

**MDA/GD/0018
February 2018
First Edition**

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	iii
1 Introduction	1
2 Scope and application	1
3 Terms and definitions	1
4 Eligibility for notification of exemption	3
5 Notification process	3
5.1 Confirm product as a medical device	4
5.2 Submission of notification	4
5.2.1 New application	4
5.2.2 Subsequent application	5
5.3 Verification with other controlling agencies	7
6 Review of the notification	7
7 Duties and responsibilities of applicant	8
8 Post handling of medical devices for the purpose of demonstration	9
Annex A (informative) flow chart for notification process	10
Annex B (normative) notification of medical device for: demonstration for marketing; or the purpose of education	11
Appendix A1 (normative) medical device for the purpose of demonstration for marketing	13
Appendix A2 (normative) medical device for the purpose of education	14
Annex C (normative) post handling notice to mda: 'disposed of or destroyed; or exported out of malaysia' of unregistered medical device	15

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 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>

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 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 date of importation

Date on which the medical device arrives within the limits of the port in Malaysia with intent then and there to unlade such merchandise.

3.4 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 incident

means any malfunction or deterioration in the characteristics or, performance of medical device or inadequacy in its labelling, which either has caused or could have caused or contributed to death or a serious deterioration in health of the patient, user or third party

3.6 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 body 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, public 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 distribution, 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 the Medical Device (Exemption) Order 2016, medical devices for the purpose of demonstration for marketing and for the purpose of education has been exempted from registration with the Authority. The medical device as described in Table 1 are eligible for notification of exemption.

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

An applicant 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/0006 *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 one month (30 days) prior to importation or supplying the medical device;
- b) The applicant shall submit the notification form (refer to Annex B) together with required supporting documents to the Chief Executive of 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 devices and locations, however this permission is valid only for a maximum of 90 days from the date of importation;
- e) For medical device for the purpose of education, multiple shipments are allowed for the approved quantity of medical device in the notification;
- f) With related to 5.2.1 (e), there shall be no similar medical device available in Malaysia market. The applicant shall 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; and
- g) 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.

Note. All periods are in calendar days unless specified as working days

5.2.2 Subsequent application

- a) 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.
- b) Any subsequent application shall be submitted at least fourteen (14) working days before the expiry date of the first notification. Permission for subsequent application is granted only to a maximum of 90 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	Top Management is the person responsible having the overall control and have the authority to make decision. Depending on the organization structure of the establishment. Person responsible includes Proprietor, President, Vice President, Director, Chief Executive Officer (CEO), Managing Director or General Manager. The top management may appoint a personnel to sign on his/her behalf. An appointment letter shall be furnished for this purpose.
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 distinguishable 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.
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/0009: <i>Guidance on The Rules of Classification for General Medical Devices</i> ; b) MDA/GD/0001: <i>In-Vitro Diagnostic (IVD) Medical Device Classification System</i> . 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 90 days from the date of importation.
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. The applicant need to declare all possible locations. Only locations declared in the notification is allowed. It is permissible that demonstration is not carried out in any of declared location.
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 institution name and address for the medical devices to be installed/supplied.
Department/ Faculty/ School/Training centre	Specific name of department, faculty, school or training centre where the medical device will be placed.
Person In-charge Name & Contact Number	Name and contact number of the person in charge of the facility administration.
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

6.1 Upon receipt of notification, the authority will issue a payment advice to the applicant. Each notification shall be subject to a of RM 300.

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

- a) the product is a medical device as according to the definition of “medical device” in Section 2 of Act 737;
- b) the medical device is eligible for exemption;
- c) the documents and information submitted are complete; and
- d) no breach of previous notifications.

6.3 If, after consideration of all the information provided, the Authority considers that all the above set criteria have been fulfilled, the Authority will notify the applicant within fourteen (14)

working days, of its decision and issue an Acknowledgement on Notification permitting the applicant to import and/or supply the medical device.

6.4 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) working days from the date of request by the Authority.

6.5 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.

6.6 Acknowledgement on Notification does not constitute an approval for the importation of medical device to be placed in the Malaysian market or distributing free sampel.

6.7 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

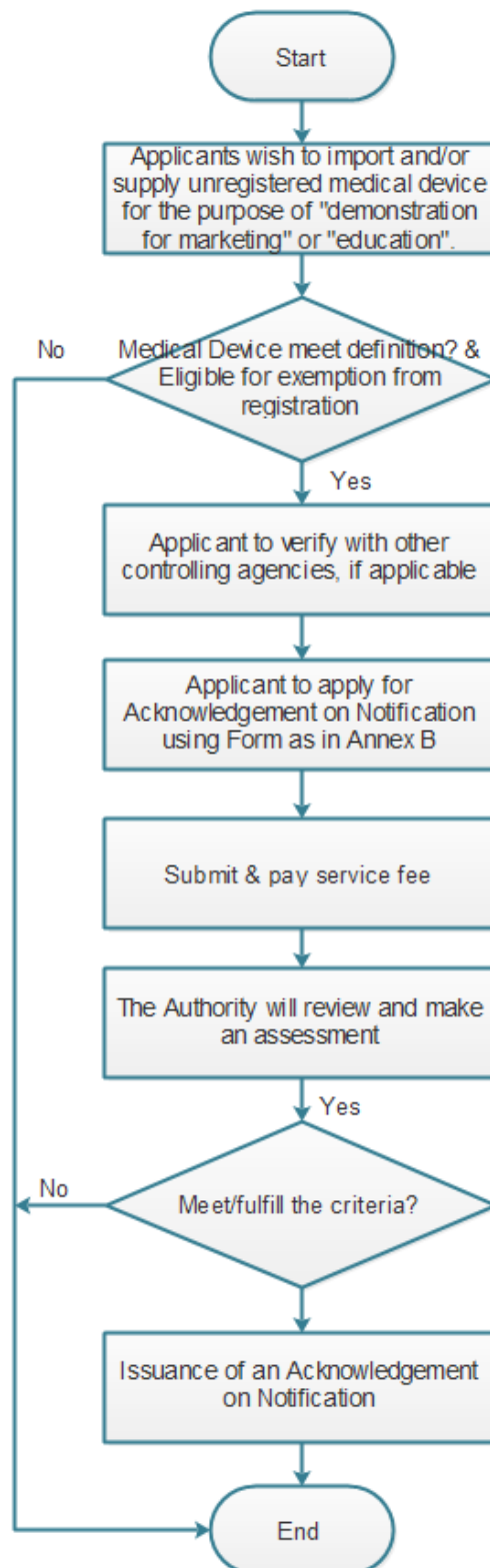
The applicant shall be fully responsible for handling the unregistered medical device during the period of the demonstration for marketing or for the purpose of education, including:

- a) used only in accordance with the purpose as declared in the Notification submission;
- b) medical devices shall be prominently indicated with labels or signage “For Demonstration or Education Purpose Only. Not For Use On Human”
- 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 demonstration. Refer Annex C. A letter of "No restriction to export" will be issued by the Authority for exportation of these medical device.
- c) the applicant shall keep relevant record as a proof for the disposal or exported out of those medical device.

**ANNEX A
(informative)**

ANNEX B
(normative)

	<p>NOTIFICATION OF MEDICAL DEVICE FOR : <i>(In accordance with Medical Device (Exemption) Order 2016)</i></p> <p>- DEMONSTRATION FOR MARKETING; OR - THE PURPOSE OF EDUCATION</p>
<p><i>Please complete all section of this form. *Please tick the appropriate boxes accordingly</i></p>	
<p>TYPE OF APPLICATION* <i>(Please tick one only)</i></p>	
<p><input type="checkbox"/> Education</p>	
<p><input type="checkbox"/> Demonstration for marketing :</p>	
<p><input type="checkbox"/> New</p>	<p><input type="checkbox"/> Subsequent application; Please state previous Notification ID:-</p>
<p>DETAILS OF APPLICANT</p>	
<p>Name of Person Responsible: <i>(Top Management)</i></p>	
<p>NRIC/Passport Number:</p>	<p>Designation:</p>
<p>Name of Contact Person:</p>	
<p>Telephone No.:</p>	<p>Email:</p>
<p>Company/Organization Name:</p>	
<p>Company/Organization Address:</p>	
<p>City:</p>	<p>State:</p>
<p>Role of Establishment*</p> <p>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 :-</p> <p><input type="checkbox"/> Manufacturer - License No. _____</p> <p><input type="checkbox"/> Authorized Representative - License No. _____</p> <p><input type="checkbox"/> Distributor / Importer - License No. _____</p>	

MEDICAL DEVICE INFORMATIONS	
<p>1. Please provide details of the medical device according to Appendix A1 (Demonstration) or A2 (Education).</p> <p>2. For new application, please provide supporting document for medical device: Sample of device label and promotional material (such as brochure, pamphlet or catalogue).</p>	
ATTESTATIONS & DECLARATION	
<i>(Please read carefully & tick as appropriate)</i>	
I, the undersigned, hereby attest and declare that:	
<input type="checkbox"/>	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).
<input type="checkbox"/>	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.
<input type="checkbox"/>	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.
<input type="checkbox"/>	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.
<input type="checkbox"/>	I shall appropriately and prominently label the medical device(s) " For Demonstration or Education Purpose Only. Not For Use On Human ".
<input type="checkbox"/>	I shall comply fully with the terms and conditions imposed in the Acknowledgement on Notification by the Authority.
<input type="checkbox"/>	I am aware that advertising of any unregistered medical device is strictly prohibited under Section 44, Act 737.
<input type="checkbox"/>	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)
<input type="checkbox"/>	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.
<input type="checkbox"/>	The information provided on this application is accurate, correct, complete and current to this date. I understand and acknowledge that it is an offence to make signs or furnish any declaration, or other document which is untrue, inaccurate or misleading as required by Section 76 of Medical Device Act 2012 (Act 737).
Signature: (person responsible or appointed personnel by top management)	
Name:	
Company stamp: Date:	

Please return this form to :

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



APPENDIX A1
MEDICAL DEVICE INFORMATION & EVENT DETAILS
(medical device for the purpose of demonstration for marketing)

Event details

Period of Demonstration:
 (Max 90 days from date of
 importation)

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

Medical Device details

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

**ANNEX C
(normative)**

		<p align="center">POST HANDLING NOTICE TO MDA : 'DISPOSED OF OR DESTROYED; OR EXPORTED OUT OF MALAYSIA' OF UNREGISTERED MEDICAL DEVICE</p>	
Please complete all information requested on this form.			
Please state Acknowledgement on Notification information:-			
Notification ID:			
PARTICULARS OF MEDICAL DEVICE(S) (Repeat as needed)			
Name Of Device (incl. accessories, components, etc)	Device details (i.e Manufacturer, Brand and Model)	Qty Import	Qty & Mode used: Disposed/ Destroyed/ Exported Out
DECLARATION (Please read carefully & tick the boxes)			
I, the undersigned, hereby declare that:			
<input type="checkbox"/>	The demonstration event is over and all medical devices involved are properly disposed of or destroyed; or exported out of Malaysia.		
<input type="checkbox"/>	The information provided on this application is accurate, correct, complete and current to this date. I understand and acknowledge that it is an offence to make signs or furnish any declaration, or other document which is untrue, inaccurate or misleading as required by Section 76 of Medical Device Act 2012 (Act 737).		
Signature:			
Name:		Designation:	
Company stamp: Date:			

Please return this form to :

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

MEDICAL DEVICE AUTHORITY

MINISTRY OF HEALTH, MALAYSIA

Contact Information:

MEDICAL DEVICE AUTHORITY
Ministry of Health Malaysia
Level 6, Prima 9, Prima Avenue II,
Block 3547, Persiaran APEC,
63000 Cyberjaya, Selangor,
MALAYSIA
T: (03) 8230 0300
F: (03) 8230 0200
Website: <http://www.mdb.gov.my>

