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**MEDICAL DEVICE
GUIDANCE DOCUMENT**

**NOTIFICATION OF EXPORT ONLY
MEDICAL DEVICE**



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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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NOTIFICATION OF EXPORT ONLY MEDICAL DEVICE

1 Introduction

The importation, exportation, or placement of a medical device in the Malaysia market requires the medical device to be registered under Medical Device Act 2012 (Act 737). The Circular Letter of Medical Device Authority No. 4 Year 2018 exempts medical devices that are for export only from registration requirements and only require notification to the Authority.

An “Acknowledgement on Notification” letter issued by MDA then permits the device to be exported.

2 Scope and application

This document is to provide guidance on notification of export only medical device. This document applies to all products that fall within the definition of medical device, as defined in MDA/GD/0006, *Definition of Medical Device, including in vitro diagnostic (IVD) medical devices*.

3 Terms and definitions

For the purposes of this document, the terms and definitions in Act 737, Medical Device Regulations 2012 and the following apply.

3.1 Authority

The Medical Device Authority established under Medical Device Authority Act 2012 (Act 738).

3.2 authorized exporter

Exporter authorized by the manufacturer or contract manufacturer.

3.3 conveyance

Conveyance includes any vessel, train, vehicle, aircraft and any other means of transport by which persons or items can be carried.

[Source: Strategic Trade Act 2010 (Act 708)]

3.4 contract manufacturer

Any physical manufacturer that manufactures a medical device under contract for the “Manufacturer” as defined in Section 2 Act 737.

3.5 export

“Export” with its grammatical variations and cognate expressions means to take or cause to be taken out of Malaysia, by land, sea or air or to place any goods in a vessel, conveyance or aircraft for the purpose of such goods being taken out of Malaysia by land, sea or air.

[Source: Custom Act 1967 (Act 235)]

3.6 exporter

Any person by whom any goods (including goods transferred from an importing aircraft or ship) are exported from Malaysia or supplied for use as aircraft's or ship's stores, and also the owner, or any person acting on his behalf, and any person who for customs purposes signs any document relating to goods exported or intended for exportation or supplied or intended for supply as aircraft's or ship's stores as aforesaid.

[Source: Custom Act 1967 (Act 235)]

3.7 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 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

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.

[Source: Section 2 Medical Device Act 2012 Act 737]

3.8 physical manufacturer

Any person who performs the activity of manufacture.

[Source: ASEAN Medical Device Directive (AMDD)]

4 Requirements for notification of export only medical device

The applicant for this notification shall be a licensed establishment or contract manufacturer/ authorized exporter who is responsible for exporting the medical device.

Notes:

1. The applicant is responsible to confirm that the products are medical devices. Such products which do not meet the medical device definition are not eligible for this requirement.
2. The applicants who require confirmation if their product is a medical device may refer to guidance document MDA/GD/0006 Definition of Medical Device or submit the 'Product Classification application form' to classification@mda.gov.my to determine the classification of the products. The guidance document and form are available to be downloaded at MDA website www.mda.gov.my.

4.1 Notification process

4.1.1 The notification shall be made according to the Flowchart in Annex A using the Form as in Annex B. Particulars and information/ documents required in the notification form are as per explained in Table 1. The applicant shall submit application form by email to exportonly@mda.gov.my.

4.1.2 Applicant shall submit a notification before exportation of the first shipment, so an "Acknowledgement on Notification" will be issued before exportation of the medical device.

4.1.3 Any additional information, particulars or documents required by the authority shall be provided by the applicant within 14 days from the date of request by the authority. Inability of the applicant to produce documents when requested by the Authority may result in the cancellation of the application and applicant shall apply new application.

Note: All periods are in calendar days unless specified as working days.

4.1.4 One notification application shall be made for only one single medical device nomenclature.

Table 1. Explanation on the information/ particulars required in the Notification Form

PARTICULARS	EXPLANATION/REQUIREMENT
1.APPLICANT DETAILS	
Name of Establishment/company	Name of establishment/of company that is responsible for the export only medical device
Address, post code, city & state	State the address of the company

Type of Establishment/company	Please tick appropriate type/ role of establishment/company
Establishment License Status	Does the company have an establishment license? Tick the appropriate box.
Name of person responsible, designation, telephone no. and email address.	State name and details of person responsible. Person responsible is the person appointed/

PARTICULARS	EXPLANATION/REQUIREMENT
	authorised by the organization who shall be responsible for all legal obligations and implications under Act 737 and its subsidiary legislations. He/ she shall have the overall control and have the authority to make decision; Depending on the organisational structure of the establishment, person responsible may include Proprietor, President, Vice President, Director, Chief Executive Officer (CEO), Managing Director, General Manager or Manager.
Name of contact person, designation, telephone no, & email address.	Name and details of contact person who is in charge of making the application.
2.MEDICAL DEVICE DETAILS (APPENDIX A)	
Device Name	Nomenclature of the medical device
Brief description	Provide a general description of the device, including variants, attributes, and indications for use.
Intended use of medical device:	Use of the medical device for which it is intended by the manufacturer, according to the data supplied by the manufacturer in the instructions for use as well as the functional capability of the device.
Medical Device Nomenclature	State the code number of GMDN or other code if available
Type of medical device	Select the type of medical device whether it is general medical device or in vitro diagnostic device
3.PURPOSE	
Please choose purpose for export only medical device	Tick the appropriate box

4.SUPPORTING DOCUMENTS ASSOCIATED WITH THE DEVICE FOR EXPORT ONLY	
Please provide following supporting document for this (these) export only medical device(s):	Attach supporting documents such as: i) An example of catalogue(s)/ booklet(s)/ leaflet(s)/ copy of labelling that contain information about the intended use, general description, mode of action of the device. ii) A copy of medical device manufacturer/ contract manufacturer QMS certificate (ISO 13485)
PARTICULARS	EXPLANATION/REQUIREMENT
	iii) Letter of authorization from manufacturer/ contract manufacturer to exporter (only applicable for authorized exporter)
5. ATTESTATION & DECLARATION	
Name of Person Responsible:	Attestation to be signed by person responsible of the Licensed Establishment or contract manufacturer or authorized exporter
Designation :	
Date	
Company stamp	

4.2 Notification fee

Each notification shall be submitted together with a RM 500 fee, with the following conditions:

- a) Notification fee shall be paid through bank draft. CASH WILL NOT BE ACCEPTED. The Authority will not be responsible for the cash sent or brought to MDA.
- b) Payable to "KUMPULAN WANG PIHAK BERKUASA PERANTI PERUBATAN".
- c) Details below shall be written at the back of the bank draft but not in the table section:
 - i. Type of application: Notification Of Export Only Medical Device
 - ii. Name and Telephone No. of the applicant

4.3 Issuance of Acknowledgement on Notification Letter

4.3.1 Upon receipt of completed application and clearance of payment, the authority will issue the Acknowledgement on Notification Letter to the applicant within 14 working days after clearance of payment, by letter and email.

4.3.2 This Acknowledgement on Notification letter permits multiple export consignments within the validity period of the Acknowledgement on Notification.

4.3.3 The validity period of the Acknowledgement on Notification for Export Only Medical device is five(5) years.

5 Conditions on Acknowledgement on Notification

5.1 The Acknowledgement on Notification of medical device for export only shall be subjected to the following conditions. Failure to comply with these conditions will result with its withdrawal.

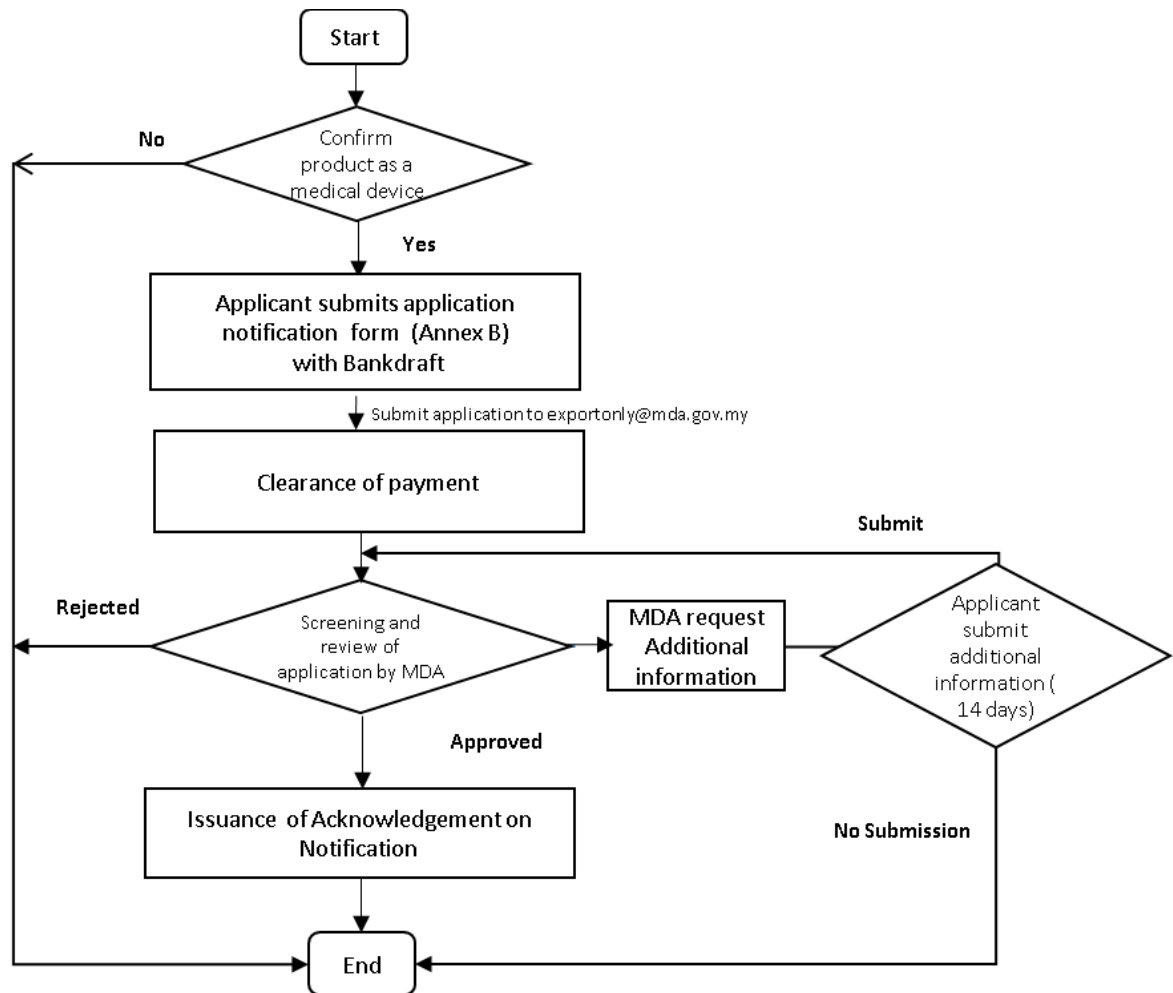
- a) The applicant shall ensure that the medical device to be exported within the validity period;
- b) The applicant shall ensure that the medical device shall not be placed in the Malaysian market unless the medical device is registered under Act 737;
- c) The applicant shall be responsible for ensuring that the quality, safety and performance of the medical device are not adversely affected during export and storage of the medical device.

5.2 Once the Acknowledgement on Notification has expired or has been cancelled/ withdrawn, no further export of the medical device, at any quantity, shall be permitted.

5.3 Any other conditions may be imposed by the Authority from time to time.

Annex A (informative)

Process flow on Notification of Export Only Medical Device



Annex B
(Normative)
Notification of Export Only Medical Device Form

NOTIFICATION OF EXPORT ONLY MEDICAL DEVICE		
(In accordance with Circular Letter of The Medical Device Authority No. 4 Year 2018 (REVISION 1): Exemption from Registration Requirement For Export Only Medical Device)		
Please complete all information requested on this form.		
<input type="checkbox"/> One notification application shall be made for only one single medical device nomenclature. <input type="checkbox"/> All fields are mandatory unless stated otherwise.		
1. APPLICANT DETAILS		
Name of establishment/company:		
Address :		
Postcode:	City:	State:
Please tick appropriate box:	<input type="checkbox"/> Licensed establishment	
	<input type="checkbox"/> Contract manufacturer	
	<input type="checkbox"/> Authorized exporter	
Establishment License Status	<input type="checkbox"/> Establishment License available	
	Please state the Establishment License Number: <input type="checkbox"/> No Establishment License (for contract manufacturer/authorized exporter)	
Person responsible:		
Designation:		
Phone no. :	Email address:	
Contact person :		
Phone No. :	Email address:	
2. MEDICAL DEVICE DETAILS		
Please provide medical device information as per Appendix A .		
3. PURPOSES		

Please choose purpose for export only medical device:

- Contract manufacturer/authorized exporter to brand owner
- Contract manufacturer/authorized exporter to brand owner's customer
- Licensed establishment/authorized exporter to customer

NOTIFICATION OF EXPORT ONLY MEDICAL DEVICE

(In accordance with Circular Letter of The Medical Device Authority No. 4 Year 2018 (REVISION 1):
Exemption from Registration Requirement For Export Only Medical Device)

4. SUPPORTING DOCUMENTS ASSOCIATED WITH THE DEVICE FOR EXPORT ONLY

Please provide following supporting document for this application:

- i. An example of catalogue(s)/ booklet(s)/ leaflet(s)/ copy of labelling that contain information about the intended use, general description, mode of action of the device.
- ii. A copy of medical device manufacturer/contract manufacturer QMS certificate (ISO 13485)
- iii. Letter of authorization from manufacturer/contract manufacturer to exporter (only applicable for authorized exporter)

Please send your application to **exportonly@mda.gov.my**
(turnaround time: 14 working days with complete documentation)

5. ATTESTATION & DECLARATION

I, < Name of person responsible >, ID < _____ >, ***licensed establishment/contract manufacturer/authorized exporter** of this device, hereby declare that :

- i. This product meet the definition of medical device as in Section 2, Medical Device Act 2012 (Act 737); and ii. This medical device is not to be placed in the Malaysian Market and intended for export only.

I, the undersigned, hereby attest that the information and documents provided in this notification are true, accurate, correct, complete and current to this date. I understand that any declaration by me in this application that is untrue, inaccurate or misleading shall, upon conviction be liable to a fine not exceeding RM 100,000.00 or to imprisonment for a term not exceeding 2 years or to both. (Section 76(1) Act 737)

***(Strikethrough accordingly)**

Signature:

Person Responsible

Name:

Designation :

Date :

Company stamp :

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APPENDIX A

EXPORT ONLY MEDICAL DEVICE DETAILS

Device Name

Brief description

:

Intended Use of the device

:



Medical Device Nomenclature

:

GMDN Code

:

HS Code

:

Other Nomenclature Code if GMDN is not applicable

:

UMDNS Code

:

UDI Code

:

Type of Medical Device

:

General Medical Device

In-Vitro Diagnostic Device (IVD)

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MEDICAL DEVICE AUTHORITY

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