



Our Ref: (38) dlm. MDA. 100-1/7/2
Date : 3 September 2018

**CIRCULAR LETTER OF THE MEDICAL DEVICE AUTHORITY
NO. 4 YEAR 2014 (REVISION 1)**

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

**MEDICAL DEVICE FOR IMPORT / EXPORT FROM / TO COUNTRIES WITHOUT
DIPLOMATIC TIES WITH MALAYSIA**

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 medical devices for import / export to / from countries without diplomatic ties with Malaysia.

BACKGROUND

2) Section 5(1) of Act 737, requires all medical devices are registered before they can be imported, exported or placed in the market. However, with regards to medical devices intended for transit only, no registration is required under the Act 737. There is also no specific provision for medical devices imported / exported from / to countries without diplomatic ties with Malaysia.

3) Section 45 of Act 737 allows an establishment to apply to the Authority for a permit to export a registered medical device.

POLICY DECISION FOR IMPLEMENTATION AND ENFORCEMENT

4) The Medical Device Authority Meeting has decided to set the policy on implementation and enforcement as follows:

Eksport Permit / Certificate of Free Sale (CFS) will not be issued for medical devices to be imported / exported from / to countries without diplomatic ties with Malaysia, such as Israel.

USAGE AND EFFECTIVE DATE

5) 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

6) 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
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Thank you.

"BERKHIDMAT UNTUK NEGARA"



(YBHG. DATUK DR NOOR HISHAM BIN ABDULLAH)
Chairman
Medical Device Authority
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