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Guidelines for implementation of medical device regulatory system

HOW TO APPLY FOR PRODUCT CLASSIFICATION APPLICATION UNDER MEDICAL DEVICE ACT 2012 (ACT 737)

Medical Device Authority
MINISTRY OF HEALTH MALAYSIA

Contents Page

Preface

This Guideline 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 Guideline 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 Guideline 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.

When a requirement is required to be “documented”, it is also required to be established, implemented and maintained.

Irrespective of the requirements of this Guideline 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 guideline 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 guideline document from time to time.

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HOW TO APPLY FOR PRODUCT CLASSIFICATION APPLICATION UNDER MEDICAL DEVICE ACT 2012 (ACT 737)

0 Introduction

Section 3(1) Act 737, a medical device shall be classified by an establishment based on the level of risk it poses, its intended use and the vulnerability of the human body in accordance with the prescribed manner.

Section 3(2) in the event of any dispute between an establishment and a conformity assessment body over a classification of a medical device, the matter shall be referred to the Authority, in the manner and within such period as may be specified by the Authority, for its decision.

Circular letter of the Medical Device Authority No. 5 Year 2016, the policy on implementation and enforcement under the Medical Device Act 2012 (Act 737) has been released upon the imposition of charges or fees for product classification.

Many manufacturers have difficulty in interpreting whether or not their product would be considered a medical device within the terms of the Malaysia Medical Device Regulations 2012 (Act 737). This guideline document has been developed to aid with some of the more common areas of confusion.

It is often assumed that because a product is considered a medical device in some countries, for example in the USA, EU, Canada or in Japan, that it will also be a medical device in the Malaysia. This is not the case and manufacturers should always refer to the Malaysia definitions of a medical device when making any borderline determinations. Any such decision will be based on the stated intended purpose of the product and its mode of action. Manufacturers should also consult the available published guidance in order to determine whether or not their product is considered a medical device in the Malaysia.

In general, medical devices must have a ‘medical purpose’ which is determined by the definition of a medical device. They must also act primarily in a way that is not metabolic, immunological or pharmacological. Should they function in any way that is metabolic, immunological or pharmacological, in conjunction with having a medical purpose, they are likely to come within the remit of the regulations covering medicinal products instead. Further information on the borderline with medicinal products is available – refer to **Guidance Document of Harmonised Borderline Products in ASEAN**

1 Scope and objective

This guideline provides guidance, reference and clarification on how to apply for Product Classification that are regulated under the Medical Device Act (Act 737). This document is applicable to establishments, healthcare facilities, and public dealing medical device and non-medical device products.
Product Classification main objective is to determine whether a product is classified as a medical device product or not under the Medical Device Act 737.

2 Terms and definitions

For the purposes of this document, the terms and definitions in Act 737, the regulations under it, and the following apply.

2.1 Medical Device

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 invitro 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.

2.2 Manufacturer

A person who is responsible for –

i. The design, the production, fabrication, assembly, processing, packaging and labelling of a medical device whether or not it is the person, or a subcontractor acting on the person's behalf, who carries out these operations; and
ii. Assigning to the finished medical device under his own name, its intended purpose and ensuring the finished products meets the regulatory requirement; or

Any other person who –

i. Assembles, packages, processes, fully refurbishes, reprocesses or labels one or more ready-made medical devices; and
ii. Assigning to the ready-made medical device under his own name, its intended purpose and ensuring the finished product meets the regulatory requirement,

But shall not include the following persons:

i. Any person who assembles or adapts medical devices in the market that are intended for individual patients; and
ii. Any person who assembles, packages or adapts medical devices in relation to which the assembling, packaging or adaptation does not change the purpose intended for the medical devices.

3 Classification Criteria

3.1 The description and primary intended purpose of the product.

3.2 The primary mode of action/ the principal mechanism of action by which the claimed effect or purpose of the product is achieved by:

3.3 Medical device is based on function by physical means eg: mechanical action, creation of a physical barrier or replacement or support of organ or body function.

3.4 Drug is based on pharmacological, immunological or metabolic action in/on the body. (Refer Definition of Medical Device: Guidance Document MDA/GD/0006)

3.5 Active ingredient, indication and pharmaceutical dosage form (those are the main criteria for classification of the drugs), kindly refer to Annex B: Medical Device – Drug – Cosmetic Interphase (MDDCI) products Table I.

3.6 Classification of the product/combination product or similar product/similar combination product in the reference countries. The reference countries are US, EU, Canada, Australia and Japan.

3.7 The primary mode of action/the principal mechanism of action may be deduced from the scientific data and the manufacturer's labelling and claims. The claims made for a product, in accordance with its mode of action may represent an important factor for its qualification as a medical device.

4 Application Procedure

4.1 Product Classification application is to be submitted via email only at: classification@mda.gov.my using the Product Classification Application Form in **Annex A**.

4.2 Applicant is required to submit completed copies of the following documentation:

i. **Product Information** on intended use, mode of action
ii. **Product Label** (indicating product name and manufacturer);
iii. **Product leaflet / brochure / catalogue** (that contain description, intended use);
iv. **Other information**, eg: User manual, Instruction for use, Packaging Insert, Declaration of Conformity, Quality Management System (QMS) Certificate, Pre-market Approval;
v. Manufacturing Process (For Human Tissue Based Products).

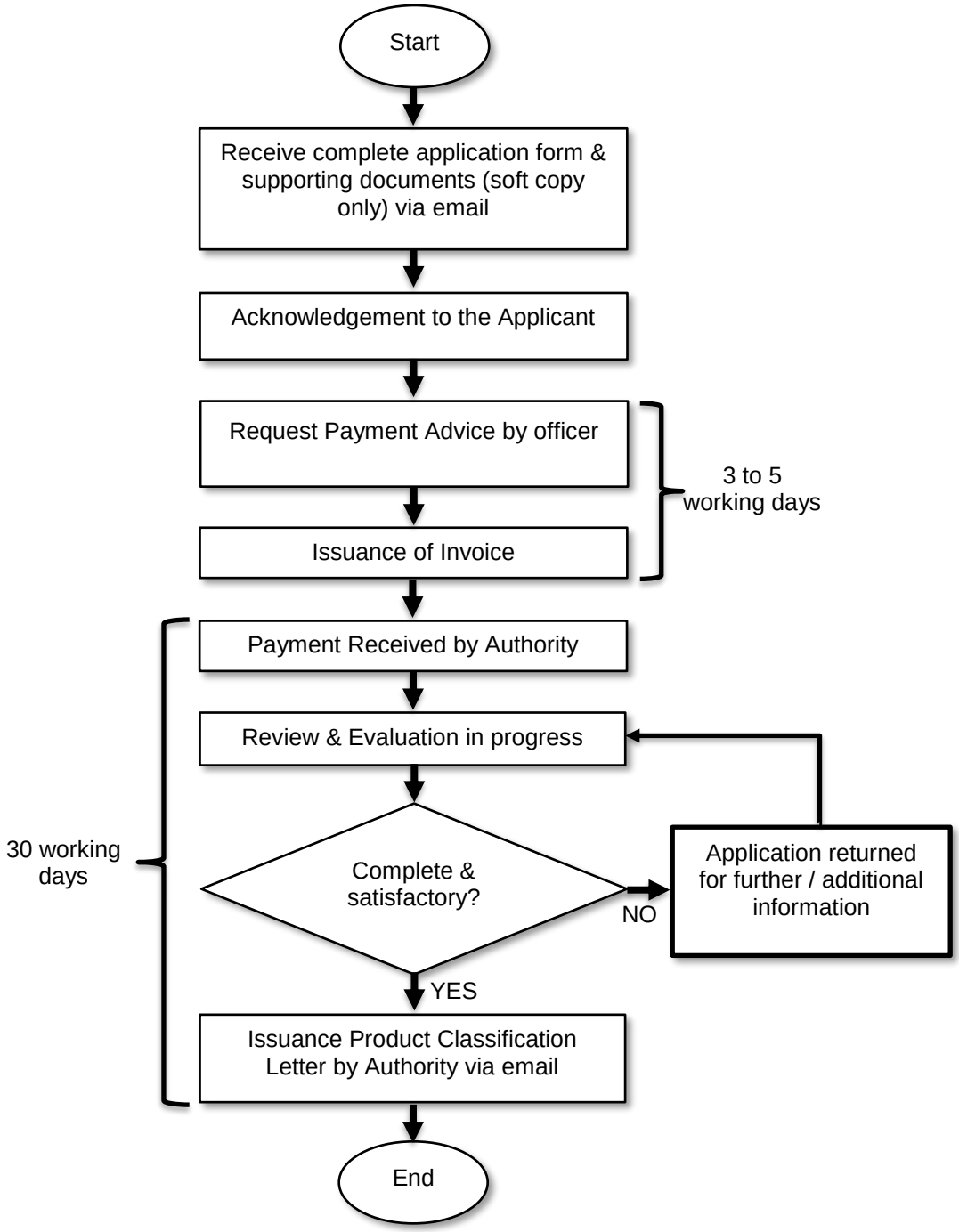
4.3 Circular Letter of the Medical Device Authority No. 5 Year 2016: The Medical Device Authority Meeting No. 3/2016 has decided to set the policy for imposition of charges or fees for product classification. The product classification will be charged **RM300.00 per application** effective on 1st December 2016.

4.4 All fees shall be paid through bank draft or online transfer. **CASH WILL NOT BE accepted**. We will not be responsible for the cash sent or brought to MDA. Payment of application fee shall be made as per table below:

No	Type of Payment	Description of Payment Process
1	Bank Draft	Must be made payable to "**KUMPULAN WANG PIHAK BERKUASA PERANTI PERUBATAN**" and sent to MDA office. Information Needed (Must be written at the back of the bank draft but not in the table section): **Title: Product Classification** **Applicant Company's Name:** **Product Name:**
2	Online Transfer	Can be made by sending an official email to classification@mda.gov.my with **complete submission of the application form with supporting documents.**

4.5 Time frame for processing application form is within **30 working days** based on the complexity of the device after the date of payment cleared. However, the time frame may take longer if the product needs to be further discussed.

4.6 Product Classification application process steps are as per process flow below:



4.7 The table below provides explanation on the above flowchart.

Steps	Explanatory Notes
1.	The applicant shall submit a complete Application Form (**Annex A**) for Product Classification Application together with required supporting documents. *Note: The Application Form must be submitted via email only to the email address: classification@mda.gov.my*
2.	Pre-Market Control Division, MDA will receive the application and send an acknowledgement email to the applicant.
3.	Pre-Market Control Division, MDA will issue a payment advice to the Finance Unit (MDA) and the Finance Unit will issue an invoice for the payment fee to the applicant via email. *Note: It will take 3 to 5 working days. The payment advice and invoice will only be sent to the applicant's email address stated in the application form.*
4.	The application will be evaluated by the Pre-Market Control Division, MDA once the payment has been received and cleared. *Note: The **process takes within 30 working days** based on the complexity of the device **from the date of payment cleared upon complete application**.*
5.	The application will be returned to the applicant during evaluation process if the application is incomplete as the supporting documents is not satisfactory and insufficient of information. **The timeline for the process will be reset**.
6.	The applicant will receive the Product Classification letter once the evaluation and verification process has been completed.
7.	The Product Classification letter will be issued by the Authority via email *Note: The Product Classification letter will only be sent to **the applicant's email address stated in the application form**.*

Annex A
(Normative)

Product Classification Application Form

OBJECTIVE:

To determine whether a product is Medical Device or non-Medical Device

THE MAIN CLASSIFICATION CRITERIA TO ASSESS MEDICAL DEVICE

The primary intended purpose/Indication

The primary mode of action/the principal mechanism of action by which the claimed effect or purpose of the product is achieved;

Medical Device:

based on function by physical means eg; mechanical action, creation of a physical barrier or replacement or support of organ or body function. (please refer to Medical device Definition)

Note:

The primary mode of action/the principal mechanism of action may be deduced from the scientific data and the manufacturer's labelling and claims. The claims made for a product, in accordance with its mode of action may represent an important factor for its qualification as a medical device or others.

SECTION 1 – APPLICANT / ORGANIZATION INFORMATION*

Salutation

☐ Mr. ☐ Mrs. ☐ Ms ☐ Mdm ☐ Dr. ☐ Prof. ☐ Others:_____

Applicant's Role (Please Tick the Appropriate Box)

☐ Local Manufacturer ☐ Authorized Representative ☐ Distributor ☐ Importer
☐ Others: _____

Name of Applicant	Designation

Contact Number (Include Area/Country Code)
Office tel.
H/p:
Email Address (few email addresses):

Name & Address of Organization

*MANDATORY TO FILL IN

SECTION 2 – PRODUCT INFORMATION

PART A – GENERAL INFORMATION

Product Name: (Refer Part B if contain more than 1 product)

**Description of Product:

**Primary Intended Purpose / Indication:

**Primary Mode of Action:

Manufacturer's Name:

Manufacturer's Address:
Country:

Classification of the product in country of Origin:

- ☐ Medical Device
- ☐ Cosmetic Product
- ☐ Health Supplement
- ☐ Medicinal Product/ Drug
- ☐ Traditional Medicine
- ☐ Others (specify):___

Classification of the product in reference countries (US, EU, Canada, Australia, Japan):

- ☐ Medical Device
- ☐ Cosmetic Product
- ☐ Health Supplement
- ☐ Medicinal Product/ Drug
- ☐ Traditional Medicine
- ☐ Others (specify):___

Attach the supporting documents

** (please attach the supporting documents on the description of the product as declared and provided by the manufacturer.

PART B – LIST OF PRODUCT

NO.	NAME OF THE PRODUCT	DESCRIPTION OF THE PRODUCT	INTENDED USE OF THE PRODUCT
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			

*Kindly note that **the description of the product & intended use of the product must be tally with the product brochure/product catalogue** (that have description & intended use)

****Maximum product per application form is **10 products only**.

***** The 10 products **must have same specific intended use and from the same manufacturer** to be compiled together in one application form.

Part C- Information on the Product Formulation (**If applicable**), Ingredient, Scientific Name, Ingredient Function, Quantity Composition Percentage (%)
(Please provide a complete product formulation in the table below.)

PART C- INFORMATION ON THE PRODUCT FORMULATION (IF APPLICABLE)				
Ingredient	**Scientific Name**	**Ingredient Function**	**Quantity**	**Composition Percentage (%)**

Note: Please provide full information and state Nil if the product not marketed in that country
*** mandatory to be provided*

SECTION 3 – SUPPORTING DOCUMENTS

☐ Product information of intended purpose, mode of action*

☐ Product label (indicating product name and manufacturer) *

☐ Product leaflet / brochure / catalogue (contain description, intended use) *

☐ Other information (please specify: _____

Please provide supporting documents as listed above; (tick the appropriate box)

SECTION 4 – APPLICANT DECLARATION

I confirm that

i. All the information and attachment provided is true and complete
ii. I will submit relevant documents pertaining to this application whenever requested by MDA
iii. I am aware on the consequences of pending of this application if I failed / refused to submit satisfactory document(s)/information as requested.
iv. I will be fully responsible for this product.

……

(Applicant's Signature)

Applicant's Name: _____
Applicant's Designation: _____
Date: _____
Email: _____
Contact Number: _____

The table below provides the explanation on the Product Classification form (**Annex A**)

No.	New Application of Product Classification Form
1.	**Section 1 – Applicant Information** *Remark: Information in Section 1 are **mandatory to be fulfilled**¸ please fill in email address of the person in-charge or a few email addresses as backup email*
2.	**Section 2 – Product Information** **Part A – General Information** *Remarks: Description of Product, Primary Intended Purpose / Indication, Primary Mode of Action must be supported with **supporting documents as declared and provided by the manufacturer (Refer Section 3 – Supporting Documents)*** **Part B – List of Products (if applicable)** *Remarks: To be filled in up if the application is **more than 1 product**. Only **products with same intended use** can be combined together in one application form (Maximum: 10 products per application form)* **Part C – Information on the Product Formulation (if applicable)** *Remarks: You may leave it blank if there is no specific ingredient or product formulation.*
3.	**Section 3 – Supporting Documents** i. Product Information on intended use, mode of action ii. Product Label (indicating product name and manufacturer); iii. Product leaflet / brochure / catalogue (that contain description, intended use); iv. Other information, eg: User manual, Instruction for use, Packaging Insert, Declaration of Conformity, Quality Management System (QMS) Certificate, Pre-market Approval; ***Remarks: Only complete application with supporting document will be evaluated within 30 working days (after cleared payment)***
4.	**Section 4 – Applicant Declaration** *Remark: Please fill in complete applicant declaration. Please make sure **applicant's name in the Section 1 & Section 4 is the same person**.*
5.	After requirements set out in paragraph 4 have been fulfilled, invoice will be issued. *Remarks: The Product Classification Application fees is **RM300.00 per application**. Payment can be made via **Bank Draft or Telegraphic Transfer/Direct Bank Transfer***
6.	**Medical Device-Drug-Cosmetic Interphase (MDDCI Table 1)** *Remarks: This is a **reference for the borderline of Medical Device-Drug-Cosmetic product** for the identification whether the product falls under Medical Device Authority (MDA) or National Pharmaceutical Regulatory Agency (NPRA)*

MEDICAL DEVICE AUTHORITY

MINISTRY OF HEALTH, MALAYSIA

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