



LIST
Master Quality System List

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ECN #: 2017-138
Effective: 09/05/17

LIST 0001

Revision: 1

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	-
<u>SOP 4-001</u>	Engineering Change Notice (ECN) Procedure	4.2.4	820.40
<u>SOP 4-002</u>	Document Control Procedure	4.2.4	820.40
SECTION 5.0 MANAGEMENT RESPONSIBILITY			
<u>SOP 5-001</u>	Management Review Procedure	5.6.1, 5.6.2, 5.6.3, 6.1, 8.5	820.20
SECTION 6.0 RESOURCE MANAGEMENT			
<u>SOP 6-001</u>	Training & Job description Procedure	6.1, 6.2	820.25
SECTION 7.0 PRODUCT REALIZATION			
<u>SOP 7-001</u>	Design Control Procedure	7.3.1-7.3.8	820.30
<u>SOP 7-002</u>	Design Review Procedure	7.3.1-7.3.7	820.30
<u>SOP 7-003</u>	Risk Management Procedure	7.3.1-7.3.9, 8.2.1	820.30
<u>SOP 7-012</u>	Process Validation Procedure	7.5.6	820.75
<u>SOP 7-015</u>	Protocols and Reports Procedure	7.5.6	820.75
<u>SOP 7-021</u>	Design Transfer Procedure	7.3.8	820.30
<u>SOP 7-022</u>	Design Change Procedure	7.3.9	820.30
<u>SOP 7-026</u>	Product Stability (Shelf Life) Procedure	7.3	820.30
<u>SOP 7-027</u>	Labeling Review and Approval Procedure	7.3	820.120
<u>SOP 7-028</u>	Product Performance Specifications	7.3	820.30
<u>SOP 7-029</u>	Design Verification and Validation Procedure	7.3.7	820.30
<u>SOP 7-030</u>	Design Risk Management Procedure	7.3, 8.2.1	820.30
<u>SOP 7-031</u>	Process Risk Management Procedure	7.3, 8.2.1	820.30
<u>SOP 7-032</u>	Design Analysis Procedure	7.3, 8.2.1	820.30
<u>SOP 7-034</u>	Biocompatibility and Toxicity Testing Procedure	7.3, 7.5.1, 7.5.2	820.75
<u>SOP 7-037</u>	Unique Device Identification (UDI) Procedure	7.3.3	820.120
<u>SOP 7-038</u>	Clinical Evaluations Procedure	MDR, 8.2, 8.2.3	820.30
<u>SOP 7-039</u>	Clinical Investigation Procedure	MDR, 8.2,8.2.3	820.30



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SOP 7-040	CE Marking Procedure	4.2.3, 7.3.10	-
SOP 7-042	Human Factors and Usability Engineering Procedure	7.3.1-7.3.8	820.30
SOP 7-046	Customer Requirements Validation	7.3.1-7.3.8	820.30
SECTION 8.0 MEASUREMENT, ANALYSIS AND IMPROVEMENT			
SOP 8-007	Statistical Techniques Procedure	8.4	820.250