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. : (21) dlm. MDA. 100-1/7/2 JLD 2
Date : 29 January 2026

CIRCULAR LETTER OF MEDICAL DEVICE AUTHORITY NO.1 YEAR 2026

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

MEDICAL DEVICE PROCUREMENT FOR HEALTHCARE INSTITUTION

PURPOSE

1) The purpose of this circular is to announce the implementation and enforcement of the Medical Device Act 2012 (Act 737) in relation to the procurement of medical device for healthcare facilities in Malaysia.

INTERPRETATION

Establisment means –

a) a person who is either a manufacturer, importer, or distributor who is responsible for placing any medical device in the market but does not include a retailer; and
b) an authorized representatives appointed by a manufacturer having a principal place of business outside Malaysia,

and such person and authorized representative being –

a) a person domiciled or resident in Malaysia; or
b) a firm or company constituted under the laws of Malaysia,

and carrying on business or practice principally in Malaysia.

Place in the market means to make available a medical device in return for payment of free of charge with a view to distributing, using, supplying or putting it into service, in Malaysia, regardless of whether it is new or reprocessed, but does not include to make available for use for clinical research or for performance evaluation of a medical device.

Tenderer means a company or representative of a supplier company participating in procurement activities for supply tender to the Government of Malaysia or private institutions.

BACKGROUND

2) Act 737 is cited in the circulars and procurement guidelines issued by the Ministry of Finance as well as the Ministry of Health Malaysia (MOH).

3) Through prosecution proceedings conducted by the MDA, procurement documents such as agreements, quotations, invoices, local orders, delivery orders, and other constitute evidence tendered in court to prove the placement in the market activities.

4) In accordance with current practices within the tender procurement process, the successful participating company (referred to as the tenderer) shall execute an agreement with the procuring healthcare facility (be it public facility under the MOH or a private entity).

5) Payments for the procurement shall be directed to them, and they are responsible for issuing the procurement documentation including quotations, invoices, local orders, and delivery order to the institutions accepting the supplied medical devices.

6) They will subsequently carry out the supply and distribution of medical devices to the healthcare facilities conducting the medical device procurement via tender.

7) Therefore, referring to Section 2 of Act 737, the tenderer meets the definition of an establishment and therefore subject to the requirements and provision under Section 15(1) of Act 737, namely the requirement to hold a valid license to carry out import, export or placing registered medical device in the market.

8) The tenderer shall implement a quality management system based on Good Distribution Practice for Medical Devices (GDPMD) and undertake post-market responsibilities regarding the safety and performance of the supplied medical devices. This includes reporting incidents to the MDA, conducting investigations into occurring

incidents, implementing field corrective actions, and recalling problematic medical devices.

IMPLEMENTATION AND ENFORCEMENT OF MEDICAL DEVICE PROCUREMENT ACTIVITIES

9) For any healthcare facility intending to carry out **medical device procurement via tender**, the facility must obtain copies of the documents listed below from the tenderer to ensure that the tenderer is a valid licensed establishments.

a) **A copy of the Establishments License as a Medical Device Distributor in the name of the tenderer (as in Appendix A); and**
b) **A copy of the Medical Device Registration Certificate for the medical device to be procured (as in Appendix B); and**
c) **A Letter of Appointment as Distributor from the Authorized Representative (AR) or establishments (Distributor) of the medical device to be procured.**

10) Any documents issued by or to healthcare facilities for the purpose of concluding tender procurements activities – including but not limited to invoices, delivery orders, testing reports, commissioning documents, and any supporting documents-shall clearly state the name of the establishments conducting the medical device distribution activities. This requirements is crucial to ensure compliance with the requirements of the Medical Device Act 2012 (Act 737) ,as well as to guarantee a complete audit trail for medical device supplied to healthcare facilities.

EFFECTIVE DATE

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

REVOCATION

12) With the issuance of this Circular Letter, the **SURAT PEKELILING PIHAK BERKUASA PERANTI PERUBATAN BILANGAN 2 TAHUN 2016 (SEMAKAN 2)** is **revoked**.

APPLICATION

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

ENQUIRIES

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

Chief Executive
Medical Device Authority
Ministry of Health Malaysia
Aras 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. MAHATHAR BIN ABD WAHAB)
Pengerusi
Pihak Berkuasa Peranti Perubatan
Kementerian Kesihatan Malaysia

APPENDIX A

ASAL
ORIGINAL

PIHAK BERKUASA
PERANTI PERUBATAN

MEDICAL DEVICE
AUTHORITY

PIHAK BERKUASA PERANTI PERUBATAN
MEDICAL DEVICE AUTHORITY
AKTA PERANTI PERUBATAN 2012 (AKTA 737)
MEDICAL DEVICE ACT 2012 (ACT 737)
LESEN ESTABLISMEN
ESTABLISHMENT LICENCE
Seksyen 15(1) Akta 737
Section 15(1) of Act 737

No. Lesen : **MDA-[redacted]** Tarikh Sah Lesen : **18/12/2025 - 17/12/2028**
Licence No. : *Licence Validity Date* :

Lesen adalah dengan ini diberi kepada: **[redacted] SDN. BHD.**
Licence is hereby granted to:

yang beralamat di:
of:
[redacted]
59200 KUALA LUMPUR
WILAYAH PERSEKUTUAN KUALA LUMPUR

Sebagai:
as:
PENGEDAR
DISTRIBUTOR

Orang yang
bertanggungjawab:
Person Responsible:
[redacted] **I/C NO.:** [redacted]

Lesen ini diberikan tertakluk kepada peruntukan-peruntukan di bawah Akta 737 dan peraturan-peraturan dibawahnya serta syarat-syarat seperti di Lampiran 1.
This licence is granted subject to the provisions under Act 737 and its subsidiary legislations and the conditions as in Attachment 1.

[redacted]

MURALITHARAN NARAMASUA
KETUA EKSEKUTIF
CHIEF EXECUTIVE
PIHAK BERKUASA PERANTI PERUBATAN
MEDICAL DEVICE AUTHORITY

APPENDIX B

ASAL
ORIGINAL

PIHAK BERKUASA
PERANTI PERUBATAN

MEDICAL DEVICE AUTHORITY

PIHAK BERKUASA PERANTI PERUBATAN
MEDICAL DEVICE AUTHORITY
AKTA PERANTI PERUBATAN 2012 (AKTA 737)
MEDICAL DEVICE ACT 2012 (ACT 737)
SIJIL PENDAFTARAN PERANTI PERUBATAN
MEDICAL DEVICE REGISTRATION CERTIFICATE
Seksyen 5(1) Akta 737
Section 5(1) of Act 737

No. Pendaftaran: GA[redacted]
Registration No.:

Tarikh Sah Pendaftaran: **24/12/2025 - 23/12/2030**
Registration Validity Date:

Sijil ini adalah dengan ini diberi kepada:
This certificate is hereby issued to:

[redacted]

yang beralamat di:
which is located at:

[redacted]

Peranan establismen
Role of establishment

Wakil Diberi Kuasa
Authorized Representative

bagi mengesahkan peranti perubatan seperti yang dinyatakan dalam Lampiran 1 adalah berdaftar di bawah Seksyen 5(1) Akta 737.
to confirm that the medical device as detailed out in Attachment 1 is registered under Section 5(1) of Act 737.

Pendaftaran ini diberikan tertakluk kepada peruntukan-peruntukan di bawah Akta 737 dan peraturan-peraturan yang dibuat dibawahnya serta syarat-syarat seperti di Lampiran 2.
This registration is granted subject to the provisions under Act 737 and its subsidiary legislations and the conditions as in Attachment 2.

[redacted]

MURALITHARAN PARAMASUA
KETUA EKSEKUTIF
CHIEF EXECUTIVE
PIHAK BERKUASA PERANTI PERUBATAN
MEDICAL DEVICE AUTHORITY

LAMPIRAN 1
Attachment 1

[redacted]

No. Pendaftaran: GA[redacted]
Registration No.:

Tarikh Sah Pendaftaran: **24/12/2025 - 23/12/2030**
Registration Validity Date:

Sijil ini adalah dengan ini diberi kepada: [redacted]
This certificate is hereby issued to:

Butir-butir peranti perubatan yang didaftarkan
Particulars of the registered medical device

Nama Peranti Perubatan [redacted]
Medical Device Name

Kelas **CLASS A** Jenama [redacted]
Class *Brand*

Kelompok **FAMILY**
Group

Nama dan alamat pembuat: [redacted]
Name and address of manufacturer

APPENDIX

NO	NAME AS PER DEVICE LABEL	IDENTIFIER	BRIEF DESCRIPTION OF ITEM
1	[redacted]	10-100-01	Used to Statically Carry and Manipulate Blade to Perform Incision during Surgical Procedure.
2	[redacted]	10-100-02	Used to Statically Carry and Manipulate Blade to Perform Incision during Surgical Procedure.
3	[redacted]	10-100-03	Used to Statically Carry and Manipulate Blade to Perform Incision during Surgical Procedure.
4	[redacted]	10-100-04	Used to Statically Carry and Manipulate Blade to Perform Incision during Surgical Procedure.
5	[redacted]	10-100-05	Used to Statically Carry and Manipulate Blade to Perform Incision during Surgical Procedure.
6	[redacted]	10-103-01	Used to Statically Carry and Manipulate Blade to Perform Incision during Surgical Procedure.