MDA/GD-01

March 2014

First Edition

# MEDICAL DEVICE GUIDANCE DOCUMENT

## DEFINITION OF MEDICAL DEVICE

Medical Device Authority
MINISTRY OF HEALTH MALAYSIA

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# MEDICAL DEVICE GUIDANCE DOCUMENT ON DEFINITION OF MEDICAL DEVICE

Medical Device Authority 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.

## 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 document is a supportive document which does not have a force of law. This document shall be read in conjunction with the Act (Act 737) and relevant regulations under it.

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 in order to allow MDA to assess the safety, effectiveness or quality of the medical device.

MDA reserves the right to amend any part of the guidance document whichever it deems fit.t.

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# 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 adopted from the Global Harmonization Task Force (GHTF) recommendation. This definition also differentiates medical devices from medicinal products which have similar intended purpose 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 a 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 Accessory

An article which is intended specifically by manufacturers to be used together with ‘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.

## 4.2 Pharmaceutical

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.

## 4.3 Immunological means

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

### 4.4 Metabolic

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

## 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.

*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 purpose.*

*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.*

*NOTE 3:*
*Accessories intended specifically by manufacturers to be used together with 'parent' medical device to enable that medical device to achieve its intended purpose should be classified as a medical device in its own right. This may result in the accessory having a different classification than the 'parent' device.*

*NOTE 4:*
*Components are included in the definition of a medical device. Components to medical devices are generally controlled through the manufacturer's quality management system and the conformity assessment procedures for device.*

# MEDICAL DEVICE AUTHORITY

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