



**LIST**  
**Master Quality System List**

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ECN #: 2020-0288  
Effective: 06/05/20

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>			
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<u>SOP 4-002</u>	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
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SOP 4-006	Specification Format Procedure	4.2.1	820.181
SOP 4-007	Device Master Record	4.2.3	820.181
<b>SECTION 5.0 MANAGEMENT RESPONSIBILITY</b>			
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<b>SECTION 6.0 RESOURCE MANAGEMENT</b>			
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<u>SOP 7-013</u>	Environmental Controls Procedure	6.4, 7.5.1, 7.5.2	820.70
<u>SOP 7-016</u>	Preventive Maintenance Procedure	6.3, 7.5.1	820.70
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<b>ID</b>	<b>SYSTEM DOCUMENT DESCRIPTION</b>	<b>ISO 13485</b>	<b>QSR</b>
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<a href="#"><u>SOP 7-012</u></a>	Process Validation Procedure	7.5.6	820.75
<a href="#"><u>SOP 7-014</u></a>	Installation Qualification Procedure	7.5.1, 7.5.6	820.70
<a href="#"><u>SOP 7-019</u></a>	Device History Record Procedure	4.2.5, 7.5.8, 7.5.9	820.184
<a href="#"><u>SOP 7-021</u></a>	Design Transfer Procedure	7.3.8	820.30
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<a href="#"><u>SOP 7-023</u></a>	Sterile Load Preparation and Release	7.5.1, 7.5.5, 7.5.9	820.70
<a href="#"><u>SOP 7-027</u></a>	Labeling Review and Approval Procedure	7.3	820.120
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