The Announcement of the Ministry of Public Health
The Quality System of Importing or Selling of Medical Devices B.E. 2566 (2023)

In order to import or sell medical devices with standard quality and safety to protect consumers, it is therefore expedient to establish a quality system of importing or selling medical devices.

According to Section 5 paragraph one and Section 6 (5) of the Medical Device Act B.E. 2551 (2008). The Minister of Public Health, through the recommendation of the Medical Device Committee, hereby issues the announcement as follows:

Article 1. This announcement will be effective after 1 year from the date of publication in the Royal Gazette.

Article 2. The quality system of importing or selling of medical devices under this announcement must follow the criteria and good practice as annexure to this announcement.

Article 3. The quality system of imports or sale of medical devices applicable to persons under section 41 (1) shall be in accordance with the following requirements:

(1) Proceed according to guidelines outlined in Chapter 2 and Chapter 3 of the " Criteria and good practice for importing and selling of medical devices" annexed to this announcement from the effective date of this announcement.

(2) Proceed according to guidelines outlined in Chapter 2, Chapter 3, and Chapter 4 of the " Criteria and good practice for importing and selling of medical devices" annexed to this announcement from January 1, 2027.
(3) Proceed according to guidelines outlined in Chapter 1, Chapter 2, Chapter 3, and Chapter 4 of the " Criteria and good practice for importing and selling of medical devices" annexed to this announcement from January 1, 2029.

Article 4. The quality system of importing or selling medical devices for registrants of importing establishments or licensees before the effective date of this announcement must be in accordance with the following requirements:

(1) Proceed according to guidelines outlined in Chapter 2 and Chapter 3 of the " Criteria and good practice for importing and selling of medical devices" annexed to this announcement after 1 year from the effective date of this announcement.
(2) Proceed according to guidelines outlined in Chapter 2, Chapter 3, and Chapter 4 of the " Criteria and good practice for importing and selling of medical devices" annexed to this announcement from January 1, 2027.
(3) Proceed according to guidelines outlined in Chapter 1, Chapter 2, Chapter 3, and Chapter 4 of the " Criteria and good practice for importing and selling of medical devices" annexed to this announcement from January 1, 2029.

Article 5. Criteria, methods, and conditions for inspecting and evaluating the quality system in Article 2 shall be in accordance with the guidelines from the Food and Drug Administration.

Article 6. The individual in charge of executing this announcement is the Secretary of the Food and Drug Administration. In cases where there are issues to be considered under this announcement, the Secretary of the Food and Drug Administration has the authority to make a final decision.

Announced on 17 November 2023

Mr. Cholnan Srikaew
Minister of Public Health

Criteria and good practice for importing and selling of medical devices Annexed to the Announcement of the Ministry of Public Health is the quality system for importing or selling medical devices B.E. 2556

Criteria and Good Practice for Importing or Selling Medical Devices with the objective of ensuring confidence in quality, safety, and performance throughout the entire supply chain. This includes procurement and sourcing, contracting, transportation and delivery, storage, disposal, or the process of rendering medical devices, installation, system performance testing, servicing, maintenance, calibration, post-sales service, monitoring, document management, and record-keeping processes are also included, as well as any other related processes, with the following criteria:

Chapter 1 Organization, Management System, and Allocation of Duties and Responsibilities

1.1 Organization and Allocation of Duties and Responsibilities

As an entrepreneur, it's important to have a management system in place that follows Criteria and Good Practice. This includes procedures for identifying and correcting any deviations from the management system when importing or selling medical devices by

1.1.1 Prepare an organizational chart and specify the responsibilities, authorities, and relationships between agencies related to good criteria and procedures for importing or selling medical devices.

1.1.2 Establishing authority, duties, and responsibilities along with providing job descriptions for all levels of positions within the organization related to the criteria. Also, ensuring internal communication within the organization.

1.1.3 Defining the responsibilities of personnel involved in the management, execution, and verification of tasks that impact the quality, safety, and performance of medical devices. This includes ensuring that personnel are competent, independent, and empowered to carry out their duties.

1.1.4 Ensuring that both management and academic personnel are confident in receiving the necessary support regarding authority and resources required to carry out their duties effectively.

1.2 Document management

1.2.1 As an entrepreneur, it is important to prepare and maintain operational documents that comply with the good criteria and procedures for importing or selling medical devices. These documents should include at least the following details:

(1) Brief history, activities, and obligations of the organization as well as activities or processes that have outsourcing.

(2) The scope of the management system that complies with the good criteria and procedures for importing or selling medical devices including details and appropriate reasons for waiving non-compliance or not applied.

(3) The essential operating procedures of the good criteria and procedures for importing or selling medical devices.

(4) The necessary documents to ensure effective planning, operations, and process controls that comply with the required criteria.

(5) The necessary records of the good criteria and procedures for importing or selling medical devices.

(6) other relevant documents or information such as;

(a) The location of the building or premises where the activities are conducted.

(b) Inspection and certification of medical devices to ensure they conform to the specified requirements and obtain permission.

1.2.2 As an entrepreneur, it is important to prepare and maintain a data file of each type of medical device. This file should consist of documents that describe the following details;

(1) Product specifications

(2) the process of importing or selling complete medical devices

(3) specific specifications for installation (if applicable)

(4) installation or service (if applicable)

1.3 Document and record control

1.3.1 Document control

(1) Prepare and maintain necessary documents of the management system in accordance with the good criteria and procedures for importing or selling medical devices.

(2) Prepare documentation of document control procedures.

(3) All documents must be prepared, approved, signed, and dated by the person authorized to operate.

(4) When changing the authorized person to carry out the operation according to Clause 1.3.1 (3), Entrepreneurs must have appropriate assignments.

(5) When there are document revisions, there must be a control system in place to prevent the unintentional use of outdated documents.

1.3.2 Record Control

(1) Prepare and maintain management system records in accordance with the good criteria and procedures for importing or selling medical devices. These records should be easy to read, identify, and locate.

(2) Prepare documentation outlining the controlling procedures essential for records, including their identification, storage, protection, retrieval, retention periods, and disposal.

(3) Keep records relating to medical devices at intervals with consideration of the following information:

(a) Timeframes specified by the Food and Drug Administration or

(b) Medical devices with a Shelf-life should have records stored for a period longer than of the shelf-life 1 year and not less than 5 years from the date of manufacture, or

(c) Throughout the lifetime of the medical device as specified by the manufacturer or the product owner (e.g., in the case of implanted or absorbable medical devices, records must be kept throughout the person's lifetime), or

(d) Not less than 2 years from the date the medical device was removed from the business operator's premises for delivery, based on the longest timeframe chosen from (a), (b), (c), or (d).

1.3.3 If records are stored or backed up electronically, it’s necessary to have access control data loss protection and data backup.

1.4 Management review

1.4.1 The top management shall appoint representatives from the management team, specifying their authority and responsibilities, to ensure that there is a management system in place that complies with the good criteria and procedures for importing or selling medical devices. This management system shall be established, implemented, maintained, and reported to the top

management for its effectiveness in operations. It shall also identify and rectify any deviations from the established good criteria and procedures for importing or selling medical devices.

1.4.2 The organization must conduct a yearly management review to ensure that the system development is continually appropriate, adequate, and effective. All topics must be reviewed within 12 months, and the results of the management review should be recorded.

1.4.3 The management review shall include at least the following topics:

(1) Results from the previous management reviews.

(2) Results from internal audits and evaluations by external agencies (if applicable).

(3) Complaints related to medical devices and feedback from customers.

(4) Reports on the performance of the management system in alignment with the good criteria and procedures for importing or selling medical devices.

(5) Monitoring and surveillance activities, including reporting on incidents of medical device malfunctions or adverse events experienced by consumers, corrective actions for safety in device usage, and product recalls.

(6) Feedback from manufacturers.

(7) Feedback and directives from regulatory authorities.

(8) Status of corrective actions and preventative actions.

(9) Changes that may impact the management system in alignment with the good criteria and procedures for importing or selling medical devices.

(10) Suggestions for improvement.

1.4.4 The results of management reviews shall include decisions and actions related to:

(1) Corrective action and preventative action

(2) The effectiveness of the management system in accordance with good criteria and procedures for the import or sale of medical devices.

(3) Essential Resources

Chapter 2 Resource Management

2.1 Personnel

2.1.1 The entrepreneur must consider establishing the necessary qualifications for personnel and ensure an adequate number of qualified staff for conducting all activities and operations within the entire supply chain of medical devices. This is to ensure the maintenance of quality, safety, and performance of medical devices.

2.1.2 Key personnel needs to have the necessary education, training, skills, and experience. This includes both administrative and operational staff, as well as technical support personnel. These individuals must adhere to good criteria and procedures for the import or sale of medical devices. The entrepreneurs should comply with the following;

(1) Provide training as necessary

(2) Evaluate the effectiveness of training.

(3) Keep records of education, training, skills, and experience.

2.2 Basic public utilities

2.2.1 The operators must ensure the provision and maintenance of essential public utilities necessary to achieve compliance with the specified requirements. These utilities include:

(1) Buildings, facilities, and related facilities

(2) Tools, measuring devices, and testing tools

(3) Support services such as transportation, communication Security management, and other related software, etc.

2.2.2 The entrepreneur should comply with the following;

(1) Ensure that the building, facilities, and equipment used are suitable, safe, and sufficient as specified by the manufacturers and legal requirements, to ensure that medical devices are properly stored and distributed.

(2) Prepare documents on the requirements for the maintenance activities of the facilities and equipment used, including the frequency of maintenance.

(3) Keep records of maintenance

2.3 Cleanliness

The entrepreneur shall prepare documents on the requirements for cleaning the facilities, method, frequency, responsible person, and keep a record of cleaning.

2.4 Pest Control

The entrepreneur shall establish a pest prevention and elimination program to prevent damage and contamination with medical equipment including keeping pest control records.

Chapter 3 Supply Chain and Device-Specific Specifications

3.1 Obtaining permission

The entrepreneurs should comply with the following;

3.1.1 Obtain authorization as an authorized representative from the relevant regulatory authority to act as the person responsible for registering the importing of medical devices or obtaining the license for selling medical devices.

3.1.2 Prepare and maintain written agreements with the relevant regulatory authori□es.

3.2 Communication channels

The entrepreneurs should comply with the following;

3.2.1 Establish and maintain effective communication channels and feedback mechanisms with relevant agencies to ensure that all medical device information is current and disseminated efficiently to concerned parties.

3.2.2 Take responsibility for managing and communicating with users of medical devices and relevant authorities involved with the operation of the medical devices.

3.2.3 Develop a feedback process to collect comments and complaints from users and the public, forwarding them to relevant agencies.

3.2.4 Develop a process to provide information on maintenance, servicing, calibration, spare parts, and other services to purchasers.

3.3 Inventory receipt, inventory storage, Inventory turnover, and delivery of medical devices

3.3.1 Inventory receipt, the entrepreneurs should comply with the following;

(1) Establish a system of inspection or other necessary activities and implement them to ensure that the received or stored medical devices comply with the specified criteria.

(2) Keep records of inspections as required in 3.3.1 (1).

3.3.2 Inventory storage

The entrepreneurs must ensure that medical devices are stored under the specified conditions to prevent deterioration from light, humidity, temperature, or other factors. The storage conditions must be monitored and records of inspections must be maintained appropriately.

3.3.3 Inventory turnover, the entrepreneurs should comply with the following;

(1) Establish a system to ensure that inventory is turnover according to the shelf-life.

(2) Separate expired medical devices from usable inventory and clearly indicate their status.

(3) Destroying or obsoleting an expired medical device (see section 3.5)

3.3.4 Delivery of medical devices, the entrepreneurs should comply with the following;

(1) Verify that medical devices have the license, notifications license, listings license, certificates, and other relevant documents, including instructions for use.

(2) Ensure that medical devices are distributed only to individuals or entities authorized to possess such devices according to the applicable laws, with necessary verification before distribution.

(3) Ensure that medical devices have clear labeling for accurate feedback information.

(4) Establish appropriate transportation methods to ensure the safe delivery of medical devices without damage from the origin to the destination.

(5) Ensure that delivered medical devices are free from contamination or adulteration by other devices or substances.

(6) Ensure sufficient safeguards

(7) Ensure that delivered medical devices are safe and not affected beyond acceptable limits by heat, cold, light, humidity, or other influences, and are not contaminated by microorganisms or pests.

(8) In the case of transporting medical devices that require specific control conditions, such as temperature or specialized environmental conditions, ensure they are transported using appropriate methods.

3.4 Control of non-compliant medical devices and return of medical devices

The entrepreneurs should comply with the following;

3.4.1 Prepare a standard operating procedure document for managing returned medical devices or devices that do not meet the specifications. This includes outlining the controls and assigning responsibilities to personnel for managing such devices.

3.4.2 Separate all returned medical devices from the saleable inventory and clearly indicate measures to prevent the distribution of devices that do not meet specifications un□l a proper handling process is established for such devices.

3.4.3 Establish acceptance criteria (for reassessment) and documented

3.4.4 Take action on medical devices that do not comply with the specifications using one or more of the following methods:

(1) Dispose of medical devices that do not comply with the requirements

(2) To be used under conditions agreed upon by an authorized person

3.4.5 Keep a record of the reassessment results. which includes the result of decision-making by authorized personnel as well as any subsequent actions taken.

3.4.6 Ensure that non-compliant medical devices will be released and used under agreed conditions only if the medical device complies with the requirements of the relevant laws.

3.4.7 Prepare an action plan and record the results regarding medical devices that do not comply with the specified requirements after delivery or commencement of use. This includes documenting the impact and potential implications of non-compliance (as appropriate).

3.5 Destruction of medical devices

The entrepreneurs should comply with the following;

3.5.1 Preparing documented procedures for the destruction or inactivation of medical devices shall be in accordance with the related regulations.

3.5.2 Ensure that medical devices that are pending destruction or deterioration are safely stored in a separate area and are identified according to related regulations.

3.5.3 Keep records of the destruction of the medical device.

3.6 Distribution records and traceability

The entrepreneurs should comply with the following;

3.6.1 Prepare documentation for all activities related to the distribution of medical devices, including receipt, storage, delivery, and disposal or expiration of stored medical devices. Refer to section 1.3.2 for details to be included in the records, ensuring that the information provided is accurate.

(1) Manufacturer, authorized representatives, importers, exporters, distributors, and customers' names, addresses, email addresses, and telephone numbers for each respective medical device should be specified.

(2) The name of the medical device, its classification, and identification information such as product codes.

3.6.2 Ensure that medical devices can be traced throughout the relevant supply chain, including model, version, production batch or serial numbers, and quantity or volume of the medical devices, as appropriate. Maintain records of the traceability of returned medical devices as needed.

3.7 Calibration

Equipment or measuring instruments used for maintaining and distributing medical devices must be appropriate and complete to calibration or verification at specified intervals or before use, according to internationally or nationally recognized measurement standards. If there is no evidence of calibration to international standards, the organization must establish criteria for verification and document it.

3.8 Special Requirements for Active Medical Devices

3.8.1 The entrepreneurs should comply with the following:

(1) Prepare documentation for the work processes and procedures that cover equipment testing, reference materials, and relevant standards for various services, including calibration, repair, maintenance, and verification, to ensure that the services comply with the specified requirements and standards.

(2) Prepare documentation that specifies acceptable criteria for the installation, testing, and operational verification of medical device systems.

(3) Define specific characteristics and testing procedures for the installation of medical devices that have special requirements and, when appropriate, include testing methods, ensuring continuous adherence to the specified special characteristics.

(4) Ensure that medical devices have been installed, tested, and their systems verified as specified.

(5) Ensure that equipment used for testing, maintenance, and conditioning of medical devices is calibrated or verified at defined intervals.

(6) Ensure that equipment calibration and maintenance are carried out according to accepted standards.

(7) Maintain records of testing, system operational verification, installation, calibration, and maintenance activities.

3.8.2 Service Requirements, the entrepreneurs should comply with the following (as applicable):

(1) Provide appropriate technical support for repair services, training, calibration, spare parts management, installation, and management of repair or maintenance workshops (service centers).

(2) Provide support for maintenance to customers.

(3) Ensure that both technical support and maintenance services comply with relevant laws or regulations.

(4) Maintain records of the provided services (if applicable).

3.9 Installation and Servicing

3.9.1 Installation

In cases where the installation of medical devices must adhere to specific requirements, the entrepreneur should comply with the following:

(1) Prepare documentation for the installation and verification procedures, including testing methods for the medical devices, according to the manufacturer's specifications.

(2) Ensure that the prepared documentation includes various instructions to ensure proper installation and that the medical devices can function as intended after installation. All installation, inspection, and testing as specified in the documentation must be carried out as described.

(3) Maintain records of any inspections and test results (if applicable) that demonstrate the appropriate installation.

3.9.2 Servicing

In cases where servicing is specified as a requirement, such as maintenance of medical devices, the business entrepreneur should prepare documentation for the procedures and review methods to ensure that the servicing complies with the specified requirements and maintain records of the servicing provided.

3.10 Outsourcing

The entrepreneur s should comply with the following;

3.10.1 Ensure that there is a controlled process for outsourcing within the framework of good criteria and procedures for the import or sale of medical devices.

3.10.2 Establish requirements to ensure that the activities carried out through outsourcing are in line with the specified requirements.

3.10.3 Ensure that the format and scope of control over the outsourced contractor depend on the impact it has on the operations to comply with the good criteria and procedures for the import or sale of medical devices.

3.10.4 Ensure that the outsourced contractor is controlled and evaluated as an integral part of the business's system unless the outsourced contractor has been certified according to good criteria and procedures for the import or sale of medical devices. within the scope of outsourcing.

3.10.5 Establish written agreements with external contracting units to ensure that appropriate checks on the safety and performance of medical devices, as well as related documentation, records, and agreements, are properly maintained in compliance with relevant laws or regulations.

3.11 Counterfeiting, adulteration, misconduct, and modification of medical devices

The entrepreneurs should comply with the following;

3.11.1 Ensure that any medical devices found to be counterfeited, adulterated, misbranded, or modified must be separated from other medical devices to prevent confusion.

3.11.2 Label clearly the medical devices identified as counterfeited, adulterated, misbranded, or modified with the wording "prohibited for sale" or similar text.

3.11.3 Notify the Food and Drug Administration and manufacturers immediately.

Chapter 4 Monitoring and Surveillance

4.1 Complaints about medical devices

The entrepreneurs should comply with the following;

4.1.1 In order to comply with the Notification from the Ministry of Public Health on Criteria, Procedures, and Conditions for Providing Complaint Channels, it is necessary to document operational procedures and relevant documents related to complaint records and the handling of complaints regarding medical devices that are manufactured, imported, or sold. This documentation will be examined by competent officials and should follow the B.E. 2563 version or any amended version of the Notification.

4.1.2 Review complaints and other relevant information, investigate the cause, and proceed with complaints which may report to the establishment, or the manufacturer from which the entrepreneur receives the product (as appropriate) in the event that the complaint affects the safety of use or device defects of the medical device or there is an event unfavorable to consumers (see section 4.2)

4.1.3 Keep a record of complaints and any action taken.

4.1.4 Evaluate the effectiveness of complaint handling.

4.2 Reporting any device defects or adverse events that occur to consumers, field safety corrective action of medical devices, and recall.

4.2.1 As an entrepreneur, it is essential to document operational procedures and relevant documents in accordance with the Announcement of the Ministry of Public Health regarding Criteria, Methods, and Conditions for Reporting Device Defects or Adverse Event Occurring to Consumers, and Reporting Field Safety Corrective Action of Medical Devices, B.E. 2563 (Revised Edition).

4.2.2 In the case of a recall, at least the following information must be included:

(1) Document the procedures for recalling medical devices in a timely and effective manner, especially when there is suspicion of defects or forgery. Make sure that the system complies with the standards required by the Food and Drug Administration.

(2) Notify the manufacturer or authorized representative of the product recall.

(3) If a product recall occurs, it will be managed by an appointed individual who is not associated with the manufacturer or authorized representative. Before initiating a product recall, it is advisable to seek guidance from the manufacturer or an authorized representative

(4) Record the progress of the recall process and provide a final report which must include checking the quantity of goods that have been distributed and returned.

(5) Report recall information to the Food and Drug Administration.

4.3 Internal audit

The entrepreneurs should comply with the following;

4.3.1 Prepare a documented procedure for implementation, specifying the planning responsibilities. Implementation of internal audit defines audit, criteria, scope, frequency, and audit method and maintenance of records internal audit.

4.3.2 Establish an internal audit program. Consider the current status and importance of the process as well as the area to be monitored. Including the results of the monitoring in the past round.

4.3.3 Conduct internal audits within the specified period to monitor the implementation of the activities and to meet the requirements of criteria and good practice for the import or sale of medical devices.

4.3.4 Take action to eliminate the cause of the detected nonconformities. It must proceed without delay.

4.3.5 Keep records of auditing activities and audit results.

4.4 Corrective actions and protection operations

The entrepreneur shall document the operating procedures and assign appropriate responsible persons in corrective actions and preventive actions must specify.

4.4.1 Corrective action when defective work is found or not as specified, including complaints about medical devices.

(1) Analysis of the cause of the problem

(2) Selection of methods and actions that are expected to best solve problems and prevent their recurrence by implementation. If possible, it should include updating the documents.

(3) Monitoring of the consequences resulting from the implementation of corrective action to ensure corrective action is effective.

(4) Keep a record of the implementation of the corrective action.

4.4.2 Preventive action when a trend is found or risks that may cause problems or non-compliance with the requirements. This includes opportunities for improvement.

(1) Analysis of the causes of trends or risks that may not conform to the requirements.

(2) Selection of methods and actions that are expected to reduce the likelihood of nonconformities being implemented.

(3) Review the effectiveness of preventive actions taken.

(4) Keep a record of the implementation of preventive actions.

Application

To apply criteria and good practices for distributing medical devices, registrants can exempt any requirements if there is no activity to comply that requirements such as calibration, special requirements for active medical devices, outsourcing, etc. Registrants must provide sufficient and appropriate justification for not applying those specific requirements.