MDA/GD/0043
MAY 2020
Second Edition

MEDICAL DEVICE GUIDANCE DOCUMENT

SPECIAL ACCESS – NOTIFICATION – GENERAL REQUIREMENTS

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 Exemption Order 2016

b) Medical Device (Duties and Obligation of Establishments) 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.

This is the revision of MDA/GD/0043 which was first published in April 2019.

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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SPECIAL ACCESS – NOTIFICATION – GENERAL REQUIREMENTS

0 Introduction

Importation and placement of a medical device in the Malaysian market requires the 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). The Medical Device (Exemption) Order 2016 however has provided for exemption from registration requirements of certain medical devices through special access if they fulfill the criteria and submit a notification to the Authority.

The rise of the emergency situation where the Covid-19 pandemic has occurred entails for the revision of this guidance document. This is to ensure the availability of medical devices in healthcare facilities, to minimise a disruption of treatments during an emergency situation such as during the Covid-19 pandemic period.

Subsequent to the receipt of notification from the applicant, a “No restriction letter” will be issued by the Authority for the purpose of importation and placement of the special access medical device after assessment of the specification by an Expert Advisory Committee established by the Authority. The applicant may proceed to import and/or place the medical device in Malaysian market only after receiving “No restriction letter” from the Authority.

This Guidance Document is used as a reference for the user, Healthcare Facilities and Government Departments on special access applications for medical devices. Through the Expert Advisory Committee and based on the requirements of this Guidance Document, a recommendation on the suitability of the medical device to be granted special access will be provided. The user/healthcare facility/government department will make their decision based on the recommendation or otherwise, depending on their need and be responsible on the use of the medical device during the emergency period.

1 Scope

This document specifies requirements on notification of medical device for special access as defined in Medical Device (Exemption) Order 2016.

This guidance document provides guidance to applicant who imports and/or places medical device through special access.

This Guidance document shall be read together with and MDA Circular No. 2 Year 2014, *Conformity assessment procedures for medical devices approved by recognised countries*.

2 Terms and definitions

For the purposes of this document, the terms and definitions in ACT 737, the regulations under it, the Exemption Order 2016 and the following terms and definitions apply.

2.1 applicant

Applicant can be either a licensed establishment, healthcare practitioner, government department, government or private healthcare facility.

2.2 batch release

Batch release can be issued when a medical practitioner requires access to a device for anticipated emergency cases for a one month period, where registered medical devices are unavailable, and where shipping delays would result in serious adverse event.

[Sources: Guidance for Health Care Professionals on Special Access and Custom-Made Medical Devices Health Canada, Date Adopted: 2016/02/18 Effective Date: 2016/02/18]

2.3 emergency

An emergency is a situation that poses an immediate risk to a patient's life or long term health.

2.4 foreign regulatory authorities

Authorities that regulate medical devices in coutries outside Malaysia.

2.5 government healthcare facility

Any facilities used or intended for use to provide established healthcare services, maintained, operated or provided by the Government but excluding government healthcare facilities privatized or incorporated;

[Source: Private Healthcare Facilities and Services Act (PHFSA), Act 586 1998]

2.6 healthcare facility

Any premise in which one or more members of the public receive healthcare services, which includes:

a) medical, dental, nursing, midwifery, allied health, pharmacy, and ambulance services and any other services provided by healthcare professionals;

b) accommodation for the purpose of healthcare services provided;

c) any service for the screening, diagnosis, or treatment of persons suffering from, or believed to be suffering from, any disease, injury or disability of mind and body;

d) any service for preventive and promotion of health purpose;

e) any service provided by any healthcare para-professional;

f) any service for curing or alleviating abnormal conditions of the human body by the application of any apparatus, equipment, instrument or device or any other medical technology; or

g) any health-related services.

[Source: Private Healthcare Facilities and Services Act 1998, Act 586]

2.7 private healthcare facility

Any premises, used or intended for use in providing services healthcare or services related to health, such as hospital, hospice, ambulatory care center, home nursing care, maternity home, psychiatric hospital, home psychiatric care, community mental health centers, centers hemodialysis, medical clinics, private dental clinics and anything else healthcare premises or health-related premises other than as may be determined by the Minister from time to time by notification in the Gazette;

[Source: Private Healthcare Facilities and Services Act 1998, Act 586]

2.8 registered medical practitioner

Any person who is registered as such under the Medical Act 1971 [Act 50] and who holds a valid practising certificate.

[Source: Private Healthcare Facilities and Services Act 1998, Act 586]

2.9 special access medical device

Medical device for the use of medical practitioners in emergency situations or in the event that conventional medical treatment has failed, is unavailable or unsuitable.

[Source: Medical Device (Exemption) Order 2016]

2.10 incident

An event related to the failure of a device, or to a deterioration in its effectiveness, or any inadequacy in its labelling or in its directions for use, that has led to the death or serious deterioration in the state of health of a patient, user or other person, or could do so were it to recur.

Note. Incident can also mean adverse event.

2.11 user

A person using or operating a medical device on any person acquiring services in a healthcare facility or other facilities.

3 Requirements

Situations where medical devices are eligible to be exempted from registration and imported/placed in the Malaysian market through special access are described in Table 1. Unregistered medical devices may only go for special access when there is a need by Healthcare Practioners/ Healthcare Facilities and as per the criteria in 3.1.

Notes:

1. 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.

2. 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@mda.gov.my to determine the classification of the products. The guidance document and form are available to be downloaded at MDA website www.portal.mda.gov.my.

3. Place in the market means to make available a medical device in return for payment or free of charge with a view to distributing, using, supplying or putting 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.

3.1 Eligibility for special access medical device and notification route

The medical device that falls under the following situations in Table 1 are eligible for special access and the respective notification route.

Table 1: Situations that require special access for medical devices

No	Situations	Notification route
1	Medical device to be used in an **emergency situation** that poses an immediate risk to a patient's life or long-term health where the required medical devices are not available in Malaysia, i.e. For persons who are seriously ill with a condition from which death is reasonably likely to occur within a matter of months, or from which premature death is reasonably likely to occur in the absence of early treatment; or when there is a declared health emergency such as a pandemic situation.	**Route A**
2	Medical devices on compassionate use basis: - Absence of alternative treatment option; or - Available alternative treatments failed or deemed ineffective or unsuitable for the patient according to the medical practitioner's clinical judgement; and - Patient's health will be clinically compromised without the requested treatment.	**Route B**
3	Alleviation of stock-out situation: • The medical device is needed to minimise disruption to the continued supply of a similar medical device. • For this purpose, consideration will only be given for circumstances such as on-going change notification process and post market actions are being undertaken.	**Route B**
4	Design and/or operation that is likely to support or enhance the outcomes of the procedure or treatment for the patient.	**Route B**

4 Notification procedure

4.1 Notification for Route A

Route A is applicable for medical device described in item 1 of **Table 1**. Table 2 provides the notification requirements and conditions for route A.

Table 2: Requirements and conditions for route A notification

Citeria no.	Requirements and conditions
1: - For medical devices approved/registered by recognised countries (US, EU, Japan, Australia, Canada) - For medical devices approved by WHO.	**Requirements:** a) The applicant shall ensure the medical device fulfils minimum technical specifications as required by the user/medical practitioner/healthcare facility. For ventilators, refer MDA/GD/0056. b) The applicant shall submit the certificate/letter of approval from recognised regulatory authorities (please also refer to MDA Circular No. 2 Year 2014, *Conformity assessment procedures for medical devices approved by recognised countries*) or WHO. c) The PMSV reports on any incidents or recall for the last 3 years (if applicable). d) Letter of authorisation from foreign manufacturer or establishment. e) Attestation and declaration signed by the applicant (refer Annex B, Section G). f) All conditions on notification in Clause 8 shall be fulfilled.
2: - For medical devices approved/registered by foreign regulatory authorities or through emergency situation requirements. - Medical devices manufactured locally.	**Requirements:** a) The applicant shall ensure the medical device fulfils minimum technical specifications as required by the user/medical practitioner/healthcare facility. For ventilators, refer MDA/GD/0056. b) The applicant shall submit the approval certificate from foreign regulatory authorities/ letter of approval during emergency period from foreign regulatory authorities. c) Letter of authorisation from foreign manufacturer or establishment. d) Attestation and declaration signed by the applicant/establishment (refer Annex B, Section G). e) All conditions on notification in Clause 8 shall be fulfilled.

4.1.1 Submission of notification for route A

An applicant who wishes to import and/or place medical device in the Malaysian market through special access route shall notify the Authority by following the steps and as in Annex A.

a) The applicant shall submit the notification form together with required information/ documents as described in Table 3 to the Chief Executive of Medical Device Authority (MDA) by email at sa.cm@mda.gov.my.

b) The form for 'Notification of Medical Devices for Special Access (Route A)' can be downloaded from the Authority website at www.mda.gov.my.

c) One notification application shall be made for only one single medical device or one medical device grouping.

d) The applicant may proceed to import and/or place the medical device in Malaysian market only after receiving the "No restriction letter" from the Authority (refer flowchart in Annex A).

Table 3. Notification form particulars for Route A

No.	Particulars	Explanation
Section A: Details of Applicant		
1.	Category of Applicant	Tick the category of applicant as applicable
2.	Name of Applicant	Full name of applicant as per NRIC/Passport
3.	NRIC/Passport Number	State NRIC for Malaysian or Passport Number for foreign citizen
4.	Designation	State designation of applicant in the organisation.
5.	Name & Address of Organization	The name and address of organisation of applicant.
6.	Telephone No.	Please state telephone number of applicant.
7.	Email Address	Please state email address of applicant.
8.	Does the company already hold Establishment License	If Yes, please state Establishment License number under Act 737 and please tick the role of company in accordance with establishment license issued by MDA. If No, please proceed to Section B
Section B: Details of Medical Practitioner/Healthcare Facility/Government Department (where applicable)		
1.	Name of responsible person	Please state the name of medical practitioner/responsible person of Healthcare Facility/Government Department who is responsible for the importation and/or placement of the medical device in the Malaysian market or requires the use of the medical device (where applicable).
2.	Title	Please state the title of the medical practitioner/responsible person.
3.	Annual Practicing Certificate Number	Please state the Annual Practicing Certificate Number issued by Malaysian Medical Council (if applicable).
4.	Telephone No.	Please state telephone number of medical practitioner/person responsible.
5.	Email Address	Please state email address of medical practitioner/person responsible.

6.	Health Care Facility(ies) Name & Address	Please state the name and address of healthcare facility(ies) at which the device is to be used. State full name of healthcare facility.
Section C: Details of Medical Device (Appendix I)		
1.	Name of Medical Device	Please state name of the medical device, brand/model as per written in the labels, IFU, brochures, etc.
2.	Grouping	Please select grouping that is applicable to medical device. The grouping should be done accordance with Rules of grouping as specified in the Second Schedule of the Medical Device Regulation (MDR) 2012 and further elaborated in guidance document on Product Grouping MDA/GD/0005.
3.	Brief Description	Please provide description of medical device.
4.	Brand	Please state brand/model of medical device.
5.	Identifier (catalogue or model number):	Please state identifier of the medical device.
6.	Intended use of the device	Please provide the intended use of the medical device.
7.	Manufacturer's Information	Please state name of manufacturer, contact details, address, telephone number and email address.
8.	Risk based classification	Please state risk class and rule of classification of medical device based on: • First Schedule MDR 2012; • MDA/GD/0001 In-Vitro Diagnostic (IVD) Medical Device Classification System; or MDA/GD/0009 Rules of Classification for General Medical Devices.
9.	Classification Rule	
10.	Quantity to be imported	Please state the quantity of the medical device to be imported into Malaysia.
11.	Marketing Approval Status in other country(-ies)	Please state the name (s) of country (ies) and provide evidence such as Declaration of Conformity /Device Licence /Registration Certificate/ 510k/etc), if applicable.
12.	List of configuration (for products in a grouping)	For medical device in a grouping, please state the name of device, accessories, constituent components, or articles.
Documents to be submitted		
1.	Documents to be submitted	• List of configuration of the medical device (for grouped devices), if applicable. • Brochure, catalogue, label, sample of device, if applicable. • Approval certificates from other countries / notified bodies, if applicable. • safety and performance validation/evidences (as according to standards), certificates, test reports, bibliographic evidences, where relevant.
Section D: Clinical Judgement/Public Health Emergency Outbreak		
• In case of an individual patient, describe the patient condition, and emergency treatment requiring the device. • In case of public health emergency, prescribe the outbreak requiring the device.		
Section E : Medical Device Safety Information		
1.	List the registered devices	List the currently available registered devices that are normally used for treatment or diagnosis in the emergency procedure and provide a rationale as to why these registered devices would not adequately meet the requirements of the patient (if available).
2.	Summarize the known safety and effectiveness	Please summarise the benefit of the device.

	information in respect of the device.	
3.	Batch release	For batch release please provide the number of the devices required for one month. i.e. outbreak situation
SECTION F : Undertaking of Medical Practitioner		
Medical practitioner are required to make an undertaking that they will inform the patient/ next of kin of the risks and benefits associated with the use of the device. It shall be signed by medical practitioner. It shall include signature, name, date and healthcare facility stamp.		
Section G : Attestations & Declaration		
i.	Signature	Attestation to be signed by medical practitioner/ person responsible for this application. Criteria for person responsible: a) Shall be from top management; i. Person responsible shall have the overall control and have the authority to make decision; ii. Depending on the organisational structure of the establishment, person responsible may include Proprietor, President, Vice President, Director, Chief Executive Officer (CEO), Managing Director, General Manager or Manager.
ii.	Name	
iii.	Designation	
iv.	Date	
v.	Company stamps	

4.2 Notification for Route B

Route B is applicable for medical device described in items 2 – 4 of Table 1.

a) The applicant may proceed to import and/or place the medical device in Malaysian market only after receiving the "No restriction letter" from the Authority (refer flowchart in Annex A).

b) The applicant shall submit the notification form together with required information/ documents as described in Table 4 to the Chief Executive of Medical Device Authority (MDA) by email at sa.cm@mda.gov.my.

c) One notification application shall be made for only one single medical device or one medical device grouping.

d) The form for 'Notification of Medical Devices for Special Access (Route B)' can be downloaded from the Authority website at www.mda.gov.my.

Table 4. Notification form particulars for Route B

No.	Particular	Explanation
Section A: Applicant details		
1	Category of Applicant	Tick the category of applicant whether applicant is a licensed establishment, healthcare practitioner, government or private healthcare facility.
2	Name of Applicant	Full name as per National Registration Identity Card Number (NRIC) or passport for foreign citizen.
3	NRIC No./Passport Number	State NRIC for Malaysian or passport number for foreign citizen.
4	Designation	State designation of applicant in the organisation.
5	Name & Address of Organization	The name and address of organisation of applicant.

No.	Particular	Explanation
6	Telephone No.	State telephone number of applicant.
7	Email Address	State email address of applicant.
8	Does the company already hold Establishment License	State whether the company has Establishment License number under Act 737. If Yes, applicant has to tick role of company accordance to Establishment license issued by MDA.
Section B: Medical Practitioner Details		
1	Name	The name of healthcare professional who or which takes responsibilities for the importation and/or supply the unregistered medical devices in Malaysia.
2	Title	State the title of the medical practitioner.
3	Annual Practicing Certificate Number	State the Annual Practicing Certificate Number issued by Malaysian Medical Council.
4	Telephone No.	State telephone number of medical practitioner.
5	Email Address	State email address of applicant.
6	Health Care Facility Name & Address	The name and address of healthcare facility at which the device is to be used by that professional. State full name of healthcare facility.
Section C: Medical Device details (Appendix I)		
1	Name of Medical Device	State name of the medical device, brand/model and intended use of the medical device as per written in the labels, IFU, brochures, etc.
2	Grouping	Select grouping that is applicable to medical device. The grouping should be done accordance with Rules of grouping as specified in the Second Schedule of the Medical Device Regulation (MDR) 2012 and further elaborated in guidance document Product Grouping MDA/GD/0005.
3	Brief Description	Provide description of medical device.
4	Brand	State brand/model of medical device.
5	Identifier (catalogue or model number):	State identifier of the medical device.
6	Intended use of the device	Please provide the intended use of the medical device.
7	Manufacturer's Information	State name of manufacturer, contact details, address, telephone number and email address.
8	Risk based classification	State risk class and rule of classification of medical device based on: • First Schedule MDR 2012; • MDA/GD/0001 In-Vitro Diagnostic (IVD) Medical Device Classification System; or • MDA/GD/0009 Rules of Classification for General Medical Devices.
9	Classification Rule	
10	Quantity to be imported and/or supplied	State the quantity of the medical device to be imported and/or supplied.
11	Marketing Approval Status in other country(-ies)	State the name (s) of country (ies) and provide evidence such as Declaration of Conformity /Device Licence /Registration Certificate/ 510k/etc) (refer to Annex E).
12	Grouping List	Name of device, accessories, constituent components, or articles as per product label. It is not applicable for single medical device.

No.	Particular	Explanation
SECTION D : Medical Rationale		
1	Medical devices on compassionate use basis	In the absence of alternative treatment option, available alternative treatment failed or deemed ineffective or unsuitable for the patient according to the medical practitioner's clinical judgments and patients health will be clinically compromised without the request treatment
2	Alleviation of stock-out situation	The medical device is needed to minimize disruption to the continued supply of a similar registered medical device. The medical device that can be imported for this purpose are those already approved in any one of the recognized countries.
3	Design and/or operation that is likely to support or enhance the outcomes of the procedure or treatment for the patient.	Please provide justification and evidence.
4	Provide the diagnosis, treatment or prevention for which the unregistered device is requested and the reasons why this unregistered device was chosen.	Evidence diagnosis, treatment or prevention for which the unregistered device is requested and the reasons device was chosen
5	List the registered devices considered and provide a rationale as to why these devices would not adequately meet the requirements of the patient	Details of the device name, medical device registration number, rationale as to why this registered device would not adequately meet the requirements of the patient
6	Identify and list the risks and benefits associated with the use of the unregistered device and indicate how the benefits obtained would outweigh the risks.	List the risks and benefits associated with the use of the unregistered device and indicate how the benefits obtained would outweigh the risks.
7	Summarize the known safety and effectiveness information in respect of the device.	
8	List the registered devices	List the registered devices considered and provide a rationale as to why these registered devices would not adequately meet the requirements of the patient.
9	Summarize the known safety and effectiveness information in respect of the device.	
10	In the case of a request for Batch Release,	Describe the emergency condition requiring treatment and provide the number of devices required for one month
SECTION E : ATTESTATIONS & DECLARATION		

No.	Particular	Explanation
i.	Signature	Attestation to be signed by medical practitioner/ person responsible for this application. Criteria for person responsible: a) Shall be from top management; i) Person responsible shall have the overall control and have the authority to make decision; ii) Depending on the organisational structure of the establishment, person responsible may include Proprietor, President, Vice President, Director, Chief Executive Officer (CEO), Managing Director, General Manager or Manager.

4.3 Administrative charge

Each notification shall be submitted together with a RM 300 administrative charge, with the following conditions:

a) Administrative charge shall be paid through bank draft. CASH WILL NOT BE accepted. The Authority will not be responsible for the cash sent or brought to MDA.

b) Payable to "KUMPULAN WANG PIHAK BERKUASA PERANTI PERUBATAN". Name and Telephone No. of the applicant must be written at the back of the bank draft but not in the table section.

c) The fee is waived on applications for the purpose of donations only.

5 Compliance with other regulatory requirement

The notification to the Authority does not exempt the applicant from abiding to any other law or regulations in Malaysia, for example:

a) Importation procedure. Please refer to the Royal Malaysian Customs department for more information; and

b) Application for irradiating apparatus, please refer to Atomic Energy Licensing Board (AELB) for more information.

6 Notification review

6.1 Upon receipt of notification and relevant documents, the Authority will review the notification and if, after consideration of all the information provided, the Authority considers that all requirements have been fulfilled, the Authority will notify the applicant, of its decision and issue a “No restriction letter” permitting the applicant to import and/or place the medical device in Malaysian market.

6.3 If 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 ten (10) working days from the date of request by the Authority.

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

6.5 The Authority has the right to withdraw a written "No restriction letter" 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 Labelling of medical device for special access

There shall be an identification for a special access medical device, and a statement that it shall be only used by a medical practitioner for patient under his care.

The content shall include instructions on storage and usage of medical device and any other special requirement e.g. sterilization, calibration, and single use medical device.

8 Conditions on notification

The applicant shall be fully responsible for handling the medical device during the period of the special access, including:

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

b) ensure proper handling of the medical devices;

c) Advertisement of special access medical device is not allowed as according to Secion 44 of Act 737.

d) comply with any directions issued by the Authority from time to time and allow for inspection from Authority at any time without prior notice;

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

f) responsible to comply with requirements of post market surveillance and vigilance as according to Chapter 3 of Act 737 and Medical Device (Duties and Obligations of Establishments) Regulations 2019;

g) ensure that labelling is sufficient to ensure safety and performance of the medical device;

h) ensure the use and storage of medical device are in accordance with manufacturer requirements;

i) the applicant shall be responsible for establishing and implementing a system to monitor safety and performance of the medical device and take the necessary actions should there be any adverse incident with regards to the use of these medical devices. The applicant shall maintain the distribution record and traceability;

j) for locally manufactured medical device, the manufacturers shall establish

Standard Operating Procedures on its manufacturing process and shall obtain certification to ISO 13485 withinn 1 year period from end of the emergency period;

k) to continue placing of the medical device in the Malaysian market, the applicant shall apply for medical device registration and license under the Act 737 once Malaysia is free from the emergency situation or after expiry of the “No restriction letter”;

l) the user/healthcare facility shall be responsible on the use of the device if the device continued to be used without registration with the Authority (refer MDA/GD/0053 on Oprhaned medical device and MDA/GD/0055 on Obsolete and discontinued medical device);

m) for active medical devices that require installation and/or designated medical devices, the following shall also be provided:

i. Proper installation, testing and commissioning, and acceptance shall be done by the manufacturer at the user facility.
ii. Adequate clinical on-site training by competent personnel shall be provided to the user.
iii. Information on warranty, technical support and maintenance shall be provided to the user.
iv. The user manual shall be provided with the device.

n) the accessories and spare parts are available and ready to be supplied to the healthcare facilities when needed; and

o) Ensure that the medical device is taken out of operations when it is no longer safe and effective for use, as according to Section 43 of Act 737.

9 Post handling of medical devices for the purposes of special access

9.1 After the end of the validity of the special access and if the medical device has not been installed or placed in the market, and has not been registered with the Authority, the applicant shall:

a) ensure these medical devices are properly disposed;

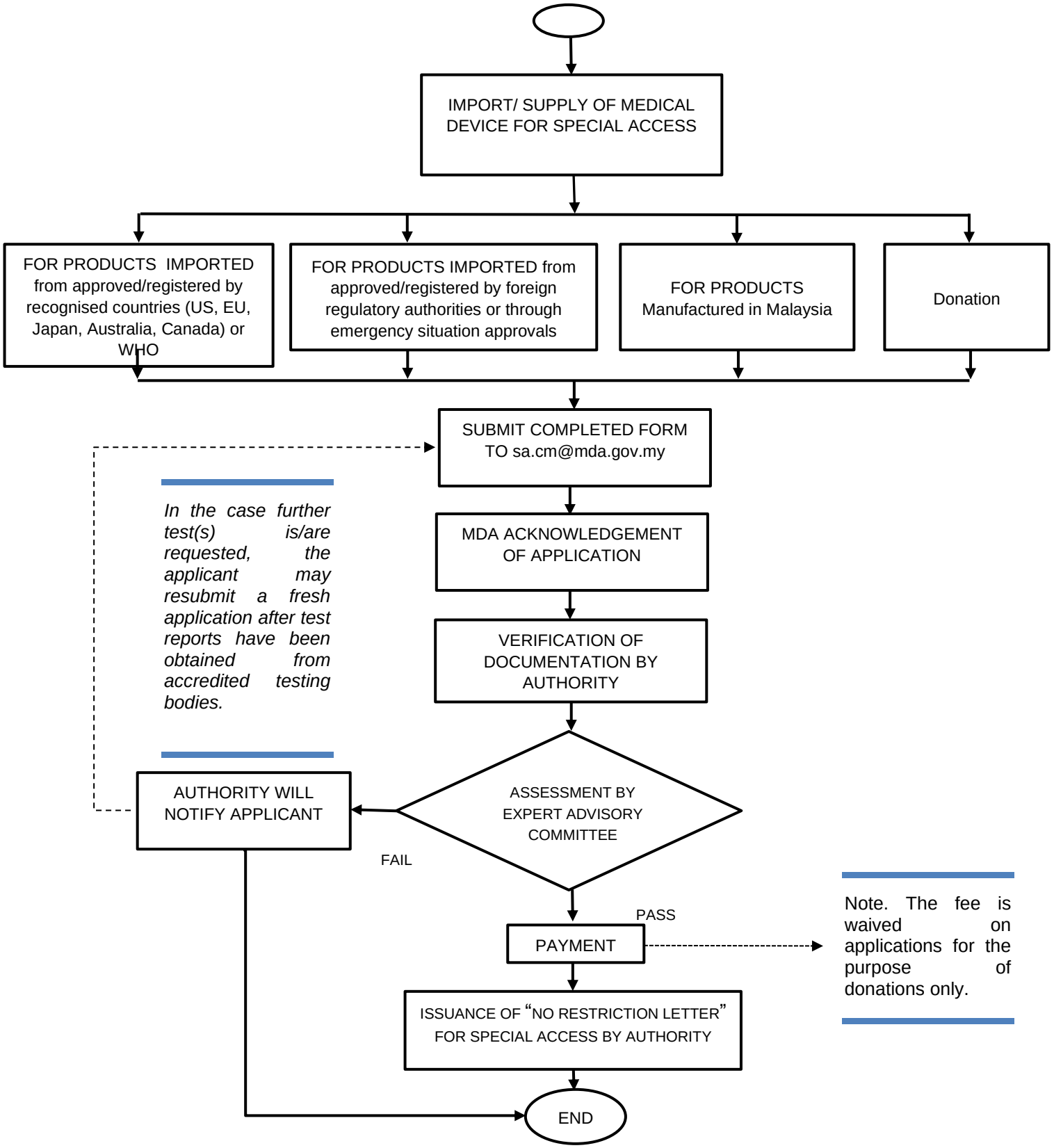
b) submit ‘Disposal of Special Access Medical Device’ Notice Form (if applicable) for special access medical device to the Authority, via email/post/fax BUT it shall reach the Authority no later than 30 days from end of the special access. Refer **Annex D**;

c) ‘Disposal of Special Access Medical Device’ Notice Form shall be endorsed by the healthcare facility where the medical device was supplied or used. Endorsement shall be made by the medical practitioner/head of department; and

d) maintain relevant record as a proof for the disposal of those medical devices.

Annex A
(informative)

Flow chart for Notification Procedure



Annex B
(normative)

PIHAK BERKUASA PERANTI PERUBATAN
Medical Device Authority
KEMENTERIAN KESIHATAN MALAYSIA
Ministry of Health Malaysia
Portal: www.mda.gov.my
Email: sa.cm@mda.gov.my

NOTIFICATION OF UNREGISTERED MEDICAL DEVICES FOR SPECIAL ACCESS (Route A)

(In accordance with Medical Device (Exemption) Order 2016)

All fields are mandatory unless stated otherwise

SECTION A : APPLICANT DETAILS
(This section is for the individual, facility or organization who or which takes responsibilities for the importation and/or supply the unregistered medical devices in Malaysia)

1. Please Tick The Appropriate Box:

- ☐ Local manufacturer
- ☐ Registered medical practitioner *(obtains directly from the manufacturer for supply the unregistered medical device to his/her patient)*
- ☐ Licensed establishment
- ☐ Government/private healthcare facility, or government department, please specify):

2. Name of Applicant:

3. NRIC No./Passport:	4. Designation:

5. Name & Address of Organization:

6. Telephone No.:	7. Email Address:

8. Does the company already hold Establishment License?	☐ Yes If Yes, please state the company Establishment License Number: ……. Company's Role : ☐ Local Manufacturer ☐ Authorized Representative ☐ Distributor ☐ Importer	☐ No

SECTION B : MEDICAL PRACTITIONER DETAILS
(*This section is for the medical practitioner who or which takes responsibilities for the importation and/or supply the unregistered medical devices in Malaysia)*

1. Name:

2. Title:	3. Annual Practicing Certificate Number:
4. Telephone No.:	5. Email Address:
6. Health Care Facility Name & Address:	

SECTION C: MEDICAL DEVICE DETAILS

Please provide details of the medical device in **Appendix 1.**

SECTION D : CLINICAL JUDGEMENT/ PUBLIC HEALTH EMERGENCY OUTBREAK

1. Please prescribes a treatment for an individual patient specific:

(Notes: This should include an outline of the seriousness of the patient's condition and details of the past treatment. If other approved medical devices are available, the applicant will need to justify the use of unregistered medical device to those treatments. It is important for the justification to balance the availability of approved medical device against the seriousness of the patient's condition and to include an appraisal of the expected benefits from the use of unapproved medical device)

2. In case of the a request for Batch Release, please describe the emergency requiring treatment, and provide the number of the devices for one month:

SECTION E : MEDICAL DEVICE SAFETY INFORMATION

1. List the registered devices considered and provide a rationale as to why these registered devices would not adequately meet the requirements of the patient.

Device Name	Medical Device Registration Number	Rationale as to why this registered device would not adequately meet the requirements of the patient

Remark: Please attach additional page if space insufficient

2. Summarize the known safety and effectiveness information in respect of the device.

SECTION F : MEDICAL PRACTITIONER UNDERTAKING

(Medical Practitioners are required to make an undertaking that they will inform the patient for whom the device is intended of the risks and benefits associated with its use)

I, < Name of Medical Practitioners >, ID <IC No. _____>,

i. undertake to inform the patient, < Patient's ID _____>, who is to be treated with the device of the risks and benefits associated with the use of this unregistered medical device.
ii. confirm that I have informed the patient, < Patient's ID _____>, who is to be diagnosed or treated with the device of the risks and benefits associated with the use of this unregistered medical device.

iii. declare that the unregistered medical device to be used on the patient is to save the life of a patient , to help a patient suffering from a serious disease or condition when existing registered medical device have failed, unavailable or are unsuitable to provide a diagnosis, treatment or prevention for patients under my care

iv. have obtained the informed consent of the patient, or the patient's legal representative, to the proposed diagnose/treatment

v. will take full responsibility for the use of this unregistered medical device on the named patient listed above and shall adhere to the conditions of approval

vi. will ensure that this medical device will be used or administered in accordance to its intended purpose and indications for use as stated in the product owner's instructions for use.

In the case of a batch release request (if applicable)

(Note : In the case of a Batch Release, (a) it is sponsor's responsibility to maintain a distribution record in respect of the device; (b) Health care professionals are requested to return any unused devices to the sponsor)

I, < Name of Medical Practitioners >, ID <IC No. _____>,

i. Undertake to inform the patients who are to be treated with the device of the risks and benefits associated with the use of this unregistered medical device.

ii. Confirm that I cannot inform the patients, who are to be diagnosed or treated with the device of the risks and benefits associated with the use of this unregistered medical device. I attest that facilityal policies will be followed.

Signature:

Date :

Health Care Facility Stamp :

SECTION G : ATTESTATIONS & DECLARATION

I, the undersigned hereby declare that :

i. This/These product(s) is/are according to the definition of medical device set out in Section 2, Medical Device Act 2012 (Act 737).

ii. The device(s) conform(s) to all relevant essential principles for safety and performance, set out in the Appendix 1 of Third Schedule of the MDR 2012.

iii. The medical device(s) has/have met all the labeling requirements set out in the Sixth Schedule of the MDR 2012.

iv. The technical documentation of the unregistered device(s) is/are prepared in accordance with the format as specified in Appendix 2 of Schedule 3 of MDR 2012 and is/are available upon request by the Authority.

Remark: Any kind of deletion in Section F please provide justification

I shall be responsible for the establishment and implementation of a system to monitor safety and performance of this/these medical device(s) and take the necessary actions should there be any adverse incident occurs for the purpose of making available this/these unregistered medical device(s) for use for special access;

I hereby attest that the information and attachment provided on this notification is/are accurate, correct, complete and current to this date.

Signature:

Person Responsible Name:

Designation :

Date :

Company stamp :

APPENDIX 1

MEDICAL DEVICE DETAILS

Name of Medical Device:					
Grouping :	☐ Single ☐ System ☐ Family		Set ☐ In Vitro test kit ☐ In vitro cluster ☐		
Brief Description:					
Brand:					
Identifier (catalogue or model number):					
Intended use of the device:					
Manufacturer's Information:	Manufacturer's Name: *(as it appears on the label)* Contact Name and Title: Address (Number , Street, City, Country) Postal Code: Telephone : Email :				
Risk-Based Classification :		**Classification Rule:** (according to First Schedule on Rules of Classification of Medical Device, MDR 2012)			
Quantity to be Imported:					
Marketing Approval Status in other country(-ies) (Please : i. state the name (s) of country (ies) ii. provide evidence such as Declaration of Conformity/Device Licence/Registration Certificate/510k/etc)	☐ Registered /Licensed		☐ Exempted/ Notified	☐ Others (please specify)	
Grouping List :	***Not Applicable to single medical device***				

No.	Name of device, accessories, constituent components, or articles as per product label:	Model	Brief Description	Quantity to be Imported

Note: If more than one (1) medical device, please fill up in a separate sheet.

Annex C
(normative)

PIHAK BERKUASA PERANTI PERUBATAN
Medical Device Authority
KEMENTERIAN KESIHATAN MALAYSIA
Ministry of Health Malaysia
Portal: www.mda.gov.my
Email: sa.cm@mda.gov.my

NOTIFICATION OF MEDICAL DEVICES FOR SPECIAL ACCESS (ROUTE B)

(In accordance with Medical Device (Exemption) Order 2016)

All field are mandatory unless stated otherwise

SECTION A : APPLICANT / COMPANY DETAILS
(This section is for the individual, facility or organization who or which takes responsibilities for the importation and/or supply of medical devices for special access in Malaysia)

1. Please tick the appropriate box:

- ☐ Local manufacturer
- ☐ Registered Medical Practitioner *(obtains directly from the manufacturer for supply the medical devices for special access to his/her patient)*
- ☐ LICENSED ESTABLISHMENT
- ☐ Government/private healthcare facility, or government department, please specify): .....

2. Name of applicant:

3. NRIC No./Passport:	4. Designation:

5. Name & Address of Organization:

6. Telephone No.:	7. Email Address:

8. Does the company already holds Establishment License?	☐ Yes If Yes, please state the company Establishment License Number: ..... Company's Role : ☐ Local Manufacturer ☐ Authorized Representative ☐ Distributor ☐ Importer	☐ No

SECTION B : MEDICAL PRACTITIONER DETAILS
(*This section is for the Medical Practitioner who or which takes responsibilities for the importation and/or supply the medical devices for special access in Malaysia)*

NOTIFICATION OF MEDICAL DEVICES FOR SPECIAL ACCESS (ROUTE B)

(In accordance with Medical Device (Exemption) Order 2016)

7. Name:	
8. Title:	9. Annual Practicing Certificate Number:
10. Telephone No.:	11. Email Address:
12. Health Care Facility Name & Address:	

SECTION C: MEDICAL DEVICE DETAILS

Please provide details of the medical device in **Appendix 1.**

SECTION D : MEDICAL RATIONALE

Please tick the appropriate box :

1. ☐ Medical devices on compassionate use basis

(Note. In the absence of alternative treatment option, available alternative treatment failed or deemed ineffective or unsuitable for the patient according to the medical practitioner's clinical judgments and patients health will be clinically compromised without the request treatment)

2. ☐ Alleviation of stock-out situation

(Note. The medical device is needed to minimize disruption to the continued supply of a similar registered medical device. The medical device that can be imported for this purpose are those already approved in any one of the recognized countries (refer to Annex E).

3. ☐ Design and/or operation that is likely to support or enhance the outcomes of the procedure or treatment for the patient.

(Note. Medical practitioner and manufacturer to provide justification and evidence that the design and/or operation that is likely to support or enhance the outcomes of the procedure or treatment for the patient)

13. Provide the diagnosis, treatment or prevention for which the medical devices for special access is requested and the reasons why this medical device was chosen.

14. List the registered devices considered and provide a rationale as to why these registered devices would not adequately meet the requirements of the patient.

Device Name	Medical Device Registration Number	Rationale as to why this registered device would not adequately meet the requirements of the patient

Remark: Please attach additional page if space is insufficient

15. Identify and list the risks and benefits associated with the use of the medical devices for special access and indicate how the benefits obtained would outweigh the risks.

NOTIFICATION OF MEDICAL DEVICES FOR SPECIAL ACCESS (ROUTE B)

(In accordance with Medical Device (Exemption) Order 2016)

16. Summarize the known safety and effectiveness information in respect of the device.

17. In the case of a request for Batch Release,

(a) describe the emergency condition requiring treatment, and

(b) provide the number of devices required for one month: _____

SECTION E : ATTESTATIONS & DECLARATION

I, the undersigned hereby declare that :

i. This/These product(s) is/are according to the definition of medical device set out in Section 2, Medical Device Act 2012 (Act 737).
ii. The device(s) conform(s) to all relevant essential principles for safety and performance, set out in the Appendix 1 of Third Schedule of the MDR 2012.
iii. The medical device(s) has/have met all the labeling requirements set out in the Sixth Schedule of the MDR 2012.
iv. The technical documentation of the medical device(s) for special access is/are prepared in accordance with the format as specified in Appendix 2 of Schedule 3 of MDR 2012 and is/are available upon request by the Authority.

Remark: Any kind of deletion in Section D please provide justification

I shall be responsible for the establishment and implementation of a system to monitor safety and performance of this/these medical device(s) and take the necessary actions should there be any adverse incident occurs for the purpose of making available this/these medical device(s) for use for special access;

NOTIFICATION OF MEDICAL DEVICES FOR SPECIAL ACCESS (ROUTE B)

(In accordance with Medical Device (Exemption) Order 2016)

I hereby attest that the information and attachment provided on this notification is/are accurate, correct, complete and current to this date.

Signature:

Person Responsible Name:

Designation :

Date :

Company stamp :

APPENDIX 1

MEDICAL DEVICE DETAILS

Name of Medical Device:			
Grouping :	☐ Single ☐ System ☐ Family ☐ Set		
Brief Description:			
Brand:			
Identifier (catalogue or model number):			
Intended use of the device:			
Manufacturer's Information:	Manufacturer's Name: *(as it appears on the label)* Contact Name and Title: Address (Number , Street, City, Country) Postal Code: Telephone : Email :		
Risk-Based Classification :		**Classification Rule:** (according to First Schedule on Rules of Classification of Medical Device, MDR 2012)	
Quantity to be Imported:			
Marketing Approval Status in other country(-ies) (Please : iii. state the name (s) of country (ies) iv. provide evidence such as Declaration of Conformity/Device Licence/Registration Certificate/510k/etc)	☐ Registered /Licensed	☐ Exempted/ Notified	☐ Others (please specify) ....
Grouping List :	***Not Applicable to single medical device***		

No.	Name of device, accessories, constituent components, or articles as per product label:	Model	Brief Description	Quantity to be Imported

Note : If more than one (1) medical device, please fill up in a separate sheet**.**

Annex D
(normative)

DISPOSAL OF MEDICAL DEVICE FOR SPECIAL ACCESS

	POST HANDLING NOTICE TO MDA: 'DISPOSAL OF MEDICAL DEVICE FOR SPECIAL ACCESS'

Please complete all information requested In this form.	
Please state "No restriction letter" 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: Disposal or Exported Out	

DECLARATION
(Please read carefully & tick the boxes)

I, the undersigned, hereby declare that:

☐	The balance of the medical devices under special access route are properly disposed of.
☐	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:	

Endorsement by the healthcare facility

Name:	Designation:
Company stamp: Date:	

Please return this form to :
Chief Executive, Medical Device Authority
Email : sa.cm@mda.gov.my

Annex E
(informative)

List of recognized foreign regulatory authorities and respective approval types.

Country/Region	Approval Type
(i) Australia	Therapeutic Goods Administration (TGA) licence
(ii) Canada	Health Canada licence
(iii) European Union (EU)	For general medical device : • Annex II Section 3 or Annex V of MDD (for Class IIA) • Annex II Section 3 or Annex III coupled with Annex V of MDD (for Class IIB) • Annex II Section 3 and 4 of MDD (for Class III) • Annex II Section 3 and 4 of AIMDD (for active implantable medical device) For IVD medical device : • Annex IV (Including Section 4 and 6) of IVDD (for List A IVD) • Annex IV (excluding Section 4 and 6) or Annex V coupled with Annex VII of IVDD (for List B and self-testing IVD)
(iv) Japan	Ministry of Health, Labour and Welfare (MHLW) licence
(v) United States of America (USA)	• US FDA 510(k) clearance letter [510(k) exempted products do not qualify for abridged evaluation route]; or • US FDA PMA approval letter
(vi) Any other notified bodies or regulatory authorities recognized by MDA from time to time	• To be determined by MDA from time to time

MDA/GD/0043

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.mda.gov.my