PIHAK BERKUASA PERANTI PERUBATAN
MEDICAL DEVICE AUTHORITY (MDA)
Aras 6, Prima 9, Prima Avenue II
Blok 3547, Persiaran APEC
63000 CYBERJAYA
SELANGOR DARUL EHSAN

Tel. : 03-8230 0300
E-mel : mdb@mda.gov.my
Portal : portal.mda.gov.my

Our Ref. : (17) dlm. MDA. 100-1/7/2 JLD 2
Date : 11 March 2025

CIRCULAR LETTER OF THE MEDICAL DEVICE AUTHORITY
NO. 1 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 Table 1;

Table 1: Approvals Issued by Recognised Competent Authorities Permitted by MDA for Conformity Assessment by Way of Verification Process

Competent Authority	Approvals
European Union/Notified Bodies (EU NB)	**For Class B** via EC certificates issued according to: • Directive 93/42/EEC Annex II section 3 or Annex V for Class IIa devices; or • Medical Device Regulation (MDR) Annex IX Chapter I and Chapter III or MDR Annex XI PART A for Class IIa; or • Directive 98/79/EC Annex IV or Annex V with Annex VII for List B and self-testing IVDs; or • In Vitro Diagnostic Medical Device Regulation (IVDR) Annex IX Chapter I and Chapter III for Class B IVD **For Class C and D** via EC certificates issued according to: • Directive 93/42/EEC Annex II section 3 or Annex III with Annex V for Class IIb; or • Medical Device Regulation (MDR) Annex IX Chapter I and Chapter III, including assessment of technical documentation for implantable, or MDR Annex X coupled with Annex XI PART A for Class IIb; or • Directive 93/42/EEC Annex II section 3 and 4 for Class III; or • Medical Device Regulation (MDR) Annex IX Chapter I and Chapter III, including assessment of the technical documentation for Class III; or • Directive 90/385/EEC Annex II section 3 and 4 for Active Implantable Medical Devices (note: Directive 90/385/EEC is incorporated into MDR and active implantable medical device is Class III under MDR); or • Directive 98/79/EC Annex IV including sections 4 and 6 for List A IVDs; or • IVDR Annex IX Chapter I and Chapter III, including assessment of technical documentation for Class D IVD; or • Directive 98/79/EC Annex IV or Annex V with Annex VII for List B and self-testing IVDs; or

Competent Authority	Approvals
	• In Vitro Diagnostic Medical Device Regulation (IVDR) Annex IX Chapter I and Chapter III, including assessment of technical documentation for companion diagnostics, self-testing & near-patient testing devices, or IVDR Annex X coupled with Annex XI (except section 5) for Class C IVD.
Japan/Ministry of Health, Labour and Welfare (MHLW)	• Pre-market certification (Ninsho) from a Japanese registered certification body; or • Pre-market approval (Shonin) from MHLW
Australia/ Therapeutic Goods Administration (TGA)	• ARTG Registration Certificate
Canada/Health Canada (HC)	• Health Canada License
US/Food and Drug Administration (US FDA)	• 510K clearance; or • Premarket approval (PMA)
United Kingdom/ Medicines & Healthcare Products Regulatory Agency (MHRA)	For Great Britain • UK Conformity Assessed (UKCA); or • EC certificates issued according to recognised approvals as listed in the above EU NB For Northern Ireland • EC certificates issued according to recognised approvals as listed in the above EU NB; or • UK Northern Island (UKNI) and EC certificates issued according to recognised approvals as listed in the above EU NB

(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 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;

Table 2: Schemes/Programs Exempt From Verification Pathway For Medical Device

Competent Authority	Scheme/Program
European Union/National Competent Authorities	• Exceptional Use Authorization
Japan/Pharmaceuticals and Medical Devices Agency (PMDA)	• Compassionate Use System • *Emergency Regulatory Pathway
Australia/Therapeutic Goods Administration (TGA)	• Special Access Scheme (SAS) • Authorised Prescriber Scheme • *Emergency Exemptions
Canada/Health Canada (HC)	• Special Access Program (SAP) • *Interim Order (IO)
US/Food and Drug Administration (FDA)	• Emergency Use Authorization (EUA) • Expanded Access (Emergency/ Compassionate Use) • Humanitarian Device Exemption (HDE)
United Kingdom/Medicines and Healthcare products Regulatory Agency (MHRA)	• Exceptional Use Authorizations

Note:

1. These schemes/programs provide temporary authorization for unapproved medical devices to enter the market for emergency use, ensuring patients could access essential medical devices in critical or urgent situations.

2. *Special approval/permission given to access the market during COVID-19 pandemic.

(d) The verification process shall be conducted by the conformity assessment body registered under Section 10 of Act 737 in accordance with the procedures as set out in **MDA/GD/0068 – Guide For Conformity Assessment Body (CAB): Conducting Conformity Assessment Through Verification (Guidance Document)**; and

(e) Competent authorities not listed in Table 1 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. 2 YEAR 2014** 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
Level 6, Prima 9, Prima Avenue II,
Block 3547, Persiaran Apec,
63000 Cyberjaya, Selangor, MALAYSIA
Tel. : (+603) 8230 0300, Fax: (+603) 8230 0200
Email: mdb@mda.gov.my

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