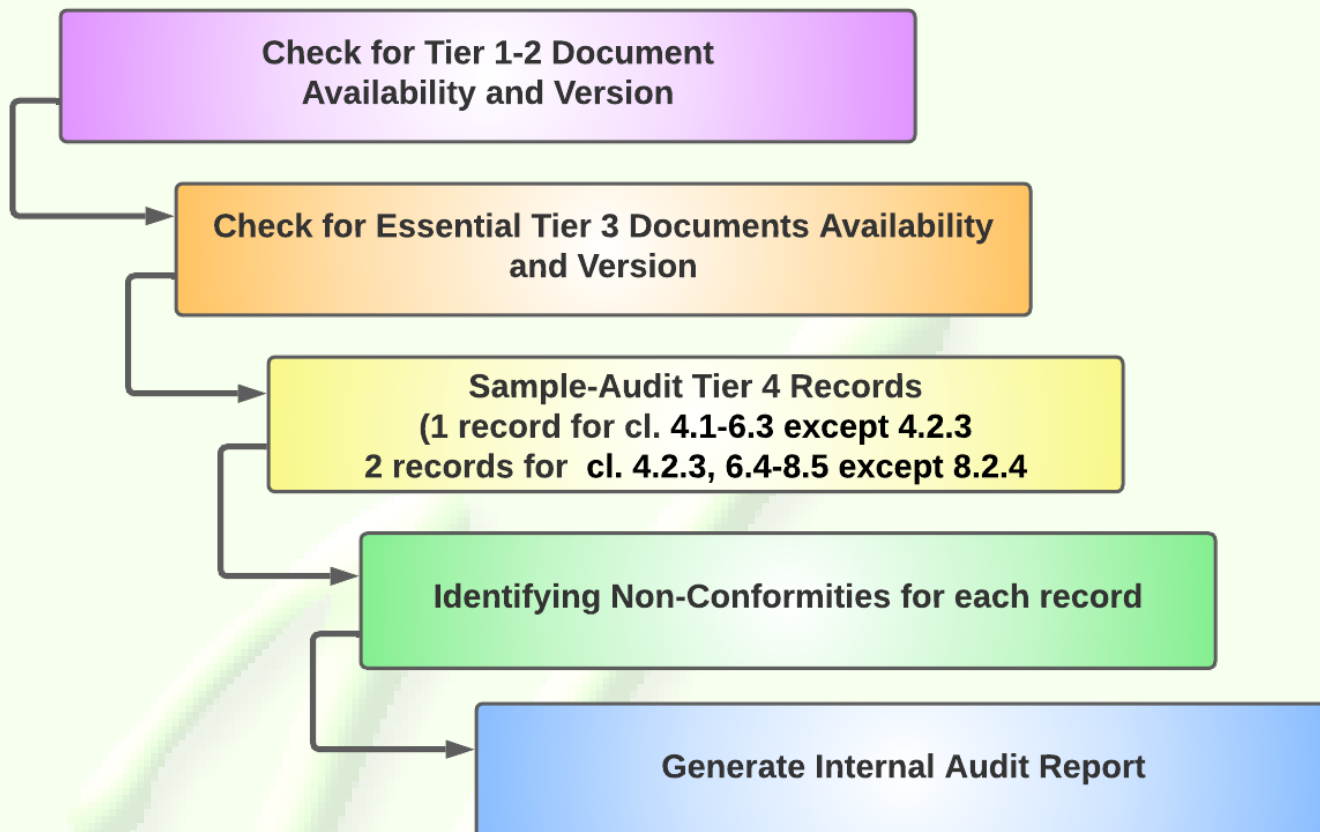


## INTERNAL AUDIT PROCESS



# D-722-2-3 INTERNAL AUDIT\_V1

## INTERNAL AUDIT DOCUMENTATION

Clause	Document Reviewed	Observation/Comment	Results
4.1.1	<ul style="list-style-type: none"><li>Quality Manual -Scope</li></ul>	▪	<input type="checkbox"/> Complied <input type="checkbox"/> Minor NC <input type="checkbox"/> Major NC
4.1.2	<ul style="list-style-type: none"><li>Quality Manual – Process Flow Chart</li></ul>	▪	<input type="checkbox"/> Complied <input type="checkbox"/> Minor NC <input type="checkbox"/> Major NC
4.1.3	<ul style="list-style-type: none"><li>Previous Management review Record</li></ul>	▪	<input type="checkbox"/> Complied <input type="checkbox"/> Minor NC <input type="checkbox"/> Major NC
4.1.4	<ul style="list-style-type: none"><li>Procedure for Control of Process Changes</li><li>Process Change Record if any</li></ul>	▪	<input type="checkbox"/> Complied <input type="checkbox"/> Minor NC <input type="checkbox"/> Major NC
4.1.5	<ul style="list-style-type: none"><li>Quality Agreements or Commercial Agreement with responsibilities defined</li></ul>	▪	<input type="checkbox"/> Complied <input type="checkbox"/> Minor NC <input type="checkbox"/> Major NC
4.1.6	<ul style="list-style-type: none"><li>Procedure for QMS software validation</li><li>Software Validation Record</li></ul>	▪	<input type="checkbox"/> Complied <input type="checkbox"/> Minor NC <input type="checkbox"/> Major NC
4.2.1	<ul style="list-style-type: none"><li>Quality Manual</li><li>Quality Policy</li><li>Quality Objectives</li><li>International Standards to be complied</li></ul>	▪	<input type="checkbox"/> Complied <input type="checkbox"/> Minor NC <input type="checkbox"/> Major NC
4.2.2	<ul style="list-style-type: none"><li>Quality Manual</li><li>Elements of ISO 13485 – reference to each procedure</li></ul>	▪	<input type="checkbox"/> Complied <input type="checkbox"/> Minor NC <input type="checkbox"/> Major NC

# D-722-2-3 INTERNAL AUDIT\_V1

Clause	Document Reviewed	Observation/Comment	Results
4.2.3	<ul style="list-style-type: none"> <li>▪ Device Master Record</li> </ul>	▪	<input type="checkbox"/> Complied <input type="checkbox"/> Minor NC <input type="checkbox"/> Major NC
4.2.4	<ul style="list-style-type: none"> <li>▪ Procedure for Document Control</li> <li>▪ Master Document List</li> <li>▪ 5 x tier 3 documents</li> </ul>	▪	<input type="checkbox"/> Complied <input type="checkbox"/> Minor NC <input type="checkbox"/> Major NC
4.2.5	<ul style="list-style-type: none"> <li>▪ Procedure for Record Control</li> <li>▪ 5 x tier 4 records</li> </ul>	▪	<input type="checkbox"/> Complied <input type="checkbox"/> Minor NC <input type="checkbox"/> Major NC
5.1	<ul style="list-style-type: none"> <li>▪ Responsibilities of Management</li> <li>▪ Approval for additional resources</li> </ul>	▪	<input type="checkbox"/> Complied <input type="checkbox"/> Minor NC <input type="checkbox"/> Major NC
5.2	<ul style="list-style-type: none"> <li>▪ Customer satisfaction record</li> </ul>	▪	<input type="checkbox"/> Complied <input type="checkbox"/> Minor NC <input type="checkbox"/> Major NC
5.3	<ul style="list-style-type: none"> <li>▪ Quality Policy</li> </ul>	▪	<input type="checkbox"/> Complied <input type="checkbox"/> Minor NC <input type="checkbox"/> Major NC
5.4	<ul style="list-style-type: none"> <li>▪ Quality Objectives</li> </ul>	▪	<input type="checkbox"/> Complied <input type="checkbox"/> Minor NC <input type="checkbox"/> Major NC
5.5.1	<ul style="list-style-type: none"> <li>▪ Organization Chart</li> </ul>	▪	<input type="checkbox"/> Complied <input type="checkbox"/> Minor NC <input type="checkbox"/> Major NC

# D-722-2-3 INTERNAL AUDIT\_V1

Clause	Document Reviewed	Observation/Comment	Results
5.5.2	<ul style="list-style-type: none"> <li>▪ MR appointment statement or letter</li> </ul>	▪	<input type="checkbox"/> Complied <input type="checkbox"/> Minor NC <input type="checkbox"/> Major NC
5.5.3	<ul style="list-style-type: none"> <li>▪ Training records on quality policy and objectives</li> </ul>	▪	<input type="checkbox"/> Complied <input type="checkbox"/> Minor NC <input type="checkbox"/> Major NC
5.6	<ul style="list-style-type: none"> <li>▪ Procedure for Management Review</li> <li>▪ Management Review Record</li> </ul>	▪	<input type="checkbox"/> Complied <input type="checkbox"/> Minor NC <input type="checkbox"/> Major NC
6.1	<ul style="list-style-type: none"> <li>▪ Organization Chart – Presence of Quality, R&amp;D, Operation &amp; MR</li> </ul>	▪	<input type="checkbox"/> Complied <input type="checkbox"/> Minor NC <input type="checkbox"/> Major NC
6.2	<ul style="list-style-type: none"> <li>▪ Procedure for Competence, Training and Awareness</li> <li>▪ Job descriptions</li> <li>▪ Position Skill Matrix</li> </ul>	▪	<input type="checkbox"/> Complied <input type="checkbox"/> Minor NC <input type="checkbox"/> Major NC
6.3	<ul style="list-style-type: none"> <li>▪ Procedure for infrastructure</li> <li>▪ Factory Floor with Personnel and Product Flow</li> <li>▪ Master Equipment List</li> <li>▪ Equipment Maintenance Schedule</li> <li>▪ Equipment Maintenance Work Instruction</li> </ul>	▪	<input type="checkbox"/> Complied <input type="checkbox"/> Minor NC <input type="checkbox"/> Major NC
6.4	<ul style="list-style-type: none"> <li>▪ Procedure to Monitor and Control the Work Environment</li> <li>▪ Humidity and Temperature Record Form</li> <li>▪ Pressure Differential Record Form</li> <li>▪ Clean Room Requirements</li> </ul>	▪	<input type="checkbox"/> Complied <input type="checkbox"/> Minor NC <input type="checkbox"/> Major NC

# D-722-2-3 INTERNAL AUDIT\_V1

Clause	Document Reviewed	Observation/Comment	Results
	<ul style="list-style-type: none"> <li>▪ Clean Maintenance Work Instruction and Record Form</li> <li>▪ Air Quality Maintenance Work Instruction and Record Form</li> <li>▪ Air Filter Maintenance Work Instruction and Record Form</li> <li>▪ Personnel Sanitary Work Instruction</li> <li>▪ Sterile Gown Changing Work Instruction</li> <li>▪ Daily Personnel Temperature Record Form</li> </ul>		
7.1	<ul style="list-style-type: none"> <li>▪ Procedure for Production Planning</li> <li>▪ Procedure for Risk Management Plan</li> <li>▪ Risk Management Plan, Report &amp; FMEA</li> </ul>	▪	<input type="checkbox"/> Complied <input type="checkbox"/> Minor NC <input type="checkbox"/> Major NC
7.2	<ul style="list-style-type: none"> <li>▪ Procedure for Customer-Related Process</li> </ul>	▪	<input type="checkbox"/> Complied <input type="checkbox"/> Minor NC <input type="checkbox"/> Major NC
7.3	<ul style="list-style-type: none"> <li>▪ Procedure for Design Control</li> <li>▪ Design History File</li> </ul>	▪	<input type="checkbox"/> Complied <input type="checkbox"/> Minor NC <input type="checkbox"/> Major NC
7.4.1	<ul style="list-style-type: none"> <li>▪ Procedure for Purchasing</li> <li>▪ Purchasing process</li> </ul>		<input type="checkbox"/> Complied <input type="checkbox"/> Minor NC <input type="checkbox"/> Major NC
7.4.2	<ul style="list-style-type: none"> <li>▪ Approved Product List</li> <li>▪ Approved Supplier List</li> <li>▪ Purchase Item Requirements</li> </ul>		<input type="checkbox"/> Complied <input type="checkbox"/> Minor NC <input type="checkbox"/> Major NC

# D-722-2-3 INTERNAL AUDIT\_V1

Clause	Document Reviewed	Observation/Comment	Results
7.4.3	<ul style="list-style-type: none"> <li>Incoming inspection Work Instructions and records</li> </ul>	▪	<input type="checkbox"/> Complied <input type="checkbox"/> Minor NC <input type="checkbox"/> Major NC
7.5.1	<ul style="list-style-type: none"> <li>Procedure for Production Control</li> </ul>	▪	<input type="checkbox"/> Complied <input type="checkbox"/> Minor NC <input type="checkbox"/> Major NC
7.5.2	<ul style="list-style-type: none"> <li>Product Cleanliness Requirements</li> </ul>	▪	<input type="checkbox"/> Complied <input type="checkbox"/> Minor NC <input type="checkbox"/> Major NC
7.5.3	<ul style="list-style-type: none"> <li>Product Installation Work Instruction</li> </ul>	▪	<input type="checkbox"/> Complied <input type="checkbox"/> Minor NC <input type="checkbox"/> Major NC
7.5.4	<ul style="list-style-type: none"> <li>Procedure for Servicing Activities</li> <li>Product Servicing Work Instruction</li> </ul>	▪	<input type="checkbox"/> Complied <input type="checkbox"/> Minor NC <input type="checkbox"/> Major NC
7.5.5	<ul style="list-style-type: none"> <li>Sterilization Process Parameter Record Form</li> </ul>	▪	<input type="checkbox"/> Complied <input type="checkbox"/> Minor NC <input type="checkbox"/> Major NC
7.5.6	<ul style="list-style-type: none"> <li>Procedure for Process Validation</li> <li>Process Validation Documentation for each special process</li> </ul>	▪	<input type="checkbox"/> Complied <input type="checkbox"/> Minor NC <input type="checkbox"/> Major NC
7.5.7	<ul style="list-style-type: none"> <li>Sterilization an packaging validation documents</li> </ul>	▪	<input type="checkbox"/> Complied <input type="checkbox"/> Minor NC <input type="checkbox"/> Major NC

# D-722-2-3 INTERNAL AUDIT\_V1

Clause	Document Reviewed	Observation/Comment	Results
7.5.8 7.5.9	<ul style="list-style-type: none"> <li>▪ Control of Production Identification and Traceability Procedure</li> <li>▪ Batch Record</li> <li>▪ Procedure for UDI</li> </ul>	▪	<input type="checkbox"/> Complied <input type="checkbox"/> Minor NC <input type="checkbox"/> Major NC
7.5.11	<ul style="list-style-type: none"> <li>▪ Procedure for Preservation of Product Conformity</li> <li>▪ Inventory Report</li> <li>▪ Warehouse environment control (based on product)</li> <li>▪ Transportation Validation Documents</li> </ul>	▪	<input type="checkbox"/> Complied <input type="checkbox"/> Minor NC <input type="checkbox"/> Major NC
7.6	<ul style="list-style-type: none"> <li>▪ Measuring Equipment List</li> <li>▪ Calibration Schedule and records</li> </ul>	▪	<input checked="" type="checkbox"/> Complied <input type="checkbox"/> Minor NC <input type="checkbox"/> Major NC
8.2.1	<ul style="list-style-type: none"> <li>▪ Procedure for Post Market Surveillance</li> <li>▪ PMS Plan/Report</li> <li>▪ Customer Satisfaction Form</li> </ul>	▪	<input type="checkbox"/> Complied <input type="checkbox"/> Minor NC <input type="checkbox"/> Major NC
8.2.2	<ul style="list-style-type: none"> <li>▪ Procedure for Complaint Handling</li> <li>▪ Customer Complaint Form</li> <li>▪ Complaint Retry</li> </ul>	▪	<input type="checkbox"/> Complied <input type="checkbox"/> Minor NC <input type="checkbox"/> Major NC
8.2.3	<ul style="list-style-type: none"> <li>▪ Procedure for Reporting to Health Authorities</li> <li>▪ Procedure for Issuing Advisory Authorities</li> <li>▪ Adverse Event Report Forms</li> </ul>	▪	<input type="checkbox"/> Complied <input type="checkbox"/> Minor NC <input type="checkbox"/> Major NC
8.2.4	<ul style="list-style-type: none"> <li>▪ Procedure for Internal Audit</li> <li>▪ Internal Audit Report</li> </ul>	▪	<input type="checkbox"/> Complied <input type="checkbox"/> Minor NC <input type="checkbox"/> Major NC

# D-722-2-3 INTERNAL AUDIT\_V1

Clause	Document Reviewed	Observation/Comment	Results
8.2.5	<ul style="list-style-type: none"><li>▪ Procedure for Process Control</li><li>▪ Process Validation Documents</li></ul>	▪	<input type="checkbox"/> Complied <input type="checkbox"/> Minor NC <input type="checkbox"/> Major NC
8.2.6	<ul style="list-style-type: none"><li>▪ Procedure for in-process inspection</li><li>▪ Procedure for final inspection</li><li>▪ Inspection Work Instructions and Records</li></ul>	▪	<input type="checkbox"/> Complied <input type="checkbox"/> Minor NC <input type="checkbox"/> Major NC
8.3	<ul style="list-style-type: none"><li>▪ Procedure for Non-conforming products</li><li>▪ Non-conformance reports and records</li></ul>	▪	<input type="checkbox"/> Complied <input type="checkbox"/> Minor NC <input type="checkbox"/> Major NC
8.3.3	<ul style="list-style-type: none"><li>▪ Procedure for Field Corrective Action</li><li>▪ Field Corrective Action Record</li></ul>	▪	<input type="checkbox"/> Complied <input type="checkbox"/> Minor NC <input type="checkbox"/> Major NC
8.4.0	<ul style="list-style-type: none"><li>▪ Procedure for Analysis of Data</li><li>▪ Data analysis plan and record</li></ul>	▪	<input type="checkbox"/> Complied <input type="checkbox"/> Minor NC <input type="checkbox"/> Major NC
8.5	<ul style="list-style-type: none"><li>▪ Procedure for CAPA</li><li>▪ CAPA forms and records</li></ul>	▪	<input type="checkbox"/> Complied <input type="checkbox"/> Minor NC <input type="checkbox"/> Major NC