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MEDICAL DEVICE GUIDANCE DOCUMENT

NOTIFICATION OF MEDICAL DEVICE FOR SPECIAL ACCESS



Medical Device Authority
MINISTRY OF HEALTH MALAYSIA

Contents	Page
Preface	iii
1 Introduction	1
2 Scope and application	1
3 Term and definitions	1
4 Requirement	3
5 Notification procedure	4
6 Notification review	11
7 Labelling of medical device for special access	11
8 Duties and responsibilities of applicant.....	11
9 Post handling of medical devices for the purposes of special access	12
Annex A Notification procedure.....	13
Annex B Notification of Medical Devices For Special Access (Route A) Form.....	14
Annex C Notification of Medical Devices For Special Access (Route B) Form	19
Annex D Disposal of medical device for special access Form	25
Annex E List of recognized foreign regulatory authorities and respective approval types.	27

1 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, and/or to facilitate their business endeavour.

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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NOTIFICATION OF MEDICAL DEVICE FOR SPECIAL ACCESS

1 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), including that the device be registered with the Medical Device Authority (MDA). The Medical Device (Exemption) Order 2016 however has provided for exemption of special access medical devices from registration requirement if they fulfill the criteria and submit a notification to the Authority.

Subsequent to the receipt of notification from the applicant, an Acknowledgement on Notification will be issued by the Authority for the purpose of importation and placement of the special access medical device in the Malaysian market.

2 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 for the purpose of special access.

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 representative of a foreign applicant; or who can be a local organization, government/private healthcare facility, or person who imports and/or places medical device in the Malaysian market for the purpose of special access.

3.2 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]

3.3 emergency

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

3.4 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]

3.5 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]

3.6 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]

3.7 registered medical practitioner

Means 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]

3.8 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]

3.9 serious adverse event

A serious adverse event is 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.

4 Requirements

Medical devices for special access are exempted from registration under the Act 737 and applicant is required to submit a notification to the Authority for the purposes of importation and placement in the Malaysian market.

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.mda.gov.my.

4.1 Eligibility for special access medical device and notification route

Under the Medical Device (Exemption) Order 2016, medical devices for special access has been exempted from registration with the Authority. The medical device that falls under the following criteria in Table 1 are eligible for special access and the respective notification route.

Table 1: Eligibility criteria for special access medical device

No	Eligibility Criteria	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.	Route A
2	Medical devices on compassionate use basis: <ul style="list-style-type: none"> • 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 with approval in any one of the recognized countries (refer to Annex E).	Route B

No	Eligibility Criteria	Notification route
3	Alleviation of stock-out situation: <ul style="list-style-type: none"> • The medical device is needed to minimise disruption to the continued place of a similar 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). • 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 with approval in any one of the recognized countries (refer to Annex E).	Route B

Active medical devices such as X-ray machines, CT scanners, and MRI machines that require installation and/or designated medical devices shall not be eligible for notification of exemption for special access.

5 Notification procedure

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

5.1 Submission of notification

5.1.1 Notification for Route A

- a) Route A is applicable for medical device described in item 1 of **Table 1**.
- b) Upon submission of notification, the applicant may proceed to imports and/or places the medical device in Malaysian market without waiting for the acknowledgment on notification from the Authority.
- c) The applicant shall submit the notification form together with required information/documents as described in **Table 2** to the Chief Executive of Medical Device Authority (MDA) by email at bpt@mda.gov.my. Refer to Annex B.
- d) The form for 'Notification of Medical Devices for Special Access (Route A)' can be downloaded from the Authority website at www.mda.gov.my.
- e) One notification application shall be made for only one single medical device or one medical device grouping.

Table 2. Notification form particulars for Route A

No.	Particular	Explanation
Section A: Applicant/Company Details		
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 accordance to Establishment license issued by MDA. If No, please proceed to Section B
Section B: Medical Practitioner Details		
1.	Name	Please state the name of medical practitioner who is responsible for the importation and/or placement of the medical device in the Malaysian market.
2.	Title	Please state the title of the medical practitioner.
3.	Annual Practicing Certificate Number	Please state the Annual Practicing Certificate Number issued by Malaysian Medical Council.
4.	Telephone No.	Please state telephone number of medical practitioner.
5.	Email Address	Please state email address of applicant.
6.	Health Care Facility Name & Address	Please state 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	Please 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	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 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:
9.	Classification Rule	<ul style="list-style-type: none"> • 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.
10.	Quantity to be imported	Please state the quantity of the medical device to be imported to 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.	Grouping List	Please state the name of device, accessories, constituent components, or articles as per product label. It is not applicable for single medical device.
Supporting Documents		
1.	Documents to be submitted	<ul style="list-style-type: none"> List of configurations of the medical device (for grouped devices), if applicable. Brochure, catalogue, label, sample of device, if applicable. Sterilization validation report for medical device supplied sterile, and relevant sterilization test reports, if applicable. Approval certificates from other countries / notified bodies, if applicable.
Quantity		
2.	Unit(s)	Please state quantity for this notification.
Section D: Clinical Judgement/Public Health Emergency Outbreak		
<ul style="list-style-type: none"> In case of an individual patient, prescribes the patient conditions, 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.
2.	Summarize the known safety and effectiveness information in respect of the device.	Please summarize the benefit of the device.
3.	Batch release	For batch release please provide the number of the devices for one month. i.e. outbreak situation
SECTION F : Medical Practitioner Undertaking		
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 health care facility stamps.		
Section G : Attestations & Declaration		
i.	Signature	Attestation to be signed by medical practitioner/ person responsible for this application.
ii.	Name	
iii.	Designation	
iv.	Date	Criteria for person responsible: a) Shall be from top management;
v.	Company stamps	

		<ul style="list-style-type: none"> 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.
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5.1.2 Notification for Route B

- a) Route B is applicable for medical device described in items 2 – 4 of Table 1 with approval in any one of the recognized countries (refer to Annex E).
- b) The applicant may import and/or place the medical device only after receiving the Acknowledgement on Notification.
- c) 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 bpt@mda.gov.my. Refer to Annex C.
- 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.

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

Table 3. Notification form particulars for Route B

No.	Particular	Explanation
Section A: Applicant /Company Details		
1.	Category of Applicant	Tick the category of applicant whether applicant is Local manufacturer, registered medical practitioner, Authorized Person from a Local Organization /Company.
2.	Name of Applicant	Full name as per National Registration Identity Card Number (NRIC).
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.
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 place the special access 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.

No.	Particular	Explanation
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: <ul style="list-style-type: none"> • 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	State the quantity of the medical device to be imported to Malaysia.
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.
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 place 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 special access device is requested and the reasons why this special access device was chosen.	Evidence diagnosis, treatment or prevention for which the special access 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	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

No.	Particular	Explanation
	requirements of the patient	
6.	Identify and list the risks and benefits associated with the use of the special access device and indicate how the benefits obtained would outweigh the risks.	List the risks and benefits associated with the use of the special access 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		
1.	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.

5.2 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.

5.3 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 demonstration/exhibition procedure. 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 an Acknowledgement on Notification 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 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 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 Duties and responsibilities of applicant

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

- d) keep all information pertaining to this medical device at the premises and shall be made available upon request by the Authority at any time;
- e) responsible to report Field Corrective Action (FCA) to the Authority for medical devices that are supplied through special access route;
- f) responsible report to the Authority any incident related to the device(s) that comes to the applicant's attention;
- g) ensure that labelling is sufficient to ensure safety and performance of the medical device; and
- h) ensure the use and storage of medical device accordance to manufacturer labelling requirements.

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

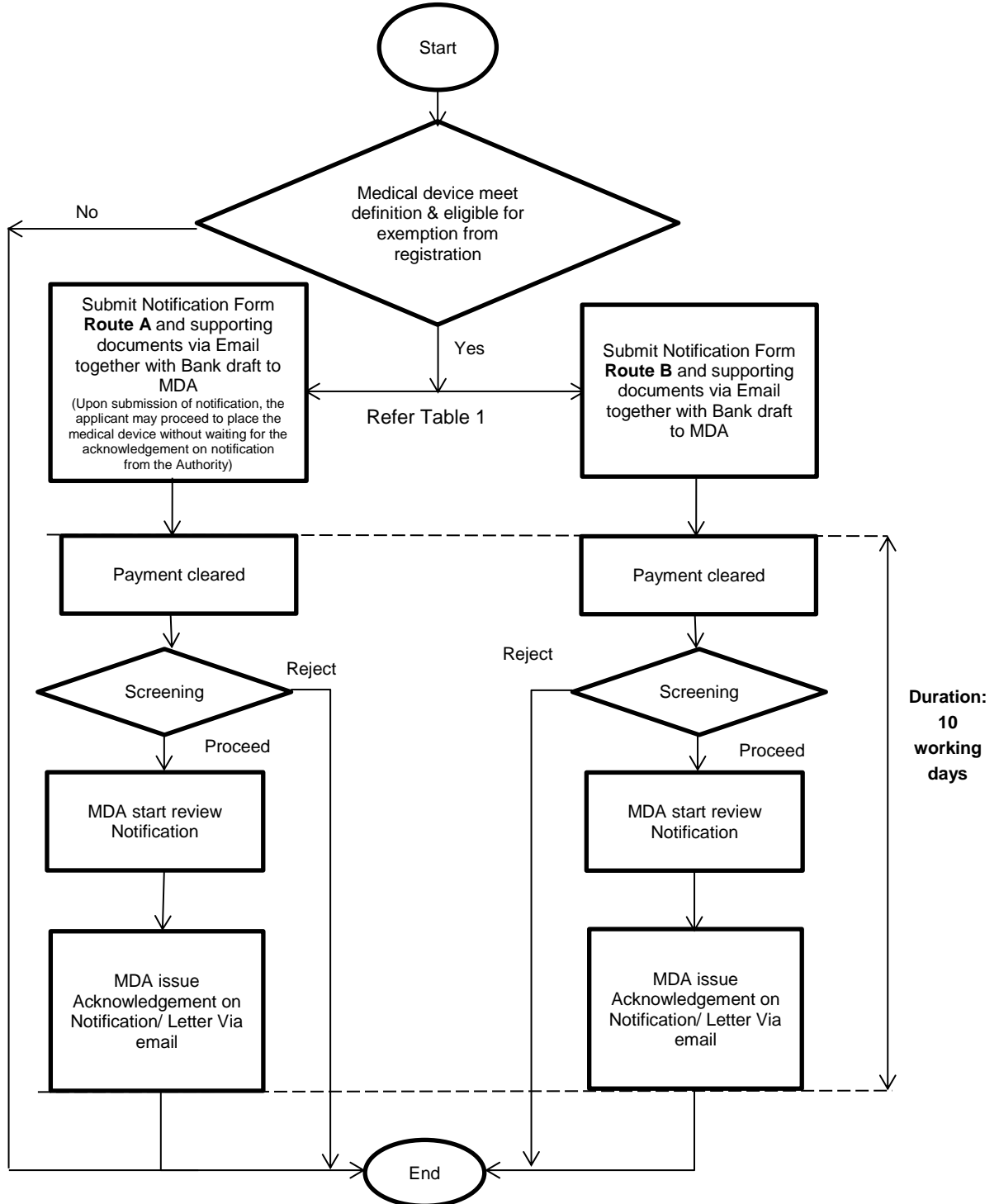
9.1 After the usage of the medical device or at the end of the validity of the special access Acknowledgement on Notification, the applicant shall:

- a) ensure the balance of 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) maintain relevant record as a proof for the disposal of those medical devices.

'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.

Annex A
(informative)

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: mda@mda.gov.my

<p>NOTIFICATION OF MEDICAL DEVICES FOR SPECIAL ACCESS (Route A) FORM (In accordance with Medical Device (Exemption) Order 2016)</p>			
<p><i>All field are mandatory unless stated otherwise</i></p>			
<p>SECTION A : APPLICANT / COMPANY DETAILS (This section is for the individual, institution or organization who or which takes responsibilities for the importation and/or placement the special access medical devices in Malaysia)</p>			
<p>1. Please Tick The Appropriate Box:</p> <p><input type="checkbox"/> Local manufacturer</p> <p><input type="checkbox"/> Registered medical practitioner <i>(obtains directly from the manufacturer for place the special access medical device to his/her patient)</i></p> <p><input type="checkbox"/> An Authorized Person from a Local Organization / Company <i>(Note: Must Have A Permanent Address In Malaysia)</i></p> <p><input type="checkbox"/> Others (Please Specify):</p>			
<p>2. Name of Applicant:</p>			
<p>3. NRIC No./Passport:</p>	<p>4. Designation:</p>		
<p>5. Name & Address of Organization:</p>			
<p>6. Telephone No.:</p>	<p>7. Email Address:</p>		
<p>8. Does the company already hold Establishment License?</p>	<table style="width: 100%; border: none;"> <tr> <td style="width: 50%; border: none;"> <p><input type="checkbox"/> Yes</p> <p>If Yes, please state the company Establishment License Number: </p> <p>Company's Role :</p> <p><input type="checkbox"/> Local Manufacturer</p> <p><input type="checkbox"/> Authorized Representative</p> <p><input type="checkbox"/> Distributor</p> <p><input type="checkbox"/> Importer</p> </td> <td style="width: 50%; border: none;"> <p><input type="checkbox"/> No</p> </td> </tr> </table>	<p><input type="checkbox"/> Yes</p> <p>If Yes, please state the company Establishment License Number: </p> <p>Company's Role :</p> <p><input type="checkbox"/> Local Manufacturer</p> <p><input type="checkbox"/> Authorized Representative</p> <p><input type="checkbox"/> Distributor</p> <p><input type="checkbox"/> Importer</p>	<p><input type="checkbox"/> No</p>
<p><input type="checkbox"/> Yes</p> <p>If Yes, please state the company Establishment License Number: </p> <p>Company's Role :</p> <p><input type="checkbox"/> Local Manufacturer</p> <p><input type="checkbox"/> Authorized Representative</p> <p><input type="checkbox"/> Distributor</p> <p><input type="checkbox"/> Importer</p>	<p><input type="checkbox"/> No</p>		

**NOTIFICATION OF MEDICAL DEVICES
FOR SPECIAL ACCESS (Route A) FORM**
(In accordance with Medical Device (Exemption) Order 2016)

SECTION B : MEDICAL PRACTITIONER DETAILS

(This section is for the medical practitioner who or which takes responsibilities for the importation and/or placement the special access 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 special access 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.

**NOTIFICATION OF MEDICAL DEVICES
FOR SPECIAL ACCESS (Route A) FORM**
(In accordance with Medical Device (Exemption) Order 2016)

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 special access 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 special access medical device.
- iii. declare that the special access 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 special access 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 special access 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 special access medical device. I attest that institutional policies will be followed.

Signature:

Date :

Health Care Facility Stamp :

**NOTIFICATION OF MEDICAL DEVICES
FOR SPECIAL ACCESS (Route A) FORM**
(In accordance with Medical Device (Exemption) Order 2016)

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 special access 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 special access 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 :

Annex C
(normative)



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

NOTIFICATION OF MEDICAL DEVICES FOR SPECIAL ACCESS (ROUTE B) FORM <i>(In accordance with Medical Device (Exemption) Order 2016)</i>					
<i>All field are mandatory unless stated otherwise</i>					
SECTION A : APPLICANT / COMPANY DETAILS <i>(This section is for the individual, institution or organization who or which takes responsibilities for the importation and/or placement of medical devices for special access in Malaysia)</i>					
1. Please Tick The Appropriate Box:					
<input type="checkbox"/> Local manufacturer <input type="checkbox"/> Registered Medical Practitioner <i>(obtains directly from the manufacturer for place the medical devices for special access to his/her patient)</i> <input type="checkbox"/> An Authorised Person from a Local Organisation / Company <i>(Note: Must Have A Permanent Address In Malaysia)</i> <input type="checkbox"/> Others (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?	<table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; padding: 5px;"> <input type="checkbox"/> Yes If Yes, please state the company Establishment License Number: Company's Role : </td> <td style="width: 50%; padding: 5px;"> <input type="checkbox"/> No </td> </tr> <tr> <td style="padding: 5px;"> <input type="checkbox"/> Local Manufacturer <input type="checkbox"/> Authorized Representative <input type="checkbox"/> Distributor <input type="checkbox"/> Importer </td> <td></td> </tr> </table>	<input type="checkbox"/> Yes If Yes, please state the company Establishment License Number: Company's Role :	<input type="checkbox"/> No	<input type="checkbox"/> Local Manufacturer <input type="checkbox"/> Authorized Representative <input type="checkbox"/> Distributor <input type="checkbox"/> Importer	
<input type="checkbox"/> Yes If Yes, please state the company Establishment License Number: Company's Role :	<input type="checkbox"/> No				
<input type="checkbox"/> Local Manufacturer <input type="checkbox"/> Authorized Representative <input type="checkbox"/> Distributor <input type="checkbox"/> Importer					
SECTION B : MEDICAL PRACTITIONER DETAILS					

**NOTIFICATION OF MEDICAL DEVICES
FOR SPECIAL ACCESS (ROUTE B) FORM**
(In accordance with Medical Device (Exemption) Order 2016)

(This section is for the Medical Practitioner who or which takes responsibilities for the importation and/or place the medical devices for special access in Malaysia)

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 place 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)

3. 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.

4. 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

**NOTIFICATION OF MEDICAL DEVICES
FOR SPECIAL ACCESS (ROUTE B) FORM**
(In accordance with Medical Device (Exemption) Order 2016)

5. 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.

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

7. 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 :

- v. This/These product(s) is/are according to the definition of medical device set out in Section 2, Medical Device Act 2012 (Act 737).
- vi. 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.
- vii. The medical device(s) has/have met all the labeling requirements set out in the Sixth Schedule of the MDR 2012.
- viii. 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

**NOTIFICATION OF MEDICAL DEVICES
FOR SPECIAL ACCESS (ROUTE B) FORM**
(In accordance with Medical Device (Exemption) Order 2016)

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;

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 :

DECLARATION <i>(Please read carefully & tick the boxes)</i>	
I, the undersigned, hereby declare that:	
<input type="checkbox"/>	The balance of the medical devices under special access route are properly disposed of.
<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:	
Endorsement by the healthcare facility	
Name:	Designation:
Company stamp: Date:	

Please return this form to :
Chief Executive Medical Device Authority
Email : bpt@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)	<p>For general medical device :</p> <ul style="list-style-type: none"> • 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) <p>For IVD medical device :</p> <ul style="list-style-type: none"> • 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)	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • To be determined by MDA from time to time

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>

