Evaluation Sheet for Compliance with the Quality Management Standards for Medical Devices

<table>
<tr><td>Business Name</td><td colspan="2"></td><td>Business License No.</td><td colspan="2"></td></tr>
<tr><td>Representative</td><td colspan="2"></td><td>Quality Manager</td><td colspan="2"></td></tr>
<tr><td>Location</td><td colspan="5">(☎) (FAX)</td></tr>
<tr><td>Applications</td><td colspan="5">□ Approval of Compliance with the Manufacturing and Quality Management Standards □ Approval of Compliance with the Foreign Manufacturing and Quality Management Standards
□ Foreign Approval of Compliance with the Manufacturing and Quality Management Standards
□ Medical Device for Clinical Trial</td></tr>
<tr><td>Classification of Review</td><td colspan="5">□ Initial review □ Periodic renewal review □ Re-examination
□ Ad Hoc review □ Others ( )</td></tr>
<tr><td rowspan="3">Product of Review</td><td>Product type</td><td colspan="4"></td></tr>
<tr><td>Commercial Name (Classification name of Classification and Model name)</td><td colspan="4"></td></tr>
<tr><td>Class</td><td colspan="4"></td></tr>
<tr><td rowspan="3">Review Board</td><td>Medical device Surveillance officer</td><td colspan="4"></td></tr>
<tr><td>Quality auditor</td><td colspan="4"></td></tr>
<tr><td>Quality Management Review Agency</td><td colspan="4"></td></tr>
<tr><td></td><td>Total Number of Evaluation Items</td><td>A(Appropriate)</td><td>B(Required to be supplemented)</td><td>C(Inappropriate)</td><td>D(Not applicable)</td></tr>
<tr><td>Audit Period</td><td colspan="5">YYYY.MM.DD~YYYY.MM.DD</td></tr>
<tr><td>Result of Review</td><td>Final Decision</td><td colspan="4">□ Conformable □ Non-conformable
□ Required to be supplemented (by YYYY.MM.DD)</td></tr>
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This is the result of quality review as provided in Article 7 of Standards for Manufacture, Import and Quality Management of Medical Device.

Day/month/year

Medical device surveillance officer : (seal)
Quality auditor : (seal)
Representative : (seal)

1. Evaluation Sheet

A. "A(Appropriate)" means that it is deemed the requirements specified in the quality management standards are met.

B. "B(Required to be supplemented)" means that the requirements specified in the quality management standards are not met or that such requirements are met but supplementary measures are required such as improvement, etc., due to insufficiency of the grounds for proof of the observance, practicality, or appropriateness of record, etc.

C. "C(Inappropriate)" means that the items decided as "required to be supplemented" at initial review are also decided as "Required to be supplemented" at re-examination.

D. "D(Not applicable)" means that the item is not applicable to the requirements specified in the quality management standards.

2. Decision criteria

A. Conformable

In case that all items are decided as "A"(Appropriate)" from review under the review criteria

B. Required to be supplemented

In case that the result of review under the review criteria showed one or more "B(Required to be supplemented)"

1) If on-site re-examination is required

Matters required in the specification or a requirement in the Procedures/Instructions are omitted in the import quality control system or wholly destroyed, or a multiple of minor supplements likely to destroy the import quality control system

2) If on-site re-examination is not required

Matters required in the specification or a few minor supplements in the Procedures/Instructions, where the requirements fail to be met partially

C. Non-conformable

In case that the result of review under the review criteria showed one or more "C(inappropriate)"

Audit Scope	contents of examination
1. Quality management system	
2. Management Responsibility	
3. Resource management	
4. Product realization	
5. Measurement, analysis and improvement	
6. General review	

Requirements for the quality control criteria	Review Criteria	Result of review				Remarks
		A	B	C	D	
4. Quality management system 4.1 General requirements	A. The manufacturer shall establish, document, implement and maintain a quality management system and maintain its effectiveness in accordance with the requirements of this Standards. B. The manufacturer shall: 1) identify the processes needed for the quality management system and their application throughout the organization; 2) determine the sequence and interaction of these processes; 3) determine criteria and methods needed to ensure that both the operation and control of these processes are effective; 4) ensure the availability of resources and information necessary to support the operation and monitoring of these processes; 5) monitor, measure and analyze these processes; and 6) Implement actions necessary to achieve planned result and maintain the effectiveness of these processes. C. These processes shall be managed by the manufacturer in accordance with the requirements of this Standard. D. Where a manufacturer chooses to outsource any process that affects product conformity with requirements, the manufacturer shall ensure control over such processes. Control of such outsourced processes shall be identified within the quality management system.					
4.2 Documentation requirements 4.2.1 General	A. The quality management system documentation shall include: 1) documented statements of a quality policy and quality objectives; 2) a quality manual; 3) documented procedures required by this Standards; 4) documents needed by the organization to ensure the effective planning, operation and control of its processes 5) records required by this Standards; and 6) any other documentation specified by related regulations B. Where this standards specifies that a requirement, procedure, activity or special arrangement be "documented", it shall, in addition, be implemented and maintained. C. For each type or model of medical device, the manufacturer shall establish and maintain a file either containing or identifying documents defining product specifications and quality management system requirement. These documents shall define the complete manufacturing process and, if applicable, installation and servicing.					
4.2.2 Quality manual	A. The manufacturer shall establish and maintain a quality manual that includes: 1) the scope of the quality management system, including details of and justification for any exclusion and/or non-application; 2) a documented procedures established for the quality management system, or reference to them; and 3) a description of the interaction between the processes of the quality management system B. The quality manual shall outline the structure of the documentation used in the quality management system.					

Requirements for the quality control criteria	Review Criteria	Result of review				Remarks
		A	B	C	D	
4.2.3 Document Control	A. Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in 4.2.4. B. A documented procedure shall be established to define the controls needed: 1) to review and approve documents for adequacy prior to issue; 2) to review and update as necessary and re-approve documents; 3) to ensure that changes and the current revision status of documents are identified; 4) to ensure that relevant versions of applicable documents are available at points of use 5) to ensure that documents remain legible and readily identifiable; 6) to ensure that documents of external origin are identified and their distribution controlled; and 7) to prevent the unintended use of obsolete documents, and to apply suitable identification of them if they are retained for any purpose C. The manufacturer shall ensure that changes to documents are reviewed and approved either by the original approving function or another designated function which has access to pertinent background information upon which to base its decisions. D. The manufacturer shall define the period for which at least one copy of obsolete controlled documents shall be retained. This period shall be not less than 5 years and not less than 2 years from the date of product release by the manufacturer.					
4.2.4 Control of records	A. Records shall be established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system. Records shall remain legible, readily identifiable and retrievable. A documented procedure shall be established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records. B. All records shall be kept to be immediately retrievable in the facilities capable of preventing damage, loss or deterioration. C. The manufacturer shall retain the record for a period of time at least equivalent to the lifetime of the medical devices as defined by the manufacturer. This period shall be not less than 5 years and not less than 2 years from the date of product release by the manufacturer.					
5. Management responsibility 5.1 Management commitment	A. The manufacturer shall provide evidence of its commitment to the development and implementation of the quality management system and maintaining its effectiveness by: 1) internal communicating the importance of meeting customer as well as statutory and regulatory requirements; 2) establishing the quality policy 3) ensuring that quality objectives are established; 4) conducting management review; and 5) ensuring the availability of resources.					
5.2 Customer focus	The manufacturer shall ensure that customer requirements are determined and are met.					

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5.3 Quality policy	The manufacturer shall ensure that the quality policy: 1) is appropriate to the purpose of the organization; 2) includes a commitment to comply with requirements and to maintain the effectiveness of the quality management system; 3) provides a framework for establishing and reviewing quality objectives; 4) is communicated and understood within the organization; and 5) is reviewed for continuing suitability.					
5.4 Planning 5.4.1 Quality objectives	The manufacturer shall ensure that quality objectives, including those needed to meet requirements for product, are established at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy.					
5.4.2 Quality management system planning	The manufacturer shall ensure that: 1) the planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives; and 2) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.					
5.5 Responsibility, authority and communication 5.5.1 Responsibility and authority	The manufacturer shall ensure that responsibilities and authorities are defined, documented and communicated within the organization. The manufacturer shall establish the interrelation of all personnel who manage, perform and verify work affecting quality, and shall ensure the independence and authority necessary to perform these tasks.					
5.5.2 Management representative	The manufacturer shall appoint a member of management who, irrespective of other responsibilities, shall have responsibility and authority that includes: 1) Quality control of the manufacturing place 2) Evaluation of the quality control result in the manufacturing place and decision of product release 3) ensuring that processes needed for the quality management system are established, implemented and maintained 4) reporting to the manufacturer on the performance of the quality management system and any need for improvement 5) ensuring the promotion of awareness regulatory and customer requirements throughout the organization					
5.5.3 Internal communication	The manufacturer shall ensure that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system.					
5.6 Management review 5.6.1 General	A. The manufacturer shall review the quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives. B. Records from management reviews shall be maintained.					

Requirements for the quality control criteria	Review Criteria	Result of review				Remarks
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5.6.2 Review input	The input to management review shall include information on: 1) results of audits; 2) customer feedback; 3) process performance and product conformity; 4) status of preventive and corrective actions; 5) follow-up actions from previous management reviews; 6) changes that could affect the quality management system; 7) recommendations for improvement; and 8) new or revised regulatory requirements.					
5.6.3 Review output	The output from the management review shall include any decisions and actions related to: 1) improvement needed to maintain the effectiveness of the quality management system and its processes; 2) improvement of product related to customer requirements; and 3) Resources needs.					
6. Resource management 6.1 Provision of resources	The manufacturer shall determine and provide the resources needed : 1) to implement the quality management system and to maintain its effectiveness; and 2) to meet regulatory and customer requirements.					
6.2 Human resources 6.2.1 General	Personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills, and experience.					
6.2.2 Competence, awareness and training	The manufacturer shall: 1) determine the necessary competence for personnel performing work affecting product quality; 2) provide training or take other actions to satisfy these needs; 3) evaluate the effectiveness of the action taken; 4) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives; and 5) maintain appropriate records of education, training, skills, and experience.					
6.3. Infrastructure	A. The manufacturer shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable: 1) buildings, workspace and associated utilities; 2) process equipment (both hardware and software); and 3) supporting services, such as transport or communication B. The manufacturer shall establish documented requirements for maintenance activities, including their frequency, when such activities or lack thereof can affect product quality. C. Record of such maintenance shall be maintained.					

Requirements for the quality control criteria	Review Criteria	Result of review				Remarks
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6.4 Work environment	The manufacturer shall determine and manage the work environment needed to achieve conformity to product requirements. Specially, the following requirements shall apply: 1) The manufacturer shall establish, document and maintain requirements for health, cleanliness and clothing of personnel if contact between such personnel and the product or work environment could adversely affect the quality of the product. 2) If work environment conditions can have and adverse effect on product quality, the manufacturer shall establish documented requirements for the work environment conditions and documented procedures or work instructions to monitor and control these work environment conditions. 3) The manufacturer shall ensure that all personnel who are required to work temporarily under special environmental conditions within the work environment are appropriately trained or supervised by a trained person. 4) If appropriate, special arrangements shall be established and documented for the control of contaminated or potentially contaminated of other product, the work environment or personnel.					
7. Product realization 7.1 Planning of product realization	A. The manufacturer shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system. B. In planning product realization, the manufacturer shall determine the following, as appropriate: 1) quality objectives and requirements for the product; 2) the need to establish processes, documentation, and provide resources specific to the product; 3) required verification, validation, monitoring and test activities specific to the product and the criteria for product acceptance; 4) records needed to provide evidence that the realization processes and resulting product meet requirements. C. The output of this planning shall bed in a form suitable for the organization's method of operations. D. The manufacturer shall establish documented requirements for risk management throughout product realization. Records arising from risk management shall be maintained					
7.2 Customer-related processes 7.2.1 Determination of requirements related to the product	The manufacturer shall determine: 1) requirements specified by the customer, including the requirement foe delivery and post-delivery activities; 2) requirements not stated by the customer but necessary for specified or intended use, where know; 3) statutory and regulatory requirements related to the product; and 4) any additional requirements determined by the manufacturer.					

Requirements for the quality control criteria	Review Criteria	Result of review				Remarks
		A	B	C	D	
7.2.2 Examination of product related requirements	A. The manufacturer shall review the requirements related to the product. This review shall be conducted prior to the manufacturer's commitment to supply a product to the customer and shall ensure that: 1) product requirements are defined and documented; 2) contract or order requirements differing from those previously expressed are resolved; and 3) the manufacturer has the ability to meet the defined requirements. B. Records of the results of the review and actions arising from the review shall be maintained. C. Where the customers provide no documented statement of requirement, the customer requirements shall be confirmed by the manufacturer before acceptance. D. Where product requirements are changed, the manufacturer shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.					
7.2.3 Customer communication	The manufacturer shall decide and execute effective means for communication with customers in relation to: 1) product information 2) enquiries, contracts or order handling, including amendments; 3) customer feedback, including customer complaints; and 4) advisory notices.					
7.3. Design and development 7.3.1 Design and development planning	A. The manufacturer shall establish documented procedures for design and development. B. The manufacturer shall plan and control the design and development of product. C. During the design and development planning, the manufacturer shall determine.: 1) the design and development stages; 2) the review, verification, validation, and design transfer activities that are appropriate at each design and development stage; and 3) the responsibilities and authorities for design and development. D. The manufacturer shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility. E. Planning output shall be documented, and updated as appropriate, as the design and development progresses.					
7.3.2 Design and development inputs	A. Inputs relating to product requirements shall be determined and records maintained. These inputs shall includes: 1) functional, performance and safety requirements, according to the intended use; 2) applicable statutory and regulatory requirements; 3) where applicable, information derived from previous similar design; 4) other requirements essential for design and development; and 5) output(s) of risk management B. These inputs shall be reviewed for adequacy and approved. Requirements shall be complete, unambiguous and not in conflict with each other.					

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7.3.3 Design and development outputs	A. The output of design and development shall be documented and provided in a form that enables verification against the design and development input and shall be approved prior to release. B. Design and development outputs shall: 1) meet the input requirements for design and development; 2) provide appropriate information for purchasing, production and for service provision; 3) contain or reference product acceptance criteria; and 4) specify the characteristics of the product that are essential for its safe and proper use. C. Record of the design and development outputs shall be maintained.					
7.3.4 Design and development review	A. At suitable stages, systematic reviews of design and development shall be performed in accordance with planned arrangements: 1) to evaluation the ability of the results of design and development to meet the requirements; and 2) to identify any problems and purpose necessary actions B. Participants in such reviews shall include representatives of functions concerned with the design and development stage(s) being reviewed, as well as other specialist personnel. C. Records of the results of the reviews and any necessary actions shall be maintained.					
7.3.5 Verification of design and development	Verification shall be performed under the planned method to make sure that output of design and development satisfies the input requirements.					
7.3.6 Validation of design and development	A. Design and development validation shall be performed in accordance with planned arrangements to ensure that the resulting product is capable of meeting the requirements. Validation shall be completed prior to delivery or implementation of the product. B. Records of the results of validation and any necessary actions shall be maintained. C. As part of design and development validation, the manufacturer shall perform clinical evaluations and/or evaluation of performance of the medical device, as required by regulations.					
7.3.7 Control of design and development changes	A. Design and development changes shall be identified and records maintained. The changes shall be reviewed, verified and validated, as appropriate, and approved before implementation. The review of design and development changes shall include evaluation of the effect of the changes on constituent parts and product already delivered. B. Records the results of the review of changes and any necessary actions shall be maintained.					
7.4. Purchasing 7.4.1 Purchasing process	A. The manufacturer shall establish documented procedure to ensure that purchased product conforms to specified purchase requirements. B. The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product. C. The manufacturer shall evaluate and select the suppliers based on their ability to supply products in accordance with the manufacturer's requirements. Criteria for selection, evaluation and re-evaluation shall be established. D. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained.					

Requirements for the quality control criteria	Review Criteria	Result of review				Remarks
		A	B	C	D	
7.4.2 Purchasing information	A. Purchasing information shall describe the product to be purchased, including where appropriate: 1) requirements for approval of product, procedure, process, facilities, and equipment; 2) Requirements for qualification of personnel; and3) quality management system requirements. B. The manufacturer shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier. C. To the extent required for traceability, the manufacturer shall maintain relevant purchasing information, i.e. documents and records.					
7.4.3 Verification of purchased product	A. The manufacturer shall establish and implement inspection or other activities necessary to ensuring that purchased product meets specified purchase requirements. B. Where the manufacturer or its customer intends to perform verification at the supplier's premises, the manufacturer shall state the intended verification arrangements and method of product release in the purchasing information. C. Records of the validation shall be maintained					
7.5 Production and service provision 7.5.1 Control of production and service provision 7.5.1.1General requirements	A. The manufacturer shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable: 1) the availability of information that describes the characteristics of the product; 2) the availability of documented procedures, documented requirements, work instructions, and reference materials and reference measurement procedures as necessary; 3) the use of suitable equipment; 4) the availability and use of monitoring and measuring devices; 5) the implementation of monitoring and measurement; 6) the implementation of release, delivery and post-delivery activities; and 7) the implementation of defined operations for labeling and packing B. The organization shall establish and maintain a record for each lot/batch of medical devices that provides traceability to the extent specified in 7.5.3, and identifies the amount manufactured and amount approved for distribution. The lot/batch record shall be 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	If the manufacturer falls under one of the followings, the manufacturer shall establish, document and maintain requirements for cleanliness of product if the product. However, if product is cleaned in accordance with 1) or 2), the requirements contained in 6.4 1) and 6.4 2) do not apply prior to the cleaning process: 1) product is cleaned by the manufacturer prior to sterilization and/or its use; or 2) product is supplied non-sterile to be subjected to a cleaning process prior to sterilization and/or its use; or 3) products is supplied to be used non-sterile and its cleanliness is of significance in use; or 4) Process agents are to be removed from the product during manufacture.					

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7.5.1.2.2 Installation activities	A. If appropriate, the manufacturer shall establish documented requirements which contain acceptance criteria for installing and verifying the installation of the medical device. B. If the agreed customer requirements allow installation to be performed other than by the manufacturer or its authorized agent, the manufacturer shall provide documented requirements for installation and verification. C. Records of installation and verification performed by the manufacturer or its authorized agent shall be maintained.					
7.5.1.2.3 Servicing activities	A. If servicing is a specified requirements, the manufacturer shall establish documented procedure, work instruction, reference materials and reference measurement procedures, as necessary, for performing servicing activities and verifying that they meet the specified requirements. B. Records of servicing activities carried out by the manufacturer shall be maintained.					
7.5.1.3 Specific requirements for sterilized medical devices	The manufacturer shall maintain records of the process parameters for the sterilization process which was used for each sterilization lot/batch. Sterilization records shall be traceable to each production lot/batch of the medical device.					
7.5.2 Validation of production and service provision process 7.5.2.1 General requirements	A. The manufacturer shall validate any process for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered. B. Validation shall demonstrate the ability of these processes to achieve planned results. C. The manufacturer shall establish arrangements for these processes including, as applicable: 1) defined criteria for review and approval of the processes; 2) approval of equipment and qualification personnel;; 3) use of specific methods and procedures; 4) requirements for records; and 5) revalidation D. The manufacturer shall establish documented procedures for the validation of the application of computer software (and changes to such software and/or its application) that affect the ability of the product to conform to specified requirements. Such software applications shall be validated prior to initial use. E. Record of validation shall be maintained.					
7.5.2.2 Particular requirements for sterile medical devices	A. The manufacturer shall establish documented procedures for the validation of sterilization processes. B. Sterilization processes shall be validated prior to initial use. C. Records of validation of each sterilization process shall be maintained.					
7.5.3 Identification and traceability 7.5.3.1 Identification	A. The manufacturer shall identify the product with suitable means throughout product realization, and shall establish documented procedures for such product identification. B. The manufacturer shall establish documented procedures to ensure that medical devices returned to the manufacturer are identified and distinguished from conforming product.					

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7.5.3.2 Traceability 7.5.3.2.1 General	A. The manufacturer shall establish documented procedures for traceability. Such procedures shall define the extent of product traceability and the records required. B. Where traceability is a requirement, the manufacturer shall control and record the unique identification of the product.					
7.5.3.2.2 Particular requirements for medical devices subject to tracking	A. In defining the records required for traceability, the manufacturer shall include records of all components, materials and work environment conditions, if these could cause the medical device not to satisfy its specified requirements. B. The manufacturer shall require that its agents or distributors maintain records of the distribution of medical devices to allow traceability and that such records are available for inspection. C. Records of the name and address of the shipping package consignee shall be maintained.					
7.5.3.3 Identification of the product status	A. The manufacturer shall identify the product states with respect to monitoring and measurement requirements. B. The identification of product status shall be maintained throughout production, storage, installation and servicing of the 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.					
7.5.4 Customer property	The manufacturer shall exercise care with customer property while is under the organization. The manufacturer shall identify, verify, protect and safeguard customer property provided for use or incorporation into the product. If any customer property is lost, damaged or otherwise found to be unsuitable for use, this shall be reported to the customer and records maintained.					
7.5.5 Preservation of product	A. The manufacturer shall establish documented procedures or documented work instructions for preserving the conformity of product during internal processing and delivery to the intended destination. B. This preservation shall include identification, handling, packaging, storage and protection, and shall also apply to the constituent parts of a product. C. The manufacturer shall establish documented procedures or documented work instructions for the control of product with a limited shelf-life or requiring special storage conditions. Such special storage conditions shall be controlled and recorded.					

Requirements for the quality control criteria	Review Criteria	Result of review				Remarks
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7.6. Control of monitoring and measuring devices	A. The manufacturer shall determine the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements. B. The manufacturer shall establish documented procedures to ensure that monitoring and measurement can be carried out and carried out in a manner that is consistent with the monitoring and measurement requirements. C. Where necessary to ensure valid results, measuring equipment shall: 1) be calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards. Where no such standards exist, the basis used for calibration or verification shall be recorded; 2) be adjusted or re-adjusted as necessary; 3) be identified to enable the calibration status to be determined; 4) be safeguarded from adjustments that would invalidate the measurement result; and 5) be protected from damage and deterioration during handling, maintenance and storage. D. The manufacturer shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The manufacturer shall take appropriate action on the equipment and the any product affected. Records of the results of calibration and vilification shall be maintained. E. When used in monitoring and measurement of the specified requirements, the ability of computer software to satisfy the intended application shall be confirmed.. This shall be undertaken prior to initial use and reconfirmed as necessary.					
8. Measurement, analysis and improvement 8.1 General	A. The manufacturer shall plan and implement the monitoring, measurement, analysis and improvement processes needed: 1) to demonstrate conformity of the product; 2) to ensure conformity of the quality management system; and 3) to maintain the effectiveness of the quality management system. B. Measurement, analysis and improvement shall include determination of applicable methods, including statistical techniques, and the extent of their use.					
8.2 Monitoring and measurement 8.2.1 Feedback	A. as one of the measurements of the performance of the quality management system, the manufacturer shall monitor information relating to of whether the manufacturer has met customer requirements. B. The methods for obtaining and using this information shall be determined. C. The manufacturer shall establish a documented procedure for a feedback system to provide early warning of the quality problems and for input into the corrective and preventive action processes. D. When new data or information is obtained in relation to safety and effectiveness of the product, it shall be reported as specified by the Commissioner of KFDA, and necessary safety measures shall be sought for.					

Requirements for the quality control criteria	Review Criteria	Result of review				Remarks
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8.2.2 Internal audit	A. The manufacturer shall conduct internal audits at planned intervals to determine whether the quality management system: 1) conforms to the planned arrangements, to the requirements of this Standards and to the quality management system requirements established by the manufacturer; and 2) is effectively implemented and maintained B. An audit program shall be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods shall be defined. Selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work. C. The responsibilities and requirements for planning and conducting audits, and reporting results and maintaining records shall be defined in a documented procedure. D. The management responsible for the area being audited shall ensure that actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities shall include the verification of the actions taken and the reporting of verification results.					
8.2.3 Monitoring and measurement of processes	The manufacturer shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate, to ensure conformity of the product.					
8.2.4 Monitoring and measurement of product 8.2.4.1 General requirements	A. The manufacturer shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stage of the product realization process in accordance with the planned arrangements and documented procedures. B. Evidence of conformity with the acceptance criteria shall be maintained. Records shall indicate the person(s) authorizing release of product. C. Product release and service delivery shall not be proceed until the planned arrangements have been satisfactorily completed.					
8.2.4.2 Particular requirements for medical devices subject to tracking	The manufacturer shall record the identity of personnel performing any inspection or testing.					

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8.3 Control of nonconforming product	A. The manufacturer shall ensure that product which dose not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The controls and related responsibilities and authorities for dealing with nonconforming product shall be defined in a documented procedure. B. The manufacturer shall deal with nonconforming product by one or more of the following ways: 1) by taking action to eliminate the detected nonconformity; 2) by authorizing its use, release or acceptance under concession; and 3) by taking action to preclude its original intended use or application C. The manufacturer shall ensure that nonconforming product is accepted by concession only if regulatory requirements are met. Records of the identify of the person(s) authorizing the concession shall be maintained D. Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained. E. When nonconforming product is corrected it shall be subject to re-verification to demonstrate conformity to the requirements. F. When nonconforming product is detected after delivery or use has started, the manufacturer shall take action appropriate to the effects, or potential effects, of the nonconformity. If product needs to be reworked (one or more times), the manufacturer shall document the rework process in a work instruction that has undergone the same authorization and approval procedure as the original work instruction. Prior to authorization and approval of the work instruction, a determination of any adverse effect of the rework upon product shall be made and documented.					
8.4 Analysis of data	A. The manufacturer shall establish documented procedures to determine, collect and analyze appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate if improvement of the effectiveness of the quality management system can be made. B. Analysis of data shall include data generated as a result of monitoring and measurement and from other relevant sources. C. The analysis of data shall provide information relating to: 1) feedback; 2) conformity to product requirements; 3) characteristics and trends of processes and products including opportunities for preventive action; and 4) supplier D. Records of the results of the analysis of data shall be maintained.					

Requirements for the quality control criteria	Review Criteria	Result of review				Remarks
		A	B	C	D	
8.5 Improvement 8.5.1 General	A. The manufacturer shall identify and implement any changes necessary to ensure and maintain the continued suitability and effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review. B. The manufacturer shall establish documented procedures for the issue and implementation of advisory notices. C. These procedures shall be capable of being implemented at any time. D. Records of all customer complaint investigations shall be maintained. If investigation determines that the activities outside the manufacturer contributed to the customer complaint, relevant information shall be exchanged between the organization involved. E. If any customer complaint is not followed by corrective and/or preventive action, the reason shall be authorized and recorded. F. The manufacturer shall establish documented procedures to report an adverse event.					
8.5.2 Corrective action	A. The manufacturer shall take action to eliminate the cause of nonconformities in order to prevent recurrence. B. Corrective actions shall be appropriate to the effects of the nonconformities encountered. C. A documented procedure shall be established to define requirements for: 1) reviewing nonconformities(including customer complaints); 2) determining the causes of nonconformities; 3) evaluating the need for action to ensure that nonconformities do not recur; 4) determining and implementing action needed, including, if appropriate, updating documentation; 5) recording the results of any investigation and of action taken; and 6) reviewing the corrective action taken and its effectiveness.					
8.5.3 Preventive action	A. The manufacturer shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems. B. A documented procedure shall be established to define requirements for: 1) determining potential nonconformities and their causes; 2) evaluating the need for action to prevent occurrence of nonconformities; 3) determining and implementing action needed; 4) recording of the results of any investigations and of action taken; and 5) reviewing preventive action taken and its effectiveness					