Referenced Procedure #	Procedure Name	Included Form#	Included Form Name	Referenced Documents NOT included
P-424	Document Control	F-424-001	Master Document List	
		F-424-002	Software Inventory Spreadsheet	
		F-424-003	Document Change Request Form	
		F-424-004	Document Revision Checklist	
P-425	Control of Quality Records	F-425-001	Quality Records table	
P-500	Management Responsibility	F-500-001	QMS Measuring, Monitoring and Analysis Table	Minutes of management review meetings
		F-500-002	Key Process Master List	
		F-542-001	QMS-Process identification worksheet	
		F-826-001	*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-620	Competence, Awareness and Training	F-620-001	Action Plan For Training Form	Employee resume or application with qualifications
		F-620-002	Group Training Sign In	
		F-620-003	Job Description Form	
P-630	Infrastructure			Preventive Maintenance Spreadsheet or database
				Preventive maintenance summaries
		F-630-001	Equipment Problem Report	
		F-630-002	Equipment Maintenance Record	
P-640	Work Environment and Contamination Control	*F-710-001*	*Quality planning table*	
		F-826-001	*Product Realization Measuring, Monitoring and Analysis Table*	
				Instructions for control of work environment and contamination
P-710	Planning of Product Realization Processes	F-710-001	Quality Planning table	
		F-700-005	Clause Inclusion, Exclusion Worksheet	
		A-710-001	Process Flow Chart - example	
P-720	Customer Related Processes	F-720-001	Client Assessment Memo	Order database
				Customer feedback spreadsheet
				Order forms
				Customer Inquiry Form
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	Records of design outputs: specifications, manufacturing procedures, etc.
		F-730-002	Design Review	Records of Validation
		F-730-003	Design Change Form	
		F-826-001	*Product Realization Measuring, Monitoring and Analysis Table*	
P-740	Purchasing	F-740-001	Supplier Quality Report	Purchasing documents required for traceability
		F-740-002	Supplier Corrective Action Request - SCAR	Records of verification of purchased product
		F-740-003	Approved Subcontractor List	
		F-826-001	*Product Realization Measuring, Monitoring and Analysis Table*	
P-750	Control of Production and service Provision			Batch Records
				Installation and Verification Records
				Sterilization Process Records
		F-750-001	Process routing summary sheet	
		F-750-002	Process routing detail sheet	
		F-542-001	QMS-Process identification worksheet	
		F-826-001	*Product Realization Measuring, Monitoring and Analysis Table*	
P-756	Validation of Processes for Product Realization	F-756-001	Process Validation Worksheet	Records of validation
		F-710-001	*Quality Planning table Form*	
P-758	Identification and Traceability	F-758-001	Traceability Serial Number Log	Production traveler
P-7510	Customer Property	F-7510-005	Customer Property Control Log	
P-7511	Preservation of Property	F-7511-001	Storage Inspection Report	
P-760	Control Of Monitoring and Measuring Devices	F-760-001	Equipment List	Equipment Logs
		F-424-002	*Software Inventory Spreadsheet*	
				Calibration Certificates and Records

Referenced Procedure #	Procedure Name	Included Form#	Included Form Name	Referenced Documents NOT included
P-820	Post Production Feedback			Customer Survey Records
		F-821-001	Customer Satisfaction Survey and Analysis	
		F-852-001	*Corrective/Preventive Action Request*	
		F-425-001	*Quality Records table*	
P-824	Internal Audits	F-824-001	Internal Audit Plan	
		F-824-002	Internal Audit Report	
		F-824-003	Applicable Procedures by Work Area	
		F-824-004	Audit Checklist	
P-826	Monitoring, Measuring and Analysis of Products and Processes	F-826-001	Product Realization Measuring, Monitoring and Analysis Table	Records as identified on the Product Inspection and Process Monitoring Table
P-830	Control of Non-Conforming Product			Department Scrap Reports
		F-830-001	Rejected Material / Disposition Report - NCR	NCR forms
				Corrective and Preventive Action Requests
		F-740-002	*Supplier Corrective Action Request*	
		F-852-001	*Corrective/Preventive Action Request*	
P-833	Advisory Notices and Product Recall	*F-852-001*	*Corrective/Preventive Action Request*	Standard reporting forms
P-840	Statistical Techniques	Standard		Standard SPC charts and forms
P-841	Root Cause Analysis	F-841-001	F-841-001 Root Cause Analysis Action Plan	Records that must be maintained. Add these records to the Quality Records Table.
				All reports generated through Root Cause Analysis proceedings
				All Associated Corrective Action / Preventive Action requests
P-852	Corrective Action	F-852-001	Corrective/Preventive Action Request	
P-853	Preventive Action	*F-852-001*	*Corrective/Preventive Action Request*	
				Records that must be maintained. Add these records to the Quality Records Table.
		Standard		Standard medical device reporting forms and instructions