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

Ruj Kami : (40) dlm. MDA. 100-1/7/2
Tarikh : 15 April 2019

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

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 control of establishment activities on refurbishment of medical device in Malaysia.

BACKGROUND

2) In accordance with the provisions of Section 2 of 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 and may bear additional risks. This process aims to restore used medical devices to original condition and specification.

4) In Malaysia, different types of refurbishment process are also been conducted apart from full refurbishment process. Requirement on all type of refurbishment activities must be regulated to ensure the safety and effectiveness of medical devices.

POLICY DECISION FOR IMPLEMENTATION AND ENFORCEMENT

5) **The Medical Device Authority Meeting No. 2/2019 has decided to set the policy for implementation and enforcement for refurbishment on medical device activities as follows:**

i) **Refurbishment activities is regulated under Act 737 and inclusive all types of refurbishment, not only limited to full refurbishment activities**

ii) **Refurbishment activities conducted by manufacturer**

- **Manufacturer shall provide the notification to the Authority;**
- **To include the refurbishment activities in the scope of quality management system (QMS);**
- **To ensure that refurbishment activities comply with *Good Refurbishment Practice for Medical Devices (GRPMD)*; and**
- **Provide technical details for medical device**

iii) **Refurbishment activities conducted by third party**

- **Third party shall obtain establishment license (Manufacturer) and responsible for product registration;**
- **To ensure that refurbishment activities comply with *Good Refurbishment Practice for Medical Devices (GRPMD)*; and**
- **Provide technical details for medical device**

USAGE AND EFFECTIVE DATE

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

ENQUIRIES

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

Chief Executive
Medical Device Authority
Ministry of Health Malaysia
Level 6, Prima 9, Prima Avenue II
Block 3547, Persiaran Apec
63000 Cyberjaya, MALAYSIA
Telefon: (+603) 8230 0300, Faksimili: (+603) 8230 0200
Emel: mda@mda.gov.my

Thank you.

"BERKHIDMAT UNTUK NEGARA"

(YBHG. DATUK DR NOOR HISHAM BIN ABDULLAH)
Chairman
Medical Device Authority
Ministry of Health Malaysia