ISO 13485:2003, EN ISO 13485:2012	ISO 13485:2016, EN ISO 13485:2016	Comments on change from ISO doc itself – Table A1	Personal interpretation /details / extracts	Surgionix QMS Changes
	0.1 General	— Includes substantially more detail related to the nature of the organization covered by this International Standard's requirements and the life-cycle stages covered. — Explains that the requirements can be used by suppliers or other external parties either voluntarily or as a result of contract arrangements. — Alerts organizations about their obligations related to regulatory requirements focused on quality management systems. — Alerts organizations about differences in local regulation definitions and their obligation to understand how these definitions will affect their quality management system. — Adds the obligation to meet the organization's own quality management system requirements. — Specifically calls out the focus on the necessity to "meet customer and applicable regulatory requirements for safety and performance." — Emphasizes that the product requirements that are important are those related to safety and performance. — Adds two influences on the nature of the quality management system that were not in the original listing (organizational environment and regulatory requirements). — Clarifies that the organization does not have to align its documentation to the clause structure of this International Standard.	- No normative content ; No impact.	-
	0.2 Clarification of concepts	— Adds two additional criteria associated with the description of appropriate requirements: — compliance with regulatory requirements; — the requirement is necessary for the organization to manage risks. — Limits application of risk to the safety or performance requirements of the medical device or meeting applicable regulatory requirements. — Clarifies that the term "documented" includes the need to establish, implement and maintain. — Clarifies that the term "product" applies to outputs that are intended for, or required by, a customer, or any intended output resulting from a product realization process.	- No normative content ; No impact.	-
	0.3 Process approach	Explanation of process approach extended.	- No normative content ; No impact.	-
	0.4 Relationship with ISO 9001	— States the relationship between ISO 13485:2016 and ISO 9001. — Indicates the structural relationship between ISO 13485:2016 and ISO 9001:2015 will be outlined in Annex B. — The use of italic text within standard to indicate changes from ISO 9001:2008 has been eliminated.	- No normative content ; No impact.	-
	1 Scope	— Indicates the applicability of this International Standard to organizations that are involved in one or more stages of the life-cycle of a medical device. — Indicates that this International Standard can also be used by suppliers or external parties that provide product, including quality management system-related services to medical device organizations. — Specifically calls out the responsibilities for monitoring, maintaining, and controlling outsourced processes. — Expands requirements that can be not applicable to those in Clauses 6 and 8. — Clarifies that the term "regulatory requirements" includes statutes, regulations, ordinances or directives and limits the scope of the "applicable regulatory requirements" to those requirements for the quality management system and the safety or performance of the medical device.	- No Direct impact.	-
	3 Terms and definitions	— Several new definitions added and some existing definitions refined.	- No Direct impact.	-

ISO 13485:2003, EN ISO 13485:2012	ISO 13485:2016, EN ISO 13485:2016	Comments on change from ISO doc itself – Table A1	Personal interpretation /details / extracts	Surgionix QMS Changes
4 Quality management system 4.1 General requirements	4 Quality management system 4.1 General requirements	— Added requirement to document the role(s) of the organization. — Requires the determination of processes "taking into account the roles undertaken by the organization." — Requires the application of a "risk based approach to the control of the appropriate processes needed for the quality management system." — Adds requirements related to changes to processes. — Added requirements related to validation of the application of computer software used in the quality management system.	4.1.1. The organization shall document the role(s) undertaken by the organization under the applicable regulatory requirements. NOTE Roles undertaken by the organization can include manufacturer, authorized representative, importeror distributor. 4.1.2. b) apply a risk based approach to the control of the appropriate processes needed for the quality management system; 4.1.4[...]Changes to be made to these processes shall be: a) evaluated for their impact on the quality management system; b) evaluated for their impact on the medical devices produced under this quality management system; c) controlled in accordance with the requirements of this International Standard and applicable regulatory requirements. Also 4.1.5 "monitor outsourced processed" – e.g. consultant – require written agreement 4.1.6 SW validation + revalidation after change	
4.2 Documentation requirements 4.2.1 General	4.2 Documentation requirements 4.2.1 General	- No Change	- No Change	-
4.2.2 Quality manual	4.2.2 Quality manual	- No Change	- No Change	-
4.2.3 Control of documents 4.2.4 Control of records	4.2.3 Medical device file 4.2.4 Control of documents 4.2.5 Control of records	Includes control of records within the document control requirements. Lists the documents that would be included in the medical device file. New requirement related to protection of confidential health information. New requirement related to deterioration and loss of documents	-	-
5 Management responsibility 5.1 Management commitment	5 Management responsibility 5.1 Management commitment	- No Change	- No Change	-
5.2 Customer focus	5.2 Customer focus	- No Change	- No Change	-
5.3 Quality policy	5.3 Quality policy	- No Change	- No Change	-
5.4 Planning 5.4.1 Quality objectives	5.4 Planning 5.4.1 Quality objectives	- No Change	- No Change	-

ISO 13485:2003, EN ISO 13485:2012	ISO 13485:2016, EN ISO 13485:2016	Comments on change from ISO doc itself – Table A1	Personal interpretation /details / extracts	Surgionix QMS Changes
5.4.2 Quality management system planning	5.4.2 Quality management system planning	- No Change	- No Change	-
5.5 Responsibility, authority and communication 5.5.1 Responsibility and authority	5.5 Responsibility, authority and communication 5.5.1 Responsibility and authority	- No Change	- No Change	-
5.5.2 Management representative	5.5.2 Management representative	- No Change	- No Change	-
5.5.3 Internal communication	5.5.3 Internal communication	- No Change	- No Change	-
5.6 Management review 5.6.1 General 5.6.2 Review input 5.6.3 Review output	5.6 Management review 5.6.1 General 5.6.2 Review input 5.6.3 Review output	— Includes requirement for the documentation of one or more procedures for management review and the requirement for management reviews at "documented planned intervals". — Lists of inputs and outputs of management review have been expanded.	Change from "management reviews at planned intervals" to "management reviews at documented planned intervals". Lists expansions are more details but no real new content	
6. Resource management 6.1 Provision of resources	6. Resource management 6.1 Provision of resources	- No Change	- No Change	-
6.2 Human resources 6.2.1 General 6.2.2 Competence, awareness and training	6.2 Human resources	— New requirement for documentation processes of establishing competence, providing needed training and ensuring awareness of personnel.	"The organization shall document the process(es) for establishing competence, providing needed training, and ensuring awareness of personnel"	
6.3 Infrastructure	6.3 Infrastructure	- Adds requirement that infrastructure prevents product mix-up and ensure orderly handling of product. - Adds information system to the listing of supporting services.	- Besides of the two points on the left – there is now a requirement for the organization to DOCUMENT THE REQUIREMENTS.	-
6.4 Work environment	6.4 Work environment and contamination control 6.4.1 Work environment 6.4.2 Contamination control	- Added documentation requirements for work environment. — Added requirement related to control of contamination with microorganism or particulate matter for sterile medical devices.	- As above – new DOCUMENTAITON requirement	-
7 Product realization 7.1 Planning of product realization	7 Product realization 7.1 Planning of product realization	— Added requirements to list.	new c) "required [...]measurement [...], handling, storage, distribution and traceability [...]	
7.2 Customer-related processes 7.2.1 Determination of requirements	7.2 Customer-related processes 7.2.1 Determination of requirements related to the product	- Added requirements to list :	- 7.2.1 "d) any user training needed to ensure specified performance and safe use of the medical device;" - 7.2.2.	-

ISO 13485:2003, EN ISO 13485:2012	ISO 13485:2016, EN ISO 13485:2016	Comments on change from ISO doc itself – Table A1	Personal interpretation /details / extracts	Surgionix QMS Changes
related to the product 7.2.2 Review of requirements related to the product	7.2.2 Review of requirements related to the product		c) applicable regulatory requirements are met; - d) any user training identified in accordance with 7.2.1 is available or planned to be available;	
7.2.3 Customer communication	7.2.3 Communication	— New requirement related to communication with regulatory authorities.	"The organization shall communicate with regulatory authorities in accordance with applicable regulatory requirements." Weird statement placement	
7.3 Design and development 7.3.1 Design and development planning	7.3 Design and development 7.3.1 General 7.3.2 Design and development planning	- Added requirements to list. — Eliminated the requirement related to the management of the interfaces between different groups involved in design and development.	7.3.2 e) the methods to ensure traceability of design and development outputs to design and development inputs; - f) the resources needed, including necessary competence of personnel.	
7.3.2 Design and development inputs	7.3.3 Design and development inputs	— Added requirements to list. — Added requirement that the requirements shall be able to be verified or validated.	- Added "usability" + ref to IEC62366	-
7.3.3 Design and development outputs	7.3.4 Design and development outputs	No Change	- No Change	-
7.3.4 Design and development review	7.3.5 Design and development review	Added details of the contents of records.	"include the - identification of the design under review, the participants involved and the date of the review"	
7.3.5 Design and development verification	7.3.6 Design and development verification	Added requirement for documentation of verification plans and interface considerations. — Requirement added for records of verification.	New : "The organization shall document verification plans that include methods, acceptance criteria and, as appropriate, statistical techniques with rationale for sample size. If the intended use requires that the medical device be connected to, or have an interface with, other medical device(s), verification shall include confirmation that the design outputs meet design inputs - when so connected or interfaced." Also added "Records of the - results AND CONCLUSIONS of […]"	
7.3.6 Design and development validation	7.3.7 Design and development validation	— Added requirement for documentation of validation plans, product to be used for validation and interface considerations. Requirement added for records of validation.	New "The organization shall document validation plans that include methods, acceptance criteria and, as appropriate,	

ISO 13485:2003, EN ISO 13485:2012	ISO 13485:2016, EN ISO 13485:2016	Comments on change from ISO doc itself – Table A1	Personal interpretation /details / extracts	Surgionix QMS Changes
			statistical techniques with rationale for sample size." New "A medical device used for clinical evaluation or performance evaluation is not considered to be released for use to the customer. If the intended use requires that the medical device be connected to, or have an interface with, other medical device(s), validation shall include confirmation that the requirements for the specified application or intended use have been met when so connected or interfaced"	
	7.3.8 Design transfer	New Sub-clause added	A medical device used for clinical evaluation or performance evaluation is not considered to be released for use to the customer. If the intended use requires that the medical device be connected to, or have an interface with, other medical device(s), validation shall include confirmation that the requirements for the specified - application or intended use have been met when so connected or interfaced	
7.3.7 Control of design and development changes	7.3.9 Control of design and development changes	Adds the requirement that the evaluation of the change effect should be made on products in process and on the outputs of risk management and product realization processes — Added detail to consider in the determination of the significance of a design and development changes	New ":The organization shall determine the significance of the change to function, performance, usability, safety and applicable regulatory requirements for the medical device and its intended use." - Also note the "products in process and on the outputs of risk management and product realization processes" as opposed to only released products + records of "changes, THEIR REVIEW […]"	
	7.3.10 Design and development files	— New sub-clause added.	- New but not really – i.e. DHF	-
7.4 Purchasing 7.4.1 Purchasing process	7.4 Purchasing 7.4.1 Purchasing process	— Focuses the supplier selection criteria on the effect of the supplier performance on the quality of the medical device, the risk associated with the medical device, and the product meeting applicable regulatory requirements. — New requirements added related to monitoring and re-evaluation of suppliers, and action to be taken when purchasing requirements are not met. — Provides addition details related to the content of the records.	- As explained	-
7.4.2 Purchasing information	7.4.2 Purchasing information	— New requirement added to include notification of changes in purchased product.	"Purchasing information shall include, as applicable, a written	

ISO 13485:2003, EN ISO 13485:2012	ISO 13485:2016, EN ISO 13485:2016	Comments on change from ISO doc itself – Table A1	Personal interpretation /details / extracts	Surgionix QMS Changes
			agreement that the supplier notify the organization of changes in the purchased product prior to implementation of any changes that affect - the ability of the purchased product to meet specified purchase requirements"	
7.4.3 Verification of purchased product	7.4.3 Verification of purchased product	New requirements added on the extent of verification activities and action to be taken when the organization becomes aware of any changes to the purchased product.	Also new "The extent of verification activities shall be based on the supplier evaluation results and proportionate to the risks associated with the purchased product. When the organization becomes aware of any changes to the purchased product, the organization shall determine whether these changes affect the product realization process or the medical device."	
7.5 Production and service provision 7.5.1 Control of production and service provision 7.5.1.1 General requirements	7.5 Production and service provision 7.5.1 Control of production and service provision	7.5.1 - Adds details related to the controls for carrying out production and service provision.	- Rewording but can't find anything really different ?	-
7.5.1.2 Control of production and service provision - Specific requirements 7.5.1.2.1 Cleanliness of product and contamination control	7.5.2 Cleanliness of product	7.5.2 - Added a requirement to the list.	- New c) product cannot be cleaned prior to sterilization or its use, and its cleanliness is of significance in use;	-
7.5.1.2.2 Installation activities	7.5.3 Installation activities		- No Change	-
7.5.1.2.3 Servicing activities	7.5.4 Servicing activities	7.5.4 -— New requirement for analysis of records for servicing activities.	New "The organization shall analyse records of servicing activities carried out by the organization or its supplier: a) to determine if the information is to be handled as a complaint; - b) as appropriate, for input to the improvement process."	

ISO 13485:2003, EN ISO 13485:2012	ISO 13485:2016, EN ISO 13485:2016	Comments on change from ISO doc itself – Table A1	Personal interpretation /details / extracts	Surgionix QMS Changes
7.5.1.3 Particular requirements for sterile medical devices	7.5.5 Particular requirements for sterile medical devices		- No change	-
7.5.2 Validation of processes for production and service provision 7.5.2.1 General requirements	7.5.6 Validation of processes for production and service provision	-Added requirements to the list — Adds details related to situations requiring procedures. — Relates the specific approach to software validation to the risk associated with the use of the software. — Adds requirements related to the validation records.	- d) as appropriate, statistical techniques with rationale for sample sizes; - f/criteria for revalidation; - g) approval of changes to the processes. The specific approach and activities associated with software validation and revalidation shall be proportionate to the risk associated with the use of the software, including the effect on the ability of the product to conform to specifications. Record of [...]results and conclusion of validation and necessary actions[...]	-
7.5.2.2 Particular requirements for sterile medical devices	7.5.7 Particular requirements for validation of processes for sterilization and sterile barrier systems	— Added requirements for sterile barrier systems.	- As explained	-
7.5.3 Identification and traceability 7.5.3.1 Identification	7.5.8 Identification	Added requirement for unique device identification. — New requirement for a documented procedure for product identification and regarding identification and product status during production	New "The organization shall identify product status with respect to monitoring and measurement requirements throughout product realization. Identification of product status shall be maintained throughout production, storage, installation and servicing of product to ensure that only product that has passed the required inspections and tests or released under an authorized concession is dispatched,used or installed. - If required by applicable regulatory requirements, the organization"	
7.5.3.2 Traceability 7.5.3.2.1 General 7.5.3.2.2 Particular requirements for active	7.5.9 Traceability		- No Change	-

ISO 13485:2003, EN ISO 13485:2012	ISO 13485:2016, EN ISO 13485:2016	Comments on change from ISO doc itself – Table A1	Personal interpretation /details / extracts	Surgionix QMS Changes
implantable medical devices and implantable medical devices 7.5.3.3 Status identification				
7.5.4 Customer property	7.5.10 Customer property		- No Change	-
7.5.5 Preservation of product	7.5.11 Preservation of product	Adds details as to how preservation can be accomplished.	The organization shall protect product from alteration, contamination or damage when exposed to expected conditions and hazards during processing, storage, handling, and distribution by: a) designing and constructing suitable packaging and shipping containers; b) documenting requirements for special conditions needed if packaging alone cannot provide preservation	
7.6 Control of monitoring and measuring devices	7.6 Control of monitoring and measuring equipment		- No change	-
8 Measurement, analysis and improvement 8.1 General	8 Measurement, analysis and improvement 8.1 General		- No Change	-
8.2 Monitoring and measurement 8.2.1 Feedback	8.2 Monitoring and measurement 8.2.1 Feedback	Indicates that feedback should come from production and post-production activities. — Adds a requirement to utilize feedback in risk management processes in order to monitor and maintain product requirements.	New The organization shall document procedures for the feedback process. This feedback process shall include provisions to gather data from production as well as post-production activities. The information gathered in the feedback process shall serve as potential input into risk management for monitoring and maintaining the product requirements as well as the product realization or improvement processes Note that link to CAPArs disappeared	
	8.2.2 Complaint handling	— New sub-clause.	- New	-
	8.2.3 Reporting to regulatory authorities	— New sub-clause.	- New	-
8.2.2 Internal audit	8.2.4 Internal audit		- No change	-
8.2.3 Monitoring and measurement of processes	8.2.5 Monitoring and measurement of processes		- No Change -	-

ISO 13485:2003, EN ISO 13485:2012	ISO 13485:2016, EN ISO 13485:2016	Comments on change from ISO doc itself – Table A1	Personal interpretation /details / extracts	Surgionix QMS Changes
8.2.4 Monitoring and measurement of product 8.2.4.1 General requirements 8.2.4.2 Particular requirement for active implantable medical devices and implantable medical devices	8.2.6 Monitoring and measurement of product	— Adds requirement to identify the test equipment used to perform measurement activities.	As appropriate, records shall identify the test equipment used to perform measurement activities.	
8.3 Control of nonconforming product	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	— Added details related to kinds of controls that shall be documented. — Generalized the requirement to include any investigation and the rationale for decisions. — Adds requirements related to concessions. — Separated requirements for nonconformities detected before delivery, detected after delivery and rework. — Adds requirements for records related to the issuance of advisory notices.	As explained	
8.4 Analysis of data	8.4 Analysis of data	Adds the requirement to include determination of appropriate methods, including statistical techniques and the extent of their use. — Adds detail to list of inputs.	Stats as explained + e) audits; f) service reports, as appropriate. If the analysis of data shows that the quality management system is not suitable, adequate or effective, - the organization shall use this analysis as input for improvement as required in 8.5.	
8.5 Improvement 8.5.1 General	8.5 Improvement 8.5.1 General		- No change -	-
8.5.2 Corrective action	8.5.2 Corrective action	Adds the requirement to verify that the corrective action does not have an adverse effect. — Added requirement for corrective action to be taken without undue delay.	- As explained	-
8.5.3 Preventive action	8.5.3 Preventive action	- Adds the requirement to verify that the preventive action does not have an adverse effect.	- As explained	-