



PIHAK BERKUASA PERANTI PERUBATAN

Medical Device Authority

KEMENTERIAN KESIHATAN MALAYSIA

Ministry of Health Malaysia

Portal: www.mda.gov.my

Email: mdb@mda.gov.my

MEDICAL DEVICE FOR EXPORT ONLY APPLICATION FORM

(In accordance with Medical Device (Exemption) Order 2024:
Exemption from Registration Requirement for Export Only Medical Device)

Please complete all information requested on this form.

- One application shall be made for only single medical device nomenclature.
- All fields are mandatory unless stated otherwise.

1. APPLICANT DETAILS

Name of establishment/company:

Address :

Postcode:

City:

State:

Please tick appropriate box:

Licensed establishment

☐

Contract manufacturer

☐

Authorized exporter

☐

Establishment License Status

☐

Establishment License available

Please state the Establishment License Number:

.....

☐

No Establishment License (for contract manufacturer/authorized exporter)

Person responsible:

Designation:

Phone No. :

Email address:

Contact person :

Phone no. :

Email address:

2. MEDICAL DEVICE DETAILS

Please provide medical device information as per **Appendix A**.

3. SUPPORTING DOCUMENTS ASSOCIATED WITH THE MEDICAL DEVICE FOR EXPORT ONLY

Please provide following supporting document for this application:

- i. Registrar of Companies (ROC) certificate of applicant
- ii. Letter of Authorization for OEM/Contract Manufacturer/Authorized Exporter
- iii. Declaration Traceability of Evidence of Conformity Attestation Template for Notification of Export Only Medical Device
- iv. A copy of establishment license (If applicable)
- v. A copy of QMS certificate ISO 13485 for medical device manufacturer/contract manufacturer
- vi. A copy of Product Datasheet/Brochure/Leaflet/Label/IFU/ that contain information on brief description and intended use.

Please send your application to **exportonly.ec@mda.gov.my**

(Turnaround time: 30 working days with complete documentation)

4. ATTESTATION & DECLARATION

I, <_____, ID <_____, 'licensed establishment/contract manufacturer/authorized exporter of this device, hereby declare that:

- i. This product meets the definition of medical device as in Section 2, Medical Device Act 2012(Act 737); and
- ii. This medical device is not placed in the Malaysian Market and intended for export only.

I, the undersigned, hereby attest that the information and documents provided in this notification are true, accurate, correct, complete and current to this date. I understand that any declaration by me in this application that is untrue, inaccurate or misleading shall, upon conviction be liable to a fine not exceeding RM 100,000.00 or to imprisonment for a term not exceeding 2 years or to both. (Section 76(1) Act 737)

*(Strikethrough accordingly)

Signature:

Person Responsible

Name:

Designation :

Date :

Company stamp :

EXPORT ONLY MEDICAL DEVICE DETAILS

1. Medical Device Name

:

Please complete table 1, if the medical devices involve more than one (1) device.
2. Brief Description

:

Please complete table 1, if the medical devices involve more than one (1) device.
3. Intended Use

:

Please complete table 1, if the medical devices involve more than one (1) device.
4. Medical Device Nomenclature

:

GMDN

:

UMDNS (if any)

:

Other

:

(Please specify)
5. Type of Medical Device

:

☐ General Medical Device

☐ In-Vitro Diagnostic Device (IVD)
6. HS Code

:
7. UDI

:

Medical Device List:

Table 1

[illegible]

