**[Attached Table 2]**

**Standards of Inspection for Medical Device Certification of Conformity, etc.**

(in connection with Articles5 and 6)

**1. Purpose**

To set forth the requirements of the quality management system applied to a manufacturer of medical device to provide design, development, production, installation and service on the medical device.

**2. Scope**

If part of the requirements under 7.Product Realizationis not applicable due to the characteristics of a medical device, a manufacturer may not include such requirements in the quality management system. However, the manufacturer shall prove that such exclusion from application is justified.

**3. Referenced Standard and Definitions**

Definitions shall be as per Attachment 1 in terms of the application of these standards.

**4. Quality Management System**

**4.1 General Requirements**

A. A manufacturer shall establish, document, implement and maintain a quality management system in accordance with the requirements of these standards.

B. A manufacturer shall implement the following:

1) Identifyingthe processes necessary for quality management system and apply such system on the entire organization;

2) Determining the order and the interaction of processes;

3) Determining the standards and the methods necessary to guarantee the fact that operation and management of the processes;

4) Guaranteeing that the information and the resources necessary for supporting operation and monitoring of the processes are available;

5) Monitoring, measurement and analysis of the processes;

6) Implement the measures necessary to accomplish the planned results to secure the effectiveness of processes.

C. A manufacturer shall manage the processes properly for the requirements of these standards.

D. If a certain process that has effect on the product conformity requirements shall be subcontracted, a manufacturer shall guarantee that such process gets controlled.Also, the control of a subcontracted process shall be verified within the quality management system.

**4.2 Documentation Requirements**

**4.2.1 General Requirements**

A. Documents of a quality management system shall include the following:

1) Quality policies and quality goals expressed by documentation;

2) Quality manual;

3) Documented procedures required by these standards;

4) Documents required by the organization to guarantee effective planning, operation and management of processes;

5) Quality records required in these standards;

6) Other documentation requirements specified in the related regulations.

B. If certain requirements, procedures, activities or special measures are set forth to be documented in these standards, a manufacturer shall implement and maintain such documentation.

C. A manufacturer shall establish and maintain a file which includes the documents that have set forth product specifications and quality management system requirements by each product item and by each type name of the medical devices. Also, such documents shall set forth the entire manufacturing process, and if applicable, the installation and services.

**4.2.2 Quality Manual**

A. A manufacturer shall establish and maintain a quality manual which includes the following:

1) Scope of applicability of quality management system including details and justification about exceptions or non-applicability;

2) Documented procedures established for the quality management system and their reference documents;

3) Descriptions on the interaction of quality management system process.

B. A quality manual shall briefly specify the structure of documents used in the quality management system.

**4.2.3 Document Management**

A. Documents necessary for the quality management system shall be managed. Quality record is a special type of document and shall be managed according to the requirements of 4.2.4.

B.The documented procedure necessary for the management of the following shall be established:

1) Review and approval of the adequacy of document prior to the publication;

2) Review, renewal and re-approval of the necessary documents;

3) Guarantee of the change of document and the identification of latest revision status;

4) Guarantee of the availability at a place where the corresponding copy of the applicable documentis used;

5) Guarantee legibility and easy identification of the document;

6) Guarantee of identification and management of distributed conditions on the external source documents;

7) Preventing the unintended use of the documents that have lost validity and apply a proper identification method if retained for a certain purpose.

C. A manufacturer shall have the change of document reviewed and approved by the first approval right holder or other persons to whom the authority has been designated.

D. A manufacturer shall retain at least one copy of the managed document that has lost validity for the duration of the period of usage. This period shall be not less than five years and shall be not less than two years after being released into the market.

**4.2.4 Record Management**

A. Record to prove the adequacy for effective operation and the requirements of the quality management system shall be prepared and maintained. The record shall be maintained to be legible and enable easy identification or search. Documented procedures that have set forth the management method necessary for identification, storage, protection, search, preservation period and handling shall be established.

B. All quality records shall be stored to enable instant search within a facility which is able to prevent damage, loss or deterioration.

C. A manufacturer shall retain the quality record for the duration of the period of usage on the product. This period shall be not less than five years and shall be not less than two years after being released into the market.

**5. Management Responsibility**

**5.1 Management Commitment**

A. A manufacturer shall prove that a quality management system is established and implemented to maintain effectiveness according to the following:

1) Internal communication on the importance of satisfying legal requirements and customer requirements;

2) Establishment of quality policies;

3) Guarantee on the establishment of quality goals;

4) Performance of management review;

5) Guarantee on the availability of resources.

**5.2 Customer Centeredness**

A manufacturer shall guarantee that the customer requirements are determined and satisfied.

**5.3 Quality Policies**

A manufacturer shall guarantee that the quality policies are shown as the following:

1) Appropriate for the purpose of the organization;

2) Willingness to comply with the requirements of quality management system and commitment on the implementation for maintaining effectiveness;

3) Providing a framework for establishment and review of the quality goals;

4) Communicated and understood within the organization;

5) Reviewed for the continued adequacy.

**5.4 Planning**

**5.4.1 Quality Goals**

A manufacturer shall guarantee that the quality goals which contain the matters necessary for satisfying the requirements on the product are established in the related functions and hierarchy within the organization. Quality goals shall be measurable and shall be consistent with the quality policies.

**5.4.2 Planning of Quality Management System**

A manufacturer shall guarantee the following:

1) Planning of quality management system is implemented to satisfy 4.1 General Requirements as well as the quality goals;

2) Integrity of quality management system is maintained when the changes on quality management system is planned and implemented.

**5.5 Responsibility, Authority and Communication**

**5.5.1 Responsibility and Authority**

A manufacturer shall guarantee that responsibility and authority are prescribed and documented to be communicated within the organization. A manufacturer shall establish an inter-relationship with all employees who manage, implement and verify the duties that have effect on quality to guarantee authority and independence necessary for performing such duties.

**5.5.2 Quality Manager**

A manufacturer shall appoint a person to have responsibilities and authorities with the inclusion of the following from among the managers of the organization regardless of other responsibilities:

1) Duties related to the quality control of the factory;

2) Evaluation on the quality management result of the factory and determination on the shipment status of the products;

3) Guarantee on establishment, implementation and maintenance of the processes necessary for the quality management system;

4) Report on the result of quality management system and necessity of improvement to the manufacturer;

5) Guarantee on the enhancement of awareness on the legal requirements and the customer requirements throughout the entire organization.

**5.5.3 Internal Communication**

A manufacturer shall guarantee that a proper communication process is established within the organization and that the communication is performed on the effectiveness of the quality management system.

**5.6 Management Review**

**5.6.1 General Requirements**

A. A manufacturer shall review as a planned cycle in order to guarantee the continuous conformity, adequacy and effectiveness of the quality management system. Quality policies and quality goals shall be included in the management review while an evaluation on the necessity of amendment on the quality management system and the possibility of improvement shall be performed.

B. Records of the management review shall be maintained.

**5.6.2 Input of Review**

The input of management review shall include the following information:

1) Audit results;

2) Customer feedback;

3) Performance of process and adequacy of product;

4) Status of preventive actions and corrective actions;

5) Follow-up measures according to the previous management reviews;

6) Changes that may have effect on the quality management system;

7) Suggestions for improvement;

8) New or amended legal requirements.

**5.6.3 Output of Review**

The output of management review shall include all determined matters and the measures related to the following:

1) Improvements necessary for effectively maintaining quality management system and the processes;

2) Improvement of the products related to the customer requirements;

3) Necessity of resources.

**6. Resource Management**

**6.1 Securing Resources**

A manufacturer shall determine and secure the resources necessary for the following:

1) Implementation of quality management system and maintaining effectiveness;

2) Satisfaction of legal and customer requirements.

**6.2 Human Resources**

**6.2.1 General Requirements**

A person who performs the duties that have effect on quality shall be qualified in terms of education, training, skilled level and experience.

**6.2.2 Qualification, Awareness and Training**

A manufacturer shall implement the following:

1) Determine the ability necessary from the person who is performing the duties that have effect on quality;

2) Provide training or take other measures to satisfy such necessity;

3) Evaluate the effectiveness of the measures that have been taken;

4) Guarantee the awareness on the relationship of one’s activity, its importance and how it contributes in terms of accomplishing the quality goals by the organization members;

5) Maintain proper records on education, training, skilled level and experience.

**6.3. Infrastructure**

A. A manufacturer shall determine, secure and maintain the infrastructures necessary for securing adequacy of product requirements. Infrastructures shall include the following if applicable:

1) Buildings, work area and related auxiliary facilities;

2) Process equipment (hardware and software)

3) Support service such as transport and communication, etc.

B. A manufacturer shall establish the documented requirements on the maintenance activity including the cycle if product quality may be affected due to the maintenance activity of infrastructure or lack of such activity.

C. Records of such maintenance activity shall be retained.

**6.4 Work Environment**

A manufacturer shall determine and manage the necessary work environment in terms of securing conformity on the product requirements. Especially, the following requirements shall be applied:

1) A manufacturer shall establish, document and maintain the requirements on health, cleanliness and outfit of workers if they come in contact with products or work environment to have risk of having harmful effect on product quality;

2) If the work environment has a risk of having harmful effect on product quality, the manufacturer shall establish documented requirements on the work environment to establish a documented standard or work guideline for monitoring and managing such environmental conditions;

3) A manufacturer shall have all personnel working temporarily under special environmental conditions to receive proper training or guarantee supervision by a trained personnel;

4) If applicable, a special action plan shall be established and documented for the management of a product that has been contaminated or has possibility of contamination in order to prevent contamination of other products, work environments or workers.

**7. Product Realization**

**7.1 Planning of Product Realization**

A. A manufacturer shall plan and develop the processes necessary for product realization. The planning of product realization shall be consistent with other process requirements of the quality management system.

B. If applicable in terms of planning product realization, a manufacturer shall determine the following:

1) Quality goals and the requirements related to the products;

2) Establishment of the processes required on the product, documentation and the necessity of securing specific resources;

3) Special verification, validation, monitoring, testing/inspection activity and determination criteria for acceptance required for the products;

4) Records necessary for proving that the product realizationprocesses and the output of their result satisfy the requirements.

C. The output of such planning shall be a form which is appropriate for the operation method of the organization.

D. A manufacturer shall document the requirements necessary for the risk management in terms of the entire product realization. Records prepared as risk management shall be maintained.

**7.2 Customer Related Process**

**7.2.1 Determination of the Requirements Related to the Products**

A manufacturer shall determine the following:

1) Requirements set forth by the customer including the requirements on delivery and the activities after the delivery;

2) Requirements necessary for specified use or intended use although not mentioned by the customer;

3) Legal requirements related to the products;

4) Other additional requirements determined by the manufacturer.

**7.2.2 Review of the Requirements Related to the Products**

A. A manufacturer shall review the requirements related to the products. Such review shall be performed by the manufacturer before determining or promising to supply the products to the customer and shall guarantee the following:

1) Requirements on the products shall be prescribed and documented;

2) Requirements of contract or order that are different from the ones presented in the past shall be settled;

3) The manufacturer shall possess the ability to satisfy the prescribed requirements.

B. Records of the results on the reviewed or accompanied measures shall be maintained.

C. If the customer has not presented the requirements by documentation, the manufacturer shall verify the customer requirements prior to the acceptance.

D. If the product requirements are changed, the manufacturer shall revise the related documents and have the related personnel recognize the changed requirements.

**7.2.3 Communication with Customers**

A manufacturer shall determine and implement the effective methods for communicating with customers concerning the following matters:

1) Product information;

2) Handling of inquiries, contracts or orders including the changes;

3) Customer feedback including customer complaints;

4) Recommendations.

**7.3. Design and Development**

**7.3.1 Design and Development Plan**

A. A manufacturer shall establish a documented procedure on design and development.

B. A manufacturer shall plan and manage the design and development related to the products.

C. For the duration of design and development planning period, a manufacturer shall determine the following:

1) Stages of design and development;

2) Review, verification, validation and design transfer activities that are appropriate for each design and development stage;

3) Responsibility and authority on design and development activities.

D. A manufacturer shall manage the connectivity between the different groups participating in design and development for effective communication and the clarification of responsibilities.

E. The output of plan shall be documented, and if applicable, shall be renewed according to the progress of design and development.

**7.3.2 Input of Design and Development**

A. The input of design and development shall include the following to determine the input related to the product requirements and maintain a record:

1) Functions, performance and safety requirements necessary for the intended use;

2) Applicable legal requirements;

3) If applicable, the information derived from the similar designs in the past;

4) Other requirements that are essential for design and development;

5) Output of risk management.

B. The adequacy of such input shall be reviewed and approved. Requirements shall be complete and shall not be unclear or be in conflict with other requirements.

**7.3.3 Output of Design and Development**

A. The output of design and development shall be documented, shall be provided as a form which may be verified by comparing with the input information of design and development, and shall be approved prior to the distribution.

B. The output of design and development shall be as follows:

1) Input requirements of design and development shall be satisfied;

2) Proper information for purchase, product and providing services shall be provided;

3) Standards for the determination of product conformity shall be included or cited;

4) Product characteristics that are essential for safe and proper use shall be prescribed.

C. Records on the output of design and development shall be maintained.

**7.3.4 Review of Design and Development**

A. A systematic review on design and development shall be performed according to a planned method in proper stages for the following purposes:

1) Evaluation on the capability of design and development results for satisfying the requirements;

2) Identification of problems and presentation of the necessary measures.

B. In such review, other experts in addition to the persons in charge related to design and development shall be included.

C. Records on review and the necessary measures shall be maintained.

**7.3.5 Verification of Design and Development**

Verification shall be performed according to a planned method in order to guarantee that the output of design and development satisfies the input requirements. Records on verification and results shall be maintained.

**7.3.6 Validation of Design and Development**

A. Validation of design and development shall be performed according to a planned method in order to guarantee that the product as an outcome satisfies the input requirements. Validation of effectiveness shall be completed before delivery or use of products

B. Records on the result of validation and the necessary measures shall be maintained.

C. A manufacturer shall perform clinical investigation and performance evaluation if required by laws and regulations in order to validate design and development.

**7.3.7 Management on the Change of Design and Development**

A. The changes of design and development shall be identified to maintain a record. Review, verification and validation shall be performed on the changed details, and if applicable, shall be approved prior to the implementation. Review on the change of design and development shall include the evaluation of effect on the components and the products that have been delivered already.

B. Records on the results of change review and the necessary measures shall be maintained.

**7.4. Purchase**

**7.4.1 Purchase Process**

A. A manufacturer shall establish a documented standard to guarantee that a purchased product conforms to the prescribed requirements.

B. Methods and level of management to apply on a supplier or a purchased product shall vary depending on their influence on product realizationand finished product.

C. A manufacturer shall evaluate and select a supplier based on the ability to supply the products which correspond to the requirements. A standard on selection, evaluation and re-evaluation shall be prescribed.

D. Records on the results of evaluation and the necessary measures shall be maintained.

**7.4.2 Purchase Information**

A. The purchase information shall describe the products that shall be purchased, if applicable, by the inclusion of the following:

1) Requirements on the approval of products, procedures, processes, facilities and equipment;

2) Requirements on the qualifications of the personnel;

3) Requirements of the quality management system.

B. A manufacturer shall guarantee the adequacy of the prescribed purchase requirements prior to the communication with the supplier.

C. A manufacturer shall maintain the related purchase information such as documents and records up to the scope for which the traceability is required.

**7.4.3 Verification of Purchased Goods**

A. A manufacturer shall establish and implement the testing and inspection or other activities necessary to guarantee that the purchased products conform to the prescribed requirements.

B. If a manufacturer or a customer intends to verify at the supplier’s site, the manufacturer shall specify the verification plan and the product shipment method on the purchase information.

C. The verification method shall be maintained.

**7.5 Providing Production and Services**

**7.5.1 Management for Providing Production and Services**

**7.5.1.1 General Requirements**

A. A manufacturer shall plan and implement the production and services provided under managed conditions. If applicable, the managed conditions shall include the following:

1) Availability of information that has prescribed the characteristics of the products;

2) Documented procedures, requirements, work instructions, and if necessary,reference materials and measurement procedures;

3) Use of appropriate devices;

4) Availability of monitoring and measuring equipment;

5) Implementation of monitoring and measurement;

6) Implementation of release, delivery and the activities after delivery;

7) Implementation of the activities prescribed for labeling and packing;

B. An organization shall provide traceability up to the scope prescribed in 7.5.3, and shall establish and maintain records by each lot/batch in order to identify the quantity approved for production and sale. Such record shall be verified and approved.

**7.5.1.2 Special Requirements on the Management for Providing Production and Services**

**7.5.1.2.1 Cleanliness and Contamination Management of Products**

A manufacturer shall establish, document and maintain the requirements on the cleanliness of products if falling under any of the following. However, if the cleaning of product conforms to 1) or 2), requirements of 1) and 2) of 6.4 shall not apply prior to the cleaning process:

1) A product cleaned by the manufacturer prior to sterilization and/or its use;

2) A product supplied as nonsterile state requiring cleaning process prior to sterilization and/or its use;

3) A product supplied as nonsterile state and for which cleanliness is important on its use;

4) The one in which process agents are eliminated from the product in the manufacturing process.

**7.5.1.2.2 Installation Activities**

A. If applicable, a manufacturer shall establish documented requirements which include acceptance criteria on installation and verification of medical devices.

B. If a customer has allowed installation by a party other than the manufacturer or the designated agents, a manufacturer shall establish documented requirements on installation and verification.

C. Records on installation and verification performed by a manufacturer or a designated agent shall be maintained.

**7.5.1.2.3 Service Activities**

A. If a service is a prescribed requirement, a manufacturer shall properly maintain documented procedures, work instructions, references and measurement procedures to verify performance of service activities and prescribed requirements.

B. Records on the service activities implemented by manufacturer shall be maintained.

**7.5.1.3 Special Requirements on Sterile Medical Devices**

A manufacturer shall maintain records on the parameters of sterilization process used on each sterile lot/batch. The sterilization record shall be able to track each manufacturing lot / batch of medical devices.

**7.5.2 Validation of the Processes for Providing Production and Services**

**7.5.2.1 General Requirements**

A. A manufacturer shall validate on all processes for providing production and services that cannot be verified by monitoring or measurement that follows the output shown as the result. Validation shall include all processes that show inconsistency only after the use of product or the delivery of service.

B. Capability of the processes for accomplishing the planned results shall be proved through validation.

C. If applicable, a manufacturer shall establish the procedures on the processes that include the following:

1) Standards prescribed in terms of review and approval of the processes;

2) Approval of equipment and qualifications of personnel;

3) Use of specific methods and procedures;

4) Requirements on records;

5) Revalidation.

D. A manufacturer shall establish a documented processes for the validation on the application of computer software (including change of software and/or its application) that has effect on the performance of products in order to satisfy the prescribed requirements. Validation shall be performed prior to the first use in terms of applying such software.

E. Records on the result of validation shall be maintained.

**7.5.2.2 Special Requirements on Sterile Medical Devices**

A. A manufacturer shall establish the documented processes for the validation of sterilization process.

B. A sterilization process shall be validated prior to the first use.

C. Records on the result of validation on each sterilization process shall be maintained.

**7.5.3 Identification and Traceability**

**7.5.3.1 Identification**

A. A manufacturer shall identify products using proper methods throughout the entire process of product realizationand a documented process shall be established for such product identification.

B. A manufacturer shall establish a documented process which guarantees identification of returned medical devices and differentiation from the conforming products.

**7.5.3.2 Traceability**

**7.5.3.2.1 General Requirements**

A. A manufacturer shall establish a documented process on traceability. Such process shall set forth the scope of traceability and the matters concerning the required records.

B. If the traceability is a requirement, a manufacturer shall manage and record the unique identification of the product.

**7.5.3.2.2 Special Requirements on the Medical Devices Subject to Tracking**

A.A manufacturer shall include the records on the conditions of components, raw materials and work environment that may induce products that do not conform to the prescribed requirements in terms of setting up the scope of traceability.

B. A manufacturer shall have an agent or a distributor maintain a record on sales and require such record to be available during investigation to enable tracking.

C. A manufacturer shall maintain a record on name and address of the package consignee.

**7.5.3.3 Identification of Product Conditions**

A. A manufacturer shall identify the conditions of products in relation to monitoring and measuring requirements.

B. The identified conditions of products shall be maintained to guarantee dispatch, use or installation of only the products that have passed the testing and inspection required in the entire process including production, storage, installation and service (or shipped according to the approved concession).

**7.5.4 Customer Property**

A manufacturer shall exercise caution on the customer assets under control or in use. A manufacturer shall identify, verify, protect and maintain safely the customer property provided to be used as a product or for commercialization. If a customer property is ascertained to be lost, damaged or improper to use, this shall be reported to the customer and a record shall be maintained.

**7.5.5 Preservation of Products**

A. A manufacturer shall establish a documented procedure or work guideline for maintaining conformity of products while delivering products to an internal process or an intended destination.

B. Such preservation shall include identification, handling, packing, storage and protection, and also shall be applied to the components which constitute a product.

C. A manufacturer shall establish a documented procedure or work guideline on the products with expiration date or special storage conditions. Such special storage conditions shall be managed and recorded.

**7.6. Management of Monitoring and Measuring Equipment**

A. A manufacturer shall determine monitoring and measuring activities to be implemented, and the equipment necessary in order to prove that a product conforms to the prescribed requirements.

B. A manufacturer shall establish a documented procedure to guarantee the implementation of monitoring and measuring activities using the methods that correspond to the requirements related to monitoring and measurement.

C. If necessary in order to guarantee valid results, the measuring equipment shall be according to the following:

1) Calibration or verification shall be performed before using and as fixed cycle by a measurement standard accredited by an international standard or a national standard. If there are no such standards, the basis used for calibration or verification shall be recorded;

2) Shall be adjusted or readjusted if necessary;

3) Shall be identified in order to determine the status of calibration;

4) Shall be protected from the adjustments that may invalidate the result of measurement;

5) Shall be protected from damage or deterioration while handling, preserving or storing.

D. A manufacturer shall evaluate and record validity on the result of previous measurement if an equipment does not conform to the requirements. A manufacturer shall take proper actions on the equipment and the products that have been affected. Records on calibration and verification shall be maintained.

E. If a computer software is used for monitoring and measurement on the prescribed requirements, whether the performance of software is appropriate for the intended use shall be verified. This shall be verified prior to the first use and shall be re-verified if necessary.

**8. Measurement, Analysis and Improvement**

**8.1 General Requirements**

A. A manufacturer shall plan and implement monitoring, measurement, analysis and improvement processes that are necessary for the following:

1) Proof of product conformity;

2) Guarantee on the conformity of quality management system;

3) Maintaining effectiveness of quality management system.

B. In measurement, analysis and improvement, applicable methods including statistical method and determination on the scope of use shall be included.

**8.2 Monitoring and Measurement**

**8.2.1 Feedback**

A. A manufacturer shall perform monitoring on whether customer requirements are satisfied as a measurement on the result of quality management system.

B. The method of acquiring and utilizing such information shall be determined.

C. A manufacturer shall establish a documented process for the input of feedback system to provide early warning on quality problems, and the process of corrective and preventive actions.

D. If new data or information related to safety and efficacy of product becomes known, this shall be reported as prescribed by the Minister of Food and Drug Safety to seek for the necessary safety measures.

**8.2.2 Internal Audit**

A. A manufacturer shall conduct an internal audit as a planned cycle in order to determine the following:

1) Whether quality management system satisfies the planned decisions, quality management system requirements set by the manufacturer and the requirements of these standards;

2) Whether implemented and maintained effectively.

B. A manufacturer shall plan an audit program considering the results of previous audit as well as conditions and importance of processes and fields that are subject to an audit. It shall set forth the standard, scope, cycle and method of audit. The audit shall be conducted by selecting an auditor in order to guarantee objectivity and fairness of the audit process. An auditor shall not conduct an audit on his or her own duties.

C. Responsibilities and requirements on planning of audit, performance, report of results and keeping records shall be prescribed in a documented procedure.

D. A manager who is responsible for the duties subject to an audit shall guarantee so that the actions for eliminating the discovered nonconformity and cause may be taken at the right time. Follow-up measures shall include the verification of actions taken and the report of verification results.

**8.2.3 Monitoring and Measurement of Processes**

A manufacturer shall apply monitoring on the process of quality management system, and if applicable, the appropriate methods for measurement. Such method shall prove the capability of process which is able to accomplish the planned results. If the planned result could not be accomplished, the proper corrections and corrective actions shall be implemented in order to guarantee the conformity of products.

**8.2.4 Monitoring and Measurement of Products**

**8.2.4.1 General Requirements**

A. A manufacturer shall monitor and measure the product characteristics in order to verify the satisfaction of product requirements. This shall be implemented in the proper stage of product implementation process according to the planned decisions and the documented procedures.

B. A proof of conforming to the criteria for determination of acceptance shall be maintained. The personnel who have approved the shipment of product shall be indicated on the record.

C. Until the planned procedures are satisfactorily completed, a product shall not be released and a service shall not be provided.

**8.2.4.2 Special Requirements on the Medical Devices Subject to Tracking**

A manufacturer shall identify and record all personnel performing testing and inspection.

**8.3 Management of Nonconforming Products**

A. A manufacturer shall guarantee that the products not conforming to the requirements are identified and managed in order to prevent unintended use or delivery. Management on handling nonconforming products, and the related responsibilities and authority shall be prescribed as a documented procedure.

B. A manufacturer shall handle the nonconforming products using the following methods:

1) Implementation of actions to eliminate the discovered nonconformity;

2) Approval of use, dispatch or acceptance under concession;

3) Implementation of actions to exclude originally intended use or application.

D. A manufacturer shall guarantee that concession is allowed only if the nonconforming product satisfies legal requirements. Records shall be maintained in order to identify the person who has approved concession.

E. Records on nonconformity status including concessions and all follow-up actions that have been taken shall be maintained.

F. If a nonconforming product is corrected, the product shall be re-verified in order to prove that it conforms to the requirements.

G. If a nonconforming product is discovered after delivery or use, a manufacturer shall take proper actions on negative impacts and potential impacts. If a re-work (once or more) of product is necessary, the re-work process shall be documented in the work guideline according to the same authority and approval procedure as the initial work guideline. All negative impacts due to the re-work of product shall be determined and documented prior to authorization and approval of work guideline.

**8.4 Analysis of Data**

A. A manufacturer shall establish a documented procedure to determine, gather and analyze proper data in order to prove conformity and effectiveness of the quality management system to evaluate the status of improving effectiveness.

B. Data created from the result of monitoring and measurement, and from other related sources, shall be included in terms of analyzing data.

C. The analysis of data shall provide information on the following:

1) Feedback;

2) Conformity of product requirements;

3) Characteristics and trend of process and product including opportunities on preventive actions;

4) Supplier.

D. Records on data analysis results shall be maintained.

**8.5 Improvement**

**8.5.1 General Requirements**

A. A manufacturer shall identify and implement all changes necessary to guarantee and maintain continuous adequacy and effectiveness of quality management system through the utilization of quality policies, quality goals, audit results, data analysis, corrective action, preventive action and management review, etc.

B. A manufacturer shall establish a documented procedure on publication and implementation of advisory notice.

C. Such procedure shall be implementable under any circumstances.

D. All customer complaint investigation records shall be maintained. If ascertained that customer complaint has occurred due to the activities outside of the organization as a result of investigation, the related information shall be exchanged between inside and outside of the organization.

E. If corrective and preventive actions on the customer complaint is not implemented, the evidence shall be approved and recorded.

F. A manufacturer shall establish a documented procedure on the adverse event report.

**8.5.2 Corrective Actions**

A. A manufacturer shall take actions to eliminate the cause of nonconformity in order to prevent the recurrence of nonconformity.

B. A corrective action shall be appropriate for the negative effect at hand.

C. Requirements for the following shall be prescribed in a documented procedure:

1) Review of nonconformity (including customer complaints);

2) Determination on the cause of nonconformity;

3) Evaluation on the necessity of the actions to guarantee recurrence prevention of nonconformity;

4) If applicable, determination and implementation of all actions including document revisions;

5)Recording the results of all investigations and actions taken;

6) Review on the corrective actions taken and their effectiveness.

**8.5.3 Preventive Actions**

A. A manufacturer shall determine the preventive actions to eliminate the cause of potential nonconformities in order to prevent the recurrence of nonconformity. A preventive action shall be appropriate for the effect of potential problem.

B. The following requirements shall be prescribed in a documented procedure:

1) Potential nonconformity and determination of its cause;

2) Evaluation on the necessity of actions to prevent the occurrence of nonconformity;

3) Determination and implementation of necessary measures;

4) Recording the results of all investigations and actions taken;

5) Review on the preventive actions taken and their effectiveness.

**9. Medical Device Conformity Certification Review Report**

**9.1 General Status**

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| **Inspection Report for Certification on Conformity for Medical Devices** | | | | | |
| Company |  | | | Business License No. |  |
| Representative |  | | | Quality Manager |  |
| Address | (☎ ) ( FAX ) | | | | |
| Applicable Standards | | □ Manufactured medical device  □ Imported medical device | | | |
| □ Medical device for clinical trial  □ Medical devices of Class 1  □Medical devices for export only | | | |
| Type of Inspection | | □ Initial Inspection □ Supplementary Inspection  □ Change Inspection □ Periodic Inspection | | | |
| Product | Product Category | |  | | |
| Product Group | |  | | |
| Class | |  | | |
| Review Group |  | | Name | | |
| Ministry of Food and Drug Safety | |  | | |
| Quality Management System Inspection Organization  (name of institution) | |  | | |
| Review Date (dd/mm/yy) | | | dd/mm/yy **～** dd/mm/yy | | |
| Result of Review | □ Conformity □ Requires corrective actions (by dd/mm/yy) □Nonconformity | | | | |
| We hereby report the result of conformity certification review in accordance with Article 6 of the 「Medical Device Good Manufacturing Practice」 Standards  Date:  Ministry of Food and Drug Safety: (seal)  Quality Management System Inspection Organization: (seal)  Representative: (Seal) | | | | | |

**9.2Information on Company Subject to Inspection**

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| Company |  | □ Corporation  □ Individual | | Business License No. |  | |
| Representative |  | | | Quality Manager |  | |
| Address | (Phone No.: , FAX : E-mail : ) | | | | | |
| Contact Info. of Department In Charge |  | | | | | |
| No. of Employees Subject to Inspection |  | | | Work Hours,  (Shifts and Change Times) |  | |
| Status of Relevant Certifications |  | | | | | |
| Date of On-site Inspection | dd/mm/yy ~ dd/mm/yy | | | | | |
| Inspector Group Information |  | | Name | | | |
| Ministry of Food and Drug Safety | |  | | | |
| Quality Management Review Agency  (name of agency) | |  | | | |
| Product | Product Group | | Title of Product Group(Class) | | | Classification Code |
|  | |  | | |  |
| Information on Previous Inspection  (If applicable) | Inspection Date | |  | | | |
| InspectionOrganization | |  | | | |
| Inspector | |  | | | |
| Standards and Scope of Inspection | |  | | | |
| Additional Information Related to Conformity Certification History | |  | | | |
| Special Notes |  | | | | | |

**9.3 Detailed Contents of Review**

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| Field of Review | Contents of Inspection |
| 1. Quality Management System |  |
| 2. Management Responsibility |  |
| 3. Resource Management |  |
| 4. Product Realization |  |
| 5. Measurement, Analysis and Improvement |  |
| 6. General Review |  |

**9.4 Inspection Form**

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| **Requirements of Quality Control Standard** | **Inspection Criteria** | **Inspection Result** | | | | **Remarks** |
| **A** | **B** | **C** | **D** |
| 4. Quality Management System  4.1 General Requirements | A. A manufacturer shall establish, document, implement and maintain a quality management system in accordance with the requirements of these standards.  B. A manufacturer shall implement the following:  1) Identifying the processes necessary for quality management system and applying such system on the entire organization;  2) Determining the order and the interaction of processes;  3) Determining the standards and the methods necessary to guarantee the effective operation and management of the processes;  4) Guaranteeing that the information and the resources necessary for supporting operation and monitoring of the processes are available;  5) Monitoring, measurement and analysis of the processes;  6) Implement the measures necessary to accomplish the planned results to secure the effectiveness of processes.  C. A manufacturer shall manage the processes properly for the requirements of these standards.  D. If a certain process that has effect on the product conformity requirements shall be subcontracted, a manufacturer shall guarantee that such process gets controlled. Also, the control of a subcontracted process shall be verified within the quality management system. |  |  |  |  |  |
| 4.2 Documentation Requirements  4.2.1 General Requirements | A. Documents of a quality management system shall include the following:  1) Quality policies and quality goals expressed by documentation;  2) Quality manual;  3) Documented procedures required by these standards;  4) Documents required by the organization to guarantee effective planning, operation and management of processes;  5) Quality records required in these standards;  6) Other documentation requirements specified in the related regulations.  B. If certain requirements, procedures, activities or special measures are set forth to be documented in these standards, a manufacturer shall implement and maintain such documentation.  C. A manufacturer shall establish and maintain a file which includes the documents that have set forth product specifications and quality management system requirements by each product item and by each type name of the medical devices. Also, such documents shall set forth the entire manufacturing process, and if applicable, the installation and services. |  |  |  |  |  |
| 4.2.2 Quality Manual | A. A manufacturer shall establish and maintain a quality manual which includes the following:  1) Scope of applicability of quality management system including details and justification;  2) Documented procedures established for the quality management system and their reference documents;  3) Description on the interaction of quality management system process.  B. A quality manual shall briefly specify the structure of documents used in the quality management system. |  |  |  |  |  |

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| **Requirements of Quality Control Standard** | **Inspection Criteria** | **Inspection Result** | | | | **Remarks** |
| **A** | **B** | **C** | **D** |  |
| 4.2.3 Document Management | A. Documents necessary for the quality management system shall be managed. Quality record is a special type of document and shall be managed according to the requirements of 4.2.4.  B. The documented procedure necessary for the management of the following shall be established:  1) Review and approval of the adequacy of document prior to the publication;  2) Review, renewal and re-approval of the necessary documents;  3) Guarantee of the change of document and the identification of latest revision status;  4) Guarantee of the availability at a place where the corresponding copy of the applicable document is used;  5) Guarantee legibility and easy identification of the document;  6) Guarantee of identification and management of distributed conditions on the external source documents;  7) Preventing the unintended use of the documents that have lost validity and applying a proper identification method if retained for a certain purpose.  C. A manufacturer shall have the change of document reviewed and approved by the first approval right holder or other persons to whom the authority has been designated.  D. A manufacturer shall retain at least one copy of the managed document that has lost validity for the duration of the period of usage. This period shall be not less than five years and shall be not less than two years after being released into the market. |  |  |  |  |  |
| 4.2.4 Record Management | A. Record to prove the adequacy for effective operation and the requirements of the quality management system shall be prepared and maintained. The record shall be maintained to be legible and enable easy identification or search. Documented procedures that have set forth the management method necessary for identification, storage, protection, search, preservation period and handling shall be established.  B. All quality records shall be stored to enable instant search within a facility which is able to prevent damage, loss or deterioration.  C. A manufacturer shall retain the quality record for the duration of the period of usage on the product. This period shall be not less than five years and shall be not less than two years after being released into the market. |  |  |  |  |  |
| 5. Management Responsibility  5.1 Management Commitment | A. A manufacturer shall prove that a quality management system is established and implemented to maintain effectiveness according to the following:  1) Internal communication on the importance of satisfying legal requirements and customer requirements;  2) Establishment of quality policies;  3) Guarantee on the establishment of quality goals;  4) Performance of management review;  5) Guarantee on the availability of resources. |  |  |  |  |  |
| 5.2 Customer Centeredness | A manufacturer shall guarantee that the customer requirements are determined and satisfied. |  |  |  |  |  |
| 5.3 Quality Policies | A manufacturer shall guarantee that the quality policies are shown as the following:  1) Appropriate for the purpose of the organization;  2) In compliance with the requirements of quality management system and includes commitment on the implementation for maintaining effectiveness;  3) Providing a framework for establishment and review of the quality goals;  4) Communicated and understood within the organization;  5) Reviewed for the continued adequacy. |  |  |  |  |  |

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| **Requirements of Quality Control Standard** | **Inspection Criteria** | **Inspection Result** | | | | **Remarks** |
| **A** | **B** | **C** | **D** |  |
| 5.4 Planning  5.4.1 Quality Goals | A manufacturer shall guarantee that the quality goals which contain the matters necessary for satisfying the requirements on the product are established in the related functions and hierarchy within the organization. Quality goals shall be measurable and shall be consistent with the quality policies. |  |  |  |  |  |
| 5.4.2 Planning of Quality Management System | A manufacturer shall guarantee the following:  1) Planning of quality management system is implemented to satisfy 4.1 General Requirements as well as the quality goals;  2) Integrity of quality management system is maintained when the changes on quality management system is planned and implemented. |  |  |  |  |  |
| 5.5 Responsibility, Authority and Communication  5.5.1 Responsibility and Authority | A manufacturer shall guarantee that responsibility and authority are prescribed and documented to be communicated within the organization. A manufacturer shall establish an inter-relationship with all employees who manage, implement and verify the duties that have effect on quality to guarantee authority and independence necessary for performing such duties. |  |  |  |  |  |
| 5.5.2 Quality Manager | A manufacturer shall appoint a person to have responsibilities and authorities with the inclusion of the following from among the managers of the organization regardless of other responsibilities:  1) Duties related to the quality control of the factory;  2) Evaluation on the quality management result of the factory and determination on the shipment status of the products;  3) Guarantee on establishment, implementation and maintenance of the processes necessary for the quality management system;  4) Report on the result of quality management system and necessity of improvement to the manufacturer;  5) Guarantee on the enhancement of awareness on the legal requirements and the customer requirements throughout the entire organization. |  |  |  |  |  |
| 5.5.3 Internal Communication | A manufacturer shall guarantee that a proper communication process is established within the organization and that the communication is performed on the effectiveness of the quality management system. |  |  |  |  |  |
| 5.6 Management Review  5.6.1 General Requirements | A. A manufacturer shall review as a planned cycle in order to guarantee the continuous conformity, adequacy and effectiveness of the quality management system. Quality policies and quality goals shall be included in the management review while an evaluation on the necessity of amendment on the quality management system and the possibility of improvement shall be performed.  B. Records of the management review shall be maintained. |  |  |  |  |  |
| 5.6.2 Input of Review | The input of management review shall include the following information:  1) Audit results;  2) Customer feedback;  3) Performance of process and adequacy of product;  4) Status of preventive actions and corrective actions;  5) Follow-up measures according to the previous management reviews;  6) Changes that may have effect on the quality management system;  7) Suggestions for improvement;  8) New or amended legal requirements. |  |  |  |  |  |

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| **Requirements of Quality Control Standard** | **Inspection Criteria** | **Inspection Result** | | | | **Remarks** |
| **A** | **B** | **C** | **D** |  |
| 5.6.3 Output of Review | The output of management review shall include all determined matters and the measures related to the following:  1) Improvements necessary for effectively maintaining quality management system and the processes;  2) Improvement of the products related to the customer requirements;  3) Necessity of resources. |  |  |  |  |  |
| 6. Resource Management  6.1 Securing Resources | A manufacturer shall determine and secure the resources necessary for the following:  1) Implementation of quality management system and maintaining effectiveness;  2) Satisfaction of legal and customer requirements. |  |  |  |  |  |
| 6.2 Human Resources  6.2.1 General Requirements | A person who performs the duties that have effect on quality shall be qualified in terms of education, training, skilled level and experience. |  |  |  |  |  |
| 6.2.2 Qualification, Awareness and Training | A manufacturer shall implement the following:  1) Determine the ability necessary from the person who is performing the duties that have effect on quality;  2) Provide training or take other measures to satisfy such necessity;  3) Evaluate the effectiveness of the measures that have been taken;  4) Guarantee the awareness on the relationship of one’s activity, its importance and how it contributes in terms of accomplishing the quality goas by the organization members;  5) Maintain proper records on education, training, skilled level and experience. |  |  |  |  |  |
| 6.3. Infrastructure | A. A manufacturer shall determine, secure and maintain the infrastructures necessary for securing adequacy of product requirements. Infrastructures shall include the following if applicable:  1) Buildings, work area and related auxiliary facilities;  2) Process equipment (hardware and software)  3) Support service such as transport and communication, etc.  B. A manufacturer shall establish the documented requirements on the maintenance activity including the cycle if product quality may be affected due to the maintenance activity of infrastructure or lack of such activity.  C. Records of such maintenance activity shall be retained. |  |  |  |  |  |
| 6.4 Work Environment | A manufacturer shall determine and manage the necessary work environment in terms of securing conformity on the product requirements. Especially, the following requirements shall be applied:  1) A manufacturer shall establish, document and maintain the requirements on health, cleanliness and outfit of workers if they come in contact with products or work environment to have risk of having harmful effect on product quality;  2) If the work environment has a risk of having harmful effect on product quality, the manufacturer shall establish documented requirements on the work environment to establish a documented standard or work guideline for monitoring and managing such environmental conditions;  3) A manufacturer shall have all personnel working temporarily under special environmental conditions to receive proper training or guarantee supervision by a trained personnel;  4) If applicable, a special action plan shall be established and documented for the management of a product that has been contaminated or has possibility of contamination in order to prevent contamination of other products, work environments or workers. |  |  |  |  |  |

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| **Requirements of Quality Control Standard** | **Inspection Criteria** | **Inspection Result** | | | | **Remarks** |
| **A** | **B** | **C** | **D** |
| 7. Product Realization  7.1 Planning of Product Realization | A. A manufacturer shall plan and develop the processes necessary for product realization. The planning of product realization shall be consistent with other process requirements of the quality management system.  B. If applicable in terms of planning product realization, a manufacturer shall determine the following:  1) Quality goals and the requirements related to the products;  2) Establishment of the processes required on the product, documentation and the necessity of securing specific resources;  3) Special verification, validation, monitoring, testing/inspection activity and determination criteria for acceptance required for the products;  4) Records necessary for proving that the product realization processes and the output of their result satisfy the requirements.  C. The output of such planning shall be a form which is appropriate for the operation method of the organization.  D. A manufacturer shall document the requirements necessary for the risk management in terms of the entire product realization. Records prepared as risk management shall be maintained. |  |  |  |  |  |
| 7.2 Customer Related Process  7.2.1 Determination of the Requirements Related to the Products | A manufacturer shall determine the following:  1) Requirements set forth by the customer including the requirements on delivery and the activities after the delivery;  2) Requirements necessary for specified use or intended use although not mentioned by the customer;  3) Legal requirements related to the products;  4) Other additional requirements determined by the manufacturer. |  |  |  |  |  |
| 7.2.2 Review of the Requirements Related to the Products | A. A manufacturer shall review the requirements related to the products. Such review shall be performed by the manufacturer before determining or promising to supply the products to the customer and shall guarantee the following:  1) Requirements on the products shall be prescribed and documented;  2) Requirements of contract or order that are different from the ones presented in the past shall be settled;  3) The manufacturer shall possess the ability to satisfy the prescribed requirements.  B. Records of the results on the reviewed or accompanied measures shall be maintained.  C. If the customer has not presented the requirements by documentation, the manufacturer shall verify the customer requirements prior to the acceptance.  D. If the product requirements are changed, the manufacturer shall revise the related documents and have the related personnel recognize the changed requirements. |  |  |  |  |  |
| 7.2.3 Communication with Customers | A manufacturer shall determine and implement the effective methods for communicating with customers concerning the following matters:  1) Product information;  2) Handling of inquiries, contracts or orders including the changes;  3) Customer feedback including customer complaints;  4) Recommendations. |  |  |  |  |  |

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| **Requirements of Quality Control Standard** | **Inspection Criteria** | **Inspection Result** | | | | **Remarks** |
| **A** | **B** | **C** | **D** |
| 7.3. Design and Development  7.3.1 Design and Development Plan | A. A manufacturer shall establish a documented procedure on design and development.  B. A manufacturer shall plan and manage the design and development related to the products.  C. For the duration of design and development planning period, a manufacturer shall determine the following:  1) Stages of design and development;  2) Review, verification, validation and design transfer activities that are appropriate for each design and development stage;  3) Responsibility and authority on design and development activities.  D. A manufacturer shall manage the connectivity between the different groups participating in design and development for effective communication and the clarification of responsibilities.  E. The output of plan shall be documented, and if applicable, shall be renewed according to the progress of design and development. |  |  |  |  |  |
| 7.3.2 Input of Design and Development | A. The input of design and development shall include the following to determine the input related to the product requirements and maintain a record:  1) Functions, performance and safety requirements necessary for the intended use;  2) Applicable legal requirements;  3) If applicable, the information derived from the similar designs in the past;  4) Other requirements that are essential for design and development;  5) Output of risk management.  B. The adequacy of such input shall be reviewed and approved. Requirements shall be complete and shall not be unclear or be in conflict with other requirements. |  |  |  |  |  |
| 7.3.3 Output of Design and Development | A. The output of design and development process shall be documented, shall be provided as a form which may be verified by comparing with the input information of design and development, and shall be approved prior to the distribution.  B. The output of design and development shall be as the following:  1) Input requirements of design and development shall be satisfied;  2) Proper information for purchase, product and providing services shall be provided;  3) Standards for the determination of product conformity shall be included or cited;  4) Product characteristics that are essential for safe and proper use shall be prescribed.  C. Records on the output of design and development shall be maintained. |  |  |  |  |  |
| 7.3.4 Review of Design and Development | A. A systematic review on design and development shall be performed according to a planned method in proper stages for the following purposes:  1) Evaluation on the capability of design and development results for satisfying the requirements;  2) Identification of problems and presentation of the necessary measures.  B. In such review, other experts in addition to the persons in charge related to design and development shall be included.  C. Records on review and the necessary measures shall be maintained. |  |  |  |  |  |

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| **Requirements of Quality Control Standard** | **Inspection Criteria** | **Inspection Result** | | | | **Remarks** |
| **A** | **B** | **C** | **D** |
| 7.3.5 Verification of Design and Development | Verification shall be performed according to a planned method in order to guarantee that the output of design and development satisfies the input requirements. Records on verification and results shall be maintained. |  |  |  |  |  |
| 7.3.6 Validation of Design and Development | A. Validation of design and development shall be performed according to a planned method in order to guarantee that the product as an outcome satisfies the input requirements. Validation of effectiveness shall be completed before delivery or use of products.  B. Records on the result of validation and the necessary measures shall be maintained.  C. A manufacturer shall perform clinical investigation and performance evaluation if required by laws and regulations in order to validate design and development. |  |  |  |  |  |
| 7.3.7 Management on the Change of Design and Development | A. The changes of design and development shall be identified to maintain a record. Review, verification and validation shall be performed on the changed details, and if applicable, shall be approved prior to the implementation. Review on the change of design and development shall include the evaluation of effect on the components and the products that have been delivered already.  B. Records on the results of change review and the necessary measures shall be maintained. |  |  |  |  |  |
| 7.4. Purchase  7.4.1 Purchase Process | A. A manufacturer shall establish a documented standard to guarantee that a purchased product conforms to the prescribed requirements.  B. Methods and level of management to apply on a supplier or a purchased product shall vary depending on their influence on product realization and finished product.  C. A manufacturer shall evaluate and select a supplier based on the ability to supply the products which correspond to the requirements. A standard on selection, evaluation and re-evaluation shall be prescribed.  D. Records on the results of evaluation and the necessary measures shall be maintained. |  |  |  |  |  |
| 7.4.2 Purchase Information | A. The purchase information shall describe the products that shall be purchased, if applicable, by the inclusion of the following:  1) Requirements on the approval of products, procedures, processes, facilities and equipment;  2) Requirements on the qualifications of the personnel;  3) Requirements of the quality management system.  B. A manufacturer shall guarantee the adequacy of the prescribed purchase requirements prior to the communication with the supplier.  C. A manufacturer shall maintain the related purchase information such as documents or records up to the scope for which the traceability is required. |  |  |  |  |  |
| 7.4.3 Verification of Purchased Goods | A. A manufacturer shall establish and implement the testing and inspection or other activities necessary to guarantee that the purchased products conform to the prescribed requirements.  B. If a manufacturer or a customer intends to verify at the supplier’s site, the manufacturer shall specify the verification plan and the product shipment method on the purchase information.  C. The verification method shall be maintained. |  |  |  |  |  |

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| **A** | **B** | **C** | **D** |
| 7.5 Providing Production and Services  7.5.1 Management for Providing Production and Services  7.5.1.1 General Requirements | A. A manufacturer shall plan and implement the production and services provided under managed conditions. If applicable, the managed conditions shall include the following:  1) Availability of information that has prescribed the characteristics of the products;  2) Documented procedures, requirements, work instructions, and if necessary, reference materials and measurement procedures;  3) Use of appropriate devices;  4) Potential use and use of monitoring and measuring equipment;  5) Implementation of monitoring and measurement;  6) Implementation of release, delivery and the activities after delivery;  7) Implementation of the activities prescribed for labeling and packing;  B. An organization shall provide traceability up to the scope prescribed in 7.5.3, and shall establish and maintain records by each lot/batch in order to identify the quantity approved for production and sale. Such record shall be verified and approved. |  |  |  |  |  |
| 7.5.1.2 Special Requirements on the Management for Providing Production and Services  7.5.1.2.1 Cleanliness and Contamination Management of Products | A manufacturer shall establish, document and maintain the requirements on the cleanliness of products if falling under any of the following. However, if the cleaning of product conforms to 1) or 2), requirements of 1) and 2) of 6.4 shall not apply prior to the cleaning process:  1) A product cleaned by the manufacturer prior to sterilization and/or its use;  2) A product supplied as nonsterile state requiring cleaning process prior to sterilization and/or its use;  3) A product supplied as nonsterile state and for which cleanliness is important on its use;  4) The one in which process agents are eliminated from the product in the manufacturing process. |  |  |  |  |  |
| 7.5.1.2.2 Installation Activities | A. If applicable, a manufacturer shall establish documented requirements which include acceptance criteria on installation and verification of medical devices.  B. If a customer has allowed installation by a party other than the manufacturer or the designated agents, a manufacturer shall establish documented requirements on installation and verification.  C. Records on installation and verification performed by a manufacturer or a designated agent shall be maintained. |  |  |  |  |  |
| 7.5.1.2.3 Service Activities | A. If a service is a prescribed requirement, a manufacturer shall properly maintain documented procedures, work instructions, references and measurement procedures to verify performance of service activities and whether such activities fulfill the prescribed requirements.  B. Records on the service activities implemented by manufacturer shall be maintained. |  |  |  |  |  |
| 7.5.1.3 Special Requirements on Sterile Medical Devices | A manufacturer shall maintain records on the parameters of sterilization process used on each sterile lot/batch. The sterilization record shall be able to track each manufacturing lot / batch of medical devices. |  |  |  |  |  |

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| 7.5.2 Validation of the Processes for Providing Production and Services  7.5.2.1 General Requirements | A. A manufacturer shall validate on all processes for providing production and services that cannot be verified by monitoring or measurement that follows the output shown as the result. Validation shall include all processes that show inconsistency only after the use of product or the delivery of service.  B. Capability of the processes for accomplishing the planned results shall be proved through validation.  C. If applicable, a manufacturer shall establish the procedures on the processes that include the following:  1) Standards prescribed in terms of review and approval of the processes;  2) Approval of equipment and qualifications of personnel;  3) Use of specific methods and procedures;  4) Requirements on records;  5) Revalidation.  D. A manufacturer shall establish a documented processes for the validation on the application of computer software (including change of software and/or its application) that has effect on the performance of products in order to satisfy the prescribed requirements. Validation shall be performed prior to the first use in terms of applying such software.  E. Records on the result of validation shall be maintained. |  |  |  |  |  |
| 7.5.2.2 Special Requirements on Sterile Medical Devices | A. A manufacturer shall establish the documented processes for the validation of sterilization process.  B. A sterilization process shall be validated prior to the first use.  C. Records on the result of validation on each sterilization process shall be maintained. |  |  |  |  |  |
| 7.5.3 Identification and Traceability  7.5.3.1 Identification | A. A manufacturer shall identify products using proper methods throughout the entire process of product realization and a documented process shall be established for such product identification.  B. A manufacturer shall establish a documented process which guarantees identification of returned medical devices and differentiation from the conforming products. |  |  |  |  |  |
| 7.5.3.2 Traceability  7.5.3.2.1 General Requirements | A. A manufacturer shall establish a documented process on traceability. Such process shall set forth the scope of traceability and the matters concerning the required records.  B. If the traceability is a requirement, a manufacturer shall manage and record the unique identification of the product. |  |  |  |  |  |
| 7.5.3.2.2 Special Requirements on the Medical Devices Subject to Tracking | A. A manufacturer shall include the records on the conditions of components, raw materials and work environment that may induce products that do not conform to the prescribed requirements in terms of setting up the scope of traceability.  B. A manufacturer shall have an agent or a distributor maintain a record on sales and require such record to be available during investigation to enable tracking.  C. A manufacturer shall maintain a record on name and address of the package consignee. |  |  |  |  |  |
| 7.5.3.3 Identification of Product Conditions | A. A manufacturer shall identify the conditions of products in relation to monitoring and measuring requirements.  B. The identified conditions of products shall be maintained to guarantee dispatch, use or installation of the products only after passing the testing and inspection required in the entire process including production, storage, installation and service (or shipped according to the approved concession). |  |  |  |  |  |

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| **Requirements of Quality Control Standard** | **Inspection Criteria** | **Inspection Result** | | | | **Remarks** |
| **A** | **B** | **C** | **D** |
| 7.5.4 Customer Property | A manufacturer shall exercise caution on the customer assets under control or in use. A manufacturer shall identify, verify, protect and maintain safely the customer property provided to be used as a product or for commercialization. If a customer property is ascertained to be lost, damaged or improper to use, this shall be reported to the customer and a record shall be maintained. |  |  |  |  |  |
| 7.5.5 Preservation of Products | A. A manufacturer shall establish a documented procedure or work guideline for maintaining conformity of products while delivering products to an internal process or an intended destination.  B. Such preservation shall include identification, handling, packing, storage and protection, and also shall be applied to the components which constitute a product.  C. A manufacturer shall establish a documented procedure or work guideline on the products with expiration date or special storage conditions. Such special storage conditions shall be managed and recorded. |  |  |  |  |  |
| 7.6. Management of Monitoring and Measuring Equipment | A. A manufacturer shall determine monitoring and measuring activities to be implemented, and the equipment necessary in order to prove that a product conforms to the prescribed requirements.  B. A manufacturer shall establish a documented procedure to guarantee the implementation of monitoring and measuring activities using the methods that correspond to the requirements related to monitoring and measurement.  C. If necessary in order to guarantee valid results, the measuring equipment shall be according to the following:  1) Calibration or verification shall be performed before using and as fixed cycle by a measurement standard accredited by an international standard or a national standard. If there are no such standards, the basis used for calibration or verification shall be recorded;  2) Shall be adjusted or readjusted if necessary;  3) Shall be identified in order to determine the status of calibration;  4) Shall be protected from the adjustments that may invalidate the result of measurement;  5) Shall be protected from damage or deterioration while handling, preserving or storing.  D. A manufacturer shall evaluate and record validity on the result of previous measurement if an equipment does not conform to the requirements. A manufacturer shall take proper actions on the equipment and the products that have been affected. Records on calibration and verification shall be maintained.  E. If a computer software is used for monitoring and measurement on the prescribed requirements, whether the performance of software is appropriate for the intended use shall be verified. This shall be verified prior to the first use and shall be re-verified if necessary. |  |  |  |  |  |
| 8. Measurement, Analysis and Improvement  8.1 General Requirements | A. A manufacturer shall plan and implement monitoring, measurement, analysis and improvement processes that are necessary for the following:  1) Proof of product conformity;  2) Guarantee on the conformity of quality management system;  3) Maintaining effectiveness of quality management system.  B. In measurement, analysis and improvement, applicable methods including statistical method and determination on the scope of use shall be included. |  |  |  |  |  |

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| **Requirements of Quality Control Standard** | **Inspection Criteria** | **Inspection Result** | | | | **Remarks** |
| **A** | **B** | **C** | **D** |
| 8.2 Monitoring and Measurement  8.2.1 Feedback | A. A manufacturer shall perform monitoring on whether customer requirements are satisfied as a measurement on the result of quality management system.  B. The method of acquiring and utilizing such information shall be determined.  C. A manufacturer shall establish a documented process for the input of feedback system to provide early warning on quality problems, and the process of corrective and preventive actions.  D. If new data or information related to safety and efficacy of product becomes known, this shall be reported as prescribed by the Minister of Food and Drug Safety to seek for the necessary safety measures. |  |  |  |  |  |
| 8.2.2 Internal Audit | A. A manufacturer shall conduct an internal audit as a planned cycle in order to determine the following:  1) Whether quality management system satisfies the planned decisions, quality management system requirements set by the manufacturer and the requirements of these standards;  2) Whether implemented and maintained effectively.  B. A manufacturer shall plan an audit program considering the results of previous audit as well as conditions and importance of processes and fields that are subject to an audit. It shall set forth the standard, scope, cycle and method of audit. The audit shall be conducted by selecting an auditor in order to guarantee objectivity and fairness of the audit process. An auditor shall not conduct an audit on his or her own duties.  C. Responsibilities and requirements on planning of audit, performance, report of results and keeping records shall be prescribed in a documented procedure.  D. A manager who is responsible for the duties subject to an audit shall guarantee so that the actions for eliminating the discovered nonconformity and cause may be taken at the right time. Follow-up measures shall include the verification of actions taken and the report of verification results. |  |  |  |  |  |
| 8.2.3 Monitoring and Measurement of Processes | A manufacturer shall apply monitoring on the process of quality management system, and if applicable, the appropriate methods for measurement. Such method shall prove the capability of process which is able to accomplish the planned results. If the planned result could not be accomplished, the proper corrections and corrective actions shall be implemented in order to guarantee the conformity of products. |  |  |  |  |  |
| 8.2.4 Monitoring and Measurement of Products  8.2.4.1 General Requirements | A. A manufacturer shall monitor and measure the product characteristics in order to verify the satisfaction of product requirements. This shall be implemented in the proper stage of product implementation process according to the planned decisions and the documented procedures.  B. A proof of conforming to the criteria for determination of acceptance shall be maintained. The personnel who have approved the shipment of product shall be indicated on the record.  C. Until the planned procedures are satisfactorily completed, a product shall not be released and a service shall not be provided. |  |  |  |  |  |

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| 8.2.4.2 Special Requirements on the Medical Devices Subject to Tracking | A manufacturer shall identify and record all personnel performing testing and inspection. |  |  |  |  |  |
| 8.3 Management of Nonconforming Products | A. A manufacturer shall guarantee that the products not conforming to the requirements are identified and managed in order to prevent unintended use or delivery. Management on handling nonconforming products, and the related responsibilities and authority shall be prescribed as a documented procedure.  B. A manufacturer shall handle the nonconforming products using the following methods:  1) Implementation of actions to eliminate the discovered nonconformity;  2) Approval of use, dispatch or acceptance under concession;  3) Implementation of actions to exclude originally intended use or application.  D. A manufacturer shall guarantee that concession is allowed only if the nonconforming product satisfies legal requirements. Records shall be maintained in order to identify the person who has approved concession.  E. Records on nonconformity status including concessions and all follow-up actions that have been taken shall be maintained.  F. If a nonconforming product is corrected, the product shall be re-verified in order to prove that it conforms to the requirements.  G. If a nonconforming product is discovered after delivery or use, a manufacturer shall take proper actions on negative impacts and potential impacts. If a re-work (once or more) of product is necessary, the re-work process shall be documented in the work guideline according to the same authority and approval procedure as the initial work guideline. All negative impacts due to the re-work of product shall be determined and documented prior to authorization and approval of work guideline. |  |  |  |  |  |
| 8.4 Analysis of Data | A. A manufacturer shall establish a documented procedure to determine, gather and analyze proper data in order to prove conformity and effectiveness of the quality management system to evaluate the status of improving effectiveness.  B. Data created from the result of monitoring and measurement, and from other related sources, shall be included in terms of analyzing data.  C. The analysis of data shall provide information on the following:  1) Feedback;  2) Conformity of product requirements;  3) Characteristics and trend of process and product including opportunities on preventive actions;  4) Supplier.  D. Records on data analysis results shall be maintained. |  |  |  |  |  |

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| **Requirements of Quality Control Standard** | **Inspection Criteria** | **Inspection Result** | | | | **Remarks** |
| **A** | **B** | **C** | **D** |
| 8.5 Improvement  8.5.1 General Requirements | A. A manufacturer shall identify and implement all changes necessary to guarantee and maintain continuous adequacy and effectiveness of quality management system through the utilization of quality policies, quality goals, audit results, data analysis, corrective action, preventive action and management review, etc.  B. A manufacturer shall establish a documented procedure on publication and implementation of advisory notice.  C. Such procedure shall be implementable under any circumstances.  D. All customer complaint investigation records shall be maintained. If ascertained that customer complaint has occurred due to the activities outside of the organization as a result of investigation, the related information shall be exchanged between inside and outside of the organization.  E. If corrective and preventive actions on the customer complaint is not implemented, the evidence shall be approved and recorded.  F. A manufacturer shall establish a documented procedure on the adverse event report. |  |  |  |  |  |
| 8.5.2 Corrective Actions | A. A manufacturer shall take actions to eliminate the cause of nonconformity in order to prevent the recurrence of nonconformity.  B. A corrective action shall be appropriate for the negative effect at hand.  C. Requirements for the following shall be prescribed in a documented procedure:  1) Review of nonconformity (including customer complaints);  2) Determination on the cause of nonconformity;  3) Evaluation on the necessity of the actions to guarantee recurrence prevention of nonconformity;  4) If applicable, determination and implementation of all actions including document revisions;  5) Recording the results of all investigations and actions taken;  6) Review on the corrective actions taken and their effectiveness. |  |  |  |  |  |
| 8.5.3 Preventive Actions | A. A manufacturer shall determine the preventive actions to eliminate the cause of potential nonconformities in order to prevent the recurrence of nonconformity. A preventive action shall be appropriate for the effect of potential problem.  B. The following requirements shall be prescribed in a documented procedure:  1) Potential nonconformity and determination of its cause;  2) Evaluation on the necessity of actions to prevent the occurrence of nonconformity;  3) Determination and implementation of necessary measures;  4) Recording the results of all investigations and actions taken;  5) Review on the preventive actions taken and their effectiveness. |  |  |  |  |  |

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| 1. Evaluation Sheet  A. “A (Appropriate)” means a case where the compliance of requirements set forth in the quality control criteria is accepted.  B. “B(Needs corrective actions)” means a case where the requirements set forth in the quality control criteria are not fulfilled, or where the requirements set forth in the quality control criteria are fulfilled but supplementary measures such as improvement, etc. is necessary as evidence of compliance, possibility of implementation or adequacy of record, etc. is unsatisfactory.  C. “C (Inappropriate)” means a case where supplementary measures are not taken on “Need corrective actions” or a case where the specifics of medical device laws and regulations have been violated.  D. “D (Not applicable)” means a case of not falling under the requirements set forth in the quality control criteria.  2. Determination Criteria  A. Conformity  If all items are “A(Appropriate)” as a result of inspectionbased on the inspection criteria.  B. Need corrective actions  If there is one or more “B(Needs corrective actions)” according to the evaluation result of the evaluation sheetduring inspection.  C. Nonconformity  1) If supplemented result is not submitted or if not supplemented.  2) If there is one or more “C(Inappropriate)”according to the evaluation result of the evaluation sheetduring inspection. |