Blue Text = This Clause Has Additional Requirements for ISO 13485 Beyond ISO 9001

ISO 9001	ISO 13485
1. SCOPE	1. SCOPE
1.1 General	1.1 General
1.2 Application	1.2 Application
2 Normative references	2 Normative references
ISO 9000:2005	ISO 9000:2005
3 Terms and definitions	3 Terms and definitions
	3.1 Active Implantable Medical Device
	3.2 Active Medical Device
	3.3 Advisory Notice
	3.4 Customer Complaint
	3.5 Implantable Medical Device
	3.6 Labeling
	3.7 Medical Device
	3.8 Sterile Medical Device
4 Quality management system	4 Quality management system
4.1 General requirements	**4.1 General requirements**
4.2 Documentation requirements	4.2 Documentation requirements
4.2.1 General	**4.2.1 General**
4.2.2 Quality Manual	**4.2.2 Quality Manual**
4.2.3 Control of Documents	**4.2.3 Control of Documents**
4.2.4 Control of Records	**4.2.4 Control of Records**
5 MANAGEMENT RESPONSIBILITY	5 Management responsibility
5.1 Management commitment	**5.1 Management commitment**
5.2 Customer focus	**5.2 Customer focus**
5.3 Quality policy	**5.3 Quality policy**
5.4 Planning	5.4 Planning
5.4.1 Quality Objectives	
5.4.2 Quality Management System Planning	
5.5 Responsibility, authority and communication	5.5 Responsibility, authority and communication
5.5.1 Responsibility and Authority	**5.5.1 Responsibility and Authority**
5.5.2 Management Representative	**5.5.2 Management Representative**
5.5.3 Internal Communication	5.5.3 Internal Communication
5.6 Management Review	5.6 Management Review
5.6.1 General	5.6.1 General
5.6.2 Review Input	**5.6.2 Review Input**
5.6.3 Review Output	**5.6.3 Review Output**
6 Resource management	6 Resource management
6.1 Provision of resources	**6.1 Provision of resources**
6.2 Human resources	6.2 Human resources
6.2.1 General	6.2.1 General
6.2.2 Competence, Training and Awareness	6.2.2 Competence, Training and Awareness
6.3 Infrastructure	**6.3 Infrastructure**
6.4 Work environment	**6.4 Work environment**
7 Product realization	7 Product realization
7.1 Planning of product realization	**7.1 Planning of product realization ISO 14971)**
7.2 Customer-related processes	7.2 Customer-related processes
7.2.1 Determination of requirements related to the product	7.2.1 Determination of requirements related to the product
7.2.2 Review of requirements related to the product	**7.2.2 Review of requirements related to the product**
7.2.3 Customer Communication	**7.2.3 Customer Communication**
7.3 Design and development	7.3 Design and development
7.3.1 Design and Development Planning	**7.3.1 Design and Development Planning**
7.3.2 Design and Development Inputs	**7.3.2 Design and Development Inputs**
7.3.3 Design and Development Outputs	**7.3.3 Design and Development Outputs**
7.3.4 Design and Development Review	**7.3.4 Design and Development Review**
7.3.5 Design and Development Verification	7.3.5 Design and Development Verification
7.3.6 Design and Development Validation	**7.3.6 Design and Development Validation**
7.3.7 Control of Design and Development Changes	7.3.7 Control of Design and Development Changes
7.4 Purchasing	7.4 Purchasing
7.4.1 Purchasing Process	**7.4.1 Purchasing Process**
7.4.2 Purchasing Information	**7.4.2 Purchasing Information**
7.4.3 Verification of Purchased Product	**7.4.3 Verification of Purchased Product**
7.5 Production and service provision	7.5 Production and service provision

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ISO 9001	ISO 13485
7.5.1 Control of Production and Service Provision	7.5.1 Control of Production and Service Provision
	7.5.1.1 General Requirements
	7.5.1.2 Control of Product & Service Provision
	7.5.1.2.1 cleanliness of Product & Contamination Control
	7.5.1.2.2 Installation Activities
	7.5.1.2.3 Servicing Activities
	7.5.1.3 Sterile Medical Device Requirements
7.5.2 Validation of Processes for Production and Service Provision	7.5.2 Validation of Processes for Production and Service Provision
	7.5.2.1 General Requirements
	7.5.2.2 Sterile Medical Device Requirements
7.5.3 Identification and Traceability	7.5.3 Identification and Traceability
	7.5.3.1 Identification
	7.5.3.2 Traceability
	7.5.3.2.1 General (Consider Configuration Management)
	7.5.3.2.2 Implantable Medical Device Requirements
	7.5.3.3 Status Identification
7.5.4 Customer Property	7.5.4 Customer Property (Can Include IP)
7.5.5 Preservation of Product	**7.5.5 Preservation of Product**
7.6 Control of monitoring and measuring Equipment	**7.6 Control of monitoring and measuring Equipment (Use ISO 10012)**
8 Measurement, analysis and improvement	8 Measurement, analysis and improvement
8.1 General	8.1 General
8.2 Monitoring and measurement	8.2 Monitoring and measurement
8.2.1 Customer Satisfaction	**8.2.1 Feedback**
8.2.2 Internal Audit	8.2.2 Internal Audit (See ISO 19011)
8.2.3 Monitoring and Measurement of Processes	8.2.3 Monitoring and Measurement of Processes
8.2.4 Monitoring and Measurement of Product	8.2.4 Monitoring and Measurement of Product
	8.2.4.1 General Requirements
	8.2.4.2 Implantable Medical Device Requirements
8.3 Control of nonconforming product	**8.3 Control of nonconforming product**
8.4 Analysis of data	**8.4 Analysis of data**
8.5 Improvement	8.5 Improvement
8.5.1 Continual Improvement	**8.5.1 General**
8.5.2 Corrective Action	**8.5.2 Corrective Action**
8.5.3 Preventive Action	**8.5.3 Preventive Action**