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MEDICAL DEVICE GUIDANCE DOCUMENT

DEFINITION OF MEDICAL DEVICE

Medical Device Authority
MINISTRY OF HEALTH MALAYSIA

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Preface

This Guidance Document was prepared by the Medical Device Authority (MDA) to help the industry and healthcare professionals in their quest to comply with the Medical Device Act (Act 737) and the regulations under it.

This Guidance Document shall be read in conjunction with the current laws and regulations used in Malaysia, which include but not limited to the following-

a) Medical Device Act 2012 (Act 737); and

b) Medical Device Regulations 2012.

In this Guidance Document, the following verbal forms are used:

- “shall” indicates a requirement;

- “should” indicates a recommendation;

- “may” indicates a permission; and

- “can” indicates a possibility or a capability.

Irrespective of the requirements of this Guidance Document, MDA has the right to request for information or material, or define conditions not specifically described in this document that is deemed necessary for the purpose of regulatory control.

MDA has put much effort to ensure the accuracy and completeness of this guidance document. In the event of any contradiction between the contents of this document and any written law, the latter should take precedence.

MDA reserves the right to amend any part of the guidance document from time to time.

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DEFINITION OF MEDICAL DEVICES

1 Introduction

The definition of medical device is legally binding in the Medical Device Act 2012 (Act 737) and it determines the scope of regulatory control of the product. This definition is a harmonized definition which was adopted from the Global Harmonization Task Force (GHTF) recommendation. This definition also differentiates medical devices from medicinal products which have similar intended purposes by putting the intended primary mode of action in the definition. The intended primary mode of action of medical devices on/in the body is not by means of metabolic, immunological or pharmacological action.

2 Purpose

To provide guidance regarding the definition of a medical device and information on products which may be considered to be a medical device in the jurisdiction under the Medical Device Act 2012 (Act 737).

3 Scope

This document applies to products that have medical purposes, including those used for the in vitro examination of specimens derived from the human body.

4 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

4.1 **immunological means**

An action in or on the body by stimulation and/or mobilization of cells and/or products which are involved in specific immune reactions.

4.2 **metabolic means**

An action involves an alteration, including stopping, starting or changing the speed of normal chemical processes participating in and available for normal body function.

4.3 **pharmacological means**

An interaction between the molecules of the substance in question and a cellular constituent, usually referred to as receptor, which either results in a direct response or which blocks the response to another agent. Although not a completely reliable criterion, the presence of a dose-response correlation is indicative of a pharmacological effect.

5 Definition of medical device

Medical device means any instrument, apparatus, implement, machine, appliance, implant, *in vitro* reagent or calibrator, software, material or other similar or related article intended by the manufacturer to be used, alone or in combination, for human beings for the purpose of -

(i) diagnosis, prevention, monitoring, treatment or alleviation of disease;

(ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury;

(iii) investigation, replacement or modification, or support of the anatomy or of a physiological process;

(iv) support or sustaining life;

(v) control of conception;

(vi) disinfection of medical device; or

(vii) providing information for medical or diagnostic purpose by means of *in vitro* examination of specimens derived from the human body,

which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but that may be assisted in its intended function by such means; and

(b) any instrument, apparatus, implement, machine, appliance, implant, in-vitro reagent or calibrator, software, material or other similar or related article, to be used on the human body, which the Minister may, after taking into consideration issues of public safety, public health or public risk, declare to be a medical device by order published in the Gazette.

NOTE 1:
The definition of a device for in vitro examination, for example, reagents, calibrators, sample collection and storage devices, control materials and related instruments or apparatus. The information provided by such an in vitro diagnostic device may be for diagnostic, monitoring or compatibility purposes.

NOTE 2:
These products may be considered to be medical devices;

- aids for disabled/handicapped people,
- accessories for medical devices
- disinfection substances,
- devices incorporating animal and human tissues which may meet the requirements of the above definition but are subject to different controls.

6 Definition of an accessory of a medical device

An article which is intended specifically by manufacturers to be used together with a 'parent' medical device to enable that medical device to achieve its intended purpose or to augment or extend the capabilities of that device in fulfilment of its intended use as a medical device.

NOTE 1:

An accessory of a medical device is an article designed specifically to support, supplement, or augment another medical device.

NOTE 2:

An article qualifies as a medical device accessory if its labeling, promotional materials, or other supporting documentation clearly indicate that it is intended to be used with a specific medical device to support or enable its intended purpose.

NOTE 3:

An accessory is regulated as a medical device. It should be classified as a medical device in its own right based on its own intended use and risk and independent of the parent device. This may result in the accessory having a different classification than the 'parent' device. It require separate registration, proper labeling, traceability, and quality system compliance.

7 Definition of components of a medical device

One of several possibly unequal subdivisions which together constitute the whole medical device to achieve the latter's intended purpose, which may also be known as part but not medical device in its own right.

[Source: Medical Device Regulations 2012]

NOTE 1:

A component of a medical device refers to any mechanical, electrical, electronic, or software element that is integrated during the pre-market manufacturing phase to enable the medical device to perform its intended medical function. Only those elements that directly affect the safety, performance, or intended medical function of the medical device fall under this definition.

NOTE 2:

A component to a medical device is not considered as a medical device, however, it is generally controlled through the manufacturer's quality management system and the conformity assessment procedures for a device.

NOTE 3:

This definition applies strictly to the pre-market stage of device development and production and does not cover parts used for post-market servicing, maintenance, or repair.

8 Definition of a spare part of a medical device

A spare part refers to a part or material intended to replace an identical or functionally equivalent part of a medical device after it has been placed on the market, for the purposes of restoring or maintaining the original safety, performance, and intended use of the device, without modifying its intended purpose or design.

NOTE 1:

A spare part is intended solely to replace a faulty, worn, or expired component of a medical device without enhancing or extending the device's original intended purpose. When a spare part is replaced or added to a medical device, the changed spare parts must maintain the original specifications of the medical device and must not affect the device's original regulatory classification or the medical device approval granted by the Authority.

NOTE 2:

A medical device spare part is not classified as a medical device. It cannot function as a standalone medical device. Therefore, such parts will not be regulated as medical devices and do not require approval under Act 737 for importation, exportation, or placement in the market.

ANNEX A
(informative)
Differences between medical devices, accessories, components and spare parts.

Table 1: Key differences and examples of medical device, accessories, components and spare parts

Category	*Definition*	Key Distinction	Examples
Medical Device	As defined in the Medical Device Act 2012	A medical device refers to the complete and final product that is intended for direct medical use, such as diagnosis, prevention, monitoring, treatment, or alleviation of disease or injury.	- MRI Scanner -Ultrasound Machine - Ventilator - Infusion Pump - Pacemaker
Accessory	As defined in the Medical Device Regulations 2012 An article which is intended specifically by manufacturers to be used together with a 'parent' medical device to enable that medical device to achieve its intended purpose or to augment or extend the capabilities of that device in fulfilment of its intended use as a medical device.	An accessory is a supporting article that is intended to enable or assist a medical device in achieving its intended purpose but cannot function independently as a medical device.	- Blood pressure cuff for blood pressure monitor) - Chest electrodes and patient cables for Electrocardiograph (ECG) - Pulse oximeter probe - Camera head for endoscope - Syringe for infusion pump
Component	One of several possibly unequal subdivisions which together constitute the whole medical device to achieve the latter's intended purpose, which may also be known as part but not medical	A component refers to a built-in part of a medical device that is integrated during manufacturing and is essential for the device to perform its intended medical function. Components are not typically sold separately to end-users.	- Motherboard of a ventilator - Battery pack of ECG -Ultrasound transducer crystal - Battery built into pacemaker - Laser diode inside surgical laser equipment

	device in its own right.		
Spare Part	A spare part is a replacement item that is sold separately for the purpose of repairing or maintaining a medical device after it has been placed on the market.	A component which constitutes part of a medical device and is not a medical device in its own right — may subsequently be used as a spare part for the repair or maintenance of the parent medical device.	- Replacement battery pack for defibrillator - Replacement display screen for patient monitor - Replacement X-ray tube for X-ray machine - Replacement Motor for infusion pump

NOTES:

1. A pack of rechargeable batteries and a charger packaged and distributed together **with the main medical device**, are usually considered **components** of that device. This is because they are **necessary to achieve the device's intended use** and are part of the configuration approved under the device's registration.

2. If the **same batteries or charger are supplied subsequently** as replacements for those originally included with the device, they would generally be treated as **spare parts**, provided that they are **identical to the approved components** and do not affect the **safety or performance** of the medical device.

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