DRAFT MEDICAL DEVICE GUIDANCE DOCUMENT

NOTIFICATION OF MEDICAL DEVICE FOR THE PURPOSE OF IMPORT FOR RE-EXPORT

Medical Device Authority
MINISTRY OF HEALTH MALAYSIA

Contents Page

Preface..... iii

1 Introduction…… 1

2 Scope and application…… 1

3 Terms and definitions…….. 1

4 Requirements ……..…..... 2

4.1 Notification process ……..……..... 2

4.2 Notification fee……. 3

4.3 Declaration on distribution records……..…… 4

4.4 Conditions on Acknowledgement on Notification ..…….. 5

5 Issuance of Acknowledgement on Notification Letter…… 5

Annex A Notification process Process Flow on Notification of Medical Device for the Purpose of Import for Re-export ….……..…… 6

Annex B Notification of Medical Device for the Purpose of Import for Re-export Form ……..... 7

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.

CONTACT INFORMATION

For further information, please contact:

MEDICAL DEVICE AUTHORITY
Ministry of Health Malaysia
Aras 6, Prima 9, Prima Avenue II
Block 3547, Persiaran APEC
63000 Cyberjaya, Selangor
MALAYSIA
Fax: (03) 8230 0200
Email: mda@mda.gov.my
Website: http://www.mda.gov.my

NOTIFICATION OF MEDICAL DEVICE FOR THE PURPOSE OF IMPORT FOR RE-EXPORT

1. Introduction

The importation or exportation of a medical device requires the device to be registered under Medical Device Act 2012 (Act 737). The Medical Device Exemption Order 2019 however provided exemption of import for reexport medical device from registration requirement if they fulfill the criteria and submit a notification to the Authority.

Prior to importation of a medical device for re-export, an “Acknowledgement on Notification” letter issued by the Authority then permits the device to be imported for re-export purpose.

2. Scope and application

This guidance document specifies requirements on the notification of medical devices for the purpose of import for re-export of unregistered medical device. This document applies to all products that fall within the definition of medical device, as defined in MDA/GD/0001: 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

Medical Device Authority established under Section 3 of Medical Device Authority Act 2012 (Act 738).

3.2 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)

3.3 country of origin

The country where the manufacturer is located.

3.4 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)]

3.5 medical device

As defined in guidance document MDA/GD-0001, *Definition of Medical Device*.

3.6 re-export

An imported product that is then exported by the importing country

4. Requirements

The applicant for this notification shall be a person or organization who is responsible for importing the medical device to be re-export.

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.

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 as per Table 1. The applicant shall submit application form by email to importforreexport@mda.gov.my.

4.1.2 Applicant shall submit a notification 30 days before importation of the first shipment to the Authority and an "Acknowledgement on Notification" will be issued before importation of the medical device.

4.1.3 Any additional information, particulars or documents required by the authority shall be provided by the applicant within 30 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 notification and applicant shall apply new notification.

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

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

PARTICULARS	EXPLANATION/REQUIREMENT
COMPANY DETAILS	
Name of Company, Business Registration No., Address, City, State & Postcode.	Name and details of company that is responsible for the medical device that imported for reexport.
Name of Contact Person, Designation, Telephone No, Mobile Phone No &Email Address.	Name and details of contact person who is in charge of making the application.
MEDICAL DEVICE DETAILS	

PARTICULARS	EXPLANATION/REQUIREMENT
Country of origin:	State the country where manufacturer is located
Temporary storage address after port of loading (if applicable):	Specified name of location and address of warehouse or location where the medical devices are to be stored/placed warehouse.
Purpose import for re-export	Purpose, e.g. medical device for the purpose of maintenance/testing, packaging/labelling, distribution, specialized processing such as sterilization. Location of these activities.
Generic Name of Device / Accessories / Components to a system:	Name given to the medical device(s) / accessories / components to a system as per label or brief description. If the notification involves more than one (1) device, please complete Attachment I of Notification of Import for Re-export Medical Device Form
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.
Brand and Model:	Name, term, design, symbol, or any other feature or identifier of a medical device given by its manufacturer that identifies a manufacturer ‘s medical device distinct from those of other manufacturers.
Manufacturer Name:	The name of manufacturer that is the brand owner of the device
Quantity (if available):	Total maximum quantity of each medical device to be imported
DECLARATION BY APPLICANT	
Signature and stamp of top management of the company, name and designation	Name and designation of top management of a company or the person having the overall control and have the authority to make decision.

4.2 Notification Fee

Each notification shall be submitted together with a RMXXX 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 Medical Device for the purpose of Import for re-export
ii. Name and Telephone No. of the applicant

4.3 Declaration on distribution records

4.3.1 Annually at every first quarter of the year, the applicant shall be required to submit a declaration of distribution records demonstrating the actual number of medical devices that have undergone the said activities and distributed out (refer Annex B). Particulars and information/documents required in the declaration on distribution records are explained in Table 2.

4.3.2 The applicant shall have to maintain documentary evidence of supply as part of their mandatory device distribution records. These shall have to be submitted to Authority upon request. Inability of the applicant to produce documents when requested by the Authority may result in the cancellation of the Acknowledgement on Notification.

4.3.3 Any balance medical devices that have not been exported out a subsequent Acknowledgement on Notification has to be obtained for the medical device. The subsequent application shall be submitted 60 days before expiry of existing Acknowledgement on Notification.

4.3.4 If a subsequent Acknowledgement on Notification is not obtained, the balance of medical device shall be disposed of locally (refer MS 2650) or exported out within 3 months from the expiry date of Acknowledgement on Notification.

Table 2. Explanation on the information/ particulars required in declaration on distribution records template

PARTICULARS	EXPLANATION/ REQUIREMENT
Reference number for current Acknowledgement on Notification	Reference number as stated in current Acknowledgement on Notification issued by Authority.
Expiry date	Expiry date as stated in current Acknowledgement on Notification issued by Authority.
Generic Name of Device / Accessories / Components to a system:	Name given to the medical device(s) / accessories / components to a system as per label or brief description. If the notification involves more than five (5) devices, please complete Attachment I in Declaration on Distribution Records template.
Brand and model	Name, term, design, symbol, or any other feature or identifier of a medical device given by its manufacturer that identifies a manufacturer‘s medical device distinct from those of other manufacturers.
Total quantity imported	Quantity of medical device stated in current Acknowledgement on Notification Letter that has been imported.
Total quantity exported	Quantity of medical device stated in current Acknowledgement on Notification Letter that have been exported out.
Balance quantity	The balance quantity of medical device stated in current Acknowledgement on Notification Letter that has NOT been exported out.

4.4 Conditions on Acknowledgement on Notification

4.4.1 The notification of medical device that has been imported to be re-exported shall be subjected to the following conditions. Failure to comply with these conditions will result in the withdrawal of this Acknowledgement on Notification.

a) The applicant shall ensure that the medical device to be re-exported within the permitted 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 ensure that the medical device is intended for import for re-export only (e.g. medical device for the purpose of maintenance/testing, packaging/labelling, distribution, specialized processing such as sterilization)

d) The applicant shall be responsible for ensuring that the quality, safety and performance of the medical device are not adversely affected during import and storage of the medical device; and

e) Annually at every first quarter of the year, the applicant shall be required to submit a declaration of distribution records demonstrating the actual number of medical devices that have been imported, undergone the said activities, and exported out.

4.4.2 Once the Acknowledgement on Notification has expired, the balance of medical device shall be disposed of locally (refer MS 2650) or exported out within 3 months from the expiry date of Acknowledgement on Notification. The Authority may cancel the Acknowledgement on Notification if the applicant has breached any condition. If Acknowledgement on Notification has been cancelled, no further import and export of the medical device, at any quantity, shall be permitted. The medical devices shall be placed under quarantine by the applicant in their facility. The applicant shall not export or remove medical devices under quarantine unless authorised by Authority. A letter of “No restriction to export” will be issued by the Authority for exportation of stock balance.

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

5. Issuance of Acknowledgement on Notification Letter

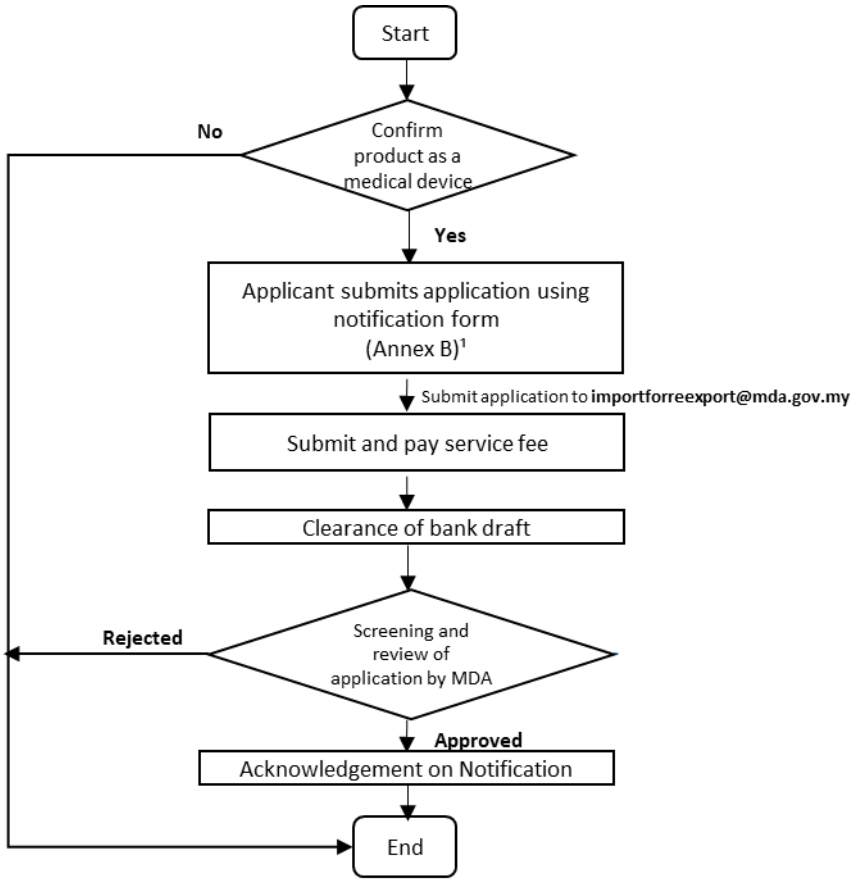
5.1 Upon receipt of completed application and clearance of payment, the authority will issue the Acknowledgement on Notification Letter to the applicant within 10 working days by letter and email.

5.2 Validity for Acknowledgement on Notification Letter is 2 years.

5.3 This Acknowledgement on Notification letter permits multiple import consignments within the validity period of the Acknowledgement on Notification.

Annex A
(informative)

Notification process Process Flow on Notification of Medical Device for the Purpose of Import for Re-export



[1] the application shall be submitted 30 days before importation of the first shipment additional information, particulars or documents required by the authority shall be provided by the applicant within 30 days

Annex B
(normative)

Notification of Medical Device for The Purpose of Import For Re-export Form

NOTIFICATION OF IMPORT FOR RE-EXPORT MEDICAL DEVICE (In accordance with Medical Device Exemption Order)		
All fields shall be completed by the applicant		
COMPANY DETAILS		
Name of company:		
Business registration no.:		
Address:		
City:	State:	Postcode:
Name of contact person:		
Designation:		
Telephone No.:	Mobile phone no.:	
Email address:		
Medical device details		
Storage Location (if applicable):		
Purpose import for re-export: ☐ maintenance/testing ☐ packaging/labelling ☐ specialized processing such as sterilization ☐ distribution ☐ others. Please specify: Location of the said activities:		
Generic name of devices/ Accessories / Components to a system:		

Country of origin:
Brand and model:
Manufacturer name:
Quantity (if available):
Note: If the notification involves more than one (1) device, please complete ***Attachment 1***
ATTESTATION & DECLARATION BY APPLICANT
I, <Name of applicant>, ID <IC No. or Passport No.> hereby declare that: i. This product meet the definition of medical device as in Section 2, Medical Device Act 2012 (Act 737); ii. This medical device is not to be placed in the Malaysian Market and intended for import for re-export only; and iii. I shall be responsible to take appropriate precautionary measures to ensure the medical device covered by this notification will remain on board the means of conveyance or be kept at the storage at the address given in this form at all times while in Malaysia; 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 mis leading 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)

Signature and stamp of top management of the company:	Date:
Name:_____ Designation:_____	

Attachment 1

MEDICAL DEVICE DETAILS

The table below shall be completed and submitted together with the Notification Form.

Storage Location address (If applicable):_____

NO.	Generic name of medical device	Details of activities & location	Country of origin	Brand & model	Manufacturer name	Quantity (if available)
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						

Signature and stamp of top management of the company:

Name:
Designation:
Date:

Annex C
(normative)

Declaration on Distribution Records Template

[To be printed on Company Letterhead of Applicant]

Chief Executive
Medical Device Authority
Ministry of Health Malaysia
Level 6, Prima 9, Prima Avenue II,
Block 3547, Persiaran APEC,
63000 Cyberjaya, Selangor
MALAYSIA

[Date]

Dear Sir/Madam,

Subject: Status of Medical Devices Import for re-export [Reference number for CURRENT Acknowledgement of Notification] – Expiry date (DD/MM/YYYY)

I, <Name & NRIC/Passport Number>, hereby declare that the information listed in the table below is complete and accurate.

	Medical Device Details					
No	*Generic name of medical device*	*Brand and model*	*Total quantity imported*	*Details of Activities*	*Total quantity exported*	*Balance quantity*
1						
2						
3						
4						
5						
	Note: If the declaration involves more than five (5) devices, please complete ***Attachment 1***					
	Declaration by applicant ***Note: Only applicable for declaration at the end of acknowledgement of notification (24 months)***					
	*I further declare that as at <date>, * the stock balance is as per declared/ the continued supply of the balance stock at the expiry of this acknowledgement on notification will be put under <Reference number for NEW acknowledgement on notification>. I shall keep relevant records as a proof for the disposal or export out of the stock balance at the end of acknowledgement on notification period.* *(*Delete accordingly)*					

[Signature]
[Full Name and Title of Company Representative]
[Company stamp]
[Date]

Attachment 1

Medical Device Details						
No	*Generic Name of Medical Device*	*Brand and Model*	*Total Quantity imported*	*Details of Activities*	*Total Quantity exported*	*Balance Quantity*
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
14						
15						

[Signature]
[Full Name and Title of Company Representative]
[Company stamp]
[Date]

MEDICAL DEVICE AUTHORITY

MINISTRY OF HEALTH, MALAYSIA

Contact information:

MEDICAL DEVICE AUTHORITY
Ministry of Health Malaysia
Level 6, Prima 9, Prima Avenue II,
Block 3547, Persiaran APEC,
63000 Cyberjaya, Selangor,
MALAYSIA
T: (03) 8230 0300
F: (03) 8230 0200
Website: http://www.mda.gov.my