MDA/GD/0060
January 2022
First Edition

MEDICAL DEVICE GUIDANCE DOCUMENT

REFURBISHED MEDICAL DEVICE - REQUIREMENTS

Medical Device Authority
MINISTRY OF HEALTH MALAYSIA

Contents Page

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

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

REFURBISHED MEDICAL DEVICE - REQUIREMENTS

Introduction

This guidance is produced to assist the manufacturer and AR (authorized representative) to submit the Notification on 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 the refurbishment activities.

1. Scope

This guidance document specifies requirements for refurbished medical devices to be place in the Malaysian market.

2. 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.

2.1 Applicant

Manufacturer or Authorised Representative

2.2 Authority

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

2.3 Establishment

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

2.4 Manufacturer

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

2.5 Refurbished Medical Device

a medical device of which the whole or any part thereof has been 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]

2.6 Refurbisher

A person who refurbish a medical device. There are two categories of refurbisher:

a) manufacturer; or
b) third party refurbisher.

2.7 Remanufacturing

Actions taken, such as processing, conditioning, renovating, repackaging, etc. on a used medical device or medical device, that significantly changes the device's or medical device's performance, safety specifications, or intended use. Remanufacturing of medical devices is not covered by this guidance document.

2.8 Maintenance

Maintenance consists of schedule maintenance and unscheduled maintenance. Scheduled maintenance is planned maintenance program to ensure an optimum performance, safe operation, minimum downtime, and maximum useful life from each medical device. Unscheduled maintenance involves those actions necessary to restore normal function, safety, performance, and reliability to malfunctioning medical devices.

2.9 Third party refurbisher

Any person who is authorised by the manufacturer to refurbish a medical device. If a third party refurbisher places a refurbished medical device in the market under its own name, he is considered a manufacturer as defined in Medical Device Act 2012 (Act 737).

2.10 Used medical device

A medical device that has been in service, taken out of service and is put back into service usually at another location.

2.11 Validation

Confirmation by examination and provision of objective evidence that a particular requirement for a specific intended use can be consistently fulfilled.

2.12 Place in the market

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

3. Requirements

The control methods as according to Circular Letter Refurbishment of Medical Device No.1 Year 2016 (Revision 2) to be implemented for refurbishment activities are as follows:

Table 1: Control methods for Refurbishment of Medical Device

Refurbishment conducted by	Status of Medical Device	Requirements	Route
Manufacturer	Un-registered refurbished medical device	Refurbished medical device to be registered is subject to the following requirements – • REGISTRATION application shall be in accordance with the prescribed registration requirements and shall be submitted through MeDC@St; • The refurbishment activities shall be included in the scope of quality management system for the manufacture of medical device; • Refurbishment activities shall comply with Good Refurbishment Practice for Medical Devices (GRPMD); • The medical device shall undergo conformity assessment by Conformity Assessment Body (CAB); and • Provide technical details for the medical device. • The label of a refurbished medical device shall comply with the requirements as per MDA/GD/0026 Requirements for Labelling of Medical Devices. • The medical device labelling shall include the term “Refurbished” and carry a different catalogue number with a suffix of [R].	**Route A**
Third party	• Local third party refurbisher who wishes to carry out refurbishment activities shall obtain establishment license as Manufacturer and shall be responsible for REGISTRATION of the medical device through MeDC@St; • Foreign refurbisher shall appoint an authorized representative (AR); • Refurbishment activities shall comply with GRPMD; • The medical device shall undergo conformity assessment by CAB; and • Provide technical details for the medical device. • Third party refurbisher shall not use the brand name of the original manufacturer. • The label of a refurbished medical device shall comply with the requirements as per MDA/GD/0026 Requirements for Labelling of Medical Devices. • The medical device labelling shall include the term “Refurbished” and carry a different catalogue number with a suffix of [R].		**Route B**

3.1 Route A

For unregistered medical device, where refurbishment is conducted by the manufacturer, Manufacturer or AR shall register the medical device via Medical Device Centralized Online Application System (MeDC@St) at https://medcast.mda.gov.my.

3.2 Route B

If a third party refurbisher places a refurbished medical device in the market under its own name, he is considered a manufacturer as defined in Medical Device Act 2012 (Act 737).
Third party refurbisher or AR shall register the medical device via Medical Device Centralized Online Application System (MeDC@St) at https://medcast.mda.gov.my.

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