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Second Edition**

MEDICAL DEVICE GUIDANCE DOCUMENT

MEDICAL DEVICE FOR THE PURPOSE OF EXPORT ONLY



Medical Device Authority
MINISTRY OF HEALTH MALAYSIA

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Preface

This Guidance Document was prepared by the Medical Device Authority (MDA) to help the industry and healthcare professionals in their quest to comply with the Medical Device Act (Act 737) and the regulations under it.

This Guidance Document shall be read in conjunction with the current laws and regulations used in Malaysia, which include but not limited to the following-

- a) Medical Device Act 2012 (Act 737);
- b) Medical Device Regulations 2012; and
- c) Medical Device (Exemption) Order 2024.

In this Guidance Document, the following verbal forms are used:

- “shall” indicates a requirement;
- “should” indicates a recommendation;
- “may” indicates a permission; and
- “can” indicates a possibility or a capability.

Irrespective of the requirements of this Guidance Document, MDA has the right to request for information or material, or define conditions not specifically described in this document that is deemed necessary for the purpose of regulatory control.

MDA has put much effort to ensure the accuracy and completeness of this guidance document. In the event of any contradiction between the contents of this document and any written law, the latter should take precedence.

MDA reserves the right to amend any part of the guidance document from time to time.

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Website: <http://www.mda.gov.my>

MEDICAL DEVICE FOR THE PURPOSE OF EXPORT ONLY

1. Introduction

The importation, exportation, or placement of a medical device in the Malaysia market requires the medical device to be registered under Medical Device Act 2012 (Act 737). In accordance with the Medical Device (Exemption) Order 2024, the medical devices for the purpose of export only are exempted from registration requirements. The exporter who wishes to export the medical device from Malaysia shall submit an application for an exemption and shall comply with the requirements as determined by the Authority.

A “Medical Device for Export Only Exemption Letter” letter is issued by the Authority then permits the medical device to be exported.

The exemption letter is a mandatory document prior to applying for the Export Certificate.

2. Scope and application

This guidance document applies to all products that fall within the definition of medical device, as defined in Section 2 of Act 737 and further elaborated in the guidance document MDA/GD/0006: Definition of Medical Device, including in vitro diagnostic (IVD) medical devices.

This guidance document specifies requirements on the application for an exemption of medical devices for the purpose of export only as according to the Medical Device (Exemption) Order 2024.

This document is applicable to licensed establishments or contract manufacturer/ authorized exporter who is responsible for exporting the medical device.

3. Terms and definitions

For the purposes of this document, the terms and definitions in Act 737, Medical Device Regulations 2012 and the following apply.

3.1 Applicant

Applicant can be either a licensed establishment or contract manufacturer/ authorized exporter who is responsible for exporting the medical device.

3.2 Authority

The Medical Device Authority established under Medical Device Authority Act 2012 (Act 738).

3.3 conveyance

Conveyance includes any vessel, train, vehicle, aircraft and any other means of transport by which persons or items can be carried.

[Source: Strategic Trade Act 2010 (Act 708)]

3.4 contract manufacturer

Any physical manufacturer that manufactures a medical device under contract for the “Manufacturer” as defined in Section 2 Act 737.

Note 1 to entry: physical manufacturer means any person who performs the activity of manufacture.

[Source: ASEAN Medical Device Directive (AMDD)]

3.5 export

“Export” with its grammatical variations and cognate expressions means to take or cause to be taken out of Malaysia, by land, sea or air or to place any goods in a vessel, conveyance or aircraft for the purpose of such goods being taken out of Malaysia by land, sea or air.

[Source: Custom Act 1967 (Act 235)]

3.6 exporter

Any person by whom any goods (including goods transferred from an importing aircraft or ship) are exported from Malaysia or supplied for use as aircraft’s or ship’s stores, and also the owner, or any person acting on his behalf, and any person who for customs purposes signs any document relating to goods exported or intended for exportation or supplied or intended for supply as aircraft’s or ship’s stores as aforesaid.

3.7 medical device

As defined in Section 2 of Act 737 and guidance document MDA/GD/0006, *Definition of Medical Device*.

3.8 medical device nomenclature

Coding and naming system used to generically classify and identify all medical devices and related health products.

[SOURCE: Nomenclature of medical devices, WHO]

4. Requirements on the application for an exemption of Medical Device for the purpose of Export Only

The application for an exemption of medical devices for the purpose of export only is mandatory based on the requirements stipulated under the Medical Devices (Exemption) Order 2024. The applicant who wishes to export the medical device from Malaysia shall apply for an exemption to the Authority prior to the exportation.

4.1 Application process

4.1.1 The process flow of the application is specified as in Annex A.

4.1.2 The applicant shall submit the application by using the form as in Annex B. One application shall be made for only one single medical device nomenclature. The explanation on information/documents required in the application form is as per Table 1 below. The complete application together with the supporting document shall be submitted via [Google form](#) or email to exportonly.ec@mda.gov.my. that is accessible via this link <https://portal.mda.gov.my/index.php/industry/notification-for-export-only-medical-device>.

- 4.1.3 If, after consideration of all the information provided, the Authority considers that the information provided is incomplete, the Authority may request the missing/incomplete information from the applicant. Any additional information, particulars or documents required by the Authority shall be provided by the applicant within 14 working days from the date of request by the Authority.
- 4.1.4 If there is no response from the applicant after 14 working days from the date of return, the authority considers that applicant has no longer interest to proceed with this application. Thus, the authority may drop the application.

Table 1. Explanation on the information/ particulars required in the Application Form

PARTICULARS	EXPLANATION/REQUIREMENT
1. APPLICANT DETAILS	
Name of Establishment/company	Name of establishment/of company that is responsible for the export only medical device Note: Refer to clause 3 (3.1)
Address, post code, city & state	State the address of the company
Type of Establishment/company	Please tick appropriate type/ role of establishment/company
Establishment License Status	Does the company have an establishment license? Tick the appropriate box.
Name of person responsible, designation, telephone no. and email address.	State name and details of person responsible. Please state the name and details person responsible in the organization. Criteria for person responsible: <ol style="list-style-type: none"> 1. Shall be from top management; or 2. Person responsible shall have the overall control and have the authority to make decision; or 3. Depending on the organizational structure of the establishment, person responsible may include Proprietor, President, Vice President, Director, Chief Executive Officer (CEO), Managing Director, General Manager or Manager.
Name of contact person, designation, telephone no, & email address.	<ol style="list-style-type: none"> 1. Name and details of contact person who is in charge of making the application. 2. Contact person is the person appointed/authorised by the organisation by the person responsible, and acts as a liaison between the Authority and the organisation in relating to this notification. 3. Person responsible may also be contact person.

PARTICULARS	EXPLANATION/REQUIREMENT
4. MEDICAL DEVICE DETAILS (as in APPENDIX A)	
Medical Device Name	Name given to the medical device(s) as per label. If the application involves more than one (1) device, please complete Table 1: Medical Device List in Annex B: Medical Device for Export Only Application Form. The medical device name as stated in the Instructions for Use (IFU), brochure, or labeling provided.
Brief description	Provide a general description of the device, including variants, attributes, and indications for use.
Intended use of medical device:	Use of the medical device for which it is intended by the manufacturer, according to the data supplied by the manufacturer in the instructions for use as well as the functional capability of the device.
Medical Device Nomenclature	State the code number of GMDN, UMDNS or other code if available <small>Note: HS Code and UDI is not fall under category of Nomenclature</small>
Type of medical device	Select the type of medical device whether it is general medical device or in vitro diagnostic device
5. SUPPORTING DOCUMENTS ASSOCIATED WITH THE MEDICAL DEVICE FOR EXPORT ONLY	
Please provide following supporting document for this (these) export only medical device(s):	Attach supporting documents such as: <ul style="list-style-type: none"> i. Registrar of Companies (ROC) certificate of applicant ii. Declaration Traceability of Evidence of Conformity Attestation Template (Medical Device for Export Only) (Refer Annex C) iii. Letter of Authorization for OEM/Contract Manufacturer/Authorized Exporter issued by QMS ISO 13485 cert holder (Refer Annex D) iv. A copy manufacturer's QMS ISO 13485 certificate v. A copy of Brochure/Leaflet/Label/IFU/ that contain information on brief description and intended use. vi. A copy of establishment license (If applicable)
6. ATTESTATION & DECLARATION	
Name of Person Responsible:	Name and designation of person responsible of a company or the person having the overall control and have the authority to make decision.
Designation	

PARTICULARS	EXPLANATION/REQUIREMENT
Date	
Company stamp	

4.2 Administrative charge

A processing fee of RM 500 is applicable for each application, with the following conditions:

- a. **Invoice generation:** Invoice will be ready within 1-7 working days on the BayarNow system (<http://bayarnow.mda.gov.my>) once the complete application form is received.
- b. **Payment method:** Payments should be made online via the BayarNow portal (for registered users).
- c. **Non-refundable:** The processing fee is non-refundable, regardless of the outcome of the application.

Payment Instructions: Refer to the BayarNow Customer Portal and Payment Gateway user manual for guidance on making payments through the BayarNow system. (<https://portal.mda.gov.my/index.php/documents/ukk/2540-mda-bayar-now-user-manual-pdf/file>)

Failure to pay within 30 working days from the date of invoice issuance may result in a drop of the application and the letter(s) will not be issued by the Authority. However, it would not affect the right of the applicant to make a fresh application.

The application that the fee has been cleared, will be reviewed by the Authority if the Authority considers that all requirements have been fulfilled, the Authority will issue a Medical Device for Export Only Exemption Letter.

4.3 Issuance of Medical Device for Export Only Approval Letter

- 4.3.1 Upon receipt of completed application and clearance of payment, the Authority will issue a Medical Device for Export Only Approval Letter to the applicant within 14 days by email.
- 4.3.2 The validity period of the Medical Device for Export Only Approval Letter is five (5) years.
- 4.3.3 There is no renewal for the application for an exemption of Medical Device Export Only. Therefore, the applicant shall submit for a new application and the validity date as per the new application approved date.

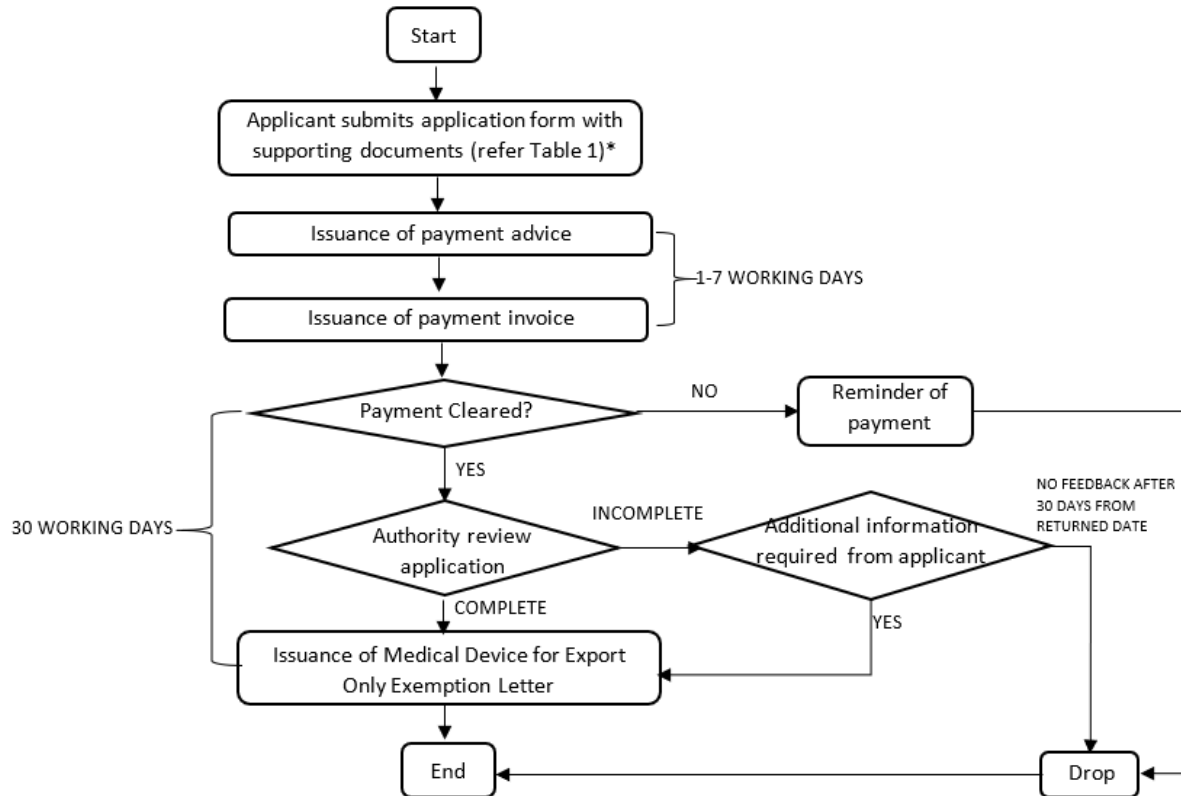
5. Conditions on Medical Device for Export Only Approval Letter

- a) The applicant shall ensure that the medical device(s) as stated in Appendix A shall not be placed in the Malaysian market unless the medical device is registered under Act 737;
- b) The applicant shall be fully responsible for ensuring that the quality, safety and performance of the medical device(s) is not adversely affected during export and storage of the medical device;
- c) All information pertaining to this medical device(s) including all supporting documents shall be kept at the premises and shall be made available upon request by the Authority;

- d) Advertising of medical device(s) as stated in Appendix A is an offence under Section 44(1), Medical Device Act 2012 [Act 737]. Any individual who commits an offence under this section can be fined up to a maximum of RM300,000 or imprisonment for a term not exceeding 3 years or to both;
- e) The Authority reserves the right to make a visit or inspection to person or establishment at any time without prior notice;
- f) The Authority may revoke the “Medical Device for Export Only Exemption Letter” if the applicant fails to comply with any conditions imposed by the Authority;
- g) Once the letter has expired or has been cancelled/withdrawn, no further exportation of the medical device, at any quantity shall be permitted; and
- h) Any other conditions may be imposed by the Authority from time to time.

ANNEX A (informative)

Process flow of the application for an exemption of medical device for the purpose of export only



**ANNEX B
(Normative)**

Medical Device for Export Only Application Form

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.		
<ul style="list-style-type: none"> ● One 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:	<input type="checkbox"/> Licensed establishment <input type="checkbox"/> Contract manufacturer <input type="checkbox"/> Authorized exporter	
Establishment License Status	<input type="checkbox"/> Establishment License available Please state the Establishment License Number: <input type="checkbox"/> No Establishment License (for contract manufacturer/authorized exporter)	
Person responsible:		
Designation:		
Phone No.:	Email address:	
Contact person:		
Phone No.:	Email address:	

MEDICAL DEVICE FOR EXPORT ONLY APPLICATION FORM

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

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. Brochure/Leaflet/Label/IFU/ that contain information on brief description and intended use.

Send your application to exportonly.ec@mda.gov.my
(Turnaround time: 14 working days with complete documentation)

4. ATTESTATION & DECLARATION

MEDICAL DEVICE FOR EXPORT ONLY APPLICATION FORM

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

I, < Name of person responsible >, 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 to be placed in the Malaysian Market and intended for export only.
- iii. All information and documents provided in this notification are true, accurate, correct, complete, and current as of this date.

I, the undersigned, hereby attest 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 Act 737)**.

***(Strikethrough accordingly)**

Signature:

Person Responsible

Name:

Designation:

Date:

Company stamp:

APPENDIX A

EXPORT ONLY MEDICAL DEVICE DETAILS

1.	Medical Device Name	: <i>Please complete table 1, if the medical devices involve more than one (1) device.</i>									
2.	Brief Description	: <i>Please complete table 1, if the medical devices involve more than one (1) device.</i>									
3.	Intended Use	: <i>Please complete table 1, if the medical devices involve more than one (1) device.</i>									
4.	Medical Device Nomenclature Code	<p>a. Nomenclature Code</p> <table border="1" data-bbox="751 824 1354 1177"> <tr> <td data-bbox="751 824 940 894">GMDN</td> <td data-bbox="940 824 978 894">:</td> <td data-bbox="978 824 1354 894"></td> </tr> <tr> <td data-bbox="751 927 940 1036">UMDNS (if applicable)</td> <td data-bbox="940 927 978 1036">:</td> <td data-bbox="978 927 1354 1036"></td> </tr> <tr> <td data-bbox="751 1036 940 1177">Other (Please specify)</td> <td data-bbox="940 1036 978 1177">:</td> <td data-bbox="978 1036 1354 1177"></td> </tr> </table> <p>b. HS Code:</p> <p>c. UDI (if applicable):</p>	GMDN	:		UMDNS (if applicable)	:		Other (Please specify)	:	
GMDN	:										
UMDNS (if applicable)	:										
Other (Please specify)	:										

5.	Type of Medical Device	<table border="1" style="width: 100%;"> <tr> <td data-bbox="751 228 1167 297">General Medical Device</td> <td data-bbox="1167 228 2030 297">In-Vitro Diagnostic Device (IVD)</td> </tr> </table>	General Medical Device	In-Vitro Diagnostic Device (IVD)
General Medical Device	In-Vitro Diagnostic Device (IVD)			

Medical Device List:

Table 1

No	Medical Device Name	Identifier (if applicable)	Brief Description	Intended Use

ANNEX C (Normative)

Template for Declaration of Compliance Attestation (Medical Device for Export Only)

Declaration of Compliance Attestation for Export Only Medical Device

Name and Address of Manufacturer

[Please print on Company Letterhead of Legal Manufacturer or QMS Certificate Holder]

Medical Device Authority

Ministry of Health Malaysia

[Date]

Dear Sir/Madam,

Subject: Declaration of Compliance for Export Only Medical Device under Medical Device (Exemption) Order 2024.

We, *[name of QMS CERT HOLDER]*, declare that the medical devices listed in Appendix 1 are for Export Only Medical Devices. Also:

- i. Not in conflict with the laws of the country to which they are intended for exportation;
- ii. Is intended for export only and not registered to be marketed in Malaysia; and
- iii. Is manufactured in accordance with the requirements of the medical device Quality Management System.

Details of Quality Management System Certificate of the QMS Certificate Holder (if applicable) QMS certificate no:	
QMS Standard:	
Issued by:	
Validity:	
The QMS documentation is available and maintained at our facility	

Yours Sincerely,

[Signature]

[Full Name and Title of Person from Company's Top Management]

[Company stamp]

Medical Device Details

No	Medical Device Name / Brand Name	Nomenclature Code

**Annex D
(Normative)**

**Template for Letter of Authorization for OEM/ Contract Manufacturer/ Authorized
Exporter**

***[To be printed on letterhead of the legal manufacturer who is the brand owner of the
medical device to be exported]***

Medical Device Authority

Ministry of Health Malaysia

[Date]

Dear Sir/Madam,

Subject: Letter of Authorization for *[name of OEM/ Contract Manufacturer/ Authorized Exporter]*

We, *[name of the foreign manufacturer]*, as the manufacturer of the medical device listed in Attachment 1, hereby authorize *[Company name (Registration Number) or Person name (IC Number) and address]*, as the *OEM/ Contract Manufacturer/ Authorized Exporter* to prepare and submit Medical Device for export only application to the Medical Devices Authority on our behalf.

We also authorize *[name of OEM/ Contract Manufacturer/ Authorized Exporter]* to make declarations and to submit documents on our behalf, regarding the above medical devices, in support of this application. These declarations and submissions are made pursuant to the requirements of the Medical Device Act 2012 (Act 737), the Medical Device Regulation 2012 and any other applicable laws that may also be in force.

This authorization shall remain in effect until our notification to the Medical Device Authority in writing that the authorization is revoked subject to any conditions imposed by the Authority.

We undertake to provide all the necessary support and assistance to the *OEM/ Contract Manufacturer/ Authorized Exporter* as may be required in relation to any matter involving the medical devices listed in Attachment 1.

We acknowledge that any non-compliance with Medical Device for Export Only Approval letter conditions issued by the Medical Device Authority may result in the suspension or cancellation of the medical device exportation.

We agree to furnish and assist the Medical Device Authority with any request for information on the above medical devices.

Yours Sincerely,

[Signature]

[Full Name]

[Designation of Senior Company Official]

[Company stamp]

MEDICAL DEVICE AUTHORITY

MINISTRY OF HEALTH, MALAYSIA

Contact Information:

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