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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);

b) Medical Device Regulations 2012; and

c) Medical Device (Exemption) Order 2024.

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:

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MALAYSIA
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IMPORTATION OF MEDICAL DEVICE FOR RE-EXPORT (IRE)

1. Introduction

Importation, placement and supply of a medical device in the Malaysia market requires the medical device to comply with the requirements of the Medical Device Act 2012 (Act 737), including registration of the medical devices.

However, there have been cases where medical devices need to be imported and re-exported for the purposes of maintenance, testing, sterilization, packaging, labelling, distribution hub or other purposes specified by the importer.

Thus, MDA has exempted the registration requirements under Section 5 of Act 737 for imported medical devices for the purpose of re-export if they fulfil the requirements and submit an application 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 and re-exported.

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 that are imported for the above-mentioned purposes and will be exported out after the activities have been completed.

This guidance document specifies requirements on the application for exemption of medical device for the purpose of IRE as according to the Medical Device (Exemption) Order 2024.

The following purposes are excluded from the scope of IRE requirements:

- For export only medical device, refer to guidance document MDA/GD/0051 Notification of Export Only Medical Device; and
- Medical devices for Research Use Only, refer to guidance document MDA/GD/0016 Notification of Exemption from Registration of Medical Devices for the Purpose of Clinical Research or Performance Evaluation.

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 Section 2 of Medical Device Act 2012 (Act 737) and further explained in the 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 shall be a registered company in Malaysia, a licensed establishment or a forwarding agent who is responsible for importing the medical device.

NOTES:

- 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.
- 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 Application process

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

b) Applicant may apply to the Authority not less than 21 days from the date of importation.

Table 1. Explanation on the information/ particulars required in the Application 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.
MEDICAL DEVICE DETAILS	
Name of medical device	Name given to the medical device(s) as per label. If the application involves more than one (1) device, please complete Attachment 1 of Application 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.

PARTICULARS	EXPLANATION/REQUIREMENT
Manufacturer information	Name and address of manufacturer
Total quantity to be imported NOTE: 1. Quantity is not compulsory for Principal/distribution Hub. 2. For single shipment, quantity declared shall be similar with the quantity stated in the shipping documents (invoice, proforma invoice, airway bills, etc). 3. Non-principal / distribution hub: The statement "Quantity declared shall be similar with the quantity stated in the shipping documents (invoice, proforma invoice, airway bills, etc)". 4. For Distribution Hub: the information of quantity to be imported is not compulsory but subject to submission of Import and Export Declaration on quarterly basis.	Total quantity of the medical device to be imported.
DECLARATION BY APPLICANT	
Signature and stamp of person responsible of the company, name and designation	Name and designation of person responsible of a company or the person having the overall control and have the authority to make decision. Person responsible shall be from top management of the company and may include Proprietor, President, Vice President, Director, Chief Executive Officer (CEO), Managing Director, General Manager; or Manager authorized by the top management.

4.2 Application review

a) Upon receipt of a complete application, 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.

b) The processing time for each application is approximately 14 days after receipt of complete application.

c) 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.

d) The Authority has the right to reject the application if the applicant fails to meet any of the criteria.

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

4.3 Issuance of IRE approval letter

a) The validity period for the IRE approval letter is 12 months, covering the permitted quantity for each approval.

b) An IRE approval letter allows multiple shipments of the medical device within the validity period.

c) The imported medical devices shall be exported before the IRE approval letter expires.

d) Amendments to the IRE approval letter are not permitted (e.g., changes to the medical device or quantity).

e) Any disputes or inquiries can be submitted via email at exemption.bhai@mda.gov.my.

4.4 Request for extension period of IRE approval letter

a) If export activities cannot be completed within the IRE validity period, the applicant may request for an extension by making a subsequent application. The subsequent application shall be made using a form attached in Annex D: Subsequent Application for Import for Re-export of Medical Devices.

b) All subsequent applications shall be submitted at least 14 working days before the expiration of the current IRE approval letter.

c) Extensions are granted for a maximum of 6 months from the original expiry date.

d) The processing time for extension applications is 7 working days upon receipt of a complete form and all necessary supporting documents.

4.5 Requirement for multiple shipments

For multiple shipments involving Principal Hubs, the information of quantity to be imported is not compulsory but subject to submission of Import and Export Declaration on quarterly basis.

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 as described in Annex C for demonstrating the actual number of medical devices that have been imported and exported out within 30 days after date of exportation and accompanied with Customs Form No. 2 (K2), the Export Declaration Form by email to exemption.bhai@mda.gov.my. The particulars and information/documents required in the declaration on Import for Re-export (IRE) records are explained in Table 2.

Table 2. Records to be supplied with declaration of IRE

PARTICULARS	EXPLANATION/ REQUIREMENT
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

b) The applicant shall have to maintain Import for Re-export (IRE) records of supply as part of their distribution records as required in the Medical Device (Duties and Obligations of Establishments) Regulations 2019. These records shall be submitted to the Authority upon request. Failure to comply with this requirement may result in the cancellation of this approval.

c) If there are any excess medical devices that have not been exported out, the devices shall be disposed of in safely manner and in accordance with the procedures outlined in the MS 2650 standard, Guidance on Disposal of Medical Devices.

6. Conditions on IRE approval letter

All IRE approvals shall be subjected to the following conditions:

a) The applicant shall ensure that the medical device is re-exported before the expiration date of the IRE approval.

b) The IRE approval applies only to the medical device and site address as approved, based on the information provided by the applicant.

c) The applicant shall submit any requested information to the Authority within a 12-month period.

d) The applicant shall comply with any directives issued by the Authority from time to time.

e) The Authority reserves the right to conduct visits or inspections of the applicant's premises at any time without prior notice.

f) The Authority may revoke the IRE approval if the applicant fails to meet any of the imposed conditions.

g) All documentation related to the medical device, including supporting documents, shall be kept in the premise and made available upon request by the Authority.

h) Once the IRE approval has expired or been canceled, no further import or export of the medical device in any quantity will be permitted.

i) For multiple shipments, the applicant shall submit quarterly declarations of import and re-export records.

j) The applicant shall declare any medical devices that cannot be re-exported under the IRE approval.

k) Advertising of the IRE approval is prohibited in accordance with Section 44 of Act 737.

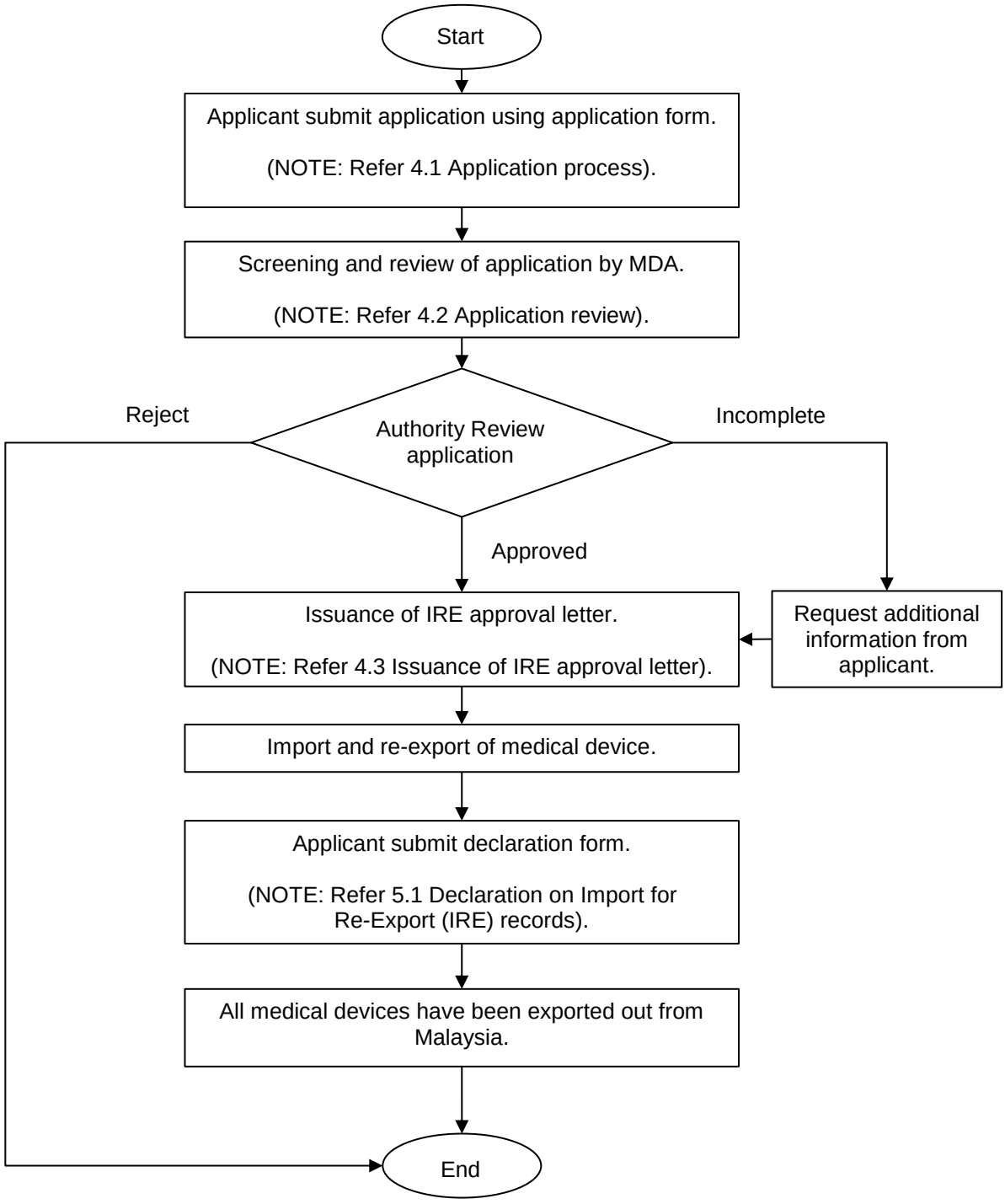
l) Any misuse of the IRE approval with the intent to place the medical devices in the Malaysian market is an offense under Section 5 of the Medical Device Act 2012 [Act 737], punishable by a fine of up to RM200,000.00, imprisonment for up to 3 years, or both.

m) The applicant shall ensure that the medical device is not placed on the Malaysian market.

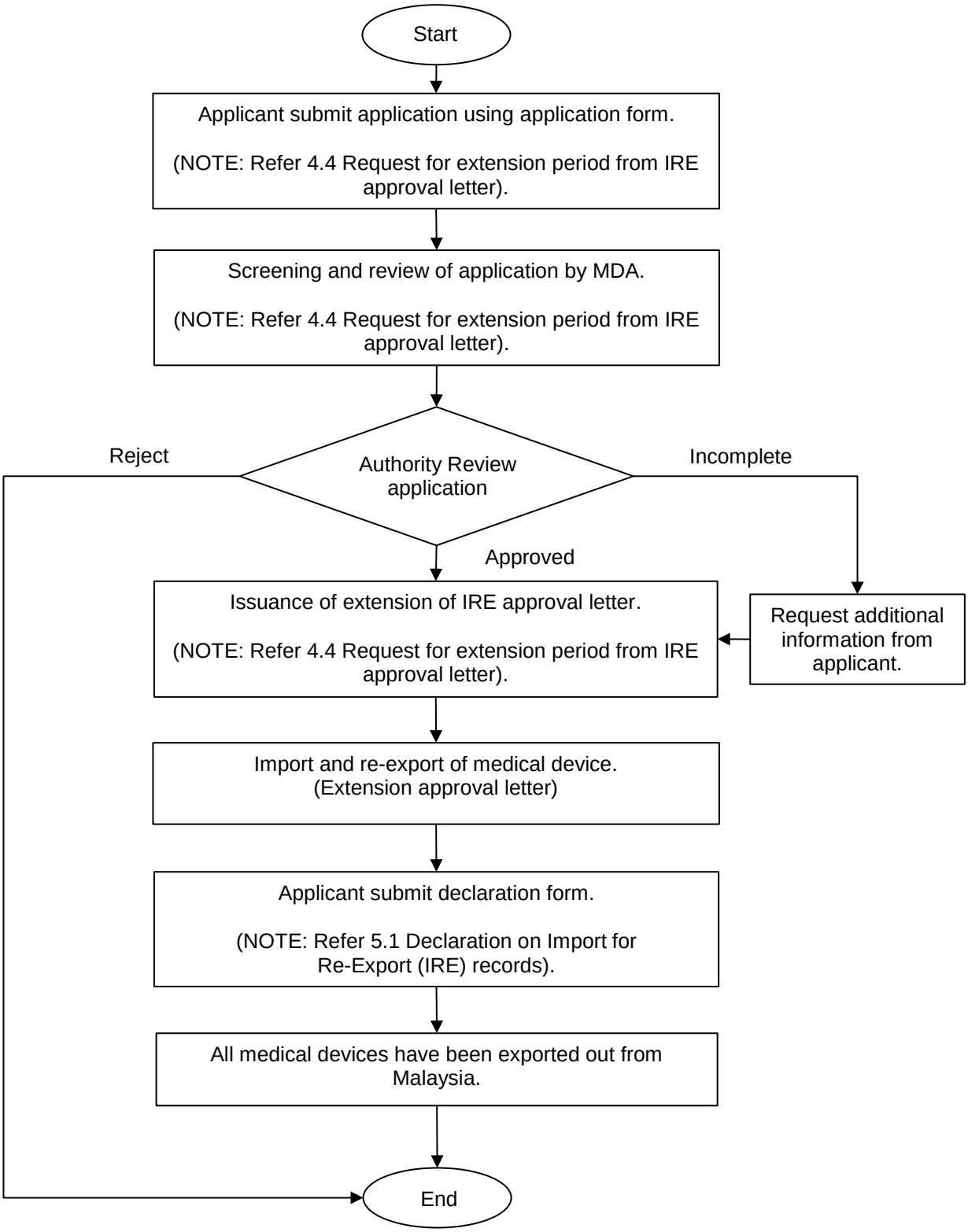
n) The Authority may impose additional conditions from time to time.

Annex A
(informative)

1. Process Flow on Application of Import for Re-export Medical Device



2. Process Flow on Subsequent Application of Import for Re-export Medical Device



Annex B
(normative)

Application 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

APPLICATION OF IMPORT FOR RE-EXPORT MEDICAL DEVICE		
Please complete all information requested on this form. • 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
☐ Repair/Testing/Sterilization/Investigation Facility address: …… Person in charge: ……	IFU or Package insert and Quotation by Service Provider
☐ Packaging/Labelling Facility address: …… Person in charge: ……	i. IFU or Package insert; and ii. Evidence of relationship between applicant and relevant party e. g.: Authorization Letter, Delivery Order or 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	:	
Tentative Date of Exportation	:	
Entry Point	:	☐ Land ☐ Air ☐ Sea ☐ Others
Please specify entry point	:	
Types of Shipment		☐ Single shipment ☐ Multiple shipment

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 application 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 application 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 Application 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 *Note: Not compulsory for multiple shipment. Refer to clause*	Quantity of medical device pending exportation if there is any leftover medical device from previous IRE approval letter *Note: Applicable for distribution hub only.*	Previous IRE Approval ID *Note: Applicable for distribution hub only.*

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,

DECLARATION ON IMPORT FOR RE-EXPORT RECORDS

IRE Approval ID	*<Reference number for CURRENT IRE approval letter>*
Expiry Date	*<(DD/MM/YYYY)>*

1. *I, <Name & NRIC/Passport Number>, hereby declare that the information listed in the Attachment 2 is complete and accurate.*

2. *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.*

3. *I also hereby attach Customs Form No.2 (K2) to support this declaration*.

4. *I further declare that as at <date>, *the stock balance is as per declared or the continuous supply of the balance stock at the expiry of IRE approval letter will be extended until <date>.*

   Note: Item No. 4 for the IRE extension approval letter.

[Signature]
[Full Name and Title of Company Representative/ Person responsible for logistic department]
[Company stamp]
[Date]

Attachment 2: Medical Device Details

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/ Person responsible for logistic department]
[Company stamp]
[Date]

Note:

1. *Total quantity exported is defined as the total quantity of medical device to be exported.*
2. *Balance quantity is defined as the balance quantity of medical device available in Malaysia that has NOT been exported out.*
3. *Please attach a copy of Customs Form No.2 (K2): Declaration of goods to be exported.*

Annex D
(normative)

Subsequent Application 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 APPLICATION 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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