



LIST  
Master Quality System List

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ECN #: 2020-0198  
Effective: 06/04/20

LIST 0001

Revision: 1

ID	SYSTEM DOCUMENT DESCRIPTION	ISO 13485	QSR
QMSM	Quality Management System Manual (QMSM)	All	820.5
<b>SECTION 4.0 QUALITY MANAGEMENT SYSTEM</b>			
LIST 0001	Master List of Quality System Operating Procedures	4.2.2	-
<a href="#">SOP 4-001</a>	Engineering Change Notice (ECN) Procedure	4.2.4	820.40
<a href="#">SOP 4-002</a>	Document Control Procedure	4.2.4	820.40
<b>SECTION 5.0 MANAGEMENT RESPONSIBILITY</b>			
<a href="#">SOP 5-001</a>	Management Review Procedure	5.6.1, 5.6.2, 5.6.3, 6.1, 8.5	820.20
<b>SECTION 6.0 RESOURCE MANAGEMENT</b>			
<a href="#">SOP 6-001</a>	Training & Job description Procedure	6.1, 6.2	820.25
<a href="#">SOP 7-016</a>	Preventive Maintenance Procedure	6.3, 7.5.1	820.70
<b>SECTION 7.0 PRODUCT REALIZATION</b>			
LIST 0004	Approved Supplier List	7.4.1, 7.5.1	820.50
<a href="#">SOP 7-001</a>	Design Control Procedure	7.3.1-7.3.8	820.30
<a href="#">SOP 7-002</a>	Design Review Procedure	7.3.1-7.3.7	820.30
<a href="#">SOP 7-003</a>	Risk Management Procedure	7.3.1-7.3.9, 8.2.1	820.30
<a href="#">SOP 7-006</a>	Supplier Management Procedure	7.4.1, 7.5.1	820.50
<a href="#">SOP 7-009</a>	Calibration System Procedure	7.6	820.72
<a href="#">SOP 7-011</a>	Lot Inspection Procedure	7.5.8	820.60
<a href="#">SOP 7-012</a>	Process Validation Procedure	7.5.6	820.75
<a href="#">SOP 7-014</a>	Installation Qualification Procedure	7.5.1, 7.5.6	820.70
<a href="#">SOP 7-019</a>	Device History Record Procedure	4.2.5, 7.5.8, 7.5.9	820.184
<a href="#">SOP 7-021</a>	Design Transfer Procedure	7.3.8	820.30
<a href="#">SOP 7-022</a>	Design Change Procedure	7.3.9	820.30
<a href="#">SOP 7-029</a>	Design Verification and Validation Procedure	7.3.7	820.30
<a href="#">SOP 7-032</a>	Design Analysis Procedure	7.3, 8.2.1	820.30
<b>SECTION 8.0 MEASUREMENT, ANALYSIS AND IMPROVEMENT</b>			
<a href="#">SOP 8-001</a>	Complaint Handling Procedure	8.2.1, 8.2.2, 8.2.3	820.198
<a href="#">SOP 8-002</a>	Complaint Trending Procedure	8.2.1, 8.2.2, 8.2.3	820.198



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