PIHAK BERKUASA PERANTI PERUBATAN
Medical Device Authority
KEMENTERIAN KESIHATAN MALAYSIA
Ministry of Health Malaysia
Portal: www.mda.gov.my
Email: mdb@mda.gov.my

NOTIFICATION OF EXPORT ONLY MEDICAL DEVICE

(In accordance with Circular Letter of The Medical Device Authority No. 4 Year 2018 (REVISION 1): Exemption from Registration Requirement For Export Only Medical Device)

Please complete all information requested on this form.

- One notification application shall be made for only one 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. PURPOSES

Please choose purpose for export only medical device:

☐ Contract manufacturer/authorized exporter to brand owner

☐ Contract manufacturer/authorized exporter to brand owner's customer

☐ Licensed establishment/authorized exporter to customer

4. SUPPORTING DOCUMENTS ASSOCIATED WITH THE DEVICE FOR EXPORT ONLY

Please provide following supporting document for this application:

i. An example of catalogue(s)/ booklet(s)/ leaflet(s)/ copy of labelling that contain information about the intended use, general description, mode of action of the device.
ii. A copy of medical device manufacturer/contract manufacturer QMS certificate (ISO 13485)

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iii. Letter of authorization from manufacturer/contract manufacturer to exporter (only applicable for authorized exporter)

Please send your application to **exportonly@mda.gov.my**
(turnaround time: 14 working days with complete documentation)

5. ATTESTATION & DECLARATION

I, <_____>, ID <_____>, *__licensed establishment/contract manufacturer/authorized exporter__ of this device, hereby declare that :

i. This product meet 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 :

Appendix A

EXPORT ONLY MEDICAL DEVICE DETAILS

Device Name :

Brief description :

Intended Use of the device :

Medical Device Nomenclature :

GMDN Code :

Other Nomenclature Code if GMDN is not applicable :

UMDNS Code :

HS Code :

UDI Code :

Type of Medical Device :

☐ **General Medical Device**

☐ **In-Vitro Diagnostic Device (IVD)**