

[organization name]

## Appendix 1 – Internal Audit Checklist for ISO 13485

ISO 13485 Clause	Requirement of the standard	Compliant	Evidence
		Yes/No	
4.1	Are the processes necessary for the QMS determined, described, managed and applied in the organization?		
4.1.2	How does the organization implement its QMS processes in the context of the applicable regulatory requirements for its quality management system, and in particular applicable regulatory requirements?		
4.1.3	Does the organization have, for each QMS process: <ul style="list-style-type: none"> <li>• Identification of methods needed to ensure that the context of these processes is effective</li> <li>• Availability of resources and allocation of resources to support the process</li> <li>• Monitoring of these processes</li> <li>• Implementing actions necessary to address observed needs</li> <li>• Monitoring the effectiveness of these processes</li> <li>• Identifying, measuring and reducing the variation</li> <li>• Implementing controls needed to ensure the effectiveness of the QMS and QMS processes</li> </ul>		
4.1.4	How does the organization manage QMS processes in accordance with the requirements of this International Standard and applicable regulatory requirements?		
4.1.5	How does the organization ensure the control of implemented processes that could affect product conformity to requirements?		
4.1.6	Do procedures exist for the validation of the application of computer software used in the Quality Management System?		
4.2.1	How does the organization implement the quality policy, quality objectives, quality manual and procedures and records required by ISO 13485?		

**Commented [134851]:** These are the requirements of the ISO 13485 standard; you should also insert the specific requirements from your own documentation.

**Commented [134853]:** To be filled in during the audit – records, verbal statements or auditor’s personal observations that confirm the finding.

**Commented [134852]:** To be filled in during the audit – fill in Yes or No depending on whether the company is compliant or not.

[organization name]

	13485 and all documents and records defined as necessary by the organization?		
4.2.2	Does the Quality Manual include the scope of interaction between the QMS processes?		
4.2.3	Does the organization have a medical device file for each medical device type?		
4.2.4-01	Does the organization have a documented review and update?		
4.2.4-02	Did the organization ensure that changes, of applicable documents are kept up to date and available for use?		
4.2.4-03	Did the organization apply suitable identification of obsolete documents to prevent their unintended use?		
4.2.4-04	Did the organization define the period for retention of documents?		
4.2.4-05	Is the period for retention of documents to which medical devices have been by the organization, but not less than the requirements?		
4.2.5	Did the organization establish records to disposition of records?		
4.2.5-01	Is the period for retention of records related to medical devices, but not less than the applicable regulatory requirements?		
5.1-01	Did top management demonstrate its		

[organization name]

	implementation of the QMS by emphasizing the importance of meeting customer requirements and enhancing customer satisfaction?		
5.1.-02	Did top management establish the Quality Policy and ensure adequate resources? management review and ensure availability of resources?		
5.2	Is top management committed to meeting customer requirements and enhancing customer satisfaction?		
5.3	Does top management ensure that the Quality Policy is implemented in the context of the organization and its environment? commitment to comply with the requirements and standards requirements of the QMS, providing resources for quality improvement activities? organization and reviewed?		
5.4.1	Does top management ensure that quality objectives, including those needed to meet customer requirements, are measurable and aligned with the Quality Policy?		
5.4.2-01	Does top management plan the QMS in order to ensure adequate resources for implementation?		
5.4.2-02	Does top management ensure the integrity of the QMS if planning and applying changes to the QMS?		
5.5.1	Are responsibilities and authorities defined by top management and communicated within the organization?		
5.5.2	Did top management appoint a management representative who has the responsibility and authority to ensure processes necessary for establishing, implementing and maintaining the QMS, and who reports to top management on QMS performance and need for improvement and resources availability? customer requirements throughout the organization?		
5.5.3	Did top management establish appropriate communication processes within the organization and with interested parties?		

[organization name]

	the effectiveness of the QMS?		
5.6.1	Does top management conduct a QMS review <small>Does the organization determine the frequency and timing of management reviews of the QMS including Quality Policy and Quality Objectives to ensure that the QMS is suitable, adequate and effective?</small> its continuous suitability, adequacy and effectiveness?		
5.6.2	Does the management review include <small>Does the management review include information on results of audits, customer feedback, process performance and control, corrective actions, follow-up action from previous management reviews, changes that affect the QMS and resource requirements?</small> corrective actions, follow-up action from previous management reviews, changes that affect the QMS and resource requirements for improvement?		
5.6.3	Do outputs from the management review <small>Do outputs from the management review include decisions and actions related to improvement of effectiveness of the QMS and its processes, improvement of product related processes, improvement of resources?</small> its processes, improvement of product related processes, improvement of resources?		
6.1	Does the organization define and provide resources needed for implementation and maintenance of the QMS, continual <small>Does the organization define and provide resources needed for implementation and maintenance of the QMS, continual improvement of the QMS and its processes?</small>		
6.2.1	Are personnel performing work affecting <small>Are personnel performing work affecting the QMS, including the QMS, training, skills and experience?</small> training, skills and experience?		
6.2.2-01	Did the organization determine necessary <small>Did the organization determine necessary resources to ensure the effectiveness of actions taken?</small> review and record effectiveness of actions taken?		
6.2.2-02	Are personnel aware of relevance and <small>Are personnel aware of relevance and importance of their work in contributing to the achievement of the QMS?</small> contribute to achievement of the QMS?		
6.3	Did the organization determine, provide, and <small>Did the organization determine, provide, and maintain the resources needed to ensure conformity to product requirements including</small> conformity to product requirements including		

[organization name]

	buildings, workspace, associated utilities, and equipment and supporting services?		
6.4-01	Did the organization determine and manage the work environment needed to address conformity to product requirements?		
6.4.2-01	Did the organization plan and document arrangements for the control of contaminated or potentially contaminated product?		
6.4.2-02	Did the organization document requirements for work environment needed for control of contaminated and the required facilities during assembly or packaging processes?		
7.1-01	Does the organization plan and develop processes needed to control resources and to planning activities with the requirements of the other processes of the QMS?		
7.1-02	While planning product realization, did the organization determine, as appropriate, quality objectives and product requirements and the work environment needed to achieve those requirements for the product?		
7.1-03	While planning product realization, did the organization determine, as appropriate, required resources of infrastructure, facilities, monitoring, measuring, controlling and testing specific for product criteria for product acceptance and records needed?		
7.1-04	Are the planning outputs in a form suitable for the organization's method of operations?		
7.1-05	Does the organization have a procedure for risk management?		
7.2.1	Did the organization determine requirements specified by the customer, statutory requirements, regulatory and other activities, requirements not stated by the customer, statutory and regulatory requirements, specifying the product and the process requirements needed necessary?		
7.2.2-01	Did the organization review and approve product requirements, which apply to the requirements regardless of whether the		

[organization name]

	requirements are documented prior to review?		
7.2.2-02	Did the organization ensure that contractual requirements are resolved and defined?		
7.2.2-03	Does the organization maintain records about results and actions arising from this review, requirements?		
7.2.3	Did the organization determine and implement effective arrangements for other handling and customer feedback including customer complaints?		
7.3.1	Does the organization have a procedures for design and development?		
7.3.2-01	Does the organization plan design and verification and validation actions that are appropriate to each design and development design and development?		
7.3.2-02	Does the organization plan design and development inputs and the resources personnel?		
7.3.3	Does the organization determine, maintain requirements, statutory and regulatory requirements essential for design and development and record maintenance?		



[organization name]

7.3.4	Are outputs suitable for verification against production and service provision, reference to and proper use and approved prior to release?		
7.3.4-01	Are output elements of design and input elements and prior to release?		
7.3.5-01	Is a systematic review of design and order to evaluate the ability of the results of and propose necessary actions?		
7.3.5-02	Among the participants of the design and maintained?		
7.3.6-01	Do design and development output elements verification records maintained?		
7.3.6-02	When the medical device is intended to be outputs meet design inputs when the devices are connected?		
7.3.7-01	Does design and development result in the where known?		
7.3.7-02	Is validation done prior to delivery or actions maintained?		
7.3.7-03	Did the organization perform clinical regulatory requirements as a part of design		

[organization name]

7.3.7-04	For medical devices that are connected to, or interface with, other medical devices, are the design records sufficient to ensure the requirements for the specified application or intended use of the other medical devices is connected or interfaced?		
7.3.8	Does the organization have a section in the design and development process that allows for the transfer of design and development outputs to manufacturing?		
7.3.9-01	Does the company identify changes in design and development records, control plans, test plans, test cases, and other applicable design prior to implementation?		
7.3.9-02	Does the design and development review process include a review of effects of changes to the design and development records?		
7.3.10	Does the organization maintain a design and development record that includes design and development records that include or reference records generated to document changes to the design and development records for design and development changes.		
7.4.1	Did the organization establish criteria for product in accordance with the organization's requirements, and maintain records of results?		
7.4.2	Is purchasing information adequate and approved for product, procedures, processes and services, and does it meet the requirements?		
7.4.3-01	Did the organization establish and implement specified purchase requirements?		



[organization name]

7.4.3-02	Did the organization state the intended [redacted] when the organization or its customer intends to perform activities in the supplier's premises?		
7.5.1-01	Does the organization plan and execute [redacted] availability of information that describes the [redacted]		
7.5.1-02	Does the organization provide conditions that [redacted] monitoring and measurement and [redacted] and post-delivery activities?		
7.5.2-01	Did the organization define requirements for [redacted]		
7.5.3-01	Did the organization document requirements [redacted] validation?		
7.5.3-02	Did the organization provide documented [redacted] party that performs installation?		
7.5.3-03	Are the records about medical device [redacted] kept?		
7.5.4-01	Has the organization documented servicing [redacted] performing servicing activities and verifying [redacted] maintained records of servicing activities?		
7.5.4-02	Did the organization analyze records of [redacted] information is to be handled as a complaint or for input to the improvement process?		

[organization name]

7.5.5-01	Did the organization maintain records of the sterilization batch?		
7.5.5-02	Are the sterilization records traceable to each production batch of medical devices?		
7.5.6	Does the organization have special processes? Is there validation of these processes?		
7.5.7	Are there requirements and procedures for sterile barrier systems?		
7.5.8	Did the organization have procedures for realization?		
7.5.9-01	Did the organization have procedures for traceability?		
7.5.9-02	Do records for traceability include records of cause the medical device not to satisfy its requirements?		
7.5.10	Did the organization have procedures for customer property?		
7.5.11	Did the organization have procedures for preservation of product?		
7.6-01	Does the organization determine monitoring to provide evidence of conformity of product to determined requirements?		
7.6-02	Does the organization establish processes to that is consistent with the monitoring and		
7.6-03	Is measuring equipment calibrated or verified, international or national measurement and verification recorded?		

[organization name]

7.6-04	Is measuring equipment adjusted or re- to determine its calibration status?		
7.6-05	Is measuring equipment safeguarded from measurement result?		
7.6-06	Is measuring equipment protected from maintenance and storage?		
7.6-07	Does the organization assess and record the to requirements and take appropriate action on the equipment and any product affected?		
7.6-08	Does the organization maintain records of the results of the calibration?		
7.6-09	Does the organization confirm the ability of monitoring and measurement of specified requirements?		
8.1-01	Does the organization plan and implement conformity to the product requirements and effectiveness of the QMS?		
8.1-02	Does this include determination of applicable the extent of their use?		
8.2.1-01	Does the organization monitor information requirements?		
8.2.1-02	Does the organization determine the methods for obtaining and using this information?		
8.2.2	Did the organization have a procedure for complaint handling?		
8.2.3	Did the organization have a procedure for notification of complaints that meet specified issuance of advisory notices?		

[organization name]

8.2.4-01	Does the organization conduct internal audits in accordance with the planned arrangements, to the organization?		
8.2.4-02	Does the organization conduct internal audits implemented and maintained?		
8.2.4-03	Does the organization plan the auditing well as results of previous audits?		
8.2.4-04	Does the organization define the audit criteria, scope, frequency and methods?		
8.2.4-05	Does the organization select auditors and auditors from auditing their own work?		
8.2.4-06	Does the organization establish documented audits, establishing and maintaining records and reporting results?		
8.2.4-07	Does the management responsible for the corrections and corrective actions are taken non-conformities and their causes?		
8.2.4-08	Do the follow-up activities include the verification results?		
8.2.5-01	Does the organization apply suitable methods system processes?		
8.2.5-02	Do methods of monitoring and measurement achieve planned results?		
8.2.6-01	Does the organization monitor and measure the characteristics of the product to verify		

[organization name]

	Has product requirements been identified?		
8.2.6-02	Does the organization maintain evidence of conformity with the acceptance criteria?		
8.2.6-03	Do records indicate the processes conforming status of product for delivery to the customer?		
8.2.6-04	In the absence of product and services to the customer, processes and the planned arrangements have been satisfactorily completed unless otherwise approved by relevant authority and, where applicable, by the customer?		
8.3.1-01	Does the organization ensure that product that does not conform to product requirements is identified and controlled to prevent its unintended use or delivery?		
8.3.1-02	Does the organization establish a documented procedure to define the control and related responsibilities and authorities for dealing with non-conforming product?		
8.3.2-01	Does the organization, where applicable, deal with non-conforming product by taking action to eliminate the detected nonconformity?		
8.3.2-02	Does the organization, where applicable, deal with non-conforming product by conforming to any, where or acceptance under conditions to relevant authority and, where applicable, by the customer?		
8.3.2-03	Does the organization, where applicable, deal with non-conforming product by taking action to prevent its original intended use or application?		
8.3.2-04	Does the organization, where applicable, deal with non-conforming product by taking action appropriate to the effects, or potential effects, of the nonconformity, where non-conforming product is detected after delivery or use has started?		
8.3.2-05	Does the organization subject corrected product to re-evaluation to demonstrate conformity to the requirements?		
8.3.2-06	Does the organization maintain the records of the nature of nonconformities and any subsequent actions taken, including		

[organization name]

	<p>conformance achieved?</p>		
8.3.3	<p>Has the organization described the actions and responses for nonconforming product detected after delivery, and does an effective action procedure exist to conform to applicable regulatory requirements?</p>		
8.3.4	<p>Has the organization described the actions for recall and the potential adverse effect of the recall on the product?</p>		
8.4-01	<p>Does the organization determine, collect and analyze appropriate data to demonstrate the usability and effectiveness of the QMS and to indicate where continual improvement of the effectiveness of the QMS is to occur?</p>		
8.4-02	<p>Does the system of data provide information relating to customer satisfaction, conformity to product requirements, characteristics and needs of processes and products, including opportunities for preventive action and control?</p>		
8.5.1	<p>Does the organization continually improve the effectiveness of the QMS through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions, and management review?</p>		
8.5.2-01	<p>Does the organization take action to eliminate the cause of nonconformities in order to prevent recurrence?</p>		
8.5.2-02	<p>Are corrective actions appropriate to the effects of the nonconformities encountered?</p>		
8.5.2-03	<p>Does the organization establish documented procedures to define requirements for reducing nonconformities including customer complaints?</p>		
8.5.2-04	<p>Does the organization establish documented procedures to define requirements for determining the cause of nonconformities?</p>		
8.5.2-05	<p>Does the organization establish documented procedures to define requirements for reducing the need for action to ensure that nonconformities do not recur?</p>		
8.5.2-06	<p>Does the organization establish documented procedures to define requirements for determining and implementing action?</p>		

[organization name]

8.5.2-07	Does the organization maintain documented procedures to define requirements for records of the results of action taken?		
8.5.2-08	Does the organization maintain documented procedures to define requirements for recording the effectiveness of the corrective action taken?		
8.5.3-01	Does the organization determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence?		
8.5.3-02	Does the organization ensure that corrective actions are appropriate to the effects of the detected problem?		
8.5.3-03	Does the organization ensure that a documented procedure has been established to define requirements for determining potential nonconformities and their causes?		
8.5.3-04	Does the organization ensure that a documented procedure has been established to define requirements for evaluating the need for action to prevent occurrence of nonconformities?		
8.5.3-05	Does the organization ensure that a documented procedure has been established to define requirements for determining and implementing action needed?		
8.5.3-06	Does the organization ensure that a documented procedure has been established to define requirements for records of results of action taken?		
8.5.3-07	Does the organization ensure that a documented procedure has been established to define requirements for recording the effectiveness of the corrective action taken?		