PIHAK BERKUASA PERANTI PERUBATAN
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Our Ref. : ( 19 ) dlm. MDA. 100-1/7/2 JLD 2
Date : 30 September 2025

# CIRCULAR LETTER OF THE MEDICAL DEVICE AUTHORITY NO. 2 YEAR 2025

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

## CONFORMITY ASSESSMENT PROCEDURES FOR MEDICAL DEVICE APPROVED BY RECOGNISED COUNTRIES

### PURPOSE

1) The purpose of this circular is to set the policy for conformity assessment procedures for medical devices that have been approved by recognised foreign regulatory authorities for the purpose of registering medical devices under the Medical Device Act 2012 [*Act 737*].

### BACKGROUND

2) Section 7 of Act 737 requires the carrying out of conformity assessment by the conformity assessment body registered within Section 10 of Act 737. This is a preconditon for having a medical device registered under the Act.

3) However, there are various medical device which have undergone conformity assessment and approved to be placed in certain recognised countries. The conformity assessment done by the respective countries are similar to the requirements under Act 737.

### POLICY DECISION FOR IMPLEMENTATION AND ENFORCEMENT

4) Recognition refers to the acceptances of conformity assessment or market placement approval of medical devices in certain countries. This recognition will prevent a repetition process of conformity assessment or approval granted on a medical device and therefore will facilitating, reducing costs and accelerating the registration of medical devices in this country.

5) For reasons stated above, as well as **the cumulative decisions from Medical Device Authority Meeting No. 2/2014, Medical Device Authority Meeting No. 4/2021 and Mesyuarat Pengurusan Tertinggi MDA No. 11/2024**, the decision on **the policy for implementation and enforcement has been set** as follows:

(a) To recognise the medical device approvals issued by recognised competent authorities, as listed in **APPENDIX 1 of the MDA/GD/0068 – Guide For Conformity Assessment Body (CAB): Conducting Conformity Assessment Through Verification (Guidance Document)**;

(b) For medical devices that have been approved by a recognised competent authority, it only needs to undergo a facilitated conformity assessment process, which is through verification of the compliance evidences obtained from the medical device manufacturer;

(c) However, medical devices that have been granted special authorisation through programs (including but not limited to) listed in **Table 2 of the Guidance Document** for market entry will not be eligible for conformity assessment through verification as stated in Paragraph 5(b) for the purpose of medical device registration;

(d) The verification process shall be conducted by the conformity assessment body registered under Section 10 of Act 737 in accordance with the full procedures as set out in **Guidance Document**; and

(e) Competent authorities not listed in **APPENDIX 1 of the Guidance Document** may be considered for inclusion from time to time, subject to approval by the Authority following a comprehensive review and evaluation process. If there is approval for a new list of recognised countries, the specific requirements will be further detailed in the **Guidance Document**.

**EFFECTIVE DATE**

6) This Circular Letter shall take effect on the date of issuance.

**REVOCATION**

7) With the issuance of this Circular Letter, the **CIRCULAR LETTER OF THE MEDICAL DEVICE AUTHORITY NO. 1 YEAR 2025** is **revoked**.

**APPLICATION**

8) This Circular Letter shall be applied as part of the requirements under Act 737.

**ENQUIRIES**

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

Chief Executive
Medical Device Authority
Ministry of Health Malaysia
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63000 Cyberjaya, Selangor, MALAYSIA
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Email: mdb@mda.gov.my

Thank you.

**"MALAYSIA MADANI"**
**"BERKHIDMAT UNTUK NEGARA"**

Saya yang menjalankan amanah,

**(DATUK DR. MAHATHAR BIN ABD WAHAB)**
Chairman
Medical Device Authority
Ministry of Health Malaysia

30/9/2025