ISO 13485:2016 Quick Reference

ISO 13485:2016 Clauses	Requirement Key Words
4. Quality Management System	
4.1 General Requirements	(title only)
4.1.1 (untitled)	Documented QMS; documented roles of organization
4.1.2 (untitled)	Processes; sequence; interaction; risk based approach
4.1.3 (untitled)	Process approach; records as evidence
4.1.4 (untitled)	Process changes; impact on QMS and medical devices
4.1.5 (untitled)	Outsourcing; responsibility retained; written agreements
4.1.6 (untitled)	Procedure for software application validation; records
4.2 Documentation Requirements	(title only)
4.2.1 General	Documented policy, objectives, and quality manual
4.2.2 Quality Manual	QMS scope; process interaction; documentation outline
4.2.3 Medical Device File	Device/ family files; conformity/compliance evidence; DMR
4.2.4 Control of Documents	Procedure; changes; availability; protection; retention
4.2.5 Control of Records	Procedure; storage; security; retention; disposal
5. Management Responsibility	
5.1 Management Commitment	Evidence of top management commitment to QMS
5.2 Customer Focus	Customer requirements; applicable regulations
5.3 Quality Policy	Commitment; framework; understood; reviewed
5.4 Planning	(title only)
5.4.1 Quality Objectives	Relevant functions and levels; measurable
5.4.2 Quality Management System Planning	Planning of QMS; maintain integrity when changes
5.5 Responsibility, Authority, and Communication	(title only)
5.5.1 Responsibility and Authority	Documented; communicated; interrelation; independence
5.5.2 Management Representative	Appointed; member of management; QMS effectiveness
5.5.3 Internal Communications	Processes for communication regarding QMS effectiveness
5.6 Management Review	(title only)
5.6.1 General	Procedure; QMS reviews; planned intervals; records
5.6.2 Review Input	Feedback; complaints; audits; measures; actions; changes
5.6.3 Review Output	Decisions; actions; improvements; changes; resource needs
6. Resource Management	
6.1 Provision of Resources	Resources; QMS implementation; effectiveness; requirements
6.2 Human Resources	Procedure; competency; training; actions; awareness; records
6.3 Infrastructure	Facilities; equipment; support services; maintenance records
6.4 Work Environment *and Contamination Control*	(title only)
6.4.1 Work Environment	Procedure; health; cleanliness; clothing; special conditions
6.4.2 Contamination Control	Documented controls; work environment; personnel; product
7. Product Realization	
7.1 Planning of Product Realization	Process planning; documented risk management; records;
7.2 Customer-Related Processes	(title only)
7.2.1 Determination of Requirements Related to ~~the~~ Product	Customer; regulatory; user training; organization
7.2.2 Review of Requirements Related to ~~the~~ Product	Documented; Reviewed prior to commitment; records
7.2.3 ~~Customer~~ Communication	Customers; regulators; products; complaints; advisory notices
7.3 Design and Development	(title only)
7.3.1 General	Documented procedures
7.3.*2* Design and Development Planning	Documented stages; reviews; V&V; responsibilities; resources
7.3.*3* Design and Development Inputs	Functions; performance; usability; safety; regulations; risks
7.3.*4* Design and Development Outputs	Criteria; safe and proper use; suitable form; records
7.3.*5* Design and Development Review	Documented arrangements; evaluation; actions; records
7.3.*6* Design and Development Verification	Documented verification plans; outputs meet inputs; records
7.3.*7* Design and Development Validation	Documented validation plans; representative product; records
7.3.8 Design and Development Transfer	Procedure; transfer to manufacturing; verification; records
7.3.*9* Control of Design and Development Changes	Procedure; evaluation of changes; actions; records
7.3.10 Design and Development Files	File for medical device or family; records of evidence; DHF

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7. Product Realization	
7.4 Purchasing	(title only)
7.4.1 Purchasing Process	Procedure; evaluation; selection; re-evaluation; records
7.4.2 Purchasing Information	Product description; agreement to notify of changes; records
7.4.3 Verification of Purchased Product	Inspection; proportionate to risks; supplier premises; records
7.5 Production and Service Provision	(title only)
7.5.1 Control of Production and Service Provision	Procedures; monitoring; controls; traceability records; DHR
7.5.2 Cleanliness of Product (was 7.5.1.2.1)	Documented cleanliness requirements; contamination controls
7.5.3 Installation Activities (was 7.5.1.2.2)	Documented installation requirements; criteria for verification
7.5.4 Servicing Activities (was 7.5.1.2.3)	Procedures; analysis of servicing records; complaints
7.5.5 Particular Requirements for Sterile Medical Devices	Records of sterilization process parameters; batch traceability
7.5.6 Validation of Processes for Production and Service Provision	Procedure; process validation; SW validation; records
7.5.7 Particular Requirements for Validation of Processes for Sterilization and Sterile Barrier Systems	Procedure; validation for implementation and change; records
7.5.8 Identification	Procedure; product status; unique device identification
7.5.9 Traceability	(title only)
7.5.9.1 General	Procedure; regulatory requirements; traceability records
7.5.9.2 Particular Requirements for Implantable Medical Devices	Supplier records; shipping package consignee records
7.5.*10* Customer Property	Protection; safeguarding; reporting of any unsuitable property
7.5.*11* Preservation of Product	Procedure; processing; storage; handling; distribution; records
7.6 Control of Monitoring and Measuring Equipment	Procedure; calibration; software validation procedure; records

8. Measurement, Analysis, and Improvement	
8.1 General	Planning; monitoring; measurement; analysis; improvement
8.2 Monitoring and Measurement	(title only)
8.2.1 Feedback	Procedure; measure of effectiveness; input to risks
8.2.2 Complaint Handling	Procedure; investigation; reporting; actions; records
8.2.3 Reporting to Regulatory Authorities	Procedure; adverse events; advisory notices; records
8.2.*4* Internal Audit	Procedure; criteria; scope; interval; methods; actions; records
8.2.*5* Monitoring and Measurement of Processes	Monitoring methods; process measurements; actions
8.2.*6* Monitoring and Measurement of Product	Procedure; evidence of conformity; personnel identification
8.3 Control of Nonconforming Product	(title only)
8.3.1 General	Procedure; nonconformity controls; decisions; records
8.3.2 Actions in Response to Nonconforming Product Detected Before Delivery	Dealing with NC product; concessions; justification; records
8.3.3 Actions in Response to Nonconforming Product Detected After Delivery	Procedure; advisory notices; actions based on effects; records
8.3.4 Rework	Procedure; potential adverse effect; verification; records
8.4 Analysis of Data	Procedure; collection; analysis; statistical techniques; records
8.5 Improvement	(title only)
8.5.1 General	Changes; QMS effectiveness; medical device safety
8.5.2 Corrective Action	Procedure; reviews; causes; actions; verification; records
8.5.3 Preventive Action	Procedure; reviews; causes; actions; verification; records

Changes to clause numbering and clause titles are in *Italics* and *underlined*.
Deleted terms in titles are shown with a ~~strikethrough~~.

See Annex A for Comparison of Content between ISO 13495:2003 and ISO 13485:2016.
See Annex B for Correspondence between ISO 13485:2016 and ISO 9001:2015.

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