



LIST
Master Quality System List

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ECN #: 2018-008
Effective: 03/24/18

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
<u>SOP 7-016</u>	Preventive Maintenance Procedure	6.3, 7.5.1	820.70
SECTION 7.0 PRODUCT REALIZATION			
LIST 0004	Approved Supplier List	7.4.1, 7.5.1	820.50
<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 7-006</u>	Supplier Management Procedure	7.4.1, 7.5.1	820.50
<u>SOP 7-009</u>	Calibration System Procedure	7.6	820.72
<u>SOP 7-011</u>	Lot Inspection Procedure	7.5.8	820.60
<u>SOP 7-012</u>	Process Validation Procedure	7.5.6	820.75
<u>SOP 7-014</u>	Installation Qualification Procedure	7.5.1, 7.5.6	820.70
<u>SOP 7-019</u>	Device History Record Procedure	4.2.5, 7.5.8, 7.5.9	820.184
<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 7-029</u>	Design Verification and Validation Procedure	7.3.7	820.30
<u>SOP 7-032</u>	Design Analysis Procedure	7.3, 8.2.1	820.30
SECTION 8.0 MEASUREMENT, ANALYSIS AND IMPROVEMENT			
<u>SOP 8-001</u>	Complaint Handling Procedure	8.2.1, 8.2.2, 8.2.3	820.198
<u>SOP 8-002</u>	Complaint Trending Procedure	8.2.1, 8.2.2, 8.2.3	820.198



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<u>SOP 8-004</u>	Corrective and Preventive Action System	8.5.2, 8.5.3	820.100
<u>SOP 8-007</u>	Statistical Techniques Procedure	8.4	820.250
<u>SOP 8-008</u>	Non-Conforming Material System Procedure	8.3	820.90