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MEDICAL DEVICE GUIDANCE DOCUMENT

IMPORTATION OF MEDICAL DEVICE FOR PERSONAL USE

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;

c) Medical Device (Duties and Obligations of Establishments) Regulations 2019;

d) Medical Device (Advertising) Regulations 2019; and

e) 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 into ensuring 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 2024 has provided an exemption from medical device registration and establishment license requirements for personal use medical devices.

This document serves as guidance for individuals who intend to bring any unregistered medical devices into Malaysia (hereinafter referred as “import”) for the purpose of personal use. The applicant may request a confirmation letter regarding the status of the personal use medical device either before its importation or if the device is restricted by the Jabatan Kastam Diraja Malaysia at the point of entry.

2. Scope and application

This guidance document specifies the requirements for the importation of personal use medical devices.

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.

Not all medical devices are eligible to be categorized as personal use medical devices and importation of registered medical devices is not covered in this document.

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)]

NOTE. Importation of a personal use medical device into Malaysia can be in the following modes of transportation:

i. in passenger's baggage whether accompanied or unaccompanied; or
ii. in parcels sent through international mail or courier

3.3 personal use

A medical device which is brought into Malaysia for the use of a particular individual only and not to be placed in the market or be used on a third party.

[SOURCE: Medical Device (Exemption) Order 2024
NOTE: Refers to Section 43 in the Act 737 for explanation on a third party.

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. Exemption

4.1 Exemption from registration of medical devices

According to the Medical Device (Exemption) Order 2024, 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 Exemption from 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. Requirements

5.1 Medical devices for personal use may be imported or purchased (including via online platform) subject to the following requirements:

a) only for home-use medical devices;

b) the medical device is for own use or the use of immediate family
Note: Personal use medical devices must be purchased under an individual (under their own name) and cannot be purchased by an establishment or organization

c) all labels and labelling information that comes with the medical device shall be retained;

d) quantity for medical device shall be appropriate according to the type of the medical device (refer Annex A)

e) to obtain a formal prescription or letter of recommendation on the medical device(s) from a registered healthcare professional upon request from the Authority.

f) not intended for the use of healthcare practitioners on patients.

5.1 person may request confirmation letter from authority by using form in Annex C, submit your application to exemption.bhai@mda.gov.my).

5.2 The Authority may issue a letter of confirmation that the imported medical device fulfils the definition and criteria of personal use, upon request. For this purpose, an application may be submitted to the Authority with supporting documents as per Annex C.

Annex A
(informative)

Examples and Situations of Personal Use Medical Device

Case 1

Ali, 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

Fall under category of personal use medical device.

Case 2

Abu 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

Do not fall under category of personal use medical device due to unreasonable quantity.

Case 3

Farid intends to buy rechargeable hearing aids for his father from the online platform. His father has a written recommendation from a registered healthcare professional 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

Fall under category of personal use medical device.

Case 4

Carol 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

Do not fall under category of personal use medical device as the same brands are available and registered in Malaysia. She shall use the pregnancy test kits that has been registered with MDA.

Case 5

Shafiq 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. He has proof of a positive COVID-19 test result and intends to bring along all medical devices to Malaysia through passenger baggage.

Solution

Fall under category of personal use medical device

Case 6

Aishah bought a Continuous Positive Airway Pressure (CPAP) machine on online platform for her father. Her father has a medical report from a registered medical 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 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 is 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.

Case 8

Liza wishes to import 10 sets of injectable dermal filler for her own use to reduce wrinkles and fine lines in her face. However, based on the IFU provided by the manufacturer, the dermal filler shall be operated by the medical practitioner who has appropriate training and experience about the anatomy at and around the injection site.

Solution

Liza is not allowed to import injectable dermal filler for personal use medical device because the injectable dermal filler is for professional use only. This medical device does not fulfil the criteria of personal use.

Case 9

Pak Mat is interested to buy one infrared pain relief device that was advertised in foreign online shopping platform. He experienced sore muscles, and that medical device is intended to be used to promote blood circulations and relieving muscle strain. The IFU stated that the medical device is safe to use by lay user if they comply with the instruction for use completely while using the medical device.

Solution

Fall under category of personal use medical device

Case 10

Klinik HQ is importing 5 sets of blood pressure monitors from China for use across its clinics in Malaysia, specifically for patient diagnosis. During the customs clearance process, however, Klinik HQ submitted a purchase order and invoice issued by an establishment that acts as an importer, rather than using a medical device registration certificate by MDA.

Solution

Medical devices which are deemed to be for a commercial or clinical purpose may be seized at the border, as they are not considered to be for personal use

Case 11

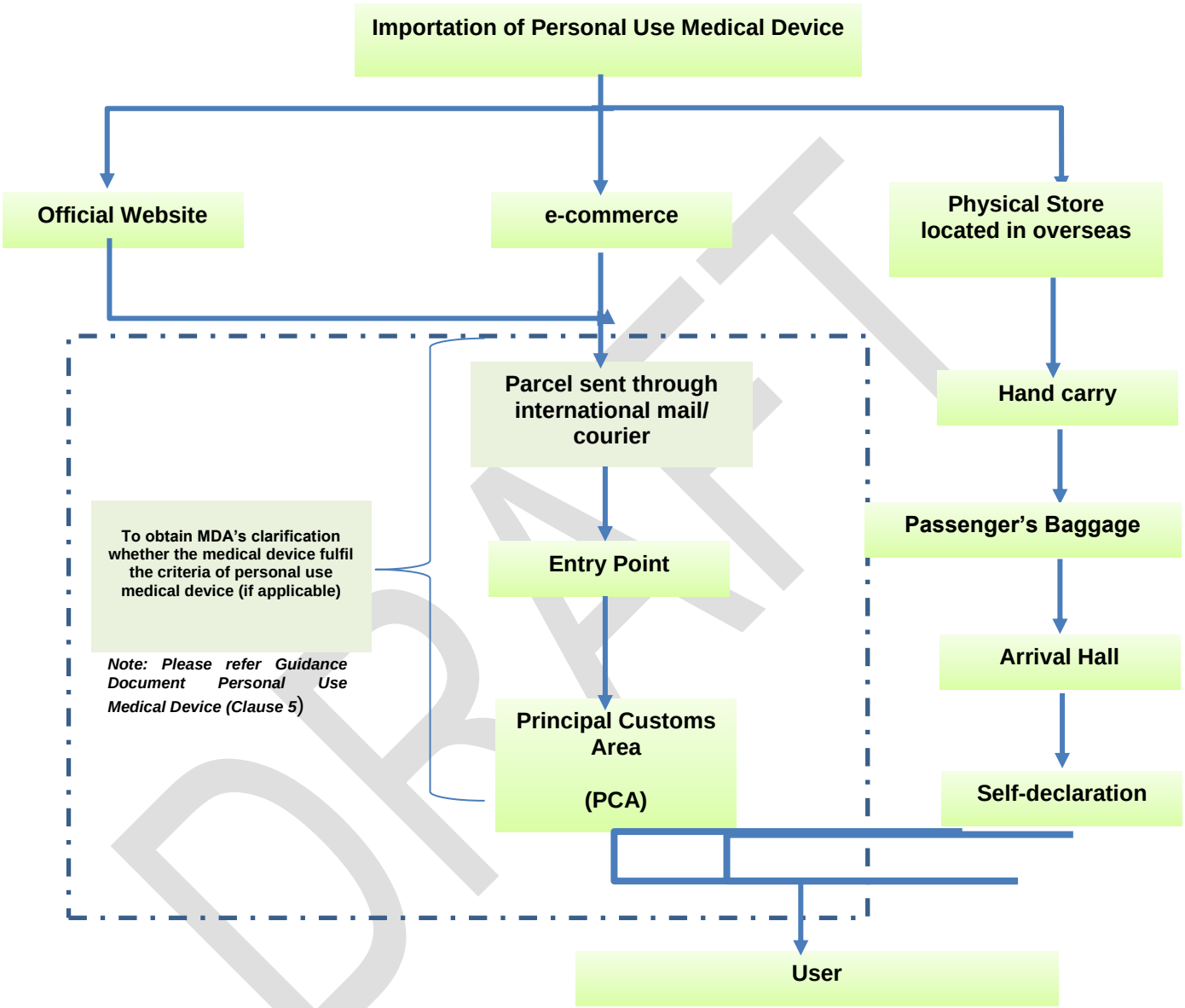
Ali bought an unregistered brand of pulse oximeter from an online platform for his own use, using his company's name for the purchase. However, the transaction was actually made under the name of company ABC. The medical device was restricted at the point of entry by Jabatan Kastam Diraja Malaysia, requesting further clarification from Ali.

Solution

Medical devices which are deemed to be for a commercial or bought under company name may be seized at the border, as they are not considered to be for personal use

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. Kindly submit your application to exemption.bhai@mda.gov.my)

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: Fill in this section if different with Section A**	
Name of User	
Address	
Relationship to Purchaser	
SECTION D – IMPORTATION DETAILS	
Date of Arrival	
Purchasing Method	☐ By official website (Please write the website address) . ☐ Others (Please specify):.

Justification for purchasing from outside Malaysia	

SECTION E – REQUIRED SUPPORTING DOCUMENT

Please provide following supporting documents for this application:

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. Recommendation letter from healthcare professional.

SECTION F - APPLICATION HISTORY

Have you imported the medical device listed in this application for personal use before?	☐ Yes ☐ No
If Yes:	
Confirmation letter No.	
Date of letter issuance	

SECTION G – ATTESTATIONS & DECLARATION

I, the undersigned hereby declare that:

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 take full responsibility for the use of the medical device.

I hereby attest that the information provided in this form is accurate, correct and complete.

Signature:

Date:

MEDICAL DEVICE AUTHORITY

MINISTRY OF HEALTH, MALAYSIA

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