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MEDICAL DEVICE GUIDANCE DOCUMENT

NOTIFICATION OF REFURBISHED MEDICAL DEVICE

Medical Device Authority
MINISTRY OF HEALTH MALAYSIA

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1. 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, and/or to facilitate their business endeavour.

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) 82300200
Email: mda@mda.gov.my
Website: http://www.mda.gov.my

NOTIFICATION OF LISTING FOR REFURBISHED MEDICAL DEVICE

1. Introduction

"Refurbished Medical Device" means a medical device of which the whole or any part thereof has been substantially rebuilt, whether or not using parts from one or more used medical devices of that same kind, so as to create a medical device that can be used for the purpose originally intended by the product owner of the original medical device, and which may have had the following work carried out on it:

(i) stripping into component parts or subassemblies;
(ii) checking their suitability for reuse;
(iii) replacement of components/sub-assemblies not suitable for reuse;
(iv) assembly of the reclaimed and/or replacement components/sub-assemblies;
(v) testing of the assembled device against either original or revised release criteria; or
(vi) identifying an assembled medical device as a refurbished medical device.

This guidance is produced to assist the manufacturer to submit the notification of refurbished medical device. Section 5(1) of Medical Device Act 2012 (Act 737) requires a medical device to be registered under the Act before it can be imported, exported or placed in the market and Circular letter No 1 Year 2016 (Revision 1) requires manufacturer to submit notification to the Authority for he refurbishment activities.

2. Scope

This guidance document specifies requirements for notification of refurbished medical devices to the Authority.

3. Terms and definitions

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

3.1 applicant

A person who refurbish a medical device. There are two categories of refurbisher:
a) manufacturer; or
b) third party refurbisher.

3.2 Authority

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

3.3 establishment

means -

(a) a person who is either a manufacturer, importer, or distributor who is responsible for placing any medical device in the market but does not include a retailer; and

(b) an authorized representative appointed by a manufacturer having a principal place of business outside Malaysia,

and such person and authorized representative being -

(A) a person domiciled or resident in Malaysia; or

(B) a firm or company constituted under the laws of Malaysia, and carrying on business or practice principally in Malaysia.

3.4 Manufacturer

As defined under Section 2 of the Medical Device Act 2012 (Act 737)

3.5 Refurbishment

To restore a used medical device or medical device to manufacturer defined safety and performance standards, which include actions such as repair, recondition, rework, software updates, replacement of worn parts with original parts. All actions shall be performed in a manner consistent with product specifications and service procedures defined by the manufacturer without changing its intended use.

3.6 Refurbished Medical Device

a) a medical device of which the whole or any part thereof has been substantially rebuilt, whether or not using parts from one or more used medical devices of that same kind, so as to create a medical device that can be used for the purpose originally intended by the product owner of the original medical device, and which may have had the following work carried out on it:
   (i) stripping into component parts or subassemblies;
   (ii) checking their suitability for reuse;
   (iii) replacement of components/sub-assemblies not suitable for reuse;
   (iv) assembly of the reclaimed and/or replacement components/sub-assemblies;
   (v) testing of the assembled device against either original or revised release criteria; or
   (vi) identifying an assembled medical device as a refurbished medical device.
   [Source: ASEAN MEDICAL Device Directive 2015]

3.7 place in the market

means an activity as defined in Section 2 of Medical Device Act 2012 (Act 737).

4. Submission of Notification of Refurbished Medical Device

4.1 Notification shall be submitted to the Authority by using the 'Notification of Refurbished Medical Device Form' in Annex B by email to Chief Executive Medical Device Authority at email address refurbishment @mda.gov.my.

4.2 The form for 'Notification/Listing of Refurbished Medical Device' is published in the Authority website at https://portal.mda.gov.my/ .

4.3 Each notification submitted can be for more than one medical device based on medical device grouping.

4.4 The explanations for filling in the application for notification is presented in **Table 1**.

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

PARTICULARS	EXPLANATION/REQUIREMENT
APPLICANT DETAILS	
Name Of Establishment, Address, City, State & Postcode.	Name and details of company that is responsible for the refurbished medical device.
Type of establishment	Select the role of establishment
Name of Person Responsible with Designation, Phone No, and Email Address. Name of Contact Person with Phone No, and Email Address.	Name and details of person responsible and contact person who is in charge of making the application.
MEDICAL DEVICE DETAILS	
Device Name and Brand Name(s)	Name given to the medical device(s) as per label. If the notification involves more than one (1) device, please complete Attachment of Grouping of Medical Device Table as per the principle of grouping
Brief description	Description for the refurbished medical device
Intended use of the device:	Use of the medical device for which it is intended by the manufacturer, according to the data supplied by the manufacturer in

PARTICULARS	EXPLANATION/REQUIREMENT
	the instructions for use as well as the functional capability of the device.
Medical Device Nomenclature	Medical Device Nomenclature such as GMDN Code, HS Code, UMDNS Code, UDI Code and ,or Other Nomenclature Code if GMDN is not applicable
Type of Medical Device	Tick the device whether it's a General Medical Device or In-Vitro Diagnostic Device (IVD) and provide the class and classification rule for the device
Quantity (if available):	Quantity of each medical device
List of lot/Batch No/Serial No.:	The new lot number/ batch number or serial number by the refurbisher
Grouping of Medical Device	Select the grouping of the medical device based on MDR 2012
SUPPORTING DOCUMENTS ASSOCIATED WITH REFURBISHED MEDICAL DEVICE (S)	
Catalogue(s)/ booklet(s)/ leaflet(s)	The catalogue(s)/ booklet(s)/ leaflet(s) shall ccontain information about the intended use, general description, mode of action of the device.
Device label	Medical Device labelling indicate that the medical device is refurbished medical device. The refurbishment date shall also be indicated.
QMS certificate (ISO 13485)	Manufacturer QMS certificate (ISO 13485) with scope of refurbishing activities
Declaration of Conformity	Declaration of Conformity based on MDR 2012
Attestation & Declaration	
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.

5. Administrative charge

Each notification shall be submitted together with a RM XXX administrative charge, with the following conditions:

(a) Administrative charge 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) The bank draft shall be made payable to "KUMPULAN WANG PIHAK BERKUASA PERANTI PERUBATAN" and sent to:

KETUA EKSEKUTIF
Medical Device Authority (MDA),
Ministry of Health Malaysia,
Level 6, Prima 9, Prima Avenue II,
Block 3547, Persiaran APEC,
63000 Cyberjaya, Selangor, MALAYSIA
U/P: UNIT KHIDMAT PENGURUSAN

(c) Name, Telephone No. of the applicant and application for 'Notification for refurbished medical device' must be written at the back of the bank draft but not in the table section.

6.0 Conditions on Acknowledgement on Notification

6.1 The notification of medical device that has been refurbished 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 Acknowledgement on Notification Letter shall not be transferable or assignable.
b) The Acknowledgement on Notification Letter must be presented upon request by any authorized officer.
c) Establishment shall not permit the Acknowledgement on Notification Letter to be abused in any way by any individual / another party.
d) The validity of the Medical Device Registration Certificate is five (5) years from the date of Notification Letter unless the notification is cancelled by the Authority before its expiry.

6.2Any other conditions may be imposed by the Authority from time to time.

7.0 Issuance of Acknowledgement on Notification Letter

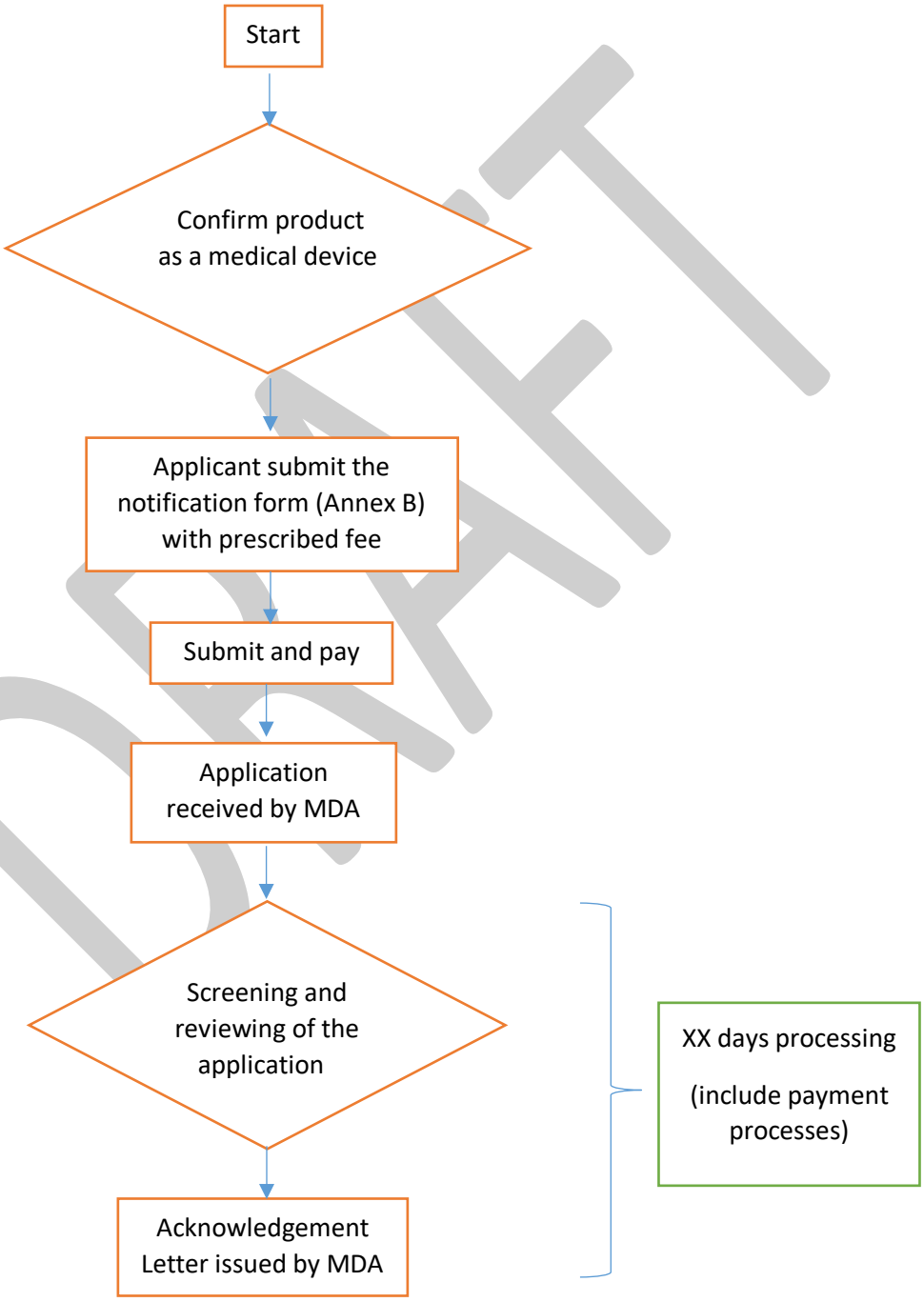
7.1 Upon receipt of completed application and clearance of payment, the authority will issue the Acknowledgement on Notification Letter to the applicant within xx working days by letter and email.

7.2 Validity for Acknowledgement on Notification Letter is 5 years.

7.3 This Acknowledgement on Notification letter permits placement of refurbished medical device into the market within the validity period of the Acknowledgement on Notification.

ANNEX A
(informative)

FLOWCHART OF APPLICATION FOR NOTIFICATION OF LISTING OF REFURBISHED 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

For office use only
Submission ID No:
Date:

ANNEX B (normative)

NOTIFICATION OF REFURBISHED MEDICAL DEVICE

In accordance with circular letter of the Medical Device Authority No. 1 Year 2016 (Revision 1): Refurbishment Of Medical Device

Please complete all information requested on this form.

- One notification application shall be made for more than one unit of medical device. Please use different form for multiple medical devices.
- All fields are mandatory unless stated otherwise.

1. APPLICANT DETAILS

Name of Establishment:		
Address :		
Postcode:	City:	State:
Type of establishment (Please tick one only)	☐ Manufacturer Please state the Establishment License Number: …… ☐ Authorized representative (AR) Please state the Establishment License Number : ……	
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. SUPPORTING DOCUMENTS ASSOCIATED WITH REFURBISHED MEDICAL DEVICE (S)

Please provide following supporting document for this (these) refurbished medical device(s):

i. A copy of catalogue(s)/ booklet(s)/ leaflet(s) that contain information about the intended use, general description, mode of action of the device.
ii. A copy of labelling indicate that the medical device is refurbished medical device. The refurbishment date shall also be indicated.
iii. A copy of manufacturer QMS certificate (ISO 13485) with scope of refurbishing activities
iv. Declaration of Conformity

Please send your application to refurbishment@mda.gov.my
(turnaround time: 30 working days with complete documentation)

For office use only
Submission ID No:
Date:

ANNEX B (normative)

4. ATTESTATION & DECLARATION

I, < Name of person responsible >, ID <_____>, ***manufacturer/authorized representative** of this (these) device(s), hereby declare that :

i. This (These) product(s) is (are) meet the definition of medical device as in Section 2, Medical Device Act 2012 (Act 737);and

ii. This (These) medical device(s) is (are) refurbished accordance to Good Refurbishment Practice for Medical device and placed in the Malaysia Market.

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 5~~1~~00,000.00 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 :

MEDICAL DEVICE AUTHORITY

MINISTRY OF HEALTH, MALAYSIA

Contact Information:

MEDICAL DEVICE AUTHORITY
Ministry of Health Malaysia
Level 6, Prima 9, Prima Avenue II,
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T: (03) 8230 0300
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