ISO 9001:2015		ISO 13485:2016	
	Introduction		Introduction
0.1	General		
0.2	Quality management principles		
0.3	Process approach		
0.3.1	General		
0.3.2	Plan-Do-Check-Act cycle		
0.3.3	Risk-based thinking		
0.4	Relationship with other management standards		
1	Scope	1	Scope
2	Normative references	2	Normative references
3	Terms and definitions	3	Terms and definitions
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 needs and expectations of interested parties		
4.3	Determining the scope of the quality management system		
4.4	Quality management system and its processes		
4.4.1	.. Establish, implement, maintain and continually improve ..		
4.4.2	.. Maintain documented information ..		
5	**Leadership**	**5**	**Management Responsibility**
5.1	Leadership and commitment	5.1	Management commitment
5.1.1	General		
5.1.2	Customer focus	5.2	Customer focus
5.2	Policy	5.3	Quality policy
5.2.1	Establishing the quality policy		
5.2.2	Communicating the quality policy		
5.3	Organizational roles, responsibilities and authorities	5.5	Responsibility, authority and communication
		5.5.1	Responsibility and authority
		5.5.2	Management representative
6	**Planning**	**5.4**	**Planning**
		5.4.2	Quality management system planning
6.1	Actions to address risks and opportunities		
6.1.1	.. Consider issues of 4.1 and requirements of 4.2 ..		
6.1.2	.. Actions to address risks and opportunities		
6.2	Quality objectives and planning to achieve them	5.4.1	Quality objectives
6.2.1	.. Quality objectives at relevant functions ..		
6.2.2	.. Determine what, who, when, how ..		
6.3	Planning of changes		
7	**Support**	**6**	**Resource Management**
7.1	Resources	6.1	Provision of resources
7.1.1	General		
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
		6.4	Work environment and contamination control
		6.4.2	Contamination control
7.1.5	Monitoring and measuring resources	7.6	Control of monitoring and measuring equipment
7.1.5.1	General		
7.1.5.2	Measurement traceability		
7.1.6	Organizational knowledge		
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		
7.5.3	Control of documented information	4.2.4	Control of documents
		4.2.5	Control of records
		4.2.2	Quality manual

		4.2.3	Medical device file
7.5.3.1	.. Documented information controlled ..		
7.5.3.2	.. Activities for control of information ..		
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
		7.2.1	Determination of requirements related to product
8.2.2	Determining the requirements for products and services	7.2.2	Review of requirements related to product
8.2.3	Review of the requirements for products and services		
8.2.3.1	.. Ensure ability to meet requirements ..		
8.2.3.2	.. Retain documented information ..		
8.2.4	Changes to requirements for products and services		
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 of development verification
		7.3.7	Design of development validation
8.3.5	Design and development outputs	7.3.4	Design and development outputs
		7.3.8	Design and development transfer
8.3.6	Design and development changes	7.3.9	Control of design and development changes
		7.3.10	Design and development files
8.4	Control of externally provided processes, products and services	7.4	Purchasing
8.4.1	General	7.4.1	Purchasing process
8.4.2	Type and extent of control	7.4.3	Verification of purchased product
8.4.3	Information for external providers	7.4.2	Purchasing information
8.5	Production and service provision	7.5	Production and service provision
8.5.1	Control of production and service provision	7.5.1	Control of production and service provision
		7.5.2	Cleanliness of product
		7.5.3	Installation activities
		7.5.4	Servicing activities
		7.5.5	Particular requirements for sterile medical devices
		7.5.6	Validation of processes for production and service provision
		7.5.7	Particular requirements for validation of processes for sterilization and sterile barrier systems
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
8.5.5	Post-delivery activities		
8.5.6	Control of changes		
8.6	Release of products and services		
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	8.2	Monitoring and measurement
9.1.1	General	8.1	General
9.1.2	Customer satisfaction	8.2.1	Feedback
		8.2.2	Complaint handling
		8.2.3	Reporting to regulatory authorities
		8.2.5	Monitoring and measurement of processes
		8.2.6	Monitoring and measurement of product
9.1.3	Analysis and evaluation	8.4	Analysis of data
9.2	Internal audit	8.2.4	Internal audit
9.2.1	.. Conduct internal audits at planned intervals ..		
9.2.2	.. Plan, establish, implement and maintain audit program ..		
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

		8.5.1	General
		8.5.2	Corrective action
		8.5.3	Preventive action
10.1	General		
10.2	Nonconformity and corrective action	8.3	Control of nonconforming product
		8.3.1	General
		8.3.2	Actions in response to nonconforming product detected before delivery
		8.3.3	Actions in response to nonconforming product detected after delivery
		8.3.4	Rework
10.2.1	.. When a nonconformity occurs ..		
10.2.2	.. Retain documented information ..		
10.3	Continual improvement	*8.5*	*Improvement*