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

Ref : (4) dlm. MDA. 100-1/7/2 Jld 2
Date : 9 May 2022

CIRCULAR LETTER OF THE MEDICAL DEVICE AUTHORITY
NO. 3 YEAR 2022

POLICY ON IMPLEMENTATION AND ENFORCEMENT UNDER THE MEDICAL DEVICE ACT 2012 (ACT 737):

REFURBISHMENT OF MEDICAL DEVICE

PURPOSE

1) The purpose of this circular is to set the policy for implementation and enforcement under the Medical Device Act 2012 (Act 737) relating to the control of medical device refurbishment activities in Malaysia.

BACKGROUND

2) In accordance with the provisions of Section 2 Act 737, manufacturer means any person who assembles, packages, process, fully refurbishes, reprocess or labels one or more ready-made medical devices.

3) Full refurbishment process is conducted on used medical device that may increase the risk of its usage. This process aims to restore used medical devices to increase the level of its safety and effectiveness.

4) Different types of refurbishment process may be performed apart from full refurbishment process. Regulatory control on all types of refurbishment activity is intended to ensure the safety and effectiveness of refurbished medical devices.

POLICY DECISION FOR IMPLEMENTATION AND ENFORCEMENT

5) **The Medical Device Authority Meeting No. 2/2022 has decided to set the policy for implementation and enforcement for medical device refurbishment activities as follows:**

i) **All types of refurbishment, not only limited to full refurbishment activities will be regulated under Act 737.**

ii) **Control methods to be implemented for refurbishment activities are as follows:**

Refurbishment conducted by	Status of Medical Device	Requirements
Manufacturer	**Un-registered** refurbished medical device	• **REGISTRATION** application shall be made 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); • 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; and • The medical device labelling shall include the term "Refurbished" and carry a different catalogue number with a suffix of [R].
	Registered medical device to be refurbished	• The refurbishment activities shall be included in the scope of quality management system for the manufacture of medical device; • Refurbishment activities shall comply with GRPMD; • The label of a refurbished medical device shall comply with the requirements as per MDA/GD/0026 Requirements for Labelling of Medical Devices; and • The medical device labelling shall include the term "Refurbished" and carry a different catalogue number with a suffix of [R].
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; • 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; and • The medical device labelling shall include the term "Refurbished" and carry a different catalogue number with a suffix of [R].	

USAGE AND EFFECTIVE DATE

6) With the issuance of this Circular Letter, the Circular Letter of MDA No. 1 Year 2016 (Revision 2) is revoked.

7) This circular shall be applicable as part of requirements under Act 737 and shall be effective from the date it is issued.

ENQUIRIES

8) Any enquiries relating to this circular can be forwarded to:

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Medical Device Authority
Ministry of Health Malaysia
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63000 Cyberjaya, Selangor, MALAYSIA
Tel. : (+603) 8230 0300, Fax: (+603) 8230 0200
Email: mdb@mda.gov.my

Thank you.

"WAWASAN KEMAKMURAN BERSAMA 2030"

"BERKHIDMAT UNTUK NEGARA"

Saya yang menjalankan amanah,

(TAN SRI DATO' SERI DR. NOOR HISHAM BIN ABDULLAH)
Chairman
Medical Device Authority
Ministry of Health Malaysia