PIHAK BERKUASA PERANTI PERUBATAN
MEDICAL DEVICE AUTHORITY (MDA)
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Our Ref. : (15) dlm.MDA.100-1/7/2 Jld 2
Date : 26 April 2024

CIRCULAR LETTER OF MEDICAL DEVICE AUTHORITY
NO. 1 YEAR 2024

POLICY ON IMPLEMENTATION AND ENFORCEMENT UNDER THE MEDICAL DEVICE ACT 2012 [ACT 737]:

MEDICAL DEVICES IMPORTED FROM OR EXPORTED TO COUNTRIES WITHOUT DIPLOMATIC TIES WITH MALAYSIA WHICH ARE SUBJECTED TO TRADE RESTRICTIONS

PURPOSE

1) The purpose of this circular is to set the implementation and enforcement under the Medical Device Act 2012 [Act 737] relating to medical devices imported from or exported to countries without diplomatic ties with Malaysia which are subjected to trade restrictions.

BACKGROUND

2) Section 5(1) of Act 737 requires that all medical devices for the purpose of import, export, or placed in the Malaysia market must be registered with the Medical Device Authority (MDA).

3) Act 737 and the regulations under it do not specify specific prohibitions for the registration of medical devices imported from or exported to countries that do not have diplomatic relations with Malaysia or that are subjected to trade restrictions.

4) However, establishments are still subject to other government policies such as import or export prohibitions imposed by the Royal Malaysian Customs Department (*Jabatan Kastam Diraja Malaysia* – JKDM) through the Customs Act 1967 as well as any latest policies issued from time to time referring to the diplomatic relationship status and trade between Malaysia with other countries.

POLICY DECISION FOR IMPLEMENTATION AND ENFORCEMENT

5) In response to this, the Medical Device Authority Board Meeting No. 1 Year 2024 has **approved** a registration process flow for medical devices imported from or exported to countries without diplomatic ties that are subjected to trade restrictions by Malaysia through the following procedure:

   (a) **the establishments must first obtain approval for the import license/export license (approved permit – AP) from the relevant agency**, as outlined in **Customs (Prohibition of Imports) Order** and **Customs (Prohibition of Exports) Order**. Possession of this AP will be an **additional criterion for medical device registration with MDA**; and

   (b) subsequently, **the establishments can proceed to apply for medical device registration with MDA in accordance with the provisions of Act 737**.

   MDA **may consider the application for medical device registration** if the establishments meet both requirements (a) and (b) as outlined above.

USAGE AND EFFECTIVE DATE

6) With the issuance of this Circular Letter, the **CIRCULAR LETTER OF THE MEDICAL DEVICE AUTHORITY NO. 4 YEAR 2014 (REVISION 1)** is **revoked**.

7) This circular shall be used 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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Thank you.

"MALAYSIA MADANI"
"BERKHIDMAT UNTUK NEGARA"

Saya yang menjalankan amanah,

(DATUK DR. MUHAMMAD RADZI BIN ABU HASSAN)
Chairman
Medical Device Authority
Ministry of Health Malaysia