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MEDICAL DEVICE GUIDANCE DOCUMENT

REQUIREMENTS FOR EXPORT PERMIT

Medical Device Authority
MINISTRY OF HEALTH MALAYSIA

Contents Page

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); and

b) Medical Device Regulations 2012.

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.

CONTACT INFORMATION

For further information, please contact:

MEDICAL DEVICE AUTHORITY
Ministry of Health Malaysia
Level 6, Prima 9, Prima Avenue II,
Block 3547, Persiaran APEC,
63000 Cyberjaya, Selangor,
MALAYSIA
Fax: (03) 8230 0200
Email: mdb@mdb.gov.my
Website: http://www.mdb.gov.my

REQUIREMENTS FOR EXPORT PERMIT

1. Introduction

This document is to provide guidance on the issuance of export permit under Section 45 of Medical Device Act 2012 (Act 737) and Part VI Regulation 15, Medical Device Regulations 2012 (MDR 2012).

Export permit or Certificate of Free Sale (CFS) is the certificate required by the importing country to certify that the products are already sold in the country of origin or eligible for export. The establishment may apply for an export permit or CFS depending on the requirement of the country for export.

2. Scope and application

This guidance document specifies requirements for application of medical device export permit that is issued by the Medical Device Authority (MDA). This document applies to all products that fall within the definition of medical device, as defined in MDA/GD/0006: Definition of Medical Device, including in vitro diagnostic (IVD) medical devices.

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 Authority

Medical Device Authority established under Section 3 of Medical Device Authority Act 2012 (Act 738).

4. Requirements

4.1 Qualifications to apply

An export permit is not a mandatory requirement to apply for exporting the medical device out of Malaysia. This depends on the requirement of the foreign country that request for an export permit to be issued by the Authority in Malaysia.

As provided in the Act, an export permit will be issued ONLY:

a) for medical device registered under Section 5 of Act 737; and

b) to an establishment who holds a license under Section 15 of Act 737.

Hence, an establishment who wishes to apply for an export permit shall first obtain an establishment license and register its medical device.

4.1.1 For medical device which is exempted from registration based on Medical Device (Exemption) Order 2016, notification shall be made to the Authority. In this case, if requested, MDA may issue a letter of no objection to export the medical device. Applicant may refer to relevant guidance documents on notification for medical device exempted from registration.

4.1.2 In addition to the requirements for registration and licensing, the establishment applying for an export permit shall be a manufacturer or an authorised representative as defined in Section 2 of Act 737, or its authorised agent.

4.2 Application process

Application for an export permit under Section 45 of Act 737 for its registered medical device shall be made using the Form in Annex A. Table 1 shows the information and documents required for application of an export permit.

4.2.1 Any additional information, particulars or documents required by the authority shall be provided by the applicant within 30 days from the date of request by the authority.

4.2.2 Each application for export permit shall be dedicated to only one medical device registration certificate. One application can be:

a) for one registered group of medical device in one medical device registration certificate; or

b) applicable for few selected medical devices within a grouping in one MD registration certificate.

4.2.3 Each application can be for more than one country for export, but individual export permit shall be issued for each requested country.

Table 1. Filling in the form for the application of medical device export permit

INFORMATION REQUESTED	EXPLANATION	DOCUMENTS TO BE SUBMITTED
PART A: PARTICULARS OF ESTABLISHMENT		
(1) Establishment license number	(i) Establishment license number as appear in the license. (ii) An establishment applying for an export permit shall be a	Copy of Establishment License

INFORMATION REQUESTED	EXPLANATION	DOCUMENTS TO BE SUBMITTED
	manufacturer or an authorised representative as defined in Section 2 of Act 737.	
(2) Contact person and address of establishment	(i) Name of contact person and the address of establishment making the application. (ii) The contact person shall be the same contact person as in the establishment license.	
(3) Authorised agent name and business address (if applicable)	(i) Name and business address the agent authorised by the establishment if the exportation is to be done by the agent. (ii) The establishment shall issue letter to authorise the agent to export the medical device on its behalf. (iii) Authorised agent can be the shipping agent, distributor or exporter of the medical device.	Letter of authorisation from establishment on company letterhead for the authorised agent stating name, address and contact number of the agent.
PART B: PARTICULARS OF MEDICAL DEVICE		
(4) Medical device registration number	Registration number for the medical device to be exported as appear in the medical device registration certificate.	Copy of medical device registration certificate
• Type and class of device	Whether the medical device is a general or IVD medical device and the class based on risk based classification according to classification rules in First Schedule of MDR2012.	
• Classification rules	The rule applied according to classification rules in First Schedule of MDR2012.	
• Generic name	Generic, non-proprietary name given to the medical device	
• Manufacturer specified name	The name should reflect the proprietary name registered and trademarked by the manufacturer. It may also address the brand and model of the device.	
• Intended use of the medical device	The intended use of the medical device as detailed out in the CSDT (refer to the Guidance Document on Common Submission Dossier Template (MDA/GD/0008).	
• Device description	The description of the medical device as detailed out in the CSDT (refer to the Guidance Document on Common Submission Dossier Template (MDA/GD/0008).	

INFORMATION REQUESTED	EXPLANATION	DOCUMENTS TO BE SUBMITTED
• Grouping of medical device	Grouping of medical device according to grouping rules as specified in Second Schedule of MDR2012.	
• Name of manufacturer	Name of the manufacturer in accordance with the definition of manufacturer in Section 2 of Act 737.	
• GMDN category	According to the listed category.	
PART C: PARTICULARS OF EXPORT		
(5) Country requesting	Country(s) where the medical device is to be exported to.	
(6) Quantity/number and value	Estimated quantity in number, weight/volume and its estimated value in RM (selling price).	
(7) Place/port of loading	Port/place where the medical device is to be exported.	

4.3 Issuance of export permit

4.3.1 Upon receipt of completed application, the authority will issue a payment advice to the applicant as follows:

a) All applications will be charged RM 100 per export permit issued (for one country);

b) Listing of medical devices to the export permit will be limited to 25 medical devices per attachment page (list of medical device) and additional attachment pages will be charged RM5.00 per page (font shall be Arial minimum size 10, refer Annex B); and

c) Calculation example :

[[RM100 + (RM5 X No. of additional attachments)] X No. of Countries] X No. of copies = Total to be paid

	No. of Countries	No. of additional attachments	No. of copies	Total
Example 1	2	0	1	[[RM100+(RM5X0)] X 2] X1 = RM 200
Example 2	2	5	1	[[RM100+(RM5X5)] X 2] X1 = RM 250
Example 3	2	5	2	[[RM 100 +(RM5X5)]X2] x 2 = RM 500

4.3.2 After receipt of payment, the Authority will issue the export permit to the applicant. Processing time for issuance of export permit is approximately 20 working days from receipt of payment and submission of complete documents.

4.3.3 Validity for export permit is 2 years.

Annex A
(normative)

Application Form for Export Permit

This Form MDA1 is made pursuant to regulation 15 of the Medical Device Regulations 2012 for the purpose of application for export permit under Medical Device Act [*Act 737*].

This application form shall be completed and submitted together with an application fee as prescribed in Fifth Schedule of the Medical Device Regulations 2012 to—

Chief Executive
Medical Device Authority
Level 6, Prima 9, Prima Avenue II,
Block 3547, Persiaran APEC,
63000 Cyberjaya, Selangor, Malaysia
Tel Number: 03-8230 0300
Fax Number: 8230 0200

Notes:

Please read carefully before filling the form.

(1) Please note that general information may be included in Medical Device Register and uploaded to the Authority's website if this application is approved

(2) Please check the boxes as appropriate

(3) Please note that the submitted information may be forwarded to third parties (such as but not limited to foreign regulatory authority or conformity assessment body) for validation purposes

(4) All relevant certificates where necessary shall be notarized

FOR OFFICIAL USE ONLY

Date received_____ Application no. _____ Officer _____

Date approved/rejected _____

PART A: PARTICULARS OF ESTABLISHMENT

1. Establishment license no.: _____

2. Contact person and address of establishment:

_____
_____
_____
_____

3. Authorised agent name and business address (if applicable):

_____
_____
_____
_____

PART B: PARTICULARS OF MEDICAL DEVICE

4. Medical device registration no. : _____

Type of Device (please tick (√) the appropriate box):

[ ] General device

[ ] *In-vitro* diagnostic device (IVD)

Class of Device (please tick (√) the appropriate box):

[ ] Class A

[ ] Class B

[ ] Class C

[ ] Class D

Classification Rules: _____

Generic name: _____

Manufacturer specified name: _____

Intended use of device: _____

Device description: _____

Grouping of medical device (please tick (√) the appropriate box):

[ ] Single

[ ] System

[ ] Family

[ ] Set

[ ] IVD Test Kit

[ ] IVD Cluster

Name of manufacturer: _____

GMDN Category (please tick (√) the appropriate box):

[ ] 01 – Active implantable devices

[ ] 02 – Anesthetic and respiratory devices

[ ] 03 – Dental Devices

[ ] 04 – Electro mechanical medical devices

[ ] 05 – Hospital hardware

[ ] 06 – In vitro diagnostic devices

[ ] 07 – Non-active implantable devices

[ ] 08 – Ophthalmic and optical devices

[ ] 09 – Reusable devices

[ ] 10 – Single-use devices

[ ] 11 – Assistive products for persons with disability

[ ] 12 – Diagnostic and therapeutic radiation devices

[ ] 13 – Complementary therapy devices

[ ] 14 – Biologically-derived devices

[ ] 15 – Healthcare facility products and adaptations

[ ] 16 – Laboratory equipment

[ ] 17 – Medical software

[ ] 18 – Others: Please specify with justification for any additional categories

GMDN Code: _____

PART C: PARTICULARS OF EXPORT

5. Country requesting:

_____

_____

6. Quantity/number and value (RM): _____

7. Place/port of loading:

☐ Lapangan Terbang Antarabangsa Kuala Lumpur 1
☐ Lapangan Terbang Antarabangsa Kuala Lumpur 2
☐ Lapangan Sultan Abdul Aziz Shah Subang
☐ Pelabuhan Pulau Pinang
☐ Pelabuhan Klang
☐ Pelabuhan Johor Pasir Gudang
☐ Pelabuhan Tanjung Pelepas Johor
Others (please specify): ……

Annex B
(normative)
Attachment for Export Permit Application

The table below shall be completed and submitted together with the application for export permit.

MEDICAL DEVICE(S) LIST:

NO.	NAME OF THE MEDICAL DEVICE	DETAIL(S) OF PRODUCT	MEDICAL DEVICE REGISTRATION NO.
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			
13			
14			
15			
16			
17			
18			
19			
20			
21			
22			
23			
24			
25			

- *This permit is valid for 24 MONTHS from the date of issue.*

MDA/GD/0024

MEDICAL DEVICE AUTHORITY

MINISTRY OF HEALTH, MALAYSIA

Contact Information:

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Ministry of Health Malaysia
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