Table 2: ISO9001:2015 VS. ISO13485:2016 Requirements

ISO 9001:2015 Requirements	ISO13485:2016 Requirements
1. Scope	1. Scope
4. Context of the organization	4. Quality Management System
4.1 Understanding the organization and its context	4.1 General Requirements
4.2 Understanding the need and expectations of interested parties	4.1 General Requirements
4.3 Determining the scope of the quality management system	4.1 General Requirements 4.2 Quality Manual
4.4 Quality Management system and its processes	4.1 General Requirements
5. Leadership	5. Management Commitment
5.1 Leadership and commitment	5.1 Management Commitment
5.1.1 General	5.1 Management Commitment
5.1.2 Customer focus	5.2 Customer Focus
5.2 Policy	5.3 Quality Policy
5.2.1 Establishing the quality policy	5.3 Quality Policy
5.2.2 Communicating the quality policy	5.3 Quality Policy
5.3 Organization roles, responsibilities and authorities	5.4.2 Quality Management System Planning 5.5.1 Responsibility and authority 5.5.2 Management representative
6. Planning	5.4.2 Quality management system planning
6.1 Actions to address risks and opportunities	5.4.2 Quality management system planning 5.5.4 Preventive action
6.2 Quality objectives and planning to achieve them	5.4.1 Quality objectives
6.3 Planning of changes	5.4.2 Quality management system planning
7.Support	6. Resource Management
7.1 Resources	6. Resource Management
7.1.1 General	6.1 Provision of resources
7.1.2 People	6.2 Human resources
7.1.3 Infrastructure	6.3 Infrastructure
7.1.4 Environment for the operation of processes	6.4.1 Work environment
7.1.5 Monitoring and measuring resources	7.6 Control of monitoring and measuring equipment
7.1.6 Organization knowledge	6.2 Human resources
7.2 Competence	6.2 Human resources
7.3 Awareness	6.2 Human resources
7,4 Communication	5.5.3 Internal communication
7,5 Documented information	4.2 Documentation requirements
7.5.1 General	4.2.1 General
7.5.2 Creating and updating	4.2.4 Control of documents 4.2.5 Control of records

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ISO 9001:2015 Requirements	ISO 13485:2016 Requirements
7.5.3 Control of documented information	4.2.3 Medical device file 4.2.4 Control of documents 4.2.5 Control of records 7.3.10 Design and development files
8. Operation	7. Product realization
8.1 Operational Planning and control	7.1 Planning of product realization
8.2 Requirements for products and services	7.2 Customer-related processes
8.2.1 Customer communication	7.2.3 Communication
8.2.2 Determining the requirements for products and services	7.2.1 Determination of requirements related to product
8.2.3 Review of the requirements for products and services	7.2.2 Review of requirements related to product
8.2.4 Changes to requirements for products and services	7.2.2 Review of requirements related to product
8.3 Design and development of products and services	7.3 Design and development
8.3.1 General	7.3.1 General
8.3.2 Design and development planning	7.3.2 Design and development planning
8.3.3 Design and development inputs	7.3.3 Design and development Inputs
8.3.4 Design and development controls	7.3.5 Design and development review 7.3.6 Design and development verification 7.3.7 Design and development validation 7.3.8 Design and development transfer
8.3.5 Design and development outputs	7.3.4 Design and development outputs
8.3.6 Design and development changes	7.3.9 Design and development changes
8.4 Control of externally provided processes, products and services	4.1 General requirements (see 4.1.5) 7.4.1 Purchasing process
8.4.1 General	7.4.1 Purchasing process
8.4.2 Type and extent of control	4.1 General requirements (see 4.1.5) 7.4.1 Purchasing process 7.4.3 Verification of purchased product
8.4.3 Information for external providers	7.4.2 Purchasing information 7.4.3 Verification of purchased product
8.5 Production and services provision	7.5 Production and service provision
8.5.1 Control of production and services provision	7.5.1 Control of production and service
8.5.2 Identification and traceability	7.5.8 Identification 7.5.9 Traceability
8.5.3 Property belonging to customers or external providers	7.5.10 Customer property
8.5.4 Preservation	7.5.11 Preservation of product

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ISO 9001:2015 Requirements	ISO 13485:2016 Requirements
8.5.5 Post-delivery activities	7.5.1 Control of production and service 7.5.3 Installation activities 7.5.4 Service Activities 8.2.2 Complaint handling 8.2.3 Reporting to regulatory authorities 8.3.3 Actions in response to nonconforming product detected after delivery
8.5.6 Control of changes	7.4.9 Control of design and development changes
8.6 Release of products and services	7.4.3 Verification of purchased product 8.2.6 Monitoring and measurement of product
8.7 Control of nonconforming outputs	8.3 Control of nonconforming product
9 Performance evaluation	8. Measurement, analysis and improvement
9.1 Monitoring, measurement, analysis and evaluation	8. Measurement, analysis and improvement
9.1.1 General	8.1 General 8.2.5 Monitoring and measurement of processes 8.2.6 Monitoring and measurement of product
9.1.2 Customer satisfaction	7.2.3 Communication 8.2.1 Feedback 8.2.2 Complaint handling
9.1.3 Analysis and evaluation	8.4 Analysis of data
9.2 Internal Audit	8.2.4 Internal audit
9.3 Management review	5.6 Management review
9.3.1 general	5.6.1 General
9.3.2 Management review inputs	5.6.2 Review input
9.3.3 Management review outputs	5.6.3 Review output
10 Improvement	8.5 Improvement
10.1 General	8.5.1 General
10.2 Nonconformity and corrective action	8.3 Control of nonconforming product 8.5.2 Corrective action
10.3 Continual improvement	5.6.1 General 8.5 Improvement
Annex A (informative) Clarification of new structure, terminology and concepts.	
Annex B (informative) Other International Standards on quality management and quality management systems developed by ISO/TC 176.	
Bibliography	