Ref.	Question *(comments in italic are not in the standard)*	Yes/ No	Comments *[evidence - data - collection plan]*
4	**Quality management system (QMS)** *[These are the system requirements that must be verified as a result of a system audit. Author helpful hints and comments are in italic type]*		**Note:** *Revising the checklist to be consistent with ISO 9001:2008 does not add any new requirements. The 2008 amendments to ISO 9001 simply clarified the intent of existing requirements.*
4.1	**General requirements**		
4.1-1	Does the established, documented, implemented, and maintained, quality management system meet the requirements of the standard? *Maintained includes maintaining the effectiveness of the QMS.*		
4.1-2	Has the organization... • Determined the processes • Determined the sequence & interaction of processes • Determined criteria and methods to ensure effectiveness • Ensured the availability of resources and information • Determined the measuring (where applicable), monitoring and analyzing of these processes • Implemented actions to achieve planned results and improvement. [*The requirements will be verified during the audit. Verify that the sequence and interaction of processes was determined in some manner.*]		
4.1-3	Are the processes managed in accordance with the requirements of the international standard?		
4.1-4	Does the organization control outsourced processes that affect product conformity to requirements?		
4.1-5	Is type and extent of control of outsourced processes needed for the QMS defined within the quality management system?		
4.2	**Documentation requirements**		
4.2.1	**General**		
4.2-1	Does the QMS documentation include: a) quality policy and objectives b) a quality manual c) documented procedures and records as required by the international standard d) documents and records required by the organization for effective planning operation and control e) documentation specified by national or regional regulators. *[ISO 13485 requires 23 documented procedures, but there may be more than or less than 23 documented procedures to address the requirements.]*		

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Ref.	Question *(comments in italic are not in the standard)*	Yes/ No	Comments *[evidence - data - collection plan]*
4.2-2	When QMS standard specifies a process (activity, planned arrangement, procedure) is it required to be documented, is it also implemented and maintained? *[Are documented procedures, activities, planned arrangements, implemented and maintained?]*		
4.2-3	*Is there a file that either contains or identifies documents defining product specifications and quality management system requirements for each type of medical device (MD)? Has the file been established and is it maintained?*		
4.2-2	*Do the documents in the MD file (question 4.2-3) define the complete manufacturing process and, if applicable, installation and servicing for each medical device? .*		

4.2.2	**Quality Manual**		
4.2.2-1	Is there a quality manual that includes the scope of the QMS, **justification for exclusions and/or non-application**, and describes the **interaction between the processes**? *The manual must be documented, but no medium is specified.*		
4.2.2-2	Does the manual contain documented procedures or are they referenced?		
4.2.2-3	*Is there an outline of the documentation structure in the QMS manual? .*		

4.2.3	**Control of documents**		
4.2.3-1	Are required QMS documents controlled? *[Identified in 4.2.1. Documents required by the organization need to be identified in some manner.]*		
4.2.3-2	Are there written procedures to control all documents (electronic or hard copy media) required for operating the quality management system? Are they being used?		
4.2.3-3	Are documents reviewed and approved for adequacy prior to release. *[There may be a need for both content approval and approval for authority to deploy, which may or may not be the same.]*		
4.2.3-4	Are documents reviewed, updated as necessary, and then re-approved?		
4.2.3-5	Is there a method that identifies the current version status of documents?		

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Ref.	Question *(comments in italic are not in the standard)*	Yes/ No	Comments *[evidence - data - collection plan]*
4.2.3-6	Are documents (*procedures, instructions*) available at points of use (*locations where quality activities are performed*)?		
4.2.3-7	Are documents legible and readily identifiable?		
4.2.3-8	Are external origin documents necessary for the planning and operation of the QMS identified and distribution controlled?		
4.2.3-9	Are obsolete documents (*retained for legal and/or knowledge purposes*) suitably identified to prevent unintended use?		
4.2.3-10	When documents are changed or updated are they reviewed and approved by either by the original approving function or another designated function which has access to pertinent background information upon which to base its decisions?		
4.2.3-11	Is the retention period for at least one copy of an obsolete controlled document defined? Are documents to which medical devices have been manufactured and tested available for at least the lifetime of the medical device as defined by the organization, but not less than the retention period of any resulting record (see 4.2.4), or as specified by relevant regulatory requirements? *[All controlled MD manufacturing documents must be kept for the lifetime of the MD and lifetime of any record resulting from the documents, such as keeping a test record for 10 years beyond the lifetime of the medical device]*		
4.2.4	**Control of records**		
4.2.4-1	Are there documented procedures for identifying, storing, **retrieval, protection, retention**, and disposing of records? Are they being used?		
4.2.4-2	Are records legible, readily identifiable, and retrievable?		
4.2.4-3	Are required records **established** and controlled?		
	At a minimum, are records retained for the lifetime of the medical device as defined by the organization, but not less than two years from the date of product release by the organization or as specified by relevant regulatory requirements.		

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Ref.	Question *(comments in italic are not in the standard)*	Yes/ No	Comments *[evidence - data - collection plan]*
4.2.4-4	Do the following records exist: Management review (5.6.1) Personnel training (6.2.2 e) Maintenance (6.3) Conformity of processes and products (7.1 d) Risk management activities (7.1) Review of customer requirements (7.2.2) Design and development inputs (7.3.2) Design output (7.3.3) Design Reviews (7.3.4) Design verification (7.3.5) Record of validation results (7.3.6) Review of design changes and actions (7.3.7) Supplier evaluations (7.4.1) Verification (7.4.3) Each batch (7.5.1) Process control parameters (7.5.1) Installation (7.5.1) Servicing (7.5.1) Process validation (qualification) (7.5.2) Sterilization (7.5.2) Product identification and traceability (7.5.3) Environmental conditions (7.5.3) Distribution (7.5.3) Names and addresses of consignee (7.5.3) Unsuitable customer product (7.5.4) Storage conditions (7.5.5) Results of calibration (7.6 a) Record of non-standard calibration (7.6) Validity of previous results (7.6) Results of internal audits (8.2.2) Verification that product passed tests (8.2.4) Identity of personnel performing testing and inspection (8.2.4) Record of nonconforming product and actions (8.3) Record of person authorizing concession (8.3) Results of analysis (8.4) Customer complaint investigation (8.5.1) Reason for non-investigation (8.5.1) Results and corrective action taken (8.5.2 e) Results and preventive action taken (8.5.3 d)		

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Ref.	Question *(comments in italic are not in the standard)*	Yes/ No	Comments *[evidence - data - collection plan]*
5	**Management Responsibility**		
5.1	**Management commitment**		
5.1-1	Is there evidence of top management commitment by: a) Communicating the importance of meeting customer and regulatory requirements; b) Establishing a quality policy c) Ensuring there are quality objectives; d) Conducting management reviews; and e) Ensuring availability of resources. *[Verify a through e. See quality policy; verify management reviews taking place and top management involved. a) is linked to 5.5.2 c)]*		
5.2	**Customer focus**		
5.2-1	Does top management ensure customer requirements are determined and met? *[This requirement is linked to 7.2. If there is a 7.2 nonconformity, there may be 5.2 nonconformity.*		
5.3	**Quality policy**		
5.3-1	Has top management ensured there is a quality policy?		
5.3-2	Is the policy appropriate for the purpose of the organization?		
5.3-3	Does the policy include commitment to meeting requirements and maintaining the effectiveness of the QMS?		
5.3-4	Does the policy statement include provision for: - ***providing a framework*** for establishing/ reviewing objectives? - ***reviewing*** for continuing suitability of the policy? *[Note: Reviewing should link with management review (5.6) of the suitability of the quality system.]*		
5.3-5	Has the quality policy been communicated, understood and implemented within of the organization?		

5.4	**Planning**		
5.4.1	**Quality objectives**		

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Ref.	Question *(comments in italic are not in the standard)*	Yes/ No	Comments *[evidence - data - collection plan]*
5.4.1-1	Are objectives established for each relevant function and level? Are the objectives measurable and consistent with the quality policy including a commitment to meeting requirements and maintaining the effectiveness of the QMS? *[Note: Seek to determine relevant functions (such as from an organizational chart) and verify that there are objectives for each.]*		
5.4.1-2	Do objectives include those needed to meet requirements for products and/or services? *[Note: This requirement is linked to 7.1. For example: objectives must include product requirements such as purity or tolerance levels. There may be a matrix (not required) to show relationship between objectives and product/ service requirements.]*		
5.4.2	**Quality management system planning**		
5.4.2-1	Does top management ensure QMS planning is carried out to meet quality objectives and requirements in clause 4.1?		
5.4.2-2	When organizational changes are planned and implemented, is the integrity of the management system maintained during the change? *[Note: How does management ensure integrity is maintained? Is there a method or records of actions?]*		
5.5	**Responsibility, authority, and communication**		
5.5.1	**Responsibility and authority**		
5.5.1-1	Have functions responsibility and authority, been defined, documented and communicated? *[May be defined in job descriptions & communicated via organization charts, outline, and so on.]*		
5.5.1-2	Has top management established the interrelation of all personnel who manage, perform and verify work affecting quality?		
5.5.1-3	Has top management ensured the independence and authority necessary to perform these tasks (manage, perform and verify work affecting quality)?		
	13485 Note: National or regional regulation might require the nomination of specific persons as responsible for activities related to monitoring experience from the post-production stage and reporting adverse events (see 8.2.1 and 8.5.1).		
5.5.2	**Management representative**		

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Ref.	Question *(comments in italic are not in the standard)*	Yes/ No	Comments *[evidence - data - collection plan]*
5.5.2-1	Has top management appointed a member within the organization's management with defined authority and responsibility to ensure quality management requirements are established, implemented and maintained? *[A Note allows the management representative to be the liaison with external parties. The management representative may be any individual from the organization's management.]*		
5.5.2-2	Does the appointed member have authority to report performance to management for review and improvement of the quality management system?		
5.5.2-3	Does the appointed member have authority for ensuring the promotion of awareness of regulatory and customer requirements throughout the organization? *[Linked to 5.1 a.)]*		
5.5.3	**Internal communications**		
5.5.3-1	Are there communication processes that communicate the **effectiveness** of the QMS? *[Is there a means for communicating, can the organization provide evidence of this type of communication. e.g. newsletter, broadcast fax, meetings, etc.]*		
5.6	**Management Review**		
5.6.1-1	Are management reviews conducted at planned intervals? *[Perhaps a schedule or specified intervals in a document or communication of some type.]*		
5.6.1-2	Does top management review the quality system to ensure its continuing suitability, **adequacy,** and effectiveness?		
5.6.1-3	Are needed changes and opportunities for improvement to the quality management system (policy, objectives) assessed?		
5.6.1-4	Are there records of management reviews?		
5.6.2-1	Does the review include information about: audit results, customer feedback, process performance and product conformance, status of corrective and preventive actions, follow-up from prior reviews, changes that could affect the QMS, recommendations for improvement, and new or revised regulatory requirements? *[This is also connected to 8.2.1 feedback and internal audit performance, 8.2.2.]*		

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Ref.	Question *(comments in italic are not in the standard)*	Yes/ No	Comments *[evidence - data - collection plan]*
5.6.3-1	Do output of reviews relate to either: - Maintaining the effectiveness of the QMS and its processes, - Improvement of product-related customer requirements - Resource needs?		

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Ref.	Question *(comments in italic are not in the standard)*	Yes/ No	Comments *[evidence - data - collection plan]*
6	**Resource management**		
6.1	**Provision of resources**		
6.1-1	Are the resources needed to establish and maintain the QMS and its effectiveness determined and provided? Are the resources used to implement, maintain and improve the QMS and meet regulatory and customer requirements? *[Linked to quality planning at 5.4 and 7.1 planning requirements. A nonconformity would indicate a system-wide breakdown in providing necessary resources.]*		
6.2	**Human resources**		
6.2.1-1	Are **competent** personnel performing work effecting product/ service conformity to requirements, assigned to QMS activities? Is competency based on education, training, skills, and experience?		
6.2.2-1	Does the organization - Determine competency needs for those affecting conformity to product requirements? - Achieve necessary competency by providing training or other actions? - Evaluate **effectiveness of training or other actions?** - Ensure employees are aware of the importance of their activities and how they contribute to achievement of objectives?		
6.2.2-2	Are there **records**? Are appropriate education, training, skills, experience records maintained?		
6.3	**Infrastructure**		
6.3-1	Has the organization identified, provided and maintained infrastructure to achieve conformity of product? Infrastructure could include workspace, buildings, utilities, equipment, hardware, software, and support services (transportation, communication, information systems). *[Verify that infrastructure items have been determined in some manner (such as in a document). If during the audit, there was a nonconformity as a result of not providing the needed facilities (infrastructure), this clause could be cited]*		
6.3-2	Are maintenance requirements documented? Are maintenance activities frequency (schedule) included when such activities or lack thereof can affect product quality?		
6.3-3	Are maintenance records maintained?		
6.4	**Work environment**		

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Ref.	Question *(comments in italic are not in the standard)*	Yes/ No	Comments *[evidence - data - collection plan]*
6.4-1	Have factors of the work environment needed to achieve conformity been determined and managed? *[Can the organization provide evidence of how they determine and manage (controlled) factors in the work environment? Work environment may include: noise, temperature, lighting, humidity, weather, work conditions, ergonomics, and so on.]*		
6.4a-2	Are there established documented requirements for health, cleanliness and clothing of personnel if contact between personnel and the product or work environment could adversely affect the quality of the product? (see 7.5.1.2.1)		
6.4b-3	When work environment condition could have an adverse effect on product quality, are there established documented requirements for the work environment conditions and documented procedures or work instructions to monitor and control these work environment conditions? (see 7.5.1.2.1). [*If the work environment could impact product quality, organizations must monitor and control the work environment conditions.*]		
6.4c-4	When there are temporary or special work conditions, are personnel performing the work appropriately trained or supervised by a trained person? [see 6.2.2 b)		
6.4d-5	Are special arrangements established and documented (if appropriate) for the control of contaminated or potentially contaminated product in order to prevent contamination of other product, the work environment or personnel? (see 7.5.3.1).		

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Ref.	Question *(comments in italic are not in the standard)*	Yes/ No	Comments *[evidence - data - collection plan]*
7	**Product realization**		
7.1	**Planning of realization processes**		
7.1-1	Is there planning of realization processes? Is it in suitable form consistent with the method of operation? *[Look for something that is documented such as a quality plan, procedure or diagram. It can be an overall plan or individual plans for the realization processes.]*		
7.1-2	Is the planning consistent with other requirements of the QMS? Has the organization determined (as appropriate) - quality objectives - requirements for product - need for establishing processes and documents - providing resources for the product - product measuring, monitoring, verification, validation - criteria for product acceptance - records of product and process meeting requirements		
7.1-3	*Are there established documented requirements for risk management throughout product realization?.Are resulting records maintained?*		
7.2	**Customer-related processes**		
7.2.1	**Identification of customer requirements**		
7.2.1-1	Are customer requirements determined *[identified]*? Do requirements include product requirements, delivery and post delivery activities, not stated requirements but necessary, and obligations such as statutory, regulatory and legal requirements, and additional requirements considered necessary by the organization? *[This is a prescriptive list. Verify items are addressed. For example, there could be a nonconformity for not determining necessary but unspecified customer requirements such as a need for traceability. A note explains that post delivery activities include warranty, contract maintenance, recycle and disposal]*		
7.2.2	**Review of product requirements**		
7.2.2-1	Are customer requirements (new or changed contracts, tenders and orders) reviewed prior to commitment?		
7.2.2-2	Are customer requirements defined and documented?		

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Ref.	Question *(comments in italic are not in the standard)*	Yes/ No	Comments *[evidence - data - collection plan]*
7.2.2-3	When requirements are not written (documented by the customer), are they confirmed by the organization before acceptance?		
7.2.2-4	Are contracts or order requirements that differ from previous expressed (those in the tender or offer) resolved?		
7.2.2-5	Are customer requirements reviewed to ensure the organization has the ability to meet them?		
7.2.2-6	Are results of reviews and (*follow-up*) actions recorded? Are records maintained?		
7.2.2-7	Are relevant documents amended and personnel notified of order changes?		
7.2.3	**Customer communication**		
7.2.3	Has the organization determined and implemented communication requirements for: a) product/ service information, b) inquiry, contracts, order handling and amendments, c) customer feedback including **customer complaints, and advisory notices**?		
7.3	**Design and development/ planning**		
7.3.1-1	Are there established documented procedures for design and development?		
7.3.1-2	Do project plans exist that determine design stages, review-verification-validation activities, design transfer and responsibility and authority? *[Design stages include verification and validation. Transfer activities are activities to ensure design outputs are suitable for manufacturing.]*		
7.3.1-3	Are the interfaces between different design/ verification groups **managed to ensure** effective communication and clear responsibilities?		
7.3.1-4	Are output plans documented and updated as the project progresses?		
7.3.2	**Design and development inputs**		
7.3.2-1	Are product functional, **performance, and safety** requirements determined and recorded?		

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Ref.	Question *(comments in italic are not in the standard)*	Yes/ No	Comments *[evidence - data - collection plan]*
7.3.2-2	Are regulatory and legal requirements determined? *[should include industry standards]*		
7.3.2-3	Are information from previous designs and other essential requirements determined? [Where applicable]		
7.3.2-4	Are other requirements that are essential to design and development determined?		
7.3.2-5	Are outputs of risk managment determined? (see 7.1)		
7.3.2-6	Have the requirements been reviewed for adequacy to ensure requirements are complete, unambiguous and are non-conflicting?		

7.3.3	**Design and development outputs**		
7.3.3-1	Is the design output in a form that is suitable for verification against inputs? *Note: The word document was avoided to provide flexibility, but most organizations document design in the form of drawings, specification sheets in various forms and mediums.*		
7.3.3-2	Does design output meet input requirements?		
7.3.3-3	Does design output provide appropriate information for purchasing, production and service operations (7.5)? *[There may be some type of transition or start-up plan.]*		
7.3.3-4	Does design output contain or reference acceptance criteria? *[These may include items such as performance target values, tolerances and attributes, durability, safety, reliability, maintainability under storage and operating conditions, validation of computer systems and software, statistical validation of tests/ inspections to the appropriate confidence level, etc.]*		
7.3.3-5	Does the design output specify those requirements that are crucial to the safe and proper use of the product? *[These may include operating, storage, handling, maintenance, disposal, reliability and maintainability, serviceability for the product (project) life cycle, project/ product failure, decomposition, etc.]*		
7.3.3-6	Are design outputs approved prior to release?		

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Ref.	Question *(comments in italic are not in the standard)*	Yes/ No	Comments *[evidence - data - collection plan]*
7.3.3-7	Are records of design output maintained? [*Records can include specifications, manufacturing procedures, engineering drawings, and engineering or research logbooks.]*		
7.3.4	**Design and development review**		
7.3.4-1	Are systematic design reviews conducted according to planned arrangements? Do the reviews include evaluation of ability to meet requirements, and identify problems and propose necessary actions?		
7.3.4-2	Does design review meeting attendance include representatives of functions concerned with the design stage being reviewed, as well as other specialist?		
7.3.4-3	Are there records of the design reviews?		
7.3.5	**Design and development verification**		
7.3.5-1	Is the design verified according to planned arrangements? *[such as qualification tests, alternative calculations, or comparison to similar designs, prototype testing, simulation]*		
7.3.5-2	Are design verification **results and** required actions recorded?		
7.3.6	**Design and development validation**		
7.3.6-1	Are validation activities performed according to planned arrangements? (Ref. 7.3.1)		
7.3.6-2	Is the design validated to ensure it meets requirements for its specified application or intended use? *[This may include evaluation of the final product or service to ensure it meets specification and performance requirements.]*		
7.3.6-3	Is the validation conducted prior to delivery or implementation? *[If a medical device can only be validated following assembly and installation **at point of use**, delivery is not considered to be complete until the product has been formally transferred to the customer]*		
7.3.6-4	Are design validation results and any necessary actions recorded?		
7.3.6-5	Were clinical evaluations performed and/or evaluation of performance of the medical device conducted, as required by national or regional regulations? [*Evaluation of performance is not considered delivery*]		

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Ref.	Question *(comments in italic are not in the standard)*	Yes/ No	Comments *[evidence - data - collection plan]*
7.3.7	**Control of design and development changes**		
7.3.7-1	Are design changes identified, and recorded?		
7.3.7-2	Are changes evaluated for effect on constituent parts and product already delivered? Are changes verified and validated and approved prior to implementation? *[Changes must go back through the same checks as the original.]*		
7.3.7-3	Are review of changes and necessary actions recorded?		
7.4	**Purchasing**		
7.4.1-1	Are there established documented procedures that ensure incoming purchased product/ service conforms to requirements? Is the type and extent of control dependent on the effect of realization processes? *[Examples of ways to accomplish this include: receiving inspection, test verification, performance evaluation and test, process capability results, supplier verification (Certificate of Compliance or Conformance), pre-shipment (source) inspection, and supplier audits. Control may be demonstrated by adherence to specified methods and records of such. For many service organizations, purchasing is not as critical as it is in manufacturing.]*		
7.4.1-2	Are suppliers evaluated and selected on the basis of their ability to supply product/ service that meets organization requirements?		
7.4.1-3	Are there established criteria for evaluation, re-evaluation and selection?		
7.4.1-4	Do supplier records show results of evaluations and actions arising from the evaluation (*subsequent follow-up actions*)?		
7.4.2	**Purchasing information**		
7.4.2-1	Does purchasing information (*contracts and purchase orders*) describe the product ordered? *[This may be type, class, style, grade, model, part number, etc.*]		
7.4.2-2	If appropriate, are requirements for approval of product, procedures, processes, processing equipment and qualification of personnel described?		

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Ref.	Question *(comments in italic are not in the standard)*	Yes/ No	Comments *[evidence - data - collection plan]*
7.4.2-3	If appropriate, is the applicable quality management system requirements identified in purchase documents? *[This may be the ISO 9001 or other recognized standards.]*		
7.4.2-4	Is the adequacy of purchasing information ensured prior to communication to the supplier?		
7.4.2-5	Are relevant purchasing information maintained to the extent required for traceability given in 7.5.3.2? [*Information may be in the form of documents and records*]		
7.4.3	**Verification of purchased product**		
7.4.3-1	Are activities established and implemented for inspection (or other activities) of incoming purchased product/service, to ensure requirements are met?		
7.4.3-2	When the organization or its customer performs on-site supplier verification, are arrangements and methods for on-site (supplier) verification (source inspection) specified (defined) in purchasing information?		
7.4.3-3	Are verification records maintained? [*Select several purchased products/services and verify inspected or tested characteristics are recorded and maintained.*]		

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Ref.	Question *(comments in italic are not in the standard)*	Yes/ No	Comments *[evidence - data - collection plan]*
7.5	**Production and service provision**		
7.5.1	**Control of product and service provision control**		
7.5.1.1	**General Requirements**		
7.5.1.1-1	Are provisions (product and service) carried out under controlled conditions?		
7.5.1.1-2	Is there product/service information available that describes product characteristics? [i.e acceptance criteria]		
7.5.1.1-3	Are there documented procedures, documented requirements, work instructions and reference materials for activities necessary to achieve quality?		
7.5.1.1-4	Is suitable equipment used on each of these identified processes (production, service)? *[linked to 6.3 and 6.4]*		
7.5.1.1-5	Are measurement and monitoring equipment available and used?		
7.5.1.1-6	Are measuring and monitoring activities (processes) implemented?		
7.5.1.1-7	Are processes for product release, delivery, and applicable post delivery implemented?		
7.5.1.1-8	Are defined operations implemented for labelling and packaging?		
7.5.1.1-9	Are records established and maintained for each batch of medical devices? Do the records provide traceability to the extent specified in 7.5.3. and identify the amount manufactured and amount approved for distribution? Are batch records verified and approved?		
7.5.1.2	**Control of production and service provision – Specific requirements**		
7.5.1.2.1.	**Cleanliness of product and contamination control**		

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Ref.	Question *(comments in italic are not in the standard)*	Yes/ No	Comments *[evidence - data - collection plan]*
7.5.1.2.1 -1	Are there established document requirements for the cleanliness of the product: a) When product is cleaned by the QMS organization prior to sterilization or use b) When product is supplied non-sterile but is subject to cleaning prior to sterilization or use c) When product is supplied to be used non-sterile but its cleanliness is of significance in use d) When process agents are to be removed from product during manufacture [process agents may be lubricants, powders or other additives to ensure smooth operations] Note: If product is handled according the a) or b) above, requirements contained in 6.4a (document health, cleanliness and clothing) and 6.4b (document work environment conditions) do not apply prior to the cleaning process.		
7.5.1.2.2 .	**Installation activities**		
7.5.1.2.2 -1	Are there establish documented requirements that contain acceptance criteria for installing and verifying the installation of the medical device? (where appropriate, meaning if it needs installing)		
7.5.1.2.2 -2.	If installation is not performed by QMS organization or its authorized agent, are documented requirements for installation and verification provided?		
7.5.1.2.2 -3	If installation is performed by QMS organization or its authorized agent, are records of installation and verification maintained?		
7.5.1.2.3	**Servicing Activities**		
7.5.1.2.3 -1	When servicing is a specified requirement, are there establish documented procedures, work instructions and reference materials and reference measurement procedures, for performing servicing activities and verifying that they meet the specified requirements? [Servicing can include, for example, repair and maintenance.]		
7.5.1.2.3 -2	Are servicing records maintained?		
7.5.1.3	**Particular requirements for sterile medical devices**		
7.5.1.3 -1	Are there records of sterilization process parameters for each batch? Are records maintained?		

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Ref.	Question *(comments in italic are not in the standard)*	Yes/ No	Comments *[evidence - data - collection plan]*
7.5.1.3-2	Are sterilization records traceable to each production batch of medical devices?		
7.5.2	**Validation of (production and service) provision processes**		
7.5.2.1	**General requirements**		
7.5.2.1-1	Have processes that result in a product/ service that cannot be verified by subsequent measurement or monitoring *(inspection and testing)* and result in deficiencies after delivery or use, been validated?		
7.5.2.1-2	Does the validation demonstrate that the process achieves planned results? *[Does evidence verify processes achieve results?]*		
7.5.2.1-3	Are arrangements defined for validation? Does the organization consider: - review and approval of the process - approval of equipment - qualification of personnel - use of methods and procedures - requirements for records - revalidation requirements		
7.5.2.1-4	Are there **establish documented procedures** for the validation of the application of computer software, including software and application changes, used in production of the product or performance of the service, that affect the ability of the product to conform to specified requirements? Are software applications **validated prior to initial use**?		
7.5.2.1-5	Are validation records maintained?		
7.5.2.2	**Particular requirements for sterile medical devices**		
7.5.2.2-1	Are there established documented procedures for the validation of sterilization processes? Are sterilization processes validated prior to initial use?		
7.5.2.2-2	Are validation records of each sterilization process maintained?		
7.5.3	**Identification and traceability**		
7.5.3.1	**Identification**		
7.5.3.1-1	Are there established documented procedures for product identification?		
7.5.3.1-2	Is product/service identified throughout production, and service operations (delivery and installation)?		
7.5.3.1-2	Are there establish documented procedures to ensure that returned medical devices are identified and distinguished from conforming product [see 6.4 d)].		

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Ref.	Question *(comments in italic are not in the standard)*	Yes/ No	Comments *[evidence - data - collection plan]*
7.5.3.2	**Traceability**		
7.5.3.2.1	**General**		
7.5.3.2.1 -1	Are there establish documented procedures for traceability. Do the procedures define the extent of product traceability and the records required (see 4.2.4, 8.3 and 8.5). [*Configuration management is a means by which identification and traceability can be maintained]*		
7.5.3.2.1 -2	Are there controls for unique identification of individual products (or batches) when traceability is a requirement? Are records maintained? (see 4.2.4).		
7.5.3.2.2	***Particular requirements for active implantable medical devices (AIMD) and implantable medical devices (IMD)***		
7.5.3.2.2 -1	*Do the records required for traceability include records of all components, materials and work environment conditions, if these could cause the medical device not to satisfy its specified requirements?*		
7.5.3.2.2 -2	*Are agents or distributors required to maintain records of the distribution of medical devices to allow traceability? Are the records available for inspection?*		
7.5.3.2.2 -3	*Are the name and address of the shipping package consignee recorded and are records maintained?*		
7.5.3.3	***Status identification***		
7.5.3.3-1	Is there provision to identify the status of the product/ service with regard to measurement and monitored requirements?		
7.5.3.3-2	Is product status identified throughout production, storage, installation and servicing of the product? Does the product status identification system ensure only product that has passed the required inspections and tests (or released under an authorized concession) been dispatched, used or installed?		
7.5.4	**Customer property** Note: Customer property includes intellectual property and personal data. [*personal data can include confidential health information*]		
7.5.4-1	Does the organization exercise care with customer property? *[see 7.1]*		
7.5.4-2	Is customer property, identified, verified, protected and safeguarded?		

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7.5.4-3	If customer property is lost, damaged, or otherwise unsuitable, is this recorded and reported to the customer?		
7.5.5	**Preservation of product**		
7.5.5-1	Are there establish documented procedures or documented work instructions for preserving the conformity of product during internal processing and delivery to the intended destination?		
7.5.5-2	Does the organization ensure conformity (quality) is maintained (**including constituent parts**) from internal processing to final delivery? Is product/ service conformity maintained, applicable, during identification, handling, packaging, storage, and protection? *[apply 7.1, verify plan exists]*		
7.5.5-3	Are there established documented procedures or documented work instructions for the control of product with a **limited shelf-life** or requiring **special storage conditions?** Are special storage conditions controlled and recorded?		
7.6	**Control of monitoring and measuring equipment**		
7.6-1	Have measurements and devices been determined that are needed to assure conformity of product to requirements?		
7.6-2	Are there established documented procedures to ensure that monitoring and measurement **can be carried out and are carried out in a manner** that is consistent with the monitoring and measurement requirements?		
7.6a-3	Has measuring equipment (and measurement devices) been calibrated? (when required to maintain valid results)		
7.6a-4	Is this equipment adjusted at prescribed intervals, or prior to use, against certified equipment having a known valid relationship to nationally recognized standards? (when required to maintain valid results)		
7.6a-5	Where no calibration standards exist, is the basis for calibration recorded? (when required to maintain valid results)		
7.6b-6	Is equipment adjusted and readjusted as necessary? *Note: There may be situations where events require calibrations checks beyond the established interval.*		
7.6c-7	Is equipment identified such that the calibration status can be determined?		
7.6d-8	Are there safeguards against adjustments that would invalidate calibration settings? (when required to maintain valid results)		

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Ref.	Question *(comments in italic are not in the standard)*	Yes/ No	Comments *[evidence - data - collection plan]*
7.6e-9	Are the handling, maintenance, and storage of this equipment such that it is protected from damage or deterioration?		
7.6f-10	Are records of the results of calibration and verification maintained?		
7.6-11	Is the validity of previous results assessed when equipment is found to be out of calibration? Is action taken on the equipment (device) and any product affected?		
7.6-12	Is computer software confirmed as being able to satisfy the intended application prior to use? Is the software reconfirmed as necessary? [*Hint: Does the organization use configuration management to confirm software capability?]*		

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Ref.	Question *(comments in italic are not in the standard)*	Yes/ No	Comments *[evidence - data - collection plan]*
8	**Measurement, analysis, and improvement**		
8.1	**General**		
8.1-1	Are measuring, monitoring, analyzing, and improvement processes planned and implemented for: * demonstrating conformity to product requirements * assuring conformity of the QMS * maintaining the effectiveness of the QMS?		
8.1-2	Has the organization determined what methods (extent and use) are applicable (including statistical techniques) for measuring, monitoring, analysis? Note that regulations may require documented procedures for implementation and control of statistical techniques.		
8.2	**Measurement and monitoring**		
8.2.1	**Feedback**		
8.2.1-1	Is customer information regarding meeting requirements monitored and used as a measure of quality management system performance? *[Crosscheck management review records] Data may include surveys, customer data on delivered product quality, lost business analysis, compliments, returns, warranty claims, agent reports.*		
8.2.1-2	Are methods for obtaining *[collecting]* and using such information determined?		
	Is there an establish a documented procedure for a feedback system (see 7.2.3 c)? Does the procedure provide an early warning of quality problems and provide input into the corrective and preventive action processes?		
	When national or regional regulations require the organization to gain experience from the post-production phase, does the review of this experience form part of the feedback system?		
8.2.2	**Internal auditing**		
8.2.2-1	Are internal audits conducted at planned intervals?		
8.2.2-2	Are audits carried out to determine conformance of the QMS to planned arrangements, the organizations QMS requirements, this International Standard, and that the QMS has been effectively implemented and maintained?		

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Ref.	Question *(comments in italic are not in the standard)*	Yes/ No	Comments *[evidence - data - collection plan]*
8.2.2-3	Does the audit program plan consider status and importance of the activities and areas to be audited and results of previous audits?		
8.2.2-4	Are audit criteria, scope, frequency, and methods defined?		
8.2.2-5	Are auditors selected and audits conducted to ensure objectivity and impartiality of the audit process? Are auditors prevented from auditing their own work?		
8.2.2-6	Are there documented procedures? Do the procedures cover responsibilities, requirements for planning and conducting, establishing records and reporting results?		
8.2.2-7	Are records of audits and their results maintained? [4.2.4]		
8.2.2-8	Is action taken by management responsible for the area to address the nonconformities (correction)? Is this done without undue delay? *[Note that actions can include corrections and corrective actions]*		
8.2.2-9	Are follow-up activities carried out to verify the effectiveness of actions taken? Are the verification results reported? [8.5.2]		
8.2.3	**Monitoring and measurement of processes**		
8.2.3-1	Are there suitable methods for monitoring (and measuring when applicable) the QMS **processes** to achieve planned results? *[Can the organization provide evidence that applied methods achieve planned results?] [A note explains that suitable methods are determined by the organization considering the type and extent of monitoring or measurement appropriate for each in relation to their impact on the conformity to product requirements and on the effectiveness of the quality management system.*		
8.2.3-2	Is correction or corrective action taken on processes not achieving planned results?		
8.2.4	**Monitoring and measurement of product *[service]***		
8.2.4.1	**General requirements**		
8.2.4.1-1	Are the product characteristics measured and monitored to verify product requirements are met?		

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Ref.	Question *(comments in italic are not in the standard)*	Yes/ No	Comments *[evidence - data - collection plan]*
8.2.4.1-2	Are measuring and monitoring carried out at appropriate stages of the realization process and in accordance with planned arrangements and documented procedures?		
8.2.4.1-3	Is evidence (measurement & monitoring evidence) showing conformance to acceptance criteria recorded?		
8.2.4.1-4	Are there records? Do the records indicate the person(s) authorizing release of the product for delivery to the customer?		
8.2.4.1-5	Is product/service release and delivery to the customer held until all planned arrangements (*specified activities*) are satisfactorily completed?		
8.2.4.2	***Particular requirement for active implantable devices (AIMD) and implantable devices (IMD)***		
8.2.4.2-1	*Is the identity of personnel performing any inspection or testing recorded?*		
8.3	**Control of nonconforming product**		
8.3-1	Are there controls to prevent nonconforming (off-specification) product/ service from unintended use or delivery? Are they being used?		
8.3-2	Are nonconforming activities defined in a documented procedure? Is responsibility and authority for review and resolving nonconforming product defined in the documented procedure?		
8.3-3	Does the organization deal with nonconforming product by one or more of the following (where applicable): - eliminate the nonconformity (corrected). *[rework, repair, blend]* - authorize its use, release or acceptance by concession *[use 'as is']* - action to preclude its original intended use or application?*[regrade, scrap]* - appropriate action taken regarding the consequences of the nonconformities found after delivery or use		
8.3-4	Is corrected product subject to re-verification activities to demonstrate conformity to requirements?		

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8.3-5	Are all regulatory requirements met for any product accepted by concession? Do records identity of the person(s) authorizing the concession? Are the records maintained?		
8.3-6	Is there a record of the nature of the nonconformance and subsequent action (*history*)? Are they maintained?		
8.3-7	When product is reworked (one or more times), is the process documented in a work instruction that has undergone the same authorization and approval procedure as the original work instruction?		
8.3-8	Before the rework instruction is authorized and approved, has any adverse effect of the rework upon product been determined and documented? (see 4.2.3 and 7.5.1).		
8.4	**Analysis of data**		
8.4-1	Are there established documented procedures to determine the collection and analyzing of data to demonstrate the suitability and effectiveness of the QMS and to evaluate areas to improve the effectiveness of the QMS? Is it being followed?		
8.4-2	Does the information include data from measuring and monitoring activities and other relevant sources?		
8.4-3	Does analysis of data provide information on: - feedback [8.2.1] - conformity to product requirements [8.2.4] - characteristics of processes, products and their trends, and opportunities for preventive action [8.2.3 and 8.2.4] - suppliers [7.4]		
8.4-4	Are records maintained?		
8.5	**Improvement**		
8.5.1	**General**		
8.5.1-1	Does the organization identify and implement any changes necessary to ensure and maintain the continued suitability and effectiveness of the quality management system through the use of a quality policy, objectives, management review, audit results, corrective and preventive actions and analysis of data?		
8.5.1-2	Are there established documented procedures for the **issue and implementation of advisory notices**? Are the procedures capable of being implemented at any time? Are they being followed? .		
8.5.1-3	Are there customer complaint investigations recorded? If investigation determines that the activities outside the organization contributed to the customer complaint, is relevant information exchanged between the organizations involved?		

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8.5.1-4	When customer complaint is not followed by corrective and/or preventive action, is the reason recorded and authorized? .		
8.5.1-5	Are there documented procedures for notification of adverse events that meet specified reporting criteria, when required by regulations? .		
8.5.2	**Corrective action**		
8.5.2-1	Are corrective actions implemented based on importance (impact of problems encountered)?		
8.5.2-2	Is there a documented procedure for corrective action? Is corrective action taken?		
8.5.2a-3	Does the corrective action procedure include requirements for reviewing nonconformities (including customer complaints)? *[Complaints may be handled separately, perhaps in the sales - marketing department.]*		
8.5.2b-4	Does the procedure include requirements of determination of causes and their elimination?		
8.5.2c-5	Does the procedure define the requirements for evaluating the need for actions? (to ensure they do not recur)		
8.5.2d-6	Are requirements for implementation actions, including updating documentation defined in the procedure?		
8.5.2e-7	Does the procedure require the results (actions) of the investigation and actions taken to be recorded? Is it being done?		
8.5.2f-8	Does the procedure establish and define the requirements for reviewing the effectiveness of corrective action taken?		
8.5.3	**Preventive action**		
8.5.3-1	Are preventive actions implemented based on importance (impact of the potential problems)?		
8.5.3-2	Is there a documented procedure for preventive action? Is preventive action taken?		
8.5.3a-3	Does the procedure define the requirements for potential nonconformity determination and their causes?		

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8.5.3b-4	Does the procedure define the requirements for evaluating the need for action to prevent occurrence?		
8.5.3c-5	Does the procedure define the requirements for determining and implementation of *(preventive*) actions needed?		
8.5.3d-6	Are results of the investigation and (*preventive*) actions taken recorded?		
8.5.3e-7	Are requirements defined for reviewing the effectiveness of preventive action taken?		

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