Appendix 1 – Internal Audit Checklist for ISO 13485

ISO 13485 Clause	Requirement of the standard	Compliant Yes/No	Evidence
4.1	Are the processes necessary for the QMS determined, described, managed and applied in the organization?		
4.1.2	[illegible]		
4.1.3	Does the organization have, for each QMS process: • [illegible] • [illegible] • [illegible] • [illegible] • [illegible] • [illegible] • [illegible]		
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	[illegible] 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	[illegible] procedures and records required by ISO		

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

[illegible]

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.

	13485 and all documents and records defined as necessary by the organization?		
4.2.2	Does the Quality Manual include the scope of [redacted] 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 [redacted] review and update?		
4.2.4-02	Did the organization ensure that changes, [redacted] 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 [redacted]		
4.2.4-05	Is the period for retention of documents to which medical devices have been [redacted] by the organization, but not less than the [redacted] requirements?		
4.2.5	Did the organization establish records to [redacted] disposition of records?		
4.2.5-01	Is the period for retention of records related [redacted] device as defined by the organization, but not [redacted] applicable regulatory requirements?		
5.1-01	Did top management demonstrate its [redacted]		

	implementation of the QMS by emphasizing [redacted]		
5.1.-02	Did top management established the Quality [redacted] resources?		
5.2	Is top management committed to meeting customer requirements and enhancing customer satisfaction?		
5.3	Does top management ensure that the [redacted] commitment to comply with the [redacted] organization and reviewed?		
5.4.1	Does top management ensure that quality objectives, including those needed to meet [redacted] measurable and aligned with the Quality Policy?		
5.4.2-01	Does top management plan the QMS in order [redacted]		
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 [redacted]		
5.5.2	Did top management appoint a management [redacted] establishing, implementing and maintaining the QMS, and who reports to top [redacted] customer requirements throughout the organization?		
5.5.3	Did top management establish appropriate [redacted]		

	the effectiveness of the QMS?		
5.6.1	Does top management conduct a QMS review [redacted] QMS including Quality Policy and Quality [redacted] its continuous suitability, adequacy and effectiveness?		
5.6.2	Does the management review include [redacted] corrective actions, follow-up action from [redacted] for improvement?		
5.6.3	Do outputs from the management review [redacted] its processes, improvement of product related [redacted]		
6.1	Does the organization define and provide resources needed for implementation and maintenance of the QMS, continual [redacted]		
6.2.1	Are personnel performing work affecting [redacted] training, skills and experience?		
6.2.2-01	Did the organization determine necessary [redacted] review and record effectiveness of actions taken?		
6.2.2-02	Are personnel aware of relevance and [redacted] contribute to achievement of the QMS?		
6.3	Did the organization determine, provide, and [redacted] conformity to product requirements including		

	buildings, workspace, associated utilities, and equipment and supporting services?		
6.4-01	Did the organization determine and manage [illegible]		
6.4.2-01	Did the organization plan and document [illegible] or potentially contaminated product?		
6.4.2-02	Did the organization document requirements [illegible] during assembly or packaging processes?		
7.1-01	Does the organization plan and develop [illegible] QMS?		
7.1-02	While planning product realization, did the organization determine, as appropriate, quality objectives and product requirements [illegible] product?		
7.1-03	While planning product realization, did the [illegible] 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 [illegible] necessary?		
7.2.2-01	Did the organization review and approve [illegible] requirements regardless of whether the		

	requirements are documented prior to [redacted] review?		
7.2.2-02	Did the organization ensure that contractual [redacted] resolved and defined?		
7.2.2-03	Does the organization maintain records about results and actions arising from this review, [redacted] requirements?		
7.2.3	Did the organization determine and implement effective arrangements for [redacted] 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 [redacted] verification and validation actions that are appropriate to each design and development [redacted] design and development?		
7.3.2-02	Does the organization plan design and [redacted] development inputs and the resources [redacted] personnel?		
7.3.3	Does the organization determine, maintain [redacted] requirements, statutory and regulatory [redacted] requirements essential for design and development and record maintenance?		

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

7.3.7-04	For medical devices that are connected to, or [blurred] the requirements for the specified application [blurred] devices is connected or interfaced?		
7.3.8	Does the organization have a section in the [blurred] outputs to manufacturing?		
7.3.9-01	Does the company identify changes in design [blurred] prior to implementation?		
7.3.9-02	Does the design and development review [blurred] products, and are related records maintained?		
7.3.10	Does the organization maintain a design and [blurred] include or reference records generated to [blurred] design and development changes.		
7.4.1	Did the organization establish criteria for [blurred] product in accordance with the organization's [blurred] results?		
7.4.2	Is purchasing information adequate and [blurred] approval of product, procedures, processes [blurred] requirements?		
7.4.3-01	Did the organization establish and implement [blurred] specified purchase requirements?		

7.4.3-02	Did the organization state the intended [redacted] when the organization or its customer intends [redacted] 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?		

7.5.5-01	Did the organization maintain records of the [blurred] 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 [blurred] sterile barrier systems?		
7.5.8	Did the organization have procedures for [blurred] realization?		
7.5.9-01	Did the organization have procedures for traceability?		
7.5.9-02	Do records for traceability include records of [blurred] cause the medical device not to satisfy its [blurred] 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 [blurred] to provide evidence of conformity of product to determined requirements?		
7.6-02	Does the organization establish processes to [blurred] that is consistent with the monitoring and [blurred]		
7.6-03	Is measuring equipment calibrated or verified, [blurred] international or national measurement [blurred] and verification recorded?		

7.6-04	Is measuring equipment adjusted or re-[illegible] to determine its calibration status?		
7.6-05	Is measuring equipment safeguarded from [illegible] measurement result?		
7.6-06	Is measuring equipment protected from [illegible] maintenance and storage?		
7.6-07	Does the organization assess and record the [illegible] 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 [illegible] monitoring and measurement of specified requirements?		
8.1-01	Does the organization plan and implement [illegible] conformity to the product requirements and [illegible] effectiveness of the QMS?		
8.1-02	Does this include determination of applicable [illegible] the extent of their use?		
8.2.1-01	Does the organization monitor information [illegible] 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 [illegible] notification of complaints that meet specified [illegible] issuance of advisory notices?		

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

	[illegible]		
8.2.6-02	[illegible]		
8.2.6-03	[illegible]		
8.2.6-04	[illegible]		
8.3.1-01	[illegible]		
8.3.1-02	[illegible]		
8.3.2-01	[illegible]		
8.3.2-02	[illegible]		
8.3.2-03	[illegible]		
8.3.2-04	[illegible]		
8.3.2-05	[illegible]		
8.3.2-06	[illegible]		

	[illegible]		
8.3.3	[illegible]		
8.3.4	[illegible]		
8.4-01	[illegible]		
8.4-02	[illegible]		
8.5.1	[illegible]		
8.5.2-01	[illegible]		
8.5.2-02	[illegible]		
8.5.2-03	[illegible]		
8.5.2-04	[illegible]		
8.5.2-05	[illegible]		
8.5.2-06	[illegible]		

	needed?		
8.5.2-07	Does the organization establish documented procedures to define requirements for records of the results of action taken?		
8.5.2-08	Does the organization establish documented procedures to define requirements for reviewing 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 preventive actions are appropriate to the effects of the potential problems?		
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 reviewing the effectiveness of the preventive action taken?		