MDA/GD/0018-4020

Nov 2017

Public comment

DRAFT MEDICAL DEVICE GUIDANCE DOCUMENT

IMPORT AND/OR SUPPLY OF UNREGISTERED MEDICAL DEVICES FOR THE PURPOSE OF DEMONSTRATION FOR MARKETING OR EDUCATION

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 incident 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 5, Menara Prisma,
No. 26, Jalan Persiaran Perdana,
Precint 3, 62675 Putrajaya,
MALAYSIA
Fax: (03) 8892 2500
Email: mdb@mdb.gov.my
Website: http://www.mdb.gov.my

IMPORT AND/OR SUPPLY OF UNREGISTERED MEDICAL DEVICES FOR THE PURPOSE OF DEMONSTRATION FOR MARKETING OR EDUCATION

1. Introduction

The Authority frequently receives inquiries regarding the importation of unregistered medical device to be used as trade show exhibits for promotional purposes in Malaysia.

The Medical Device (Exemption) Order 2016 has been gazetted on 18 April 2016 has provided an exemption from registration for medical devices for the purpose of demonstration for marketing and for the purpose of education. The exhibits are usually imported for a short period and may be exported to another trade show in another country or back to the country of origin; or destroyed following the conclusion of the event.

Prior to supplying a device potentially eligible for exemption the manufacturer or importer of the device must submit a notification to Medical Device Authority for an exemption. An acknowledgement on the notification in the form of a "No Restriction Letter" issued by the Authority then permits the device to be supplied or imported lawfully for the specific defined use.

This guidance document explains the process of notification, including the requirements for obtaining the permission from the Authority to import and/or supply these medical devices. It also specifies the responsibilities and obligations of the importer/manufacturer when dealing with this category of medical device.

2. Scope and application

This guidance document specifies requirement on notification for importation and/or supply of medical devices intended solely for the purpose of demonstration for marketing or for the purpose of education. It applies to all applicants who wish to import and/or supply these medical devices, of any risk classification into Malaysia.

3. Terms and definitions

For the purposes of this document, the terms and definitions in ACT 737, the regulations under it and the following terms and definitions apply.

3.1 applicant

Applicant can be either local applicant; or local authorized representative of a foreign applicant; or who can be a local organization or company or local person who imports and/or supply medical device for the purpose of demonstration for marketing or for the purpose of education.

3.2 Authority

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

3.3 export

Means to bring or cause to be brought out of Malaysia

3.4 import

means to bring or cause to be brought a medical device manufactured in another country or jurisdiction, into Malaysia by land, sea or air

3.5 medical device

a) Any instrument, apparatus, implement, machine, appliance, implant, *in-vitro* reagent or calibrator, software, material or other similar or related article intended by the manufacturer to be used, alone or in combination, for human beings for the purpose of:

(i) diagnosis, prevention , monitoring, treatment or alleviation of disease;

(ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury;

(iii) investigation, replacement or modification, or support of the anatomy or of a physiological process;

(iv) support or sustaining life

(v) disinfection of medical device; or

(vi) providing information for medical or diagnostic purpose by means of *in-vitro* examination of specimens derived from the human body which does not achive its primary intended action in or on the human bosy by pharmacological, immunological or metabolic means, but that may be assisted in its intended function by such means; and

b) any instrument, apparatus, implement, machine, appliance, implant, *in-vitro* reagent or calibrator, software, material or other similar or related article, to be used on the human body, which the Minister may, after taking into consideration issues of public safety, publis health or public risk, declare to be a medical device by order published in the *Gazette.*

3.6 place in the market

Means to make available a medical device in return for payment or free of charge with a view to disturbing, using, supplying or putting in 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.

4. Eligibility for notification of exemption

Under Medical Device (Exemption) Order 2016, the Minister exempts for six categories of medical device from section 5 of the Act 737. But for the purpose of this guidance, only two categories are describe, as per Table 1

Table 1. Description of medical devices for demonstration and education purposes.

No.	Category of exemption	Description
1.	Medical device for the purpose of demonstration for marketing.	The importation and/or supplying of medical devices for an activity purely intend for : 1. Direct presentation or explanation to medical officer ; 2. Exhibits or display in trade shows, fairs, and exhibitions.
2.	Medical device for the purpose of education.	The importation and/or supplying of medical devices for an activity purely intend for teaching, training or educating people.

5. Notification process

Any person who wishes to import and/or supply of a medical device for the purpose of demonstration for marketing or education shall notify the Authority by following the steps as summarized in Annex A.

5.1 Confirm product as a medical device

The applicant is responsible to confirm that the products are medical devices. Such products which do not meet the medical device definition are not eligible for this requirement.

The applicants who require confirmation if their product is a medical device may refer to guidance document MDA/GD-01 *Definition of Medical Device* or submit the 'Product

Classification application form' to classification@mdb.gov.my to determine the classification of the products. The guidance document and form are available to be downloaded at MDA website www.mdb.gov.my.

5.2 Submission of notification

5.2.1 New application

a) Notification shall be submitted to the Authority at least 4 weeks prior to importation or supplying the medical device;

b) The applicant shall submit together with the notification form (refer Annex B), required supporting documents to the Chief Executive, Medical Device Authority (MDA) by email at bpt@mdb.gov.my ;

c) The form for 'Notification of Medical Device for the purpose of Demonstration for Marketing or for Education Purpose' is published in the Authority website at www.mdb.gov.my ;

d) For medical device for the purpose of demonstration, each notification submitted can be for more than one medical device and location, however this permission is valid only for a maximum of 60 days from the date of importation;

e) For medical device for the purpose of education, each notification applies only for one importation or supply; and

f) Quantity of medical device to be imported shall be appropriate to the declared purpose and the applicant shall provide justification or description on this requirement.

5.2.2 Subsequent application

A subsequent application may be made of any applicant who wish to request for extension of demonstration period after the expiry of the first notification. This process follows the same procedure as described in new application except that certain information e.g. supporting document for medical device may not be required.

Any subsequent application shall be submitted at least 2 weeks before the dateline of the first notification. Permission for subsequent application is granted only to a maximum of 60 days and demonstration location shall be different from the first notification.

Table 2 : Explanation on the information/particulars required in the Notification Form

Information/ Particulars	Explanation & Documents to be Submitted
Education	Request notification for the purpose of education.
Demonstration for marketing	Request notification for the purpose of demonstration for marketing.
New	First or fresh application.
Subsequent application	Application made for extension of demonstration period for a different demonstration location
Notification ID	Identification number assigned by the Authority in the Acknowledgement on Notification.
Ref. No.	Reference number assigned by the Authority in the Acknowledgement on Notification.
Name of person responsible, NRIC/ Passport no. & designation	Name and details of top management of a company or the person having the overall control and have the authority to make decision.
Name of contact person, telephone no. & email	Name and details of person in charge of making the application.
Name of device, components, accessories or reagents	Name given to the medical device(s) as per label.
Brand/ Model	Name, term, design, symbol, or any other feature or identifier of a medical device given by its manufacturer that identifies a manufacturer's medical device distinct from those of other manufacturers.
Manufacturer	Name of manufacturer. Note: Manufacturer according to manufacturer term as specified in Section 2, Act 737 and it appears on the device label.
Serial Number	A number that is one of a series and is used for identification, for an individual medical device and it appears on the label.
Batch Number	A number used for identification to a particularly quantity or lot of disposable or consumable medical device from a same manufacturer and it appears on the label.

Device Intended Use	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.
Device Class Risk & Rule	The risk associated with medical device according to the Classification Rules in First Schedule of MDR2012. Note.The applicant who require further guidance on the classification may refer to the following documents— a) MDA/GD-04: *Guidance on The Rules of Classification for General Medical Devices*; b) MDA/GD/IVD-1: *In-Vitro Diagnostic (IVD) Medical Device Classification System*. The guidance documents are available at MDA website www.mdb.gov.my
Marketing Approval Status	Status of pre-market clearance/approval from foreign countries.
Attestations & Declaration	A sworn declaration which recites duties, responsibilities and obligations of applicant and shall be made by person responsible.
Demonstration	
Period of demonstration	Period of medical device to be used for demonstration. Maximum period is 60 days.
Demonstration date	Date of the event to be held.
Type of event	Activity purely intend for demonstration/presentation or exhibits in trade shows, fairs, and exhibitions. Please provide event details, e.g. brochures, official website, or letter.
Demo location (Name & address)	Specific location of the event.
Quantity Supplied/Location or Quantity to be imported/ supplied	Total quantity of device per location. Provide justification or description on this requirement.

Education	
Name & location address	Specific instituition name and address for the medical devices to be installed/supplied.
Department/ Faculty/ School	Specific name of department, faculty or school of the user of medical device
Person In-charge Name & Contact Number	Name and contact number of the user of medical device.
Justification	State reason on why it has to be the specific medical device and list/ make comparison with medical devices already available in the Malaysian market.

5.3 Verification with other controlling agencies.

The notification to the Authority does not exempt the applicant from abiding to any other law or regulations in Malaysia.

For example:

a) Refer to the Royal Malaysian Customs department for more information about the importation procedures; and

b) Refer to Atomic Energy Licensing Board (AELB) for more information about application for irradiating apparatus demonstration/exhibition procedure.

6. Review of the notification

Upon receipt of notification, the authority will issue a payment advice to the applicant as all notifications shall be accompanied with a fee of RM XXX per notification which shall be made using bank draft payable to “Kumpulan Wang Pihak Berkuasa Peranti Perubatan”.

The Authority will review the information and make an assessment of the documentation provided against the following criteria:

a) Is the product being notified a medical device according to the definition of “medical device” in Section 2 of Act 737?;

b) Does the medical device meet the criteria and eligible for the exemption?;

c) Is the information submitted complete and appropriate?;

d) Does the applicant have any unresolved issues related to contravention of Act 737 or breach any terms and conditions from previous notifications?; and

e) Have all relevant fields in the form been completed and relevant documents submitted?.

If, after consideration of all the information provided, the Authority considers that all the above set criteria have been fullfill, the Authority will notify the applicant within (14) days, of its decision and issue an Acknowledgement on Notification permitting the applicant to import and/or supply the medical device.

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 fourteen (14) days from the date of request by the Authority.

Failure to meet any of the criteria and/or to reply within the specified timeframe may result in rejection of the application. The fee for the notification is non refundable. However it would not affect the right of the applicant to make a fresh application provided that these grounds have been addressed.

Acknowledgement on Notification does not constitute an approval for the importation of medical device for commercial release or be place in the Malaysian market and shall not be used for the purpose of promoting or advertising of the product. The advertising of any unregistered medical device is strictly prohibited under Section 44, Act 737.

The Authority has the right to withdraw a written Acknowledgement on Notification if in its opinion, there has been a breach or non-compliance with the specified terms and conditions and/or duties and responsibilities of the applicant.

7. Duties and responsibilities of applicant

The applicant shall be fully responsible for handling the unregistered medical device during the period of the demonstration for marketing or for the purpose of education, including:

a) used only in accordance with the purpose as declared in the Notification submission;

b) appropriately label the medical device according to the requirement in the Sixth Schedule of the MDR 2012 and MDA/GD/0026, *Guidance Document on Requirement for Labelling of Medical Devices*;

c) ensuring that the medical devices are not used on human or used to provide result or information to support or reject any patient's diagnosis/treatment;

d) ensure proper handling of the medical devices;

e) comply with any directions issued by the Authority from time to time and allow for inspection

from Authority at any time without prior notice;

f) keep all information pertaining to this unregistered medical device at the premises and shall be made available upon request by the Authority at any time; and

g) report to the Authority any incident related to the device(s) that comes to the applicant's attention.

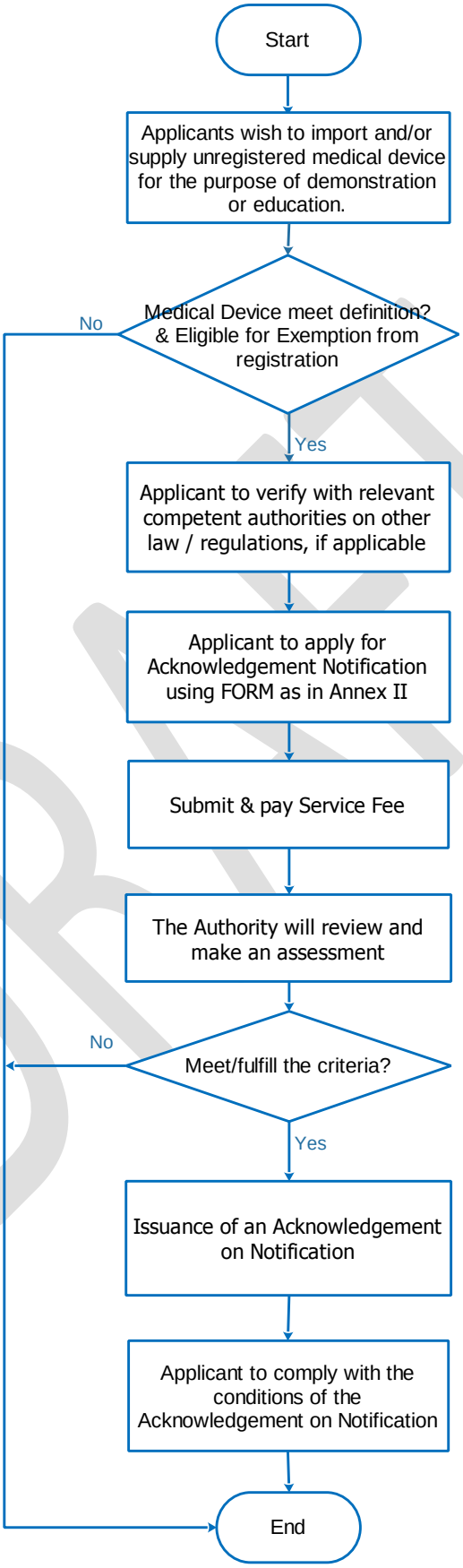
8. Post handling of medical devices for the purpose of demonstration

After the demonstration activity is over:

a) the applicant shall ensure that these medical devices are properly disposed of, or export out of Malaysia; and

b) the applicant shall submit *'Dispose or Exported Out of Malaysia' Notice Form for Unregistered Medical Device* to the Authority, via email/ post/ fax BUT it shall reach the Authority no later than 30 days from end of the demostration.

ANNEX A



ANNEX B

	NOTIFICATION OF MEDICAL DEVICE FOR : *(In accordance with Medical Device (Exemption) Order 2016)* ■ **DEMONSTRATION FOR MARKETING; OR** ■ **THE PURPOSE OF EDUCATION**

Please complete all section of this *form. *Please tick the appropriate boxes accordingly*

TYPE OF APPLICATION*	
☐ **Education**	
☐ **Demonstration for marketing** :	
☐ New	☐ Subsequent application; Please state previous Notification ID:-

DETAILS OF APPLICANT	
Name of Person Responsible: *(Top Management)*	
NRIC/Passport Number:	Designation:
Name of Contact Person:	
Telephone No.:	Email:
Company/Organization Name:	
Company/Organization Address:	
City:	State:

Role of Establishment*

If your company hold an "establishment license" according to the type of establishment in Section 2 Act 737, please select type of license and state license number :-

☐ Manufacturer - License No. _____

☐ Authorized Representative - License No. _____

☐ Distributor / Importer - License No. _____

MEDICAL DEVICE INFORMATIONS	
1. Please provide details of the medical device according to **Appendix A1 (Demonstration) or A2 (Education).** 2. For **new** application, please provide supporting document for medical device: Sample of device label and promotional material (such as brochure, pamphlet or catalogue).	
ATTESTATIONS & DECLARATION *(Please read carefully & tick as appropriate)*	
I, the undersigned, hereby attest and declare that:	
☐	The product(s) indicated on this application is/are medical device(s) according to the definition of "medical device" set out in Section 2, Medical Device Act 2012 (Act 737).
☐	I shall not import and/or supply unregistered medical device(s) as in Appendix A1 or A2 prior to obtaining Acknowledgement on Notification from the Authority.
☐	I shall import and/or supply unregistered medical device(s) as in Appendix A1 or A2 only for the purpose stated in this application only.
☐	I shall not use the unregistered medical device(s) as in Appendix A1 or A2 on a human or use to provide result or information to support or reject the patient's diagnosis/treatment.
☐	I shall appropriately label the medical device(s) "**For Demonstration or Education Purpose Only. Not For Use On Human**".
☐	I shall comply fully with the terms and conditions imposed in the Acknowledgement on Notification by the Authority.
☐	I am aware that advertising of any unregistered medical device is strictly prohibited under Section 44, Act 737.
☐	I shall verify with relevant competent authorities on any other law or regulations in Malaysia, if applicable (i.e. Royal Malaysian Customs, Atomic Energy Licensing Board, etc)
☐	For the purpose of demonstration for marketing, I shall ensure that the unregistered medical device(s) as in Appendix A will properly dispose of or destroyed or exported out of Malaysia within the timeframe stipulated by the Authority.
☐	The information and attachment provided on this notification is/are 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 be liable to a fine not exceeding RM 500,000.00 or to imprisonment for a term not exceeding 3 years or to both.
Signature:	
Name:	
Company stamp: Date:	

Please return this form to :

Chief Executive Medical Device Authority
Email : bpt@mdb.gov.my

Medical Device AUTHORITY MALAYSIA	**APPENDIX A1** **MEDICAL DEVICE INFORMATION & EVENT DETAILS** ***(medical device for the purpose of demonstration for marketing)***

Event details

Period of Demonstration:
(Max 60days)

No.	Demonstration Date	Type of Event *(please provide event details e.g. brochures, official website, letter etc)*: ❖ Trade show, fair or exhibition ❖ Presentation / Explanation	Demo location (Name & address)	Quantity Supplied/Location *(Provide separate justification / description on this requirement)*

Medical Device details

No.	Name of device, components, accessories or reagents as per product label:	Brand/ Model & Manufacturer	Serial Number/ Batch No	Device Intended use	Class & Rule *(according to Medical Device Regulation 2012)*	State Marketing Approval Status in other country(-ies) ❖ Registered ❖ Exempted/Self-declared

APPENDIX A2

MEDICAL DEVICE INFORMATION & EDUCATION CENTRE DETAILS

(medical device for the purpose of education)

Education/training Centre details

Name & location address : _____

Department /Faculty/School : _____

Person In-charge Name & Contact Number : _____

Justification : _____
(Please make separate attachment if required)

Medical Device details

No.	Name of device, components, accessories or reagents as per product label:	Brand/ Model & Manufacturer	Device Intended use	Class & Rule *(according to Medical Device Regulation 2012)*	Quantity to be imported/ supplied	State Marketing Approval Status in other country(-ies) ❖ Registered ❖ Exempted/Self-declared

MEDICAL DEVICE AUTHORITY

MINISTRY OF HEALTH, MALAYSIA

Contact Information:

MEDICAL DEVICE AUTHORITY
Ministry of Health Malaysia
Level 5, Menara Prisma,
No. 26, Jalan Persiaran Perdana,
Precint 3, 62675 Putrajaya,
MALAYSIA
T: (03) 8892 2400
F: (03) 8892 2500
Website: www.mdb.gov.my