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# PLACEMENT OF MEDICAL DEVICES ON THE MALAYSIAN MARKET

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## Conformity assessment and placement on the market

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Medical device regulatory system is intended to ensure protection of public health and safety. It is based on the safety and performance of medical devices throughout their life cycle. Essentially, prior to placing a medical device into the market, conformity assessment is conducted to provide objective evidence of safety, performance and benefits and risks to maintain public confidence.

## What is conformity assessment?

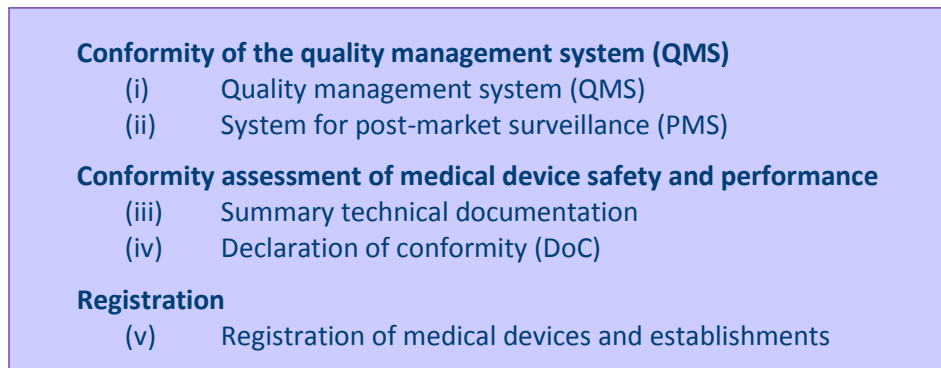
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Conformity assessment is the technical term given to the process of evaluation and approval. In the context of medical device regulatory system, it is a systematic examination of evidence generated and procedures undertaken by the manufacturer, under requirements established by the Regulatory Authority (RA), to determine that a medical device is safe and performs as intended by the manufacturer and, therefore, conforms to Essential Principles of Safety and Performance (EPSP) for Medical Devices.

## Elements of conformity assessment

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The elements of a conformity assessment system are as shown in Figure 1.



*Figure 1: Elements of conformity assessment of medical devices*

## Parties involved (and their roles) in conformity assessment

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Three parties will be involved in conformity assessment, namely;

- (i) The manufacturer of medical device;
- (ii) Conformity assessment body (CAB);
- (iii) The regulatory authority (RA).

Conformity assessment is primarily the responsibility of the medical device manufacturer. However, it is done in the context of the established regulatory requirements. The processes and conclusions derived

from conformity assessment are subject to further review by CAB and/or RA. Ultimately, the RA shall decide on;

- (i) the result of the conformity assessment;
- (ii) the registration of medical devices and establishments dealing with medical devices.

Figure 2 shows the parties involved and their respective roles in conformity assessment of medical device.

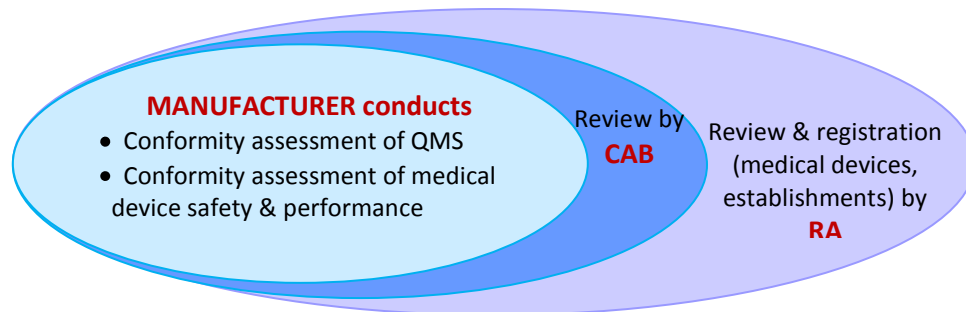


Figure 2: The parties involved (and their respective roles) in conformity assessment of medical device

## NOTES

### *What is an establishment?*

Establishment means a person/organization who is either a manufacturer, importer or distributor of medical devices, but does not include a retailer.

### *Who is a manufacturer of medical device?*

Manufacturer of medical device is a person/organization who places a medical device on the market under his own name, and thereby, shall hold the full responsibilities and shall make the application to register medical devices to be placed on the Malaysian market. The functions of a manufacturer include one or more of the following activities related to medical devices;

- (i) design;
- (ii) assignment of the intended purpose;
- (iii) production/fabrication;
- (iv) assembly;
- (v) labeling;
- (vi) sterilization or other processing;
- (vii) packaging;
- (viii) modification or re-labeling or refurbishment.

When any of these functions are sub-contracted, the manufacturer remains the responsible party. Where a manufacturer, has a principal place of business outside Malaysia, it shall appoint a local authorized representative (LAR) in Malaysia.

### *What is a local authorized representative (LAR)?*

LAR means any person explicitly designated by a manufacturer, to represent it within Malaysia, in respect of matters raised by the RA, with regard to the manufacturer's obligations under the Malaysian medical device regulatory system. LAR must be a legal person incorporated in Malaysia or natural or legal person with business registration in Malaysia. LAR must maintain linkage with their foreign manufacturers and should be able to obtain the support of their foreign manufacturers whenever required.

### *What is a distributor?*

Distributor is any natural or legal person in the supply chain who, on his own behalf, furthers the availability of medical devices to the end-user. In some circumstances, more than one distributor may be involved in this process.

## NOTES

### *What is an importer?*

Importer is any natural or legal person in the supply chain who first makes a medical device, manufactured in other countries, available in the Malaysian market. An importer does not re-package or re-label a medical device or its package, and does not transform or modify a medical device in a way that affect its safety, performance and intended use.

### *Who is the RA?*

RA is a Government body that exercises a legal right to control the use or sale of medical devices within its jurisdiction, and that may take enforcement action to ensure that medical devices marketed within its jurisdiction comply with the regulatory requirements. In the Malaysian context, RA is the Medical Devices Bureau (MDB).

### *What is a CAB?*

CAB is a body engaged in the performance of procedures for determining whether the relevant requirements in technical regulations or standards are fulfilled. A CAB is authorized by the RA to undertake specified conformity assessment activities and the RA will monitor the performance of the CAB and, if necessary, withdraw authorization.

## Conformity assessment of quality management system (QMS)

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Conformity assessment of QMS needs to be performed on two components, namely the QMS and the system for post-market surveillance (PMS).

### Quality management system (QMS)

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Good management of the manufacturing process is important in the production of medical devices. Poor management may bring about inconsistency in products quality even though the prototype has been well designed. QMS provides a preventive approach to assuring medical device quality. A manufacturer needs to demonstrate the ability to produce medical devices that are consistently meeting customer and regulatory requirements through the establishment and implementation of an effective QMS.

Conformity assessment of QMS is determined by the class of the medical device. For Class B, C and D medical devices, the manufacturer should put an effective and appropriate QMS in place. Manufacturers of Class C and D devices shall have a full QMS that includes design and development. The QMS is subject to periodic audits and reviews by the CAB and/or RA.

### System for post-market surveillance (PMS)

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Prior to placing a medical device on the market, the manufacturer shall put in place, as part of its QMS, a system for PMS. PMS is a mixture of pro-active and reactive activities to ensure continued conformity of a medical device to the EPSP through the post-market phase. It includes pro-active collection and assessment of information on quality, safety or performance of medical devices after they have been placed on the market as well as reactive vigilance activities which include reporting and investigation of adverse events and corrective and preventive actions.

As part of the conformity assessment of QMS, the RA or CAB shall determine whether the PMS has been established and meets the requirements.

## Conformity assessment of medical device safety and performance

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Conformity assessment of medical safety and performance consists of two components, namely summary technical documentation and declaration of conformity.

### Summary technical documentation

The concept, design, development and testing require the scrutiny of scientific experts to ensure that design parameters and performance characteristics do not impose unwarranted risks. Technical documentation provides the evidence to demonstrate that a medical device conforms to EPSP. For the purposes of conformity assessment, the manufacturer shall establish a subset of technical documentation to be submitted to RA or CAB, in the format of Common Submission Dossier Template (CSDT). The main sections of CSDT are;

- (i) Executive summary
- (ii) Relevant Essential Principles for Safety and Performance (EPSP) and method used to demonstrate conformity
- (iii) Device description
- (iv) Summary of design verification and validation documents
- (v) Device labeling
- (vi) Risk analysis
- (vii) Manufacturer information

#### **NOTES**

##### *What is CSDT?*

CSDT is a format to be used for submitting the required information for the purpose of registration of medical devices. Essentially, the CSDT contains elements of the GHTF document “Summary Technical Documentation (STED) for demonstrating conformity to EPSP”. The format of CSDT is based upon the goal to strive for the least burdensome means to demonstrate conformity to the EPSP for all classes of medical devices.

The RA or CAB reviews and determines the adequacy of the documented evidence in support of the manufacturer’s declaration of conformity to the EPSP through a review of the manufacturer’s submission. The extent of evidence to be included in the submission and the level of scrutiny by the RA or CAB increase with the risk class of the medical device, its complexity and the extent to which it incorporates new technology.

### Declaration of conformity (DoC)

The manufacturer of a medical device shall be required to attest that its medical device complies fully with all applicable EPSP and draws up a written Declaration of Conformity (DoC). The DoC should contain the following;

- (i) An attestation that each device complies with the applicable EPSP, has been classified accordingly and has met the applicable conformity assessment elements
- (ii) Information sufficient to identify the device including its nomenclature
- (iii) The risk class allocated to the device
- (iv) Which of the conformity assessment elements have been applied
- (v) The date from which the DoC is valid
- (vi) The name and address of the device manufacturer
- (vii) The name, position and signature of the responsible person who has been authorized to complete the DoC on behalf of the manufacturer

The RA or CAB reviews and confirms the adequacy of the DoC by examining the supporting documents or other evidence.

### Registration of medical devices and establishments

Registration of medical devices and establishments dealing with medical devices by the RA is considered to be the most basic level of regulatory control of medical devices available on the market. The registration enables RA to know “who” dealing with “what” in the market and to track the responsible parties in the event of difficulty or emergency situation associated with medical devices. It will also enable the RA to carry out regular inspections and audits to ensure ongoing compliance.

Only medical devices that have undergone conformity assessment and therefore conform to EPSP will be registered and subsequently allowed to enter the Malaysian market.

### Conditions for registration of establishments

Establishments that will be registered are those who are involved in the supply chain which include local manufacturers, LARs, importers, distributors and exporters of medical devices. Certain conditions and obligations will be imposed for the registration of establishments dealing with medical devices. These include compliance with certain standards such as ISO13485 and good distribution practice, maintenance of distribution records, establishment of procedures for handling product recalls and adverse events involving their products. Access to designated (certain types of complicated or potentially harmful) medical devices will be restricted so that such devices will only be supplied to and used by qualified persons.

### Conformity assessment system

Figure 3 summarizes conformity assessment elements that are applicable to Classes A, B, C and D medical devices.

| Conformity assessment element                        |                                 | Manufacturer responsibility  |         |                                  |         | RA/CAB responsibility   |   |         |         |
|--|---------------------------------|--|---------|----------------------------------|---------|---|---|---------|---------|
|  |                                 | Class A  | Class B | Class C                          | Class D | Class A   | Class B   | Class C | Class D |
| Conformity assessment of QMS                         | QMS                             | Establish & maintain full QMS or QMS without design & development controls |         | Establish & maintain full QMS    |         | Audit only for special cases, eg assurance of sterility, measuring function | Be satisfied that a current and appropriate QMS is in place or otherwise conduct a QMS audit prior to marketing authorization |         |         |
|  | PMS                             | Establish & maintain PMS including adverse event reporting procedure       |         |                                  |         | May be audited for specific concerns  | Be satisfied that a current and appropriate PMS is in place as part of the QMS  |         |         |
| Conformity assessment of device safety & performance | Summary technical documentation | Prepare CSDT & have it available for review by RA upon request             |         | Prepare & submit CSDT for review |         | Submission is not required  | Conduct premarket review of CSDT sufficient to determine conformity to EPSP   |         |         |
|  | DoC                             | Prepare, sign & maintain   |         | Prepare, sign & submit           |         |   | Review & verify compliance with requirements  |         |         |
| Registration of devices & establishments             |                                 | Perform according to regulatory requirements                               |         |                                  |         | Maintain & verify as appropriate  |   |         |         |

Figure 3: Conformity assessment elements applicable to different classes of medical devices

## Advertising

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When a medical device is placed on the market, advertisement has the potential to create expectations and influence the belief in the capabilities of the device. Misleading or fraudulent advertising of a medical device may deprive patient of more appropriate treatment and could lead to injury. Medical advertisement shall not contain any misleading or false claims inconsistent with the safety, quality and intended uses of the product. Medical device advertising will be monitored to ensure it does not mislead patients, users and public on the capabilities of a medical device.