ID	SYSTEM DOCUMENT DESCRIPTION	ISO 13485	QSR
QMSM	Quality Management System Manual (QMSM)	All	820.5
SECTION 4.0 QUALITY MANAGEMENT SYSTEM			
LIST 0001	Master List of Quality System Operating Procedures	4.2.2	-
LIST 0002	External Standards List	4.2.4	820.40
SOP 4-001	Engineering Change Notice (ECN) Procedure	4.2.4	820.40
SOP 4-002	Document Control Procedure	4.2.4	820.40
SOP 4-003	Record Retention Procedure	4.2.5	820.180
SOP 4-004	External Standards Procedure	4.2.4	820.40
SOP 4-005	Good Documentation Practices	-	-
SOP 4-006	Specification Format Procedure	4.2.1	820.181
SOP 4-007	Device Master Record	4.2.3	820.181
SECTION 5.0 MANAGEMENT RESPONSIBILITY			
SOP 5-001	Management Review Procedure	5.6.1, 5.6.2, 5.6.3, 6.1, 8.5	820.20
SOP 5-002	Organization, Responsibilities, and Authority	5.5.1, 5.5.2	820.20
SECTION 6.0 RESOURCE MANAGEMENT			
SOP 6-001	Training & Job description Procedure	6.1, 6.2	820.25
SOP 6-005	Controlled Environment Gowning	6.4.1, 6.4.2	820.70
SOP 7-013	Environmental Controls Procedure	6.4, 7.5.1, 7.5.2	820.70
SOP 7-016	Preventive Maintenance Procedure	6.3, 7.5.1	820.70
SOP 7-018	Controlled Environment Cleaning Procedure	6.4, 7.5.1, 7.5.2	820.70
SECTION 7.0 PRODUCT REALIZATION			
LIST 0004	Approved Supplier List	7.4.1, 7.5.1	820.50
SOP 7-001	Design Control Procedure	7.3.1-7.3.8	820.30
SOP 7-002	Design Review Procedure	7.3.1-7.3.7	820.30
SOP 7-003	Risk Management Procedure	7.3.1-7.3.9, 8.2.1	820.30
SOP 7-004	Contract Review Procedure	7.2.1, 7.2.2, 7.2.3	820.30
SOP 7-005	Purchase Order Procedure	7.4.1, 7.4.2, 7.4.3	820.50
SOP 7-006	Supplier Management Procedure	7.4.1, 7.5.1	820.50

ID	SYSTEM DOCUMENT DESCRIPTION	ISO 13485	QSR
SOP 7-007	Identification Procedure	7.5.8	820.60
SOP 7-008	Receiving Procedure	7.5.8	820.60
SOP 7-009	Calibration System Procedure	7.6	820.72
SOP 7-010	Finished Goods Shipping Procedure	7.5.1, 7.5.8	820.160
SOP 7-011	Lot Inspection Procedure	7.5.8	820.60
SOP 7-012	Process Validation Procedure	7.5.6	820.75
SOP 7-014	Installation Qualification Procedure	7.5.1, 7.5.6	820.70
SOP 7-015	Protocols and Reports Procedure	7.5.6	820.75
SOP 7-017	First Article Inspection Procedure	7.4.3	820.80
SOP 7-019	Device History Record Procedure	4.2.5, 7.5.8, 7.5.9	820.184
SOP 7-020	Line Clearance Procedure	7.5.1	820.70
SOP 7-021	Design Transfer Procedure	7.3.8	820.30
SOP 7-022	Design Change Procedure	7.3.9	820.30
SOP 7-023	Sterile Load Preparation and Release	7.5.1, 7.5.5, 7.5.9	820.70
SOP 7-025	Returned Goods Procedure	7.5.8	820.60
SOP 7-026	Product Stability (Shelf Life) Procedure	7.3	820.30
SOP 7-027	Labeling Review and Approval Procedure	7.3	820.120
SOP 7-028	Product Performance Specifications	7.3	820.30
SOP 7-029	Design Verification and Validation Procedure	7.3.7	820.30
SOP 7-030	Design Risk Management Procedure	7.3, 8.2.1	820.30
SOP 7-031	Process Risk Management Procedure	7.3, 8.2.1	820.30
SOP 7-032	Design Analysis Procedure	7.3, 8.2.1	820.30
SOP 7-033	Software Validation Procedure	7.5.6	820.75
SOP 7-034	Biocompatibility and Toxicity Testing Procedure	7.3, 7.5.1, 7.5.2	820.75
SOP 7-035	Ethylene Oxide Sterilization Validation Procedure	7.5.6, 7.5.7	820.75
SOP 7-036	Gamma Irradiation Validation and Monitoring	7.5.6, 7.5.7	820.75
SOP 7-037	Unique Device Identification (UDI) Procedure	7.3.3	820.120
SOP 7-040	CE Marking Procedure	4.2.3, 7.3.10	-

ID	SYSTEM DOCUMENT DESCRIPTION	ISO 13485	QSR
SOP 7-046	Customer Requirements Validation Procedure	7.3.1-7.3.8	820.30
SECTION 8.0 MEASUREMENT, ANALYSIS AND IMPROVEMENT			
SOP 8-001	Complaint Handling Procedure	8.2.1, 8.2.2, 8.2.3	820.198
SOP 8-002	Complaint Trending Procedure	8.2.1, 8.2.2, 8.2.3	820.198
SOP 8-003	Remedial Action / Recall Procedure	8.2.3	820.198
SOP 8-004	Corrective and Preventive Action System	8.5.2, 8.5.3	820.100
SOP 8-005	Internal Audit Procedure	8.2.4	820.22
SOP 8-006	Medical Device Reports (MDR) Procedure	-	QSR
SOP 8-007	Statistical Techniques Procedure	8.4	820.250
SOP 8-008	Non-Conforming Material System Procedure	8.3	820.90
SOP 8-010	Product Hold Procedure	8.3	820.90
SOP 8-012	Post-Market Surveillance	MDR, 8.2.1, 8.2.3	820.198
SOP 8-014	Failure Investigation Procedure	8.2.1, 8.2.2, 8.2.3	820.198

ISO 13485 SECTION / APPLICABLE REGULATION		DOCUMENT / SOP
4.0 Quality Management System [title only]		
4.1	General requirements	QMSM
4.2	Documentation requirements [title only]	[title only]
4.2.1	General	QMSM
4.2.2	Quality Manual	QMSM, LIST 0001
4.2.3	Medical Device File	SOP 4-007
4.2.4	Control of documents	QMSM, LIST 0002, SOP 4-001, SOP 4-002, SOP 4-004
4.2.5	Control of quality records	QMSM, SOP 4-003, SOP 4-005, SOP 7-019
5.0 Management Responsibility [title only]		
5.1	Management commitment	QMSM, SOP 6-001
5.2	Customer focus	QMSM
5.3	Quality policy	QMSM
5.4	Planning [title only]	[title only]
5.4.1	Quality objectives	QMSM, [PROCEDURE NOT INCLUDED]
5.4.2	Quality planning	QMSM, [PROCEDURE NOT INCLUDED]
5.5	Responsibilities, Authority and Communication [title only]	[title only]
5.5.1	Responsibility and authority	QMSM, SOP 5-002, ORG CHART
5.5.2	Management representative	QMSM, SOP 5-001, SOP 5-002
5.5.3	Internal communication	QMSM
5.6	Management Review [title only]	[title only]
5.6.1	General	QMSM, SOP 5-001
5.6.2	Review input	QMSM, SOP 5-001
5.6.2	Review output	QMSM, SOP 5-001
6.0 Resource Management [title only]		
6.1	Provision of resources	QMSM, SOP 5-001
6.2	Human resources [title only]	[title only]
6.2.1	General	QMSM, SOP 6-001

6.2.2	Competence, Awareness and Training	QMSM, SOP 6-001
6.3	Infrastructure	QMSM, SOP 7-016
6.4	Work environment and contamination control	QMSM, SOP 6-002, SOP 6-003, SOP 6-004, SOP 6-005, SOP 7-013, SOP 7-018
7.0 Product Realization [title only]		
7.1	Planning of product realization	QMSM, SOP 7-001, SOP 7-002, SOP 7-003, SOP 7-028
7.2	Customer related processes [title only]	[title only]
7.2.1	Determination of requirements related to the product	QMSM, SOP 7-001, SOP 7-002, SOP 7-004, SOP 7-027, SOP 7-040
7.2.2	Review of requirements related to the product	QMSM, SOP 7-004
7.2.3	Customer communication	QMSM, SOP 7-004, SOP 7-046, SOP 8-001, SOP 8-003, SOP 8-010, SOP 8-012, SOP 8-014
7.3	Design and Development [title only]	[title only]
7.3.1	General	QMSM
7.3.2	Design and development planning	QMSM, SOP 7-001
7.3.3	Design and development inputs	QMSM, SOP 7-001, SOP 7-003
7.3.4	Design and development outputs	QMSM, SOP 7-001
7.3.5	Design and development review	QMSM, SOP 7-001, SOP 7-002
7.3.6	Design and development verification	QMSM, SOP 7-029
7.3.7	Design and development validation	QMSM, SOP 7-029
7.3.8	Design and development transfer	QMSM, SOP 7-021
7.3.9	Control of design and development changes	QMSM, SOP 4-001, SOP 4-002, SOP 7-001, SOP 7-022
7.3.10	Design and development files	QMSM, SOP 7-001
7.4	Purchasing [title only]	[title only]
7.4.1	Purchasing process	QMSM, LIST 0004, SOP 7-006
7.4.2	Purchasing information	QMSM, LIST 0004, SOP 7-005
7.4.3	Verification of purchased product	QMSM, SOP 7-005, SOP 7-008, SOP 7-011, SOP 7-012, SOP 7-017, SOP 7-023, SOP 7-034, SOP 7-035, SOP 7-036, SOP 8-007
7.5	Production and service provision [title only]	[title only]

7.5.1	Control of production and service provision	QMSM, SOP 7-006, SOP 7-007, SOP 7-009, SOP 7-011, SOP 7-012, SOP 7-019, SOP 7-020, SOP 7-023, SOP 7-034, SOP 8-007
7.5.2	Cleanliness of product	QMSM, SOP 7-001, SOP 7-003
7.5.3	Installation activities	QMSM, [PROCEDURE NOT INCLUDED]
7.5.4	Servicing activities	QMSM, [PROCEDURE NOT INCLUDED]
7.5.5	Particular requirements for medical devices	QMSM, SOP 7-005, SOP 7-019, SOP 7-023
7.5.6	Validation of processes for production and service provision	QMSM, SOP 7-012, SOP 7-014, SOP 7-015, SOP 7-033, SOP 7-035, SOP 7-036, SOP 8-007
7.5.7	Particular requirements for validation of process for sterilization and sterile barrier systems	QMSM, SOP 7-013, SOP 7-026, SOP 7-034, SOP 7-035, SOP 7-036
7.5.8	Identification	QMSM, SOP 7-007
7.5.9	Traceability [title only]	[title only]
7.5.9.1	Traceability general	QMSM, SOP 7-004, SOP 7-007, SOP 7-008, SOP 7-010, SOP 7-011, SOP 7-019, SOP 7-023, SOP 8-008
7.5.9.2	Particular requirements for active medical devices and implantable medical devices	QMSM, SOP 7-004, SOP 7-011, SOP 7-013, SOP 7-018, SOP 7-019
7.5.10	Customer property	QMSM, [PROCEDURE NOT INCLUDED]
7.5.11	Preservation of product	QMSM, SOP 7-001, SOP 7-010, SOP 7-013 [MAY REQUIRE ADDITIONAL PRODUCT SPECIFIC PROCEDURE]
7.6	Control of monitoring and measurement devices	QMSM, SOP 7-009
8.0 Measurement, Analysis and Improvement [title only]		
8.1	General	QMSM, SOP 8-007
8.2	Monitoring and feedback [title only]	[title only]
8.2.1	Feedback	QMSM, SOP 7-003, SOP 8-012
8.2.2	Complaint handling	QMSM, SOP 8-001, SOP 8-002
8.2.3	Reporting to regulatory authorities	QMSM, SOP 8-003, SOP 8-006, SOP 8-009, SOP 8-013
8.2.4	Internal audit	QMSM, SOP 8-005
8.2.5	Monitoring and measurement of processes	QMSM, SOP 5-001, SOP 7-011, SOP 7-012, SOP 8-004, SOP 8-005, SOP 8-007
8.2.6	Monitoring and measurement of product	QMSM, SOP 7-001, SOP 7-002, SOP 7-011, SOP 7-021, SOP 7-029,

8.3	Control of nonconforming product	QMSM, SOP 8-008
8.4	Analysis of data	QMSM, SOP 8-007
8.5	Improvement [title only]	[title only]
8.5.1	General	QMSM, SOP 8-001, SOP 8-002, SOP 8-003
8.5.2	Corrective action	QMSM, SOP 8-004
8.5.3	Preventive action	QMSM, SOP 8-004