

MEDICAL DEVICE GUIDANCE DOCUMENT

IMPORTATION OF MEDICAL DEVICE FOR PERSONAL USE



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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;
- c) Medical Device (Duties and Obligations of Establishments) Regulations 2019; and
- d) Medical Device (Advertising) Regulations 2019.

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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IMPORTATION OF MEDICAL DEVICE FOR PERSONAL USE

1. Introduction

Importation and placement of a medical device in the Malaysian market requires the medical device to comply with the requirements of the Medical Device Act 2012 (Act 737), and the medical device shall be registered with the Medical Device Authority (MDA) under Section 5 of Act 737. However, the Medical Device (Exemption) Order 2016 has provided an exemption from medical device registration and establishment license requirements for personal use medical devices.

This document serves as guideline for individuals who intend to bring any medical devices into Malaysia (hereinafter referred as “import”) for the purpose of personal use.

2. Scope and application

This document applies to all home use medical devices that fall within the definition of a medical device, as defined in MDA/GD/0006: Definition of Medical Device, including in vitro diagnostic (IVD) medical devices.

This guidance document specifies the criteria for the importation of personal use medical devices as defined in the Medical Device (Exemption) Order 2016.

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 home use medical device

A home use medical device is a medical device labelled for use in any environment outside a professional healthcare facility and intended for use by healthcare professionals and/or lay persons. This includes but is not limited to outdoor environments, office environments, schools, vehicles, emergency shelters, and independent living retirement homes.

NOTES:

1. Lay person includes patient (care recipient), caregiver (includes non-healthcare professionals), or family member that directly uses the device or provides assistance in using the device.
2. A home use medical device requires adequate labelling for the user and may require training for the user by a healthcare professional in order to be used safely and effectively.

3.2 import

To bring or cause to be brought into Malaysia, by land, sea or air or by any other means.

[SOURCE: Custom Act 1967 (Act 235)]

3.3 personal use

A medical device which is brought into Malaysian market for the use of a particular individual only and not to be placed in the market.

[SOURCE: Medical Device (Exemption) Order 2016]

3.4 place in the market

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

[SOURCE: Medical Device Act 2012 (Act 737)]

4. Requirement

4.1 Requirement for registration of medical devices

According to the Medical Device (Exemption) Order 2016 medical device for the purpose of personal use have been exempted from the requirement for registration of medical device under Section 5 of Act 737.

4.2 Requirement for establishment license

A person who imports medical device for the purpose of personal use are exempted from the requirement of an establishment license under Section 15 of Act 737.

5. Medical device for the purpose of importation of personal use medical device (including medical device bought via online platform)

5.1 The person is allowed to import medical device for personal use into Malaysia and shall comply with the following criteria:

- a) The medical device is intended for home-use medical devices;
- b) The medical device is for own treatment or the treatment of immediate family;
- c) Where possible, keep the medical device in their original packaging with any labels intact;
- d) Quantity for medical device shall be reasonable;
- e) The person allowed to import medical device into Malaysia in any of the following modes of transportation:
 - i. in passenger's baggage whether accompanied or unaccompanied;
or
 - ii. in parcels sent through international mail or courier; and

- f) Medical device does not have brand, similar design, technology and mode of operation in the Malaysian market; and/or
- g) Obtain written prescription from healthcare professional (Not applicable for Class A medical devices).

5.2 The following criteria shall not be applied for importation for personal use medical device:

- a) Medical devices intended to be used by healthcare professional; and
- b) To supply or place the medical device in Malaysian market (includes provide services) to any other person.

5.3 The Authority may issue a letter confirming the imported medical device fulfills the definition and criteria of personal use, upon request; and

5.4 For the purpose of issuance confirmation letter, applicant may submit complete application with supporting documents as per *Annex C Importation of Personal Use Medical Devices Declaration Form* through email to ebantuan@mda.gov.my.

5.5 The importation of medical device for the purpose of personal use is exempted from the requirements of import permit under Customs (Prohibitions of Imports) Order 2023.

Annex A (informative)

Examples and Situations of Personal Use Medical Device

Case 1

Nadhir Nasar who travels to the United Kingdom bought a blood pressure monitor for his own use from a pharmacy. He has a history of hypertension and uses a blood pressure monitor to monitor his blood pressure readings. He wants to bring the blood pressure monitor to Malaysia through the passenger's baggage.

Solution

Personal use medical device imported through passenger's baggage shall not be subjected to request of confirmation letter.

Case 2

Syamsul Yusuf who travels to the United States of America bought 500 COVID-19 IVD self-test kits from a pharmacy. He wants to bring 500 self-test kits to Malaysia through hand-carry for his own monitoring.

Solution

Personal use medical device imported through passenger's baggage shall not be subjected to request of confirmation letter. However, Syamsul Yusuf shall not import medical devices for personal use into Malaysia due to unreasonable quantity.

Case 3

Farid Kamil intends to buy rechargeable hearing aids for his father from the online platform. His father has a written recommendation from a registered medical practitioner to treat his hearing loss problem. The hearing aid's model is recommended from the ENT specialist and will be shipped to Malaysia through an international courier.

Solution

Farid Kamil may apply for the importation of a personal use medical device and submit the application form with the information and supporting documents as prescribed in Annex C to the MDA since the hearing aid has recommendation from the healthcare professional.

Case 4

Daiyan Trisha purchased a pack of 50 strips of the IVD Early Detection Pregnancy Test for her own use from the foreign online platform. She does not have a written recommendation from a registered medical practitioner to justify her purchase and the same brand and types of pregnancy test kits are available and registered in Malaysia.

Solution

Daiyan Trisha is not allowed to import medical device for personal use due to same brand of pregnancy test kits are available in Malaysia. She shall purchase the pregnancy test kits that has been registered with MDA in Malaysia.

Case 5

Shafiq Kyle bought a pulse oximeter, 2 boxes of medical face masks, and 5 COVID-19 self-test kits from a pharmacy in India because he was infected with COVID-19 while travelling to India. He has proof of a positive COVID-19 test result and intends to bring along all medical devices to Malaysia through passenger baggage.

Solution

Personal use medical device imported through passenger's baggage shall not be subjected to request of confirmation letter.

Case 6

Aishah Sinclair bought a wheelchair on online platform for her father. Her father has a medical report from a registered medical practitioner to confirm his physical disability. The wheelchair is recommended from the healthcare practitioner. Upon confirming the payment and receiving delivery tracking number notification from the seller, the medical device will be shipped through international courier. Aishah plans to appoint a forwarding agent on her behalf to submit a personal use medical device application with the MDA.

Solution

Aishah Sinclair may apply for the importation of a personal use medical device and submit the application form with the information and supporting documents as prescribed in Annex C to the MDA as an applicant on behalf of his father as a user. The forwarding agent is not allowed to submit personal use medical device declaration form to MDA.

Case 7

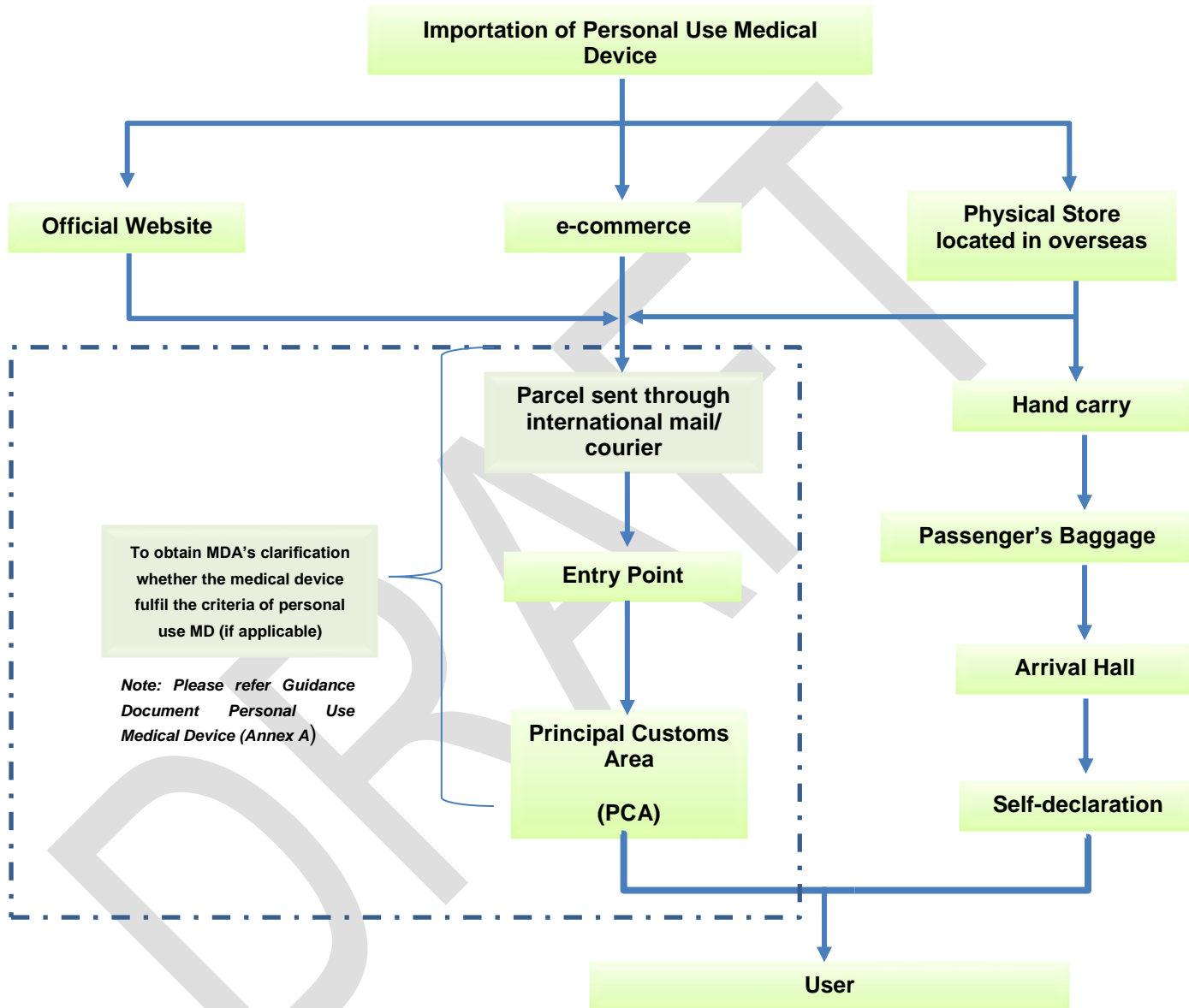
Dr Azizah has finished her medical studies at Harvard Medical School. She intends to purchase her stethoscope set through online platform. The stethoscope will be for her own use for diagnostic and screening purposes on patients.

Solution

Dr Azizah is not allowed to import her stethoscope for personal use medical device to Malaysia because the stethoscope set is a professional use medical device.

Annex B (informative)

Regulatory Framework for Importation of Personal Use Medical Device



**Annex C
(normative)**

Importation of Personal Use Medical Devices Declaration Form

(Note: All sections are mandatory to be filled in)

SECTION A – PURCHASER INFORMATION	
Name	
NRIC No./Passport	
Telephone No.	
Email Address	
Home Address	
SECTION B – MEDICAL DEVICE DETAILS	
Name of Medical Device	
Quantity to be Imported	
Brand	
Description/ Intended use	
Name and Address of Manufacturer	
Delivery tracking number (if applicable)	
SECTION C – USER INFORMATION OF THE PERSONAL USE MEDICAL DEVICE	
NOTE: If different with Section A	
Name of User	
Address	
Relationship to Purchaser	
SECTION D – IMPORTATION DETAILS	
Date of Arrival	
Purchasing Method	<input type="checkbox"/> By official website (Please write the website address) _____ <input type="checkbox"/> Others (Please specify): _____

Justification for purchasing from outside Malaysia	
SECTION E – REQUIRED SUPPORTING DOCUMENT	
Please provide following supporting documents for this application:	
<ul style="list-style-type: none"> i. An example of brochure/catalogue/IFU that contain information about the intended use, general description, mode of action of the medical device; and ii. Proof of purchase; and/or iii. Written prescription from medical practitioner. 	
SECTION F - APPLICATION HISTORY	
Have you imported the medical device listed in this application for personal use before?	<input type="checkbox"/> Yes <input type="checkbox"/> No
If Yes:	
Confirmation letter No.	
Date of letter issuance	
SECTION G – ATTESTATIONS & DECLARATION	
I, the undersigned hereby declare that:	
<ul style="list-style-type: none"> i. This/These medical device(s) is/are solely used for the purpose of personal use only. ii. The medical device(s) shall not be placed in the Malaysian market. iii. I will be full responsible to the medical device used for personal use. iv. I also understand that the Medical Device Authority (MDA) can give no guarantee to the safety and performance of the above medical devices. Therefore, I will take full responsibility for all hazards or risks due to usage. 	
I hereby attest that the information provided in this form is accurate, correct and complete.	
Signature:	
Date:	

MEDICAL DEVICE AUTHORITY

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