



Ref : (49) dlm. MDA. 100-1/7/2

Date : 7 September 2020

OBSOLETE

**CIRCULAR LETTER OF THE MEDICAL DEVICE AUTHORITY
NO. 1 YEAR 2016 (REVISION 2)**

**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. 2/2020 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 activities conducted by manufacturer	Un-registered refurbished medical device	<p>Refurbished medical device to be registered is subject to the following requirements –</p> <ul style="list-style-type: none"> • 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.
	Registered medical device to be refurbished	<p>Registered medical device, that will undergo refurbishment process is subject to the following requirements –</p> <ul style="list-style-type: none"> • Manufacturer/ Authorised Representative (AR) shall provide NOTIFICATION to the Authority; • The refurbishment activities shall be included in the scope of quality management system for manufacture of medical device; • Refurbishment activities shall comply with GRPMD; and • Provide technical details for the medical device.
Refurbishment activities conducted by third party	<ul style="list-style-type: none"> • Third party 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; • Refurbishment activities shall comply with GRPMD; • The medical device shall undergo conformity assessment by CAB; and • Provide technical details for the medical device. 	

USAGE AND EFFECTIVE DATE

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

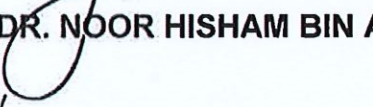
ENQUIRIES

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

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Thank you.

"BERKHIDMAT UNTUK NEGARA"


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