**Good Criteria and Practice for Importing and Selling of Medical Devices**

**Annexed to the Notification of the Ministry of Public Health Re: the quality system for importing or selling medical devices B.E. 2566 (2023)**

The objective of this document is to ensure the quality, safety and performance of medical device during all aspects of medical device supply-chain, which include, but not limited to, product sourcing and procurement; transportation and delivery; storage; installation, commissioning, service and maintenance, calibration and after sales service; tracking, documentation and record-keeping practices.

## Chapter 1 Organization, Management System and Responsibilities

### 1.1 Organization and responsibilities

The establishment shall establish and maintain the management system in compliance with the good criteria and practice for importing or selling medical devices, including a process for identifying and correcting deviations from the established management system by

1.1.1 Prepare an organizational chart and indicate the responsibility, authority and interrelationship of all key personnel that related to the good criteria and practice for importing and selling of medical devices;

1.1.2 Define the duties and responsibilities with written job descriptions for every level of the organization;

1.1.3 Establish the interrelation between all personnel who manage, perform and verify works that affect quality, safety and performance of medical device and shall ensure the independence and authority to perform these tasks;

1.1.4 Ensure managerial and technical personnel have the authority and resources needed to carry out their duties.

### 1.2 Documentation

1.2.1 The establishment shall establish and maintain an operational documents in compliance with the good criteria and practice for importing and selling of medical devices which shall include the following information—

(1) Brief of establishment's profile, activities/operations, including those outsourced processes or activities/operations;

(2) The scope of the management system in compliance with the good criteria and practice for importing or selling medical devices, including details of, and justification for any exclusion and/or non-application;

(3) Procedures required by the good criteria and practice for importing or selling medical devices;

(4) Documents needed by the establishment to ensure the effective planning, operation and control of processes for compliance;

(5) Records required by the good criteria and practice for importing or selling medical devices;

(6) Information regarding—

(a) The premises where activities are conducted;

(b) The medical device conformity assessment and the registration holder.

1.2.2 The establishment shall establish and maintain a file containing documents for each medical device that define—

(1) Product specifications;

(2) Complete importing or selling process;

(3) Installation qualifications (if applicable);

(4) Installation or service (if applicable).

**1.3 Document and record control**

1.3.1 Document control

(1) Establish and maintain the documents required by the management system in compliance with the good criteria and practice for importing or selling medical devices;

(2) Establish a documented procedure for the control of documents;

(3) All documents shall be prepared, approved, signed and dated by an authorized person;

(4) The establishment shall give appropriate authorization on any change on authorized person permitted to carry out the task in sub-clause (2);

(5) When a document has been revised, the control system shall prevent unintended use of the outdated version.

1.3.2 Record control

(1) Establish and maintain records of the management system in compliance with the good criteria and practice for importing or selling medical devices that are legible, readily identifiable and retrievable;

(2) Establish a documented procedure to define the controls for the identification, storage, protection, retrieval, retention time and disposition of records;

(3) Retain the records for a period of time—

(a) Specified by the Thai FDA;

(b) Longer than of the shelf-life 1 year and not less than 5 years from the manufacturing date;

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

(d) No less than 2 years from the date that the medical device is shipped from the establishment, whichever is the longest from (a), (b), (c), or (d).

1.3.3 In case that records are stored or backed up electronically, this shall require an access control, data loss protection, and data backup.

**1.4 Management review**

1.4.1 The top management shall appoint a designated person who shall have the defined responsibility and authority to ensure that the management system in compliance with the good criteria and practice for importing or selling medical devices is established, implemented and maintained; and to report to top management on the performance of an operation, as well as to identify and correct deviations from the established management system in compliance with the good criteria and practice for importing or selling medical devices

1.4.2 The organization shall conduct a management review at least once a year (all chapters within 12 months) to ensure that the system development is constantly suitable, sufficient, and effective, and keep records of management reviews.

1.4.3 The management review shall include—

(1) Follow-up actions from previous management reviews;

(2) Results of internal and external audits (if applicable);

(3) Customer complaints/feedback;

(4) Report on the performance of the management system in compliance with the good criteria and practice for importing or selling medical devices;

(5) Surveillance and vigilance activities including medical device defects, or adverse events, field safety corrective actions and recalls

(6) Feedback from manufacturer;

(7) Feedback and directives from the authority;

(8) Status of preventive and corrective actions;

(9) Changes that could affect the management system in compliance with the good criteria and practice for importing or selling medical devices;

(10) Recommendations for improvement.

1.4.4 The output from the management review shall include any decisions and actions related to—

(1) The corrective and preventive actions required;

(2) The effectiveness of the management system in compliance with the good criteria and practice for importing or selling medical devices;

(3) Essential resources

## Chapter 2 Resource Management

### 2.1 Personnel

2.1.1 The establishment shall consider determining the necessary competence for the personnel and possess an adequate number of competent personnel involved in all activities/operations in the supply-chain of the medical devices in order to ensure the quality, safety and performance of the medical device are maintained.

2.1.2 Key personnel in charge of managing activities/operations within the scope of the good criteria and practice for importing or selling medical devices, including technical support shall possess appropriate education, training, skills and experience. The establishment shall—

(1) Provide training to satisfy these needs;

(2) Evaluate the effectiveness of the training;

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

### 2.2 Basic utilities

2.2.1 The establishment shall determine, provide and maintain the basic utilities needed to achieve conformity to specified requirements which includes, as applicable—

(1) Premises and associated utilities;

(2) Tools, measuring and test equipment;

(3) Supporting services (e.g. transportation, communication, security management, and other related software, etc.).

2.2.2 The establishment shall—

(1) Ensure that the premises and equipment used are suitable, safe and adequate in accordance with the manufacturer and regulatory requirements to ensure proper conservation and distribution of medical devices;

(2) Establish documented requirements for maintaining the premises and equipment, including their frequencies;

(3) Maintain records of such maintenance activities.

**2.3 Cleanliness**

The establishment shall establish documented requirements for the cleaning of premises, methods, frequency, responsible person, and including maintain records of cleaning.

**2.4 Pest control**

The establishment shall establish a pest control and elimination program to prevent damage and contamination with medical devices, and maintain records of pest control program.

## Chapter 3 Supply Chain and Specification

**3.1 Authorization**

The establishment shall—

3.1.1 obtain appropriate authorization from the relevant authority to become authorized representative, importer or distributor of medical devices;

3.1.2 Establish and maintain written agreement with the relevant party.

**3.2 Communication channels**

The establishment shall—

3.2.1 Establish and maintain communication channels and feedback mechanisms with the relevant party to ensure that all relevant and updated medical device information can be disseminated to the related parties effectively;

3.2.2 Be responsible to manage and to communicate with users, public and authority on matters pertaining to medical devices it deals with;

3.2.3 Establish feedback mechanism for collecting comments and complaints from users and public, to be forwarded to the relevant party;

3.2.4 Establish mechanism to provide information on maintenance services, including calibration, provision of spare parts and other services, to the users.

**3.3 Receipt of stock, inventory storage, stock rotation and delivery of medical devices**

3.3.1 Receipt of stock

The establishment shall—

(1) Establish and implement inspection or other activities necessary to ensure that medical devices received meet the specified requirements;

(2) Maintain records of verification as required in 3.3.1 (1).

3.3.2 Inventory storage

The establishment shall ensure that medical devices are stored under specified conditions to prevent deterioration from light, humidity, temperature, or other factors. Storage conditions must be monitored, and inspection records must be maintained (as appropriate).

3.3.3 Stock rotation

The establishment shall—

(1) Establish a system to ensure stock rotation according to the shelf-life;

(2) Separate medical devices beyond their expiry date or shelf life from usable stock and clearly labeled;

(3) Dispose the expired medical devices in accordance with clause 3.5

3.3.4 Delivery of medical devices

The establishment shall—

(1) Verify that the registered medical device is accompanied by Licensing license, Notification license, Listing license, Certificate of registration and other relevant documents and instructions for use;

(2) Ensure the designated medical devices should only be sold and/or distributed to persons or entities that are entitled to acquire such medical devices as specified by the regulatory requirements by obtaining the proof of such authority prior to the distribution of medical devices to such person;

(3) Ensure that medical device has clear identification to provide traceability information;

(4) Establish proper methods of delivery to achieve safe and secure delivery of medical device from the point of collection to the point of delivery;

(5) Ensure medical devices are not contaminated or adulterated with other devices or substances;

(6) Ensure adequate protection to prevent falls, leaks, breaks, damage or loss;

(7) Ensure that delivered medical devices are safe and unaffected exceed the acceptance criteria 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 storage under specific control conditions, such as temperature or special control or special environment; ensure they are transported using special or appropriate methods.

**3.4 Control of nonconforming medical devices and return of medical devices**

The establishment shall—

3.4.1 Establish documented procedures for handling of returned medical device or nonconforming medical device, and define the controls and related responsibilities and authorities for dealing with;

3.4.2 Separate all returned medical devices from the saleable inventory and clearly identification to prevent the distribution of nonconforming medical devices and establish handling method such devices;

3.4.3 Establish acceptance criteria (for reassessment) and documented;

3.4.4 Deal with nonconforming product by one or more of the following ways—

(1) Eliminate the detected nonconformity

(2) Use 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 and any subsequent actions taken;

3.4.6 Ensure that nonconforming medical device is delivered and used by concession only if the regulatory requirements are met;

3.4.7 Prepare an action plan and record the results regarding nonconforming medical device that detected after delivery or commencement of use. This includes the effects, or potential effects of the nonconformity (as appropriate).

**3.5 Disposal of medical devices**

The establishment shall—

3.5.1 Establish a documented procedure for the disposal of medical devices in accordance with regulatory requirements and any other applicable statutory requirements.

3.5.2 Ensure that medical devices sent for disposal shall be kept in a clearly segregated, safe and secured area and identified in accordance with regulatory requirements and any other applicable statutory requirement.

3.5.3 Keep records of the disposal.

**3.6 Distribution records and traceability**

The establishment shall—

3.6.1 Prepare documentation for all activities related to the distribution of medical devices including receipt, storage, delivery, and disposal throughout product shelf-life, refer to clause 1.3.2. The information in the records shall include details as practicable.

(1) The names, address, e-mail, and telephone number of the manufacturer, authorized representative, importer, exporter, distributor, and customer

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

3.6.2 Ensure that medical devices can be traced throughout the relevant supply-chain, which include the make, model, batch number, serial number, and quantity of devices, as appropriate, and maintain records of the traceability.

**3.7 Calibration**

Tools or test equipment used for maintaining and distributing medical devices shall be appropriate and calibrated or verified at specific intervals or before use, according to international or national measurement standards. If there is no evidence traced back to international standards, verification criteria shall be documented established.

**3.8 Specific requirements for active medical devices**

3.8.1 The establishment shall—

(1) Establish documented procedures and work instructions that cover test equipment, tools, reference materials, and reference measurement standard for performing servicing activities including calibration, repair, maintenance and verifying that they meet the regulatory requirements and applicable standards;

(2) Establish documented requirements which contain acceptance criteria for installation, testing and commissioning of the medical device;

(3) Establish installation qualification and inspection instructions for the medical devices that have special installation requirements, and where appropriate, including test procedures, and ensuring continuous compliance with the specified qualification;

(4) Ensure proper installation, testing and commissioning;

(5) Ensure equipment used for testing, maintenance and conservation of medical devices are calibrated or verified at specific intervals;

(6) Ensure the calibration and maintenance of test equipment conforms to the accepted standards;

(7) Maintain testing and commissioning, installation, calibration and maintenance service records.

3.8.2 Service requirements, the establishment shall, as appropriate—

(1) Establish an appropriate technical support for maintenance service, training, calibration, management of spare parts, workshop setup and management;

(2) Establish maintenance support for the customers;

(3) Ensure the technical and maintenance support services conform to the relevant laws or regulations;

(4) Maintain service records (if applicable).

**3.9 Installation and servicing**

3.9.1 Installation

In case where the installation of medical devices shall conform to specific requirements, the establishment shall—

(1) Establish documentation for the installation and verification procedures, including test procedures in accordance with the manufacturer's specifications;

(2) Ensure that the prepared documentation contains various instructions for accurate installation and that the medical devices can function as intended after installation. Installation, inspection, and testing as defined in the documentation must be carried out as described.

(3) Maintain records of inspections and any test results (if applicable) that show proper installation.

3.9.2 Servicing

In case where servicing is specified requirements, such as maintenance of medical devices etc., the establishment shall establish documentation for the work procedures and verification procedures to ensure that servicing complies with the specified requirements and maintain records of the servicing.

**3.10 Outsourced activities**

The establishment shall—

3.10.1 Ensure control over outsourced process within the scope of the good criteria and practice for importing or selling medical devices;

3.10.2 Establish requirements to ensure that the outsourced activities conform to specified requirements;

3.10.3 Ensure the type and extent of control applied to outsource are dependent on the impact on meeting the requirements of the good criteria and practice for importing or selling medical devices;

3.10.4 Ensure that the outsourced is controlled and evaluated as part of the establishment's system unless the outsourced is already certified according to good criteria and procedures for the importing or selling of medical devices covering the scope of the outsourced activities;

3.10.5 Develop written agreements with outsourced party to ensure that appropriate measures are taken to safeguard the safety and performance of the medical

devices, including maintaining appropriate documentation and records, and such agreements should be in accordance with regulatory requirements and any relevant statutory requirements.

**3.11 Counterfeit, adulterated, unwholesome and tampered medical devices**

The establishment shall—

3.11.1 Ensure that any counterfeit, adulterate, unwholesome, and tampered medical devices must be physically segregated from other medical devices to avoid any confusion;

3.11.2 Clearly label any counterfeit, adulterate, unwholesome, and tampered medical devices as “Not for Sale” or other similar phrases;

3.11.3 Inform the Thai FDA immediately.

## Chapter 4 Audit and Surveillance

**4.1 Medical device complaints**

The establishment shall—

4.1.1 Establish a documented procedure and relevant documents to comply with the Notification of the Ministry of Public Health Re: *Criteria, Procedures, and Conditions for Providing Complaint Channels, Complaint Records, and Management System of Manufactured/Imported/Sold Medical Device Complaints for Regulator’s Inspection B.E. 2563 (2020) or the amendment.*

4.1.2 Review complaints and other relevant information, investigate the cause, and take action with complaints which may report to the establishment or manufacturer where the establishment receives the product from (as appropriate) in case the complaint affects safety of use or causes device defects of the medical device or adverse event (see clause 4.2).

4.1.3 Maintain records of the complaint, and any subsequent actions taken.

4.1.4 Evaluate the effectiveness of complaint handling.

**4.2 Reporting of Medical device defect, Adverse event, Field safety corrective action (FSCA) and recall**

4.2.1 The establishment shall establish documented procedures and relevant documentation in compliance with the Notification of Ministry of Public Health Re: *Criteria, Procedures, and Conditions for Reporting Medical Device Defects or Adverse Event and Reporting Field Safety Corrective Action of Medical Devices, B.E. 2563 (2020), or the amendment.*

4.2.2 In case of a recall, The establishment shall at least—

(1) Establish a documented procedure to effectively and promptly recall medical device known or suspected to be defective or counterfeit and to ensure that the system comply with the Thai FDA requirements;

(2) Inform the manufacturer or authorized representative in the event of a recall;

(3) Where a recall is instituted by an entity other than the manufacturer and/or authorized representative, consultation with the manufacturer and/or authorized representative should, where possible, take place before the recall is instituted;

(4) Record the progress of a recall process and issue a final report which includes a reconciliation between delivered and recovered quantities of products;

(5) Report recall information to the Thai FDA.

**4.3 Internal audits**

The establishment shall—

4.3.1 Establish a documented procedure defining the responsibilities for planning and conducting audits; define the audit criteria, scope, frequency and methods; maintain records of the audits;

4.3.2 Plan an audit program, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits;

4.3.3 Conduct internal audits at planned intervals to monitor the implementation of and compliance with the requirements of the good criteria and practice for importing or selling medical devices;

4.3.4 Take actions to eliminate the causes of the detected nonconformities without undue delay.

4.3.5 Maintain records of the audits and their results.

**4.4 Corrective action and Preventive action**

The establishment shall establish a documented procedure and assign appropriate responsible person. Corrective action and Preventive action shall define—

4.4.1 Corrective action when work is found to be defective or nonconform to specified requirements, including medical device complaints.

(1) Analysis of the cause of problem;

(2) Selection of methods and actions expected to best solve and prevent recurrence through implementation, including, if possible, updating documentation;

(3) Monitoring the results of any corrective action taken to ensure it is effective.

(4) Record the implementation of corrective action

4.4.2 Preventive action when trends or risks are found that may cause problems or nonconformities with the requirements, including 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 expected to eliminate the causes of potential nonconformities;

(3) Reviewing preventive action taken and its effectiveness;

(4) Record the implementation of preventive action

**Application**

To apply the Good Distribution Practice for Medical Devices, an establishment can exempt any requirements that are not met, such as calibration, special requirements for active medical devices, outsourced activities etc. However, the establishment shall provide adequate and appropriate reasons for not implementing those requirements.