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

Our Ref : (36) dlm. MDA. 100-1/7/2
Date : 3 September 2018

CIRCULAR LETTER OF THE MEDICAL DEVICE AUTHORITY NO. 4 YEAR 2018 (REVISION 1)

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

EXEMPTION FROM REGISTRATION REQUIREMENT FOR EXPORT ONLY 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 exemption from registration requirement for export only medical device.

BACKGROUND

2) Section 5(1) Act 737 states that no medical device shall be imported, exported or placed in the market unless the medical device is registered under this Act.

3) There is no risk to the public for an export only medical device because it does not enter the Malaysian market.

4) In view of the medical device not intended to be placed in Malaysian market, it is therefore inappropriate to strictly impose the registration requirements in Section 5 Act 737 because;

(a) Medical devices will be subjected to registration requirements in the importing country.
(b) Encourage the development of national economic by attracting investors to invest in Malaysia due to minimal regulatory requirements.
(c) Generate national income growth by eliminating trade barriers.

5) Section 77 of Act 737 requires the exemption of any person or medical device from any provision of the Act or any regulation made under this Act may be declared by the Minister, if he considers it consistent with the purposes of the Act, by order published in the Gazette.

POLICY DECISION FOR IMPLEMENTATION AND ENFORCEMENT

6) **The Medical Device Authority Meeting No. 2/2018 has decided to set the policy for implementation and enforcement for exemption from registration requirement for export only medical device as follows:**

a) **Exemption from medical device registration requirement under Section 5 of Act 737;**
b) **Compliance with notification requirement with certain charges as may be specified by the Authority; and**
c) **The medical device is not allowed to be placed in Malaysian market.**

7) **This exemption is implemented administratively before order is published in the Gazette.**

USAGE AND EFFECTIVE DATE

8) 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

9) 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, Selangor, MALAYSIA
Telefon: (+603) 8230 0300, Faksimili: (+603) 8230 0200
Emel: mdb@mdb.gov.my

Thank you.

"BERKHIDMAT UNTUK NEGARA"

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