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DRAFT MEDICAL DEVICE GUIDANCE DOCUMENT

IMPORTATION OF MEDICAL DEVICE FOR RE-EXPORT (IRE)

Medical Device Authority
MINISTRY OF HEALTH MALAYSIA

Contents

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: mdb@mda.gov.my
Website: http://www.mda.gov.my

IMPORTATION OF MEDICAL DEVICE FOR RE-EXPORT (IRE)

1. Introduction

Placement and supply of a medical device in the Malaysian market requires the medical device to comply with the requirement of the Medical Device Act 2012 (Act 737), including the medical device shall be registered with the Medical Device Authority (MDA).

However, MDA has exempted the registration requirements under Section 5 of Act 737 for imported medical device for re-export if they fulfil the requirements and submit a notification to the Authority. Prior to importation of a medical device for re-export, an "IRE approval" letter issued by the Authority then permits the medical device to be imported for re-export purpose.

2. Scope and application

This guidance 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.

This guidance document is intended to provide requirements and notification process for applicant such as established company in Malaysia, licensed establishment or forwarding agent to obtain permission from the Authority for import for re-export medical devices for the purposes of maintenance, testing, sterilization, packaging, labelling, distribution hub or other purposes specified by the applicant and intends not to be placed in the Malaysian market.

Upon issuance of IRE approval letter, the applicant allows to import medical devices to Malaysia through international courier or accompanied with passengers through various modes of transportation by land, sea or air.

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)]

3.4 export

To take or cause to be taken out of Malaysia, by land, sea, air, or by any other means or to place any goods in a conveyance for the purpose of such goods being taken out of Malaysia by land, sea, air, or by any other means.

[SOURCE: Custom Act 1967 (Act 235)]

3.5 import

To bring or cause to be brought into Malaysia, by land, sea or air or by any other means.

[SOURCE: Custom Act 1967 (Act 235)]

3.6 medical device

As defined in guidance document MDA/GD-01, *Definition of Medical Device*.

3.7 re-export

The export of any medical devices that has previously been imported.

4. Requirements during pre-importation

The applicant for this notification shall be an established company in Malaysia, licensed establishment or forwarding agent 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 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

a) The notification shall be made according to *Annex A Process Flow on Notification of Import for Re-export Medical Device* using Form as in *Annex B Notification of Import for Re-export Medical Device Form.* The explanation of particulars and information/documents required in the notification form is as per Table 1. The applicant shall submit application form by email to ebantuan@mda.gov.my.

b) Applicant may apply to the Authority as early as 21 days before the importation date and an "IRE approval" letter will be issued to the applicant upon the complete submission and payment clearance.

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 re-export.
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.

PARTICULARS	EXPLANATION/REQUIREMENT
MEDICAL DEVICE DETAILS	
Name of medical device	Name given to the medical device(s) as per label. If the notification involves more than one (1) device, please complete Attachment 1 of Notification of Import for Re-export Medical Device Form
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.
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.
Manufacturer information:	Name and address of manufacturer
Total quantity imported: Note: 1. Quantity is not compulsory for Principal/distribution Hub. 2. Quantity declared shall be similar with the quantity stated in the shipping documents (invoice, proforma invoice, airway bills, etc)	Total quantity of 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 Administrative charge

The administrative charge is RM 500 for each of applications, with the following conditions:

i. The payment shall be made online via portal BayarNow (for registered users) or bank draft. For the bank draft, it shall be payable to "KUMPULAN WANG PIHAK BERKUASA PERANTI PERUBATAN" and it shall be submitted to:

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

NOTE: Information on the name and phone number of the applicant and a statement of "Importation of Medical Device for Re-export (IRE)" shall be written at the back of the bank draft, not in the table section.

ii. The administrative charge is non-refundable.

iii. Applicant may refer to user manual *BayarNow Customer Portal and Payment Gateway* for online payment using BayarNow system.

4.3 Notification review

a) Upon receipt of complete application and payment clearance, the Authority will review the application and if, after consideration of all the information provided, the Authority considers that all requirements have been fulfilled, the Authority will issue an IRE approval letter permitting the applicant to import for re-export the medical devices within 14 days.

b) If any additional information, particulars or documents required is not given by the applicant within 30 days from the date of request by the Authority or any extension of time granted by the Authority, the application shall be deemed to be withdrawn and shall not be further proceeded with, but without affecting the right of the applicant to make fresh application.

NOTE: All periods **are specified as working days.**

4.4 Issuance of IRE approval letter

a) Validity period for IRE approval letter is 12 months for each application.

b) An IRE approval letter allows multiple shipment for importation of medical device within IRE validity period of 12 months.

c) The imported medical device shall be exported out before the expiry of validity period of IRE approval letter.

d) Amendment of any information to the IRE approval letter issued by the Authority is not allowed (e.g. additional, change to medical device and quantity).

4.5 Request for extension period of IRE approval letter

a) A subsequent notification may be made of any applicant who wish to request for extension in the case of exportation activity cannot be completed within the IRE validity period. This process follows the same procedure as described in *Annex D Subsequent Notification for Import for Re-export Medical Device* except that certain information e.g. supporting document for medical device may not be required and does not requires payment.

b) Any subsequent notification shall be submitted at least 14 working days before the expiry date of the expiry date of previous IRE approval. Permission for subsequent notification is granted only to a maximum of 6 months from the expiry date of previous IRE approval.

5. Requirements during post-importation

5.1 Declaration on Import for Re-export (IRE) records

a) The applicant shall be required to submit a declaration of Import for Re-export (IRE) records demonstrating the actual number of medical devices that have been imported and exported out. Applicant shall submit complete form as described in Annex B within 30 days after date of exportation and accompanied with form of custom declaration of exportation. Particulars and information/documents required in the declaration on Import for Re-export (IRE) records are explained in Table 2.

b) The applicant shall have to maintain Import for Re-export (IRE) records 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 maintain records when requested by the Authority may result in the cancellation of the IRE approval letter.

c) The balance quantity of medical devices that has not been exported out and required disposal shall be disposed safely. Applicant may refer to *Guidance on disposal of medical devices (MS 2650)* to comply with requirements of disposal process.

Table 2. Explanation on the additional information/ particulars required in declaration on Import for Re-export (IRE) records template

PARTICULARS	EXPLANATION/ REQUIREMENT
Date of re-export	Date of medical devices that has been exported out from Malaysia
Total quantity exported	Total quantity of medical device to be exported
Balance quantity	The balance quantity of medical device available in Malaysia that has NOT been exported out
Copy Customs K2 Declaration	Attach Customs Form No.2: Declaration of goods to be exported

6. Conditions on IRE approval letter

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 IRE approval letter.

a) The applicant shall ensure that the medical device to be re-exported within the IRE validity period letter of 12 months;

b) The applicant shall ensure that the medical device shall not be placed in the Malaysian market;

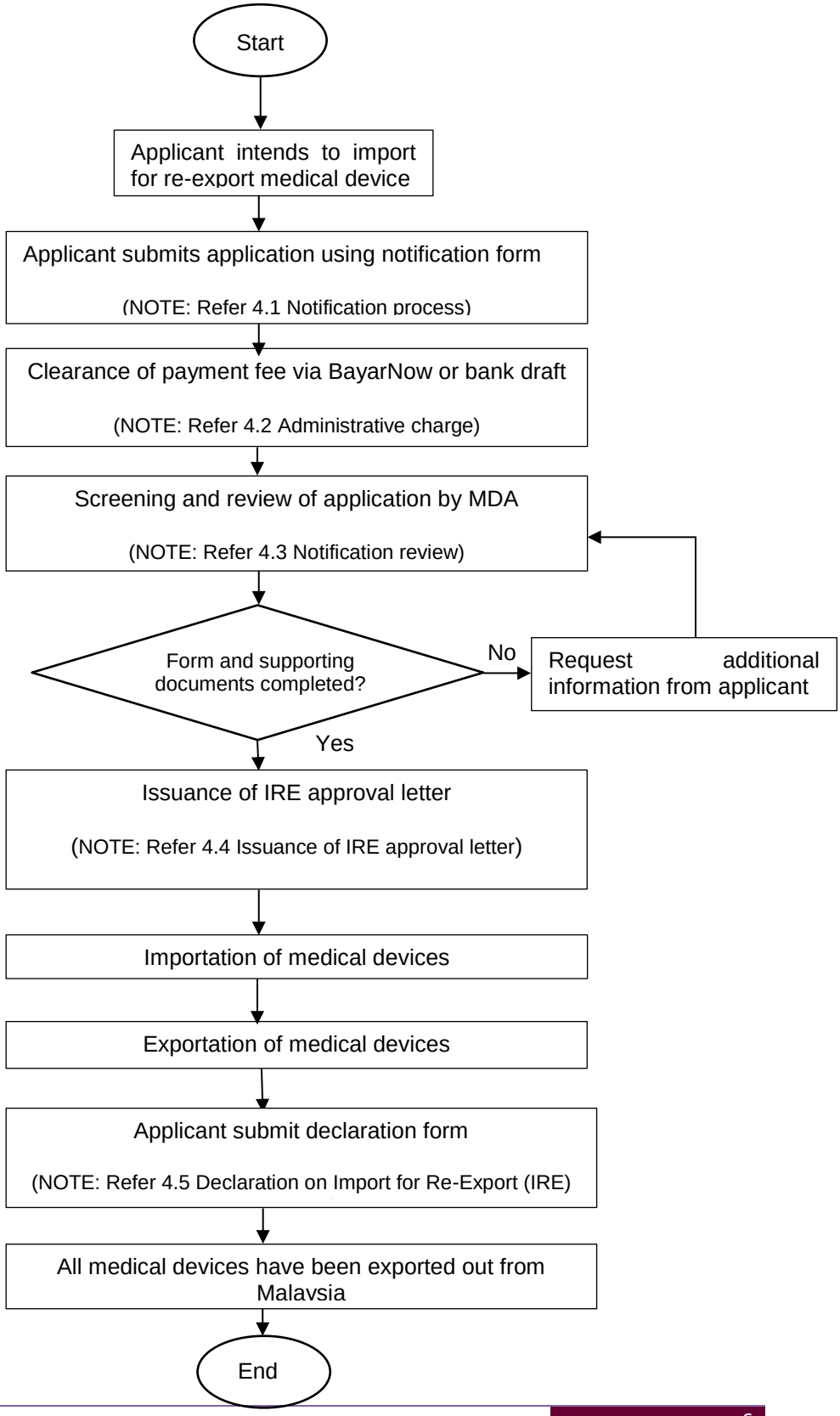
c) The applicant shall be responsible and ensure that any incidents involving its medical device is properly recorded;

d) Once the IRE approval letter has expired or has been cancelled, no further import and export of the medical device, at any quantity, shall be permitted; and

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

Annex A
(informative)

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



Annex B
(normative)

Notification of Import for Re-export Medical Device Form

PIHAK BERKUASA PERANTI PERUBATAN
Medical Device Authority
KEMENTERIAN KESIHATAN MALAYSIA
Ministry of Health Malaysia

Portal: www.mda.gov.my
Email: mdb@mda.gov.my

NOTIFICATION OF IMPORT FOR RE-EXPORT MEDICAL DEVICE		
Please complete all information requested on this form. • One application shall be made only for one medical device grouping. • All fields are mandatory unless stated otherwise.		
1. APPLICANT DETAILS		
Name of establishment/company:		
Address:		
Postcode :	City :	State :
Please tick appropriate box:	☐ Licensed establishment ☐ Contract manufacturer ☐ Others (Please specify):.....)	
Establishment License Status	☐ Establishment License available Please state the Establishment License Number: ..... Company's role: ☐ Local Manufacturer ☐ Authorized Representative ☐ Distributor ☐ Importer	☐ No Establishment License
Name of Person Responsible:		
Designation :		
Phone No. :	Email :	
Name of Contact Person :		
Phone No.:	Email :	

2. PURPOSES

Please **tick** the appropriate box & provide following **Supporting Document** for this application.

Purposes	Supporting Document
☐ Maintenance/Testing/Sterilization/ Investigation Facility address: ..... Person in charge:	IFU/ Package insert **AND** Quotation by Service Provider
☐ Packaging/Labelling Facility address: ..... Person in charge:	IFU/ Package insert **AND** Evidence of relationship between applicant and relevant party i.e.: Authorization Letter, Delivery Order, certificate of ISO 13485
☐ Distribution Hub Facility address: ..... Person in charge:	
☐ Others: Please specify ..... Facility address: ..... Person in charge:	

3. MEDICAL DEVICES DETAILS

Please provide medical device information as per **Attachment 1**

4. DETAILS OF IMPORTATION

Date of Importation	:	
Date of Exportation	:	
Entry Point	:	☐ Land ☐ Sea ☐ Air ☐ Others
Please specify entry point	:	

5. ATTESTATION & DECLARATION

I, <_____>, ID <_____>, hereby declare that:

i. This product meets 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 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)

Signature:

Person Responsible

Name:

Designation:

Date:

Company stamp:

Attachment 1

MEDICAL DEVICE DETAILS

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

NO.	Name of medical device	Brand & model (if applicable)	Brief Description/ Intended use of medical device	Manufacturer's details	HS Code	Quantity to be Imported
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						

Annex C
(normative)

Declaration on Import for Re-Export Records

[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

[Date]

Dear Sir/Madam,

Subject: Status of Imported Medical Device(s) for Re-export Purpose <Reference number for CURRENT IRE approval letter> – 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	***Name of medical device***	***Brand and model (if applicable)***	***Total quantity imported***	***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					
*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 IRE approval letter will be extended until <date>* *I shall keep relevant records as a proof for the disposal or export out of the stock balance at the end of IRE approval letter's period.* *(*Delete accordingly)*					

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

Attachment 1

Medical Device Details					
No	*Name of Medical Device*	*Brand and Model (if applicable)*	*Total Quantity imported*	*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]

Annex D
(normative)

Subsequent Notification of Import for Re-Export Medical Device

PIHAK BERKUASA PERANTI PERUBATAN
Medical Device Authority
KEMENTERIAN KESIHATAN MALAYSIA
Ministry of Health Malaysia

Portal: www.mda.gov.my
Email: mdb@mda.gov.my

SUBSEQUENT NOTIFICATION OF IMPORT FOR RE-EXPORT MEDICAL DEVICE		
Please complete all information requested on this form. • One application shall be made only for one medical device grouping. • All fields are mandatory unless stated otherwise.		
1. APPLICANT DETAILS		
Name of establishment/company :		
Address :		
Postcode :	City :	State :
Please tick appropriate box:	☐ Licensed establishment ☐ Contract manufacturer ☐ Others (Please specify):.....)	
Establishment License Status	☐ Establishment License available Please state the Establishment License Number: ..... Company's role: ☐ Local Manufacturer ☐ Authorized Representative ☐ Distributor ☐ Importer	☐ No Establishment License
Name of Person Responsible :		
Designation :		
Phone No. :	Email :	
Name of Contact Person :		
Phone No. :	Email :	
2. PREVIOUS IRE APPROVAL LETTER		
Please attach previous IRE approval letter as supporting document		

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
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