Chapter 1 General Provisions

Article 1
This set of regulations is formulated in accordance with regulations of Paragraph 4, Article 22 of the Medical Device Act (hereafter referred as the Act).

Article 2
In this Part, standards related to the facilities, equipment, organization and personnel, production, quality control, storage, distribution, handling of customer complaints and other matters of medical devices are prescribed in accordance with the contents of medical device quality management system of the International Standard Organization (ISO 13485: Medical Devices — Quality Management Systems — Requirements for Regulatory Purposes).

Article 3
The terms used in this Part are defined as follows:

(1) Advisory notice: It refers to supplementary information or recommended measures issued by the manufacturers, after delivery of medical devices, for the use, modification, recall, destruction or other related matters of the medical devices;

(2) Customer complaint: It means a message showing dissatisfaction in written, electronic or oral forms related to the features, quality, durability, reliability, safety or performance of a medical device on the market;

(3) Implantable medical device: It means a medical device intended to be totally or partially introduced into the human body or a natural orifice, to replace an epithelial surface or the surface of the eye, by surgical intervention, and which is intended to remain after the procedure for at least 30 days, and can only be removed by medical or surgical intervention;

(4) Post-marketing surveillance: It refers to the systematic collection and analysis by the manufacturer of the actual user experience of the medical devices that have been listed;

(5) Product: It refers to the output of the operation process related to the manufacturing of the medical devices, including service, software, hardware and processing materials;

(6) Risk management: It refers to systematic application of management policies, procedures, and practices on the analysis, evaluation, and control of risks;

(7) Sterilization barrier system: It refers to the minimum package that prevents ingress of microorganisms and allow aseptic presentation of the product at the point of use.

Chapter 2 Quality Management System

Article 4

The manufacturer shall establish a quality management system in writing in accordance with the provisions of these Regulations and maintain its effectiveness. The manufacturer shall take the following steps to establish, implement and maintain the requirements, procedures, activities or arrangements set out in the foregoing system:

1. To determine and implement the processes required for the quality management system;
2. To monitor the quality management system process based on risk assessment;
3. To determine the order and interaction of the implementation process of the system mentioned in the first paragraph.

Article 5
The manufacturer shall take the following measures on the quality management system process;

1. The decision on the benchmarks and methods adopted to establish and maintain the quality management system;
2. The acquisition of resources and information needed to establish and maintain the quality management system;
3. The necessary actions to achieve the expected results of the quality management system and to maintain the effectiveness of its processes;
4. The monitoring, analysis and necessary measurement of the quality management system process;
5. The establishment and maintenance of necessary records in order to prove compliance with the Act and these Regulations.

Article 6
The manufacturer shall establish a quality management system process in accordance with the provisions of these Regulations and supervise to ensure the implementation of the process.

The formulation and changes of the foregoing process shall not be carried out without the impact assessment of the quality management system and the medical device to ensure compliance with the requirements of the Act and these Regulations.

Article 7
The manufacturer shall implement monitoring on the part of outsourced services in the quality management system process, which may affect the product’s compliance with the requirements.

The manufacturer shall ensure that the outsourcing process complies with the requirements of these Regulations, the customers and other relevant regulations, and shall adopt control measures commensurate with the risk of outsourcing and
the ability of the trustees to comply with the law, including the signing of a written contract.

Article 8
The manufacturer shall establish and document the validation procedures for the effectiveness of computer software in the quality management system. The software shall be validated prior to initial use; the same applies to the changes of software or its applications, if necessary.
The specific methods and activities used for software validation and re-validation shall be commensurate with the risk of use of the software.
The manufacturer shall keep record of the foregoing measures of validation and re-validation.

Article 9
The content of the quality management system document shall include the following matters:
1. Statement of quality policy and quality objectives;
2. The quality manual;
3. Procedures and records required by these Regulations;
4. Documents and records developed by the manufacturer to ensure the effectiveness of planning, operation and control of the quality management system process;
5. Other documents required by central competent authorities.

Article 10
The manufacturer shall establish a quality manual, and the content of which shall include the following items:
1. The scope of the quality management system and reasons of exclusions from application or non-enforcement, if any;
2. The procedures established by the quality management system;
3. The interaction between quality management system processes.
The foregoing quality manual shall document the file structure used by the quality management system.

Article 11
The manufacturer shall file for each type or series of medical devices as evidence that their manufacture complies with the provisions of the Act or these Regulations. The foregoing file shall include the following content:
1. An overview of the medical device, its intended use or purpose, and labeling;
2. Product specifications;
3. Specifications or procedures for manufacturing, packaging, storage, handling and distribution;
4. Measurement and monitoring procedures;
5. Installation requirements;
6. Service requirements.
The presentation of the foregoing content may be in the form of a document or an index.

Article 12
The documents used for the quality management system including the records shall be under control.
The manufacturer shall establish control procedures in writing for the following matters:
1. The review and approval of the foregoing documents before release and circulation; the same applies to the renewal and re-approval;
2. The identification and verification of the serial number of versions and the history of revisions and status;
3. The availability of the documents in respective places;
4. The confirmation of document version and readability;
5. Ascertaining the effectiveness of the planning and operation of the quality management system, the validity of the necessary external original documents, and the control of the distribution of the documents;
6. Prevention of damage or loss of documents;
7. Identification of void documents and preventive measures against misuse.
The manufacturer shall ensure that the changes to the documents are based on the review and approval by the offices issuing the original approval or their designated offices with reference to relevant background information.
Except as otherwise provided in these Regulations, the manufacturer shall specify the period of keeping the void documents to ensure the availability of the data of manufacturing and testing, which shall not be less than the period specified in the relevant laws and regulations. The records and documents thus developed shall be handled in accordance with the provisions of Article 13.

Article 13
The manufacturer shall establish and maintain a record sufficient enough to prove compliance with the requirements of the quality management system and effective operation. For the foregoing record, the provisions in the preceding Article apply mutatis mutandis.
The manufacturer shall formulate and implement protection measures for sensitive health information in records in accordance with the provisions of the Personal Data Protection Act.
The retention period of the record in the first paragraph shall be no less than the
validity period of the medical device and shall be no less than three years from the
date of release of the product by the manufacturer. Other laws and regulations, in
which a longer period is required, shall prevail.

Chapter 3 Management Responsibility

Article 14
The top management shall ensure the establishment, implementation and effective
maintenance of the quality management system, and shall provide evidence of
participation in the following matters:
1. Internal communication of customer needs and the importance of compliance
with laws and regulations.
2. Establishment of quality policies.
3. Establishment of quality objectives.
5. The supply of resources required by the quality management system.

Article 15
The top management shall confirm the demands of customers and the laws and
regulations that shall be complied with to satisfy the demands, and shall ensure
their implementation.

Article 16
The top management shall ensure that the formulation of the quality policies is
consistent with the establishment purposes of the manufacturer, and its content
includes the following matters:
1. Compliance with the requirements of the quality management system and the
commitment to maintain the effectiveness of the system;
2. The framework for establishing and reviewing quality objectives.

The suitability of the quality policy shall be reviewed and communicated within the
manufacturer's organization to ensure the understanding by members of each group.

Article 17
The top management shall ensure that all levels of offices complete the
establishment of the quality objectives.
The foregoing quality objectives shall be set on the basis of the quality policies, and
the content includes measurable items that shall be completed in order to comply
with regulations and product requirements.

Article 18
The top management shall confirm the following:
1. The planning of the quality management system conforms to the quality
objectives and the requirements of Articles 4 to 8;
2. The change of the quality management system does not damage the integrity of
the system.

Article 19

The top management shall specify in writing the duties and functions of the staffs of its internal offices and have all the staffs of these offices informed of the same. Written statement shall be made on the relationship among the foregoing staffs whose jobs involve the management, execution, and monitoring of quality. The top management shall bestow on the staff the necessary power and the independence to exercise the power.

Article 20

The quality management system shall have one person as the management representative, who shall be assigned by the top management. The duties and functions of the aforementioned representative shall be stated in writing covering the following matters:

1. Confirmation of the establishment of the quality management system process in writing;
2. Submission to the top management the report on the confirmation of the effectiveness of the quality management system and the necessary improvement measures;
3. Promotion of the understanding among all the staffs of the manufacturer of relevant laws and regulations and customer demands.

Article 21

The top management shall establish appropriate communication channels within the organization to ensure that matters related to the effectiveness of quality management system are reflected.

Article 22

The manufacturer shall establish, in writing, the management level review procedure of the quality management system, and its content shall include the evaluation of the changes or advancement of the quality management system including quality policy and objectives.

The top management level shall periodically review the quality management system in accordance with the provisions of the preceding paragraph to ensure its suitability, adequacy and effectiveness; its review shall be recorded and kept on file.

Article 23

The review as mentioned in the preceding Article shall include the following matters:

1. Feedback;
2. The handling customer complaints;
3. Reports to the competent central competent authority;
4. Results of internal or external audits;
5. Monitoring and measurement of the process and the results;
6. Monitoring and measurement of the products and the results;
7. Corrective measures;
8. Preventive measures;
9. Follow-up treatment of the conclusions of the previous review;
10. Changes that may affect the quality management system;
11. Recommendations for improvement;
12. Measures to cope with the amendments to the law.

Article 24
The record mentioned in Article 22 shall include the following matters:
1. Matters reviewed and their content;
2. Necessary improvement measures to maintain the suitability, appropriateness and effectiveness of the quality management system and its processes;
3. Product improvement measures based on customer demands;
4. Measures to cope with the amendments of laws and regulations;
5. Resource requirements for implementing the first three sub-paragraphs above.

Chapter 4 Resource Management

Article 25
The manufacturer shall confirm and provide the necessary resources to maintain the effective implementation of the quality management system and comply with the laws and regulations and the demands of customers.

Article 26
Members of the team engaged in work affecting product quality shall be properly educated, trained, or have certain skills or experience to ensure their job competencies.

Article 27
The manufacturer, regarding the establishment of team members' capabilities, the provision of necessary training and the correct awareness of their responsibilities, shall establish in writing the procedures for the following matters:
1. Identification of the competence of personnel engaged in work affecting product quality.
2. The provision of necessary training or other measures to maintain personnel capabilities.
3. Evaluation of the effectiveness of the training or measures in the preceding sub-paragraphs.
4. The insurance of the awareness of personnel mentioned in the first
sub-paragraphs of the relevance and importance of their operation and the attainment of the quality objectives.

5. Record keeping in the forms of audio recording, photographs, video recording, certificates and citations of the education, training, skills and experience of the personnel.

Article 28
In order to meet product requirements, the manufacturer shall specify in writing the conditions of the infrastructure to avoid product confusion and disorderly handling. The foregoing facilities shall include the following matters:
2. Hardware and software process equipment.
3. Support services such as transportation, communication or information systems.
If the implementation of the maintenance or the lack of which on the aforementioned facilities affects the product quality, the manufacturer shall determine the content and frequency of the implementation of the maintenance activities; the implementation shall be recorded and kept on file. These provisions apply to the control, monitoring, and measurement of work environment mutatis mutandis.

Article 29
In order to ensure the consistency of product manufacturing, the manufacturer shall specify in writing the requirements on working environment and impose monitoring and control on those which may adversely affect the product quality. The foregoing requirements shall include the following:
1. The health, cleanliness and clothing conditions of the personnel when their contact with the product or the operating environment can cause adverse effects on the safety or performance of medical devices;
2. The insurance of the necessary capabilities of temporary personnel working under special environmental conditions or of their monitoring by those who possess the capabilities.

Article 30
In order to prevent pollution caused by other products, working environment or personnel, the manufacturer shall plan and establish in writing control measures for contaminated or susceptible products.
The manufacturer shall establish in writing contamination control measures of microbes or particulates on sterile medical devices; the necessary sanitation shall also be maintained in the process of assembly or packaging.

Chapter 5 Product Realization

Article 31
The manufacturer shall plan and establish the processes required for product realization, and the plans shall comply with other process requirements of the quality management system.

The manufacturer shall specify in writing the risk management process necessary for product realization. The implementation of risk management shall be recorded and kept on file.

The content of planning mentioned in the first paragraph shall include the following items, as appropriate:
1. Quality objectives and product requirements;
2. The establishment of necessary processes and documents, and the provision of specific resources by individual products including the infrastructure and working environment;
3. The verification, validation, monitoring, measurement, inspection, testing, handling, storage, distribution and source tracing measures of individual products, and their acceptance criteria;
4. Records sufficient to prove that both the product realization process and the final product meet the requirements.

The content of the aforementioned planning shall be done in writing and specified in the format acceptable with the operation mode of the manufacturer.

Article 32
The manufacturer shall confirm the following matters:
1. Requirement specified by the customers, which scope covers both before and after delivery;
2. Requirement not specified by the customers, but is evidently necessary in order to meet known regulations or intended uses;
3. Applicable laws and regulations of the products;
4. The necessary training to be received by the users in order to ensure that the use of medical devices meets the expected performance and safety;
5. Other matters.

Article 33
Before accepting product orders, the manufacturer shall review the requirements related to the products and complete the confirmation of the following matters:
1. Specified requirements on products;
2. Handling of the difference between the content of the contract or order and that as previously specified;
3. The compliance of laws and regulations;
4. Provision of user training courses;
5. The manufacturer’ possession of the ability to meet various requirements.
The results of the review and the measures to be taken related to the foregoing review shall be recorded and kept on file.

If the customer does not state the requirement in writing, the manufacturer shall ascertain it before accepting the order.

If there are changes occurring in the agreement between the manufacturer and the customer, the manufacturer shall revise the relevant documents and inform its staffs of the changes.

Article 34
The manufacturer shall specify in writing the following matters on the communication with customers;
1. Product information;
2. Customer inquiries, and processing and revision of contracts or orders;
3. Customer feedback including complaints;
4. Advisory notice.

The manufacturer shall apply for, notify or report matters specified in laws and regulations to the competent authority.

Article 35
The manufacturer shall specify in writing the procedures and requirements for product design and development. The content shall include the following:
1. The schedule of design and development, and the review to be implemented at each phase of the procedure;
2. The verification, validation and design transfer measures as implemented in each phase stated in the preceding sub-paragraphs;
3. The duties and functions of the staffs at each phase of the procedure stated in the first sub-paragraphs;
4. The method of tracing the design, development and output to its original items of input;
5. The resources required for product realization, including the necessary capabilities of the personnel.

The written documents mentioned in the preceding paragraph shall be kept on file and updated in due course.

Article 36
The manufacturer shall review the appropriateness of the design and development input items of the following matters, and verify, record and maintain the same:
1. The functions, features, usability and safety based on the intended use;
2. Applicable legal requirements and standards;
3. Output of applicable risk management assessment and measures resulted from research;
4. Information available from similar product designs;
5. Other basic requirements for product and product realization process design and development.

The matters in the preceding paragraphs shall be clear, complete and reasonable, and shall be presented with methods for verification or validation.

Article 37
The product design, development and output shall comply with the following:
1. Conformity with the content approved in the first paragraph of the preceding Article and shall be presented with methods of verification;
2. Provision of necessary information for the procurement, production and service;
3. Specification of the acceptance criteria of products;
4. Specification of the product characteristics that are essential for the product safe and proper use.

The output mentioned in the preceding paragraph shall be subject to approval before being released; its records shall be kept on file.

Article 38
The manufacturer shall perform review on the design and development based on the plans in writing to complete the following matters:
1. Evaluation of the compliance of the results of design and development with requirement;
2. Identification and proposal of necessary actions.

Participants in the foregoing review shall include representatives of the design and development departments, representatives of the departments affected by the design and development results, and other technical personnel.

The results of the review and the necessary measures indicated therewith shall be recorded and kept on file.

The content of the record as mentioned in the preceding paragraph shall clearly record the subject of the review, the staff conducting the review and the date of review.

Article 39
In order to ensure the consistency of design, development input and output, the manufacturer shall specify in writing its consistency verification plan and implement it accordingly.

The content of the foregoing plan shall include the verification methods, acceptance criteria, necessary statistical techniques with rationale for sample size.

The verification mentioned in the first paragraph shall include the requirement of connection or interface conforming with input and output consistency when and if the intended use of the product involves the connection or interface with other
medical devices.
The verification results, conclusions and necessary measures proposed at the end of
the verification shall be recorded and kept on file.

Article 40
In order to ensure that the final product designed and developed meets the specific
application or expected requirements, the manufacturer shall establish in writing a
validation plan, which includes the validation methods, acceptance criteria, and the
necessary statistical techniques with rationale for sample size.
The subject of validation in the preceding paragraph shall be selected from
representative products such as the first batch of production, and the reasons for
selection shall be recorded.
The validation mentioned in the first paragraph shall include the requirement of
specific application or expected requirements when and if the intended use of the
product involves the connection or interface with other medical devices.
The validation mentioned in the first paragraph shall be completed before the
product is released. The verification result and the necessary measures proposed
shall be recorded and kept on file.

Article 41
The manufacturer shall specify in writing the procedures for the transfer and
application of the design and development results to actual manufacturing, to
ensure that the manufacturing process and production capacity have been verified
to meet the requirements. The process and content of the transfer shall be recorded
in detail.

Article 42
The manufacturer shall specify in writing the control procedures on the changes of
the design and development to determine the degree of impact of the changes on
the functions, performance, usability, safety, regulatory requirements and intended
use of the medical devices.
The control mentioned in the preceding paragraph regarding the content of the
change shall be exercised in the following forms and be completed before the
change takes place:
1. Review;
2. Verification;
3. Necessary validation;
4. Approval.
The review mentioned in the preceding paragraph shall include an assessment of
the impact of changes on product components, products in process or delivered,
risk management input or output, and the process of product realization.
The results of changes, the review and its related necessary measures shall be recorded and maintained.

Article 43
The manufacturer should, for the design and development of each model or series of medical devices, establish and maintain a file.
The foregoing file shall include or provide an index to records that can prove compliance with the design and development requirements and the changes on the design and development.

Article 44
The manufacturer shall establish in writing a validation procedure to ensure that the purchased products meet its requirements.
The manufacturer shall formulate evaluation and selection criteria on the suppliers. These are to be set based on the following considerations:
1. The ability of the supplier to provide products that meet the specifications of the manufacturer;
2. The supplier's past performance;
3. The degree of influence of the products provided by suppliers on the quality of medical devices;
4. Risks of medical devices to be manufactured.
The manufacturer shall plan mechanisms for the monitoring and re-evaluation of the suppliers. The results of purchasing requirement compliance control are to be used as a reference for re-evaluation.
The manufacturer shall take necessary measures if it finds that the supplier does not meet the purchasing requirements.
The evaluation, selection, monitoring, re-evaluation and necessary measures mentioned in the first three items above shall be recorded and kept on file.

Article 45
The purchasing requirements mentioned in the preceding article shall include the following matters and be made available for reference in writing or by other index methods:
1. Product specifications;
2. Requirements on the acceptance, procedures, processes and equipment of the products;
3. Requirement for qualification of supplier personnel;
4. Requirements of quality management system.
The manufacturer shall determine the adequacy of purchasing requirements before approaching suppliers.
The manufacturer, when necessary, shall enter into agreement in writing that the
supplier shall notify the manufacturer in advance before implementing the changes that may affect purchasing requirements.
The manufacturer shall maintain documents and records of purchasing information required for traceability as set forth in these Regulations.

Article 46
The manufacturer shall formulate and implement inspections or other necessary verification measures to ensure that the purchased products meet the purchasing requirements.
The selection of the measures and content of the preceding paragraph shall refer to the results of the risk assessment of the supplier and the medical device to be manufactured.
If there is a change in the purchased product, the manufacturer shall determine the impact of the change on the medical device or its manufacturing process.
The measures mentioned in the first paragraph which can be implemented by the manufacturer or its customers at the supplier's premises, shall be stated in the purchasing information mentioned in the preceding Article, with the implementation measures and the method of product release specified.
The implementation of the measures mentioned in the first paragraph shall be recorded and maintained.

Article 47
The manufacturer shall plan the production and service processes, and implement, monitor and control them to ensure that products meet specifications.
The content of production control in the preceding paragraph shall include, as appropriate, the following matters:
1. Control procedures and methods for production stated in writing;
2. Validation of the suitability of infrastructure;
3. Implementation of monitoring and measurement on process parameters and product characteristics;
4. Confirmation of the integrity of the equipment implementing the monitoring and measurement stated in the preceding subparagraph;
5. Implementation of labeling and packaging operations.
The manufacturer shall establish and maintain a production control record for each batch (piece) of medical devices, and the content of which shall include the scope of traceability set out in these Regulations, as well as the amount of production and distribution. The record shall be verified and approved.

Article 48
The manufacturer, under any of the following circumstances, shall formulate in
writing the requirements for product cleaning or pollution control:
1. The product shall be cleaned by the manufacturer before sterilization or use.
2. The product is supplied in a non-sterilized state, but the cleaning process is completed before sterilization or use.
3. The product cannot be cleaned before sterilization or use, but its cleanliness has a significant impact on use.
4. The product does not need to be sterilized for use, but its cleanliness has a significant impact on use.
5. The pharmaceuticals used in the manufacturing process must be removed from the product.
Subparagraphs 1 and 2 of the preceding paragraph do not apply the provisions of Article 29 before cleaning.
Article 49
The manufacturer should, when necessary, formulate in writing the verifiable installation requirements and acceptance criteria for specific medical devices.
If, upon the request of the buyer, the manufacturer agrees for the medical device to be installed by a third party other than the buyer and its authorized agent, the manufacturer shall provide to the third party the documents of the matters and criteria set out in the preceding paragraph.
The manufacturer shall record and maintain the records of the installation by itself or its authorized agents.
Article 50
If there are specific specifications for the after-sales service of medical devices, the manufacturer shall formulate, in writing, the service procedures, the reference measurement methods or other information for implementation and verification.
For the aforementioned service, the manufacturer or its authorized agent shall record and keep it on file.
The manufacturer shall analyze the foregoing records to determine whether there are any complaints that shall be handled, and if necessary, include them in the reference for product improvement.
Article 51
The manufacturer shall keep a record of the sterilization process parameters of each sterilization batch.
The content of the foregoing record shall be traceable to the production batch of the medical device.
Article 52
The deficiencies of production or service, which cannot be revealed without being used or received, shall be confirmed by the operator of the process of production or
service.
Where the results of production or service cannot be verified by subsequent monitoring and measurement and as a result the deficiencies are not revealed without being used or received, the operator shall confirm its process of production and service.

The procedure of confirmation mentioned in the preceding paragraph to prove that the production and service are in accordance with its planned schedule shall be set in writing, and its content includes the following matters:
1. Review standards and approval procedures;
2. The required equipment and their specifications, and the qualifications of the implementing personnel;
3. Specific methods, procedures and acceptance criteria adopted;
4. The statistical techniques with rationale for sample size;
5. The requirements for record confirmation in accordance with Article 13;
6. Revalidation and its criteria;
7. Approval of changes of the confirmation procedures;

The manufacturer shall establish procedures in writing to confirm the computer software they use before production or service provision; the same applies to changes adopted in their software. The choice of software validation and revalidation methods shall take into account the impact of software on product specification compliance.

The results of the foregoing validation and revalidation, the conclusions obtained based on the results, and necessary actions for subsequent implementation shall be recorded and kept on file.

Article 53
The manufacturer shall establish in writing the procedures for validation of the sterilization process and the sterile barrier system. The scope of application includes the product itself, and the same applies when the manufacturing process is changed.

The results of validation mentioned in the preceding paragraph, their conclusions and the necessary follow-up measures shall be recorded and kept on file.

Article 54
The manufacturer shall establish in writing the procedures and methods for identifying products in the product realization process.

The manufacturer shall identify product compliance during the process of product realization. The process includes production, storage, installation, and service processes so as to ensure that only products that pass specific inspections, tests, or approvals are released, used, or installed.
The manufacturer shall establish in writing a single identification system for medical devices in accordance with relevant regulations. The identification procedure mentioned in the first paragraph shall be established in writing by the manufacturer and care shall be taken to ensure that the recycled product is separated from other products.

Article 55
The manufacturer should, within the scope and record content stipulated by laws and regulations, set in writing the traceability procedures of the sources and flows of products.

Article 56
Where the record mentioned in the preceding Article relates to traceability of implantable medical devices, it shall include all parts, materials and production environmental conditions that may cause non-compliance with safety and performance requirements.

The manufacturer of the product mentioned in the preceding paragraph shall require the logistics and distributor of its product to keep the logistic or sales records; and whereas the product is delivered by parcel, the record of the voucher of the name and address of the consignee shall be kept by the manufacturer.

Article 57
The manufacturer shall identify, verify, protect and safeguard the tools, storage equipment, transportation vehicles, development designs, materials, or other tangible or intangible assets provided by the customer for use or forming part of the product.

If the asset in the preceding paragraph is lost, damaged or unusable, the manufacturer shall notify the customer and produce a record and keep on file.

Article 58
The manufacturer shall establish in writing protection procedures to ensure that the product specifications are not affected by the processing, storage, handling and distribution process.

In the procedures mentioned in the preceding paragraph, in order to prevent the product from being exposed to the anticipated state or hazard, which lead to the risks of alteration, contamination or damage, the manufacturer shall implement the following matters:

1. Designing and manufacturing suitable packaging and shipping containers.
2. Providing special additional conditions in writing, if the package or container in the preceding subparagraph fails to provide adequate protection under specific circumstances, and the conditions shall be under control and listed in records.

The above two provisions also apply to the protection of product components.
Article 59

The manufacturer shall plan the monitoring and measurement operations to fully certify the product conformity and shall have the relevant equipment necessary to perform the operations.

The procedure mentioned in the preceding paragraph shall be specified in writing by the manufacturer.

The use of the measurement equipment mentioned in the first paragraph shall comply with the following requirements:

1. Calibration or verification with clear international or national measurement standards before use; where there are no clear standards, the basis used for calibration or verification shall be recorded. The same shall be done regularly after the equipment is commissioned;

2. Making necessary adjustments and readjustments and keeping a record of them;

3. The calibration status shall be determined and identified;

4. Avoiding adjustments that cause invalidated measurement results;

5. Taking precautionary measures to avoid damage or deterioration in case of handling, maintenance or storage.

The manufacturer shall perform the calibration or verification in accordance with the provision of the second paragraph, and record and keep the results.

If inconformity is found on the equipment as mentioned in the first paragraph, the manufacturer shall evaluate the effectiveness of the measurement of its output and record it. Appropriate measures shall be taken for the affected products.

The manufacturer shall establish in writing a validation procedure for the suitability of the computer software for monitoring and measurement purposes, and complete the confirmation before the software is used, or after actual use, or upon changes made in the software.

The validation and revalidation of the software mentioned in the preceding paragraph shall be based on the risks of using the software and exercised with appropriate methods and activities. The results, conclusions reached and necessary follow-up actions shall be recorded and kept on file.

The risks mentioned in the preceding paragraph include the effects of the capability of the medical device to meet its intended use.

Chapter 6 Measurement, Analysis and Improvement

Article 60

The manufacturer shall plan and implement monitoring, measurement, analysis and improvement processes to ensure the conformity of products and the conformity and effectiveness of quality systems.

The foregoing planning shall include validation of the appropriate methods
including statistical techniques and the scope of application.

Article 61
In order to evaluate the effectiveness of the quality management system, the manufacturer shall gather and monitor information on compliance with customer requirements.

The manufacturer shall formulate in writing the methods for collecting and using the information mentioned in the preceding paragraph.

Article 62
The manufacturer shall formulate in writing procedures for receiving and processing the information as mentioned in the preceding article. Specific provisions of laws and regulations, if available, shall prevail.

The foregoing procedures shall include the aggregation of production and post-production information; the consolidated information shall be used by the manufacturer as a reference for risk management, monitoring and product conformity maintenance, and the process of product realization and improvement.

Article 63
The manufacturer shall formulate in writing the procedures and deadlines for complaints handling, and the content of the procedures shall include the following matters:
1. Acceptance and record of the cases of complaint;
2. Evaluation if the case is established;
3. Investigation of the incident;
4. Matters and methods of statutory notification;
5. Treatment of the products based on investigation results;
6. Decisions on subsequent correction and content of corrective actions.

If the complaint case referred to in the preceding paragraph is found not caused by the manufacturer, the manufacturer shall provide the content of the complaint and the appropriate information obtained from the investigation to the relevant stakeholders.

The record mentioned in the first paragraph shall include the matters in all the sub-paragraphs in the same paragraph and the reasons for not having exercised incident investigation. The record shall be kept on file.

Article 64
The manufacturer shall handle the reporting of adverse incidents, recovery and advisory notices in accordance with the provisions of Article 48, Article 49 and Article 58 of the Act and its stipulations, and formulate the procedures for operation.

The notification, recovery and announcement as mentioned in the preceding
The process, place and results of the audit shall be thoroughly recorded and kept on file.

The management of the auditee shall propose corrective measures for the non-compliance of the audit results as mentioned in the preceding paragraph and correct them in time to ensure that the non-compliances and their causes are removed.

The manufacturer shall submit verification reports on the content and results of the implementation of corrective measures.

The manufacturer shall adopt appropriate methods to monitor and measure the various processes of the quality management system.

The manufacturer shall, if the objectives of processes as mentioned in the preceding paragraph are not achieved, propose corrective measures and implement the same to ensure product compliance.

The manufacturer shall, during the product realization process, formulate in writing the monitoring and measurement procedures at appropriate stages based on the characteristics of the product, to verify the conformity of the product.

The products shall not be released unless verified in the foregoing procedure.

The execution of the procedure mentioned in the first paragraph shall be recorded, and its contents shall include the following matters:

1. The name of the person authorized to give permit of the release;
2. Evidence that the acceptance criteria are met;
3. The name of the test equipment, if any equipment is used;
4. The names of the inspectors or testers of implantable medical devices, if the devices are used.

Article 70

The manufacturer shall identify and control products that do not meet the requirements to prevent unintended use or delivery.

In order to meet the requirements of the preceding paragraph, the manufacturer shall formulate in writing the definition of rights and responsibilities in the procedures of identification, recording, segmentation, evaluation, discarding, etc. of the products that do not meet the requirements of the original manufacturer.

The evaluation mentioned in the preceding paragraph shall include the decision to initiate an investigation and to notify the relevant external authorities.

The manufacturer shall record the non-conformity as mentioned in the first paragraph, the reasons for subsequent evaluation and investigation, and reasons for decisions made, and keep the record in file.

Article 71

The manufacturer shall impose the following treatments separately or simultaneously on unqualified products:
1. Measures to remove non-conformities;
2. Measures to prevent the use or application of substandard products mistakenly for their intended purposes;
3. Authorization of the use, release or acceptance of the product under concession.

The manufacturer adopting the treatment method in the third sub-paragraph of the preceding paragraph may do so only with sufficient valid reasons to meet the requirements of laws and regulations, and receive the approval of the responsible personnel. The name and title of the person giving the approval shall be recorded and kept on file.

Article 72

If any non-conformity is found after the product is released, the manufacturer shall take appropriate measures with regard to its impact or potential impact, and keep a record of the same.

The manufacturer shall, in accordance with laws and regulations, formulate in writing the procedure for issuing advisory notices to external parties, and shall follow the said procedure.

The issuance of advisory notices shall be recorded and maintained by the manufacturer.

Article 73
The manufacturer shall, in light of the possible effects of product reprocessing, formulate in writing appropriate rework procedures and have the procedures under review in accordance with the provisions of Chapter 5.
Reprocessed products shall be verified to ensure compliance with acceptance criteria and laws and regulations.
The implementation of rework shall be recorded and kept on file.
Article 74
The manufacturer shall formulate in writing the items and analysis procedures of data collection to prove the adequacy, suitability and effectiveness of the quality management system.
The procedure mentioned in the preceding paragraph shall include implementation methods including the use of statistical techniques and selection of their scope of application.
The data of analysis mentioned in the first paragraph shall include the results from monitoring and measurement. The analysis shall provide at least the following information:
1. Customers' opinions, comments and expressions on the product, service or complaint handling process;
2. The compliance of product specifications;
3. The characteristics and trends of changes of the processes and products, and the timing of intervention for appropriate improvements;
4. Evaluation on the raw materials or services provided by suppliers;
5. Result of the audit on the manufacturer;
6. Evaluation of service reports, when necessary.
If the quality management system is found to be unsuitable, inappropriate, or ineffective through the analysis made in the preceding paragraph, the manufacturer shall take the analysis results as basis of improvements following the provisions of Articles 75, 76, and 77.
The aforementioned results of analysis shall be recorded and kept on file.
Article 75
The manufacturer shall, based on its quality policies and objectives, make necessary changes to ensure and maintain the adequacy, suitability and effectiveness of the quality management system, and the safety and performance of the medical device.
The changes mentioned in the preceding paragraph shall be based on the audit results, post-marketing surveillance, data analysis, and corrective and preventive actions, and shall be implemented after the review and validation of the content of changes by the management.
Article 76
The manufacturer shall take corrective actions to remove the cause of non-conformity and prevent its recurrence.
The implementation of the corrective actions mentioned in the preceding paragraph shall not be delayed for no reason, and the content of the actions shall be formulated based on the degree of influence of the non-conformity.
In order to implement the corrective action mentioned in the first paragraph, the manufacturer shall formulate in writing the procedures for completing the following items:
1. Review of non-conformities including customer complaints.
3. Evaluation of the adoption of corrective actions.
4. The planning, formulation and implementation of corrective actions, and the necessary updates of quality system documents.
5. Validation that corrective actions do not conflict with laws and regulations, and do not degrade the safety and performance of the medical device.
6. Review of the implementation of corrective actions and their effectiveness.
With regard to the formulation of corrective actions, the manufacturer shall record and keep the results of investigations it has performed on non-conformities and the implementation of corrective actions.

Article 77
The manufacturer shall take preventive actions to remove possible causes of non-conformity and prevent its occurrence.
The aforementioned content of the preventive actions shall be based on the degree of impact of potential non-conformities.
In order to implement the preventive actions in the first paragraph, the manufacturer shall formulate in writing the procedures for completing the following items:
1. Judgment of potential non-conformities and their possible causes.
2. Evaluation of the adoption of preventive measures.
3. The planning, formulation and implementation of preventive actions, and the necessary updating of quality system documents.
4. Validation that the preventive actions are not in conflict with laws and regulations, and do not degrade the safety and performance of medical equipment;
5. Review of the implementation of preventive actions and their effectiveness.
In order to determine preventive actions, the manufacturer shall record and keep on file the results of investigations of potential non-conformities and the implementation of preventive actions.
Chapter 7 Essential Mode

Article 78
The items of medical devices produced by the manufacturer are limited to those announced by the central competent authority in accordance with regulations of Paragraph 4, Article 22 of the Act. Each type or series of product shall be recorded and filed separately to implement measures of record control, complaint handling, and corrective and preventive actions.

The manufacturer mentioned in the preceding paragraph, shall not be subject to other provisions of this Part of these Regulations, except for the provisions of Article 11, Article 13, Article 63, Article 76 and Article 77.

Article 79

The Regulations shall be implemented from the date of enforcement of the Act.