

Referenced Procedure #	Procedure Name	Included Form#	Included Form Name	Referenced Documents NOT Included
P-423	Document Control	F-423-001	Master Document List	
		F-423-002	Software Inventory Spreadsheet	
		F-423-003	Document Change Request Form	
		F-423-004	Document Revision Checklist	
P-424	Control of Quality Records	F-424-001	Quality Records table	
P-500	Management Responsibility	F-500-001	QMS Measuring, Monitoring and Analysis Table	<i>Minutes of management review meetings</i>
		F-500-002	Key Process Master List	
		F-824-001	Product Realization Measuring, Monitoring and Analysis Table	
		F-560-001	Management Review Agenda	
		F-560-002	Management Review Checklist	
		A-500-001	Quality Policy	
		A-550-001	Organization Chart	
P-622	Competence, Awareness and Training	F-622-001	Action Plan For Training Form	<i>Employee resume or application with qualifications</i>
		F-622-002	Group Training Sign In	
		F-622-003	Job Description Form	
P-630	Infrastructure			<i>Preventive Maintenance Spreadsheet or database</i> <i>Preventive maintenance summaries</i>
		F-630-001	Equipment Problem Report	
		F-630-002	Equipment Maintenance Record	
P-640	Work Environment	None		<i>Instructions for control work environment conditions</i>
P-710	Planning of Product Realization Processes	F-710-001	Quality Planning table Form	
		F-700-005	Clause 7 Inclusion, Exclusion Worksheet	
		A-710-001	Process Flow Chart - example	
P-720	Customer Related Processes	F-720-001	Client Assessment Memo	<i>Order database</i> <i>Customer feedback spreadsheet</i> <i>Order forms</i> <i>Customer Inquiry Form</i>
P-722	Risk Management	F-722-001	Risk Management Plan	
		F-722-002	Risk List	
P-730	Design and Development	F-730-001	Design Plan	<i>Records of design outputs: specifications, manufacturing procedures, etc.</i>
		F-730-002	Design Review	<i>Records of Validation</i>
		F-730-003	Design Change Form	
		F-824-001	Product Realization Measuring, Monitoring and Analysis Table	
P-740	Purchasing	F-740-001	Supplier Quality Report	<i>Purchasing documents required for traceability</i>
		F-740-002	Supplier Corrective Action Request	<i>Records of verification of purchased product</i>
		F-740-003	Approved Subcontractor List	
		F-824-001	Product Realization Measuring, Monitoring and Analysis Table	
P-750	Control of Production and service Provision			<i>Batch Records</i> <i>Installation and Verification Records</i> <i>Sterilization Process Records</i>
		F-750-001	Process routing summary sheet	
		F-750-002	Process routing detail sheet	
		F-824-001	Product Realization Measuring, Monitoring and Analysis Table	
P-752	Validation of Processes for Product Realization	F-752-001	Process Validation Worksheet	<i>Records of validation</i>
		F-710-001	Quality Planning table Form	
P-753	Identification and Traceability	F-753-001	Traceability Serial Number Log	<i>Production traveler</i>
P-754	Customer Property	F-754-005	Customer Property Control Log	
P-755	Preservation of Property	F-755-001	Storage Inspection Report	
P-760	Control Of Monitoring and Measuring Devices	F-760-001	Equipment List	<i>Equipment Logs</i> <i>Calibration Certificates and Records</i>
P-820	Post Production Feedback (for ISO 13485 only)			<i>Customer Survey Records</i>
		F-821-001	Customer Satisfaction Survey and Analysis	
		F-852-001	Corrective/Preventive Action Request	
		P-424-001	Quality Records table	
P-821	Monitoring, Measuring and Analysis of Customer Satisfaction (for ISO 9001 only)	F-821-001	Customer Satisfaction Survey and Analysis	<i>Project records as identified by management</i>
P-822	Internal Audits	F-822-001	Internal Audit Plan	
		F-822-002	Internal Audit Report	
		F- 822-003	Applicable Procedures by Work Area	
		F- 822-004	Audit Checklist	
P-824	Monitoring and Measuring of Product Realization Processes	F-824-001	Product Realization Measuring, Monitoring and Analysis Table	<i>Records as identified on the Product Inspection and Process Monitoring Table</i>
P-830	Control of Non-Conforming Product			<i>Department Scrap Reports</i> <i>NCR forms</i> <i>Corrective and Preventive Action Requests</i>
		F-830-001	Rejected Material / Disposition Report - NCR	
		F-740-002	Supplier Corrective Action Request	
		F-852-001	Corrective/Preventive Action Request	
P-840	Statistical Techniques	Standard		<i>Standard SPC charts and forms</i>
P-841	Root Cause Analysis	F-841-001	F-841-001 Root Cause Analysis Action Plan	<i>Records that must be maintained. Add these records to the Quality Records Table.</i> <i>All reports generated through Root Cause Analysis proceedings</i> <i>All Associated Corrective Action / Preventive Action requests</i>
P-852	Corrective Action	F-852-001	Corrective/Preventive Action Request	
P-853	Preventive Action	F-852-001	Corrective/Preventive Action Request	
P-854	Product Recall and Advisory Notices			<i>List the forms that you have referred to above</i> <i>Records that must be maintained. Add these records to the Quality Records Table.</i> <i>Standard medical device reporting forms and instructions</i>
		Standard		