

# MEDICAL DEVICES REGULATORY FRAMEWORK IN MALAYSIA

## Harmonization and the use of standards

The Malaysian medical devices regulatory framework is based on the global harmonization trend as promoted by the Global Harmonization Task Force (GHTF), Asian Harmonization Working Party (AHWP) and Medical Device Product Working Group (MDPWG) of the ASEAN Consultative Committee for Standards and Quality (ACCSQ) and supported by the World Health Organization (WHO).

International standards shall be widely used to demonstrate conformance to essential principles of safety and performance of a medical device as well to show compliance with process, product and management requirements. International standards are building blocks for harmonized regulatory processes and their use is essential in simplifying the regulatory process and promoting global harmonization efforts.

## Definition, classification and the degree of control

The definition of medical device is in accordance with the global harmonized (GHTF) definition which covers any products used in healthcare for the diagnosis, prevention, monitoring or treatment of illness or handicap but excludes drugs.

All medical devices carry certain level of the associated risks which depend on the intended purposes and the effectiveness of the risk management techniques during design, manufacture and use. Based on a set of rules, medical devices are classified into four risk classes. In general, low-risks devices are those that are applied external to the body; and if applied correctly, involve minimum risk to the patients. The higher risk devices are those that penetrate the human body, and involve a high-energy source, or used to sustain life. Some examples of medical devices and their classes are shown in Figure 1. In regulating medical devices, the degree of control should be proportional to the level of the associated risks (as shown in Figure 2), taking into account the benefits offered by the use of the devices.

Class	Risk Level	Device examples
A	Low	Simple surgical instruments, tongue depressor, thermometer, examination light, simple wound dressing, oxygen mask, stethoscopes
B	Low-Moderate	Hypodermic needles, suction equipment, anesthetic breathing circuits, aspirator, external bone growth simulators, hearing aids, hydrogel dressings, patient controlled pain relief, phototherapy unit, x-ray films
C	High-Moderate	Lung ventilator, orthopedic implants, baby incubator, blood oxygenator, blood bag, contact lens disinfecting/cleaning products, deep wound dressing, defibrillator, radiological therapy equipment, ventilator
D	High	Pacemakers and their leads, implantable defibrillators, implantable infusion pumps, heart valves, inter-uterine contraceptive devices, neurological catheters, vascular prostheses, stents

Figure 1: General classification system for medical devices

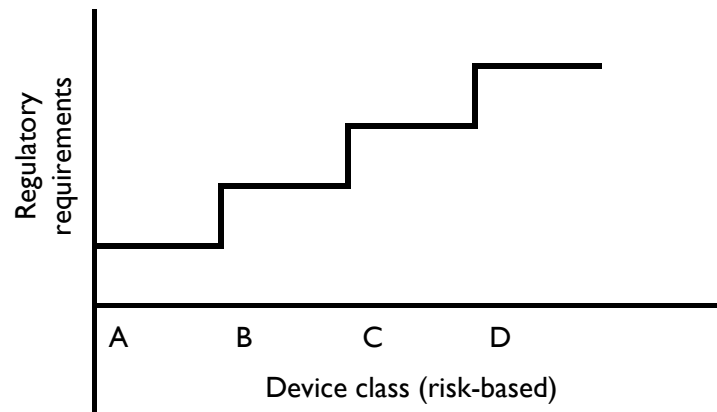


Figure 2: Conceptual illustration of regulatory controls increasing with device risk class

### Scope of medical device regulatory system

The life-cycle of a medical device is calculated from its design and development to manufacture and its subsequent disposal. It can be divided into three common stages, namely pre-market, placement on-market and post-market. Safety and performance of a medical device may affect at each of these stages. It is therefore important that the scope of the regulatory control covers the entire life-cycle of the device. In addition to the device itself, the regulatory control shall also cover the representation of the device, the manufacturer or local authorized representative (of foreign manufacturer of imported device) and the users.

### Factors affecting safety and performance of medical devices and the corresponding regulatory activities

Factors that affect safety and performance of medical devices and the corresponding regulatory activities at the different stages of the life-cycle of a medical device can be summarized in Figure 3.

STAGE	PRE-MARKET	PLACEMENT ON-MARKET	POST-MARKET
<i>Regulated persons</i>	<ul style="list-style-type: none"> <li>• Manufacturer/ authorized representative</li> <li>• Importer</li> </ul>	<ul style="list-style-type: none"> <li>• Manufacturer/ authorized representative</li> <li>• Distributor</li> </ul>	<ul style="list-style-type: none"> <li>• Manufacturer/ authorized representative</li> <li>• Distributor</li> <li>• User</li> </ul>
<i>Regulated items/ activities</i>	<ul style="list-style-type: none"> <li>• Product safety &amp; performance</li> <li>• Manufacturing</li> <li>• Labeling</li> </ul>	<ul style="list-style-type: none"> <li>• Supply chain</li> <li>• Advertising</li> </ul>	<ul style="list-style-type: none"> <li>• Surveillance &amp; vigilance</li> <li>• Usage, maintenance, disposal</li> </ul>
<i>Regulatory activities</i>	<ul style="list-style-type: none"> <li>• Pre-market review</li> <li>• Inspection &amp; audit</li> </ul>	<ul style="list-style-type: none"> <li>• Registration</li> <li>• Advertisement control</li> </ul>	<ul style="list-style-type: none"> <li>• Monitoring</li> <li>• Inspection &amp; audit</li> <li>• Enforcement</li> </ul>

Figure 3: Regulated persons, items/activities and the regulatory activities and different stages of medical device life-cycle

## **Pre-market**

Medical device shall be designed and developed in such a way that it does not compromise safety and health of patients, users or other persons and it should achieve the performance intended by the manufacturer. Risk analysis and clinical evaluation shall be done at the design and development stage to ensure that design parameters and performance characteristics do not impose unnecessary risks to users, patients and public. Manufacturing process shall be properly managed as poor manufacturing management may bring about inconsistency in the quality of the products. Subsequently, it is important that medical devices are appropriately packaged to ensure the delivery of clean, sterile and protected medical devices to the point of use. It is also crucial that a medical device is properly labeled to provide users with adequate documentation relating to its proper use.

Conformity assessment is performed to determine that a medical device is safe and performs as intended by the manufacturer. The manufacturer shall gather the necessary evidence to show that its medical device satisfies essential principles of safety and performance requirements including clinical evidence, quality system and labeling requirements. Prior to placing a medical device into the market, a manufacturer shall make an application to register his medical device. The manufacturer shall be required to submit all the relevant information pertaining to the device using a standardized format. The authority will review the application and only devices that comply with all the requirements will be registered and permitted to be placed in the market.

## **Placement on the market**

Local manufacturers, distributors and authorized representatives of imported medical devices shall be registered. Local authorized representatives for imported medical devices must maintain good communications with their foreign manufacturers and should be able to obtain the support of their foreign manufacturers whenever required. This will facilitate tracking of the responsible parties and taking prompt remedial actions should any problem or emergency situation associated with medical devices takes place. This will also enable regular audits and inspections to ensure ongoing compliance.

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. Product representation will be controlled to prevent misleading or fraudulent advertisements.

## **Post-market**

Assuring safety throughout the lifespan of a medical device requires oversight of the use of the devices at the post-market stage. Monitoring the performance and reporting the problems associated with the use of medical devices are important components of regulatory control as failures or incidents arising from the use of a device could not be predicted or prevented at the pre-market stage. At the post-market stage, manufacturers or their local authorized representatives are required to perform post-market surveillance study and adverse event reporting. Post market activities provide an opportunity for identification and remedial action for problematic medical devices, such as product modification or recall, as well as allow for timely dissemination of information that is necessary to prevent recurrence of similar problem.

In post-market surveillance study, manufacturers are required to establish a system to collect post-market surveillance data of medical devices. Adverse incident reporting requires manufacturers or local authorized representatives to report adverse incidents that reasonably suggest that death or serious injury has been caused or contributed by the use of a medical device. The manufacturers or their representatives are required to investigate and carry out follow-up actions, such as product recall, and report the results to the authority. Healthcare professionals are also encouraged to notify manufacturers or local authorized representatives of adverse incidents. Injuries arising from the use of medical devices by non-health professionals should also be reported.

### **Operation and usage**

Unfamiliarity with a certain technology or operating procedure, and the use of a device for clinical indications outside its scope can cause device failure even in the absence of inherent design or manufacturing defects. In addition, the re-use of disposable devices not in accordance with the instructions, and without proper control or precautions for minimizing associated risks, can be detrimental. Certain categories of medical devices require proper installation (including testing and commissioning) prior to usage and scheduled maintenance/calibration to ensure the devices continue to function properly. The lack of, or inappropriate, testing, maintenance/calibration may jeopardize safety and performance of such devices. Some sophisticated medical devices require specialized and trained personnel to ensure their safe operation and performance. At the end of its life, the disposal of certain types of medical devices should follow specific safety rules as the possibility of contamination can cause hazards to the public and the environment.

The objective of operation and usage control is to prevent unnecessary harms or complications arising from the improper use of certain categories of medical devices. Owners and users of such devices are required to get the approval to possess and use these devices and they must comply with the requirements for personnel, safe handling, installation, maintenance/calibration and disposal.

### **Quality system**

The key advantage of a quality system is it represents a preventive approach to assuring the quality of medical devices. The introduction of a quality system is proven to be more efficient and cost effective in controlling manufacturing processes and maintaining quality. The quality system identifies organizational structure, responsibilities, procedures, processes and resources required to manage product quality. It imposes strict quality assurance on every aspect of the production that will reduce the likelihood of non-conforming products, ensure consistency in the quality and provide the basis for greater reliability in safety and performance of a medical device.

### **Audit**

Audit is a critical component of the regulatory compliance process. It is carried out to verify whether the manufacturing process, distribution and usage of medical devices comply with the regulatory requirements. For example, at the pre-market stage, audit is conducted to determine whether the manufacturer's quality management and post-market surveillance systems meet the regulatory requirements. The nature of the regulatory audit is influenced by the risk class of the medical device, its complexity and the extent to which it incorporates new technology. At the post-market stage audit is conducted to verify the effectiveness of the corrective and preventive actions taken on adverse relating to medical devices. Compliance to the requirements on usage of medical devices will also be audited.