

MDA/GD/0043
Mei 2025
Second Edition

MEDICAL DEVICE GUIDANCE DOCUMENT

IMPORT AND/OR SUPPLY OF UNREGISTERED MEDICAL DEVICES UNDER SPECIAL ACCESS EXEMPTION APPLICATION



Medical Device Authority
MINISTRY OF HEALTH MALAYSIA

Contents

Preface 3

1. Introduction 4

2. Scope and Application 4

3. Terms and definitions..... 4

4. Criteria for Special Access Medical Device 6

5. Application Process..... 7

6. Labelling of Medical Devices for Special Access 8

7. Validity Period of Exemption Application..... 8

8. Post handling of medical devices after Validity Period Ended / Termination 8

9. Duties and responsibilities of applicant 9

ANNEX A (normative) PROCESS FLOW FOR SPECIAL ACCESS MEDICAL DEVICE APPLICATION..... 11

ANNEX B (normative) Information requirements are as outlined in the MeDC@St..... 12

ANNEX C(normative) TEMPLATE HEALTHCARE PROFESSIONAL REQUEST LETTER.... 16

ANNEX D (normative) Disposal Form of Medical Device for Special Access..... 18

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-

- i. Medical Device Act 2012 (Act 737);
- ii. Medical Device Regulations 2012; and
- iii. Medical Device (Exemption) Order 2024.

In this Guidance Document, the following verbal forms are used:

- “shall” indicates a requirement;
- “should” indicates a recommendation;
- “may” indicates a permission; and
- “can” indicates a possibility or a capability.

Notwithstanding the provisions of this Guidance Document, the MDA reserves the right to request additional information or materials, or to impose conditions not explicitly outlined in this document, as deemed necessary for regulatory control.

The MDA has made significant efforts to ensure the accuracy and completeness of this guidance document. However, in the event of any conflict between the content of this document and written law, the provisions of the law shall prevail.

MDA reserves the right to amend any part of the guidance document from time to time.

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Website: <http://www.mda.gov.my>

IMPORT AND/OR SUPPLY OF UNREGISTERED MEDICAL DEVICES UNDER SPECIAL ACCESS EXEMPTION APPLICATION

1. Introduction

In the domain of healthcare, access to vital medical devices is of paramount significance, particularly in critical or emergent situations. It is essential to ensure the availability of these devices when conventional medical treatments have proved ineffective, are unavailable, or are unsuitable. Special access provisions are designed to address these unique circumstances by establishing a regulated framework for obtaining unregistered medical devices.

Under the Medical Device (Exemption) Order 2024, the Minister has exercised Section 77 of the Act 737, exempting special access medical devices from the requirement of registration under Section 5 of the Act. Additionally, medical devices qualifying for this exemption must comply with the application procedures established by the Authority.

This document outlines the general requirements for notifying the Authority regarding special access medical devices, ensuring that these devices are appropriately handled in accordance with the exemption provisions and regulatory expectations.

2. Scope and Application

This guidance applies to the importation and use of special access medical devices as defined under the Medical Device (Exemption) Order 2024. Therefore, it provides details about who qualifies for exemption, the steps for notifying authorities, and the responsibilities of applicants regarding unregistered medical devices intended for Special Access.

Medical devices intended for donation are excluded from the scope of special access medical devices. All donated medical devices must comply with the relevant requirements of Act 737 and its subsidiary legislations.

This application must be obtained prior to importation involving medical devices, and serve to facilitate the process of importing or placing medical devices for their use in healthcare settings.

3. Terms and definitions

For the purpose of this document, the terms and definitions in Act 737, the regulations under it and the following terms and definitions apply.

3.1 applicant

The applicant is either the person responsible from the manufacturer or an Authorized Representative (AR).

3.2 Authority

The Medical Device Authority established under Medical Device Authority Act 2012 (Act 738).

3.3 competent authorities

Competent regulatory authorities or notified bodies recognised by MDA as listed in the Appendix 1 that exercises a legal right to control the use or sale of medical devices within its jurisdiction, and can take legal action to ensure that medical devices marketed within its jurisdiction comply with legal requirements.

Note: Refer Circular Letter No. 1/2025: Conformity Assessment Procedures for Medical Device Approved by Recognised Countries

3.4 import

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

[SOURCE: Custom Act 1967 (Act 235)]

3.5 medical device

As defined in Section 2 of the Medical Device Act 2012 (Act 737).

3.6 medical practitioner

The medical practitioner who requests or assumes responsibility for unregistered medical devices within the declared premises in Malaysia

3.7 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 2024]

3.8 validity period

The timeframe during which a medical device can be imported and distributed under special access approval.

4. Criteria for Special Access Medical Device

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

Table 1: Situations that require special access for medical devices

No.	Situations	Description
1.	Medical Devices in Emergency Situations	In the context of medical devices intended for use in emergency situations that present an imminent threat to a patient's life or long-term well-being, particularly in scenarios where the required medical equipment is unavailable within the Malaysian healthcare system. Such situations encompass individuals facing severe illness with a prognosis of imminent death within a few months or a heightened risk of premature death without prompt intervention. Additionally, this pertains to instances of declared health emergencies, including pandemic situations.
2.	Medical Devices on Compassionate Use Basis	<p>A. Lack of Viable Treatment Alternatives: There must be a demonstrated absence of alternative treatment options available.</p> <p>B. Failure or Unsuitability of Alternatives: Available alternative treatments should either have failed to produce the desired results or have been deemed ineffective or unsuitable based on the clinical judgment of the attending medical practitioner.</p> <p>C. Clinical Imperative: It must be established that the patient's health would suffer significant clinical compromise in the absence of the requested treatment.</p>
3.	Alleviation of stock-out situation	Medical device which is essential to prevent any interruptions in the ongoing availability of a similar device. MDA will consider such requests when specific situations, like certain cases in the registration process, ongoing change notifications or post-market actions, are in progress.
4.	Enhancing Procedure Outcomes Through Design and Functionality	This pertains to the design and operation of a medical device, which should have the potential to positively influence and improve the results of a patient's procedure or treatment.

5. Application Process

An applicant who wishes to import and/or supply a special access medical device shall notify the Authority by adhering to the outlined procedures provided in Annex A.

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 under the purview of the Authority.
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 <https://portal.mda.gov.my/industry/product-classification.html>.

5.1 Submission of application

- 1) The applicant must complete the prescribed application online form as shown in Annex B via Medcast system. All required sections, including details about the medical practitioner, medical device, and justification for special access, must be accurately filled.
- 2) The submission must include supporting documents such as:
 - a. Manufacturer's QMS ISO 13485 Certificate
 - b. Pre-market Approval / Registration Certificate in other countries
 - c. Instruction for Use (IFU), Operations Manual or Product Brochure by Manufacturer
 - d. Clinical evidence demonstrating the device's safety and effectiveness for the intended use, if relevant.
 - e. Special Access Medical Device Label
 - f. Establishment License (AR & Importer)
 - g. Letter of Authorization (LOA) from Legal Manufacturer. (if applicable)
 - h. A letter from the requesting medical practitioner detailing the clinical justification for the special access request and statement of undertaking. (Annex C)
- 3) Applicants are advised to submit applications as early as possible, especially for urgent requests, to allow adequate time for MDA's review and processing.
- 4) Upon successful submission, MDA will issue an exemption application letter. This letter should be retained as proof of application and will be required for any further correspondence with the Authority.

5.2 Administrative charge and Reviewing Process

- 1) Each special access application is subject to an administrative charge of RM 300. The payment must be made online via the BayarNow portal, available to registered users. Detailed guidance on making payments can be found in the BayarNow Customer Portal and Payment Gateway user manual. It is important to note that the administrative charge is non-refundable, regardless of the outcome of the application process.
- 2) Once the application is submitted, the Authority will review the provided information. If the Authority finds that any required information or documentation is incomplete, the applicant will be notified and requested to provide the missing details. The applicant is expected to submit the additional information within 10 working days from the date of the Authority's request.
- 3) Failure to submit the requested information within the specified timeframe may result in the rejection of the application. In such cases, the administrative charge is non-refundable, but the applicant retains the right to submit a fresh application. Additionally, the Authority reserves the right to revoke any written Exemption Application if there is a breach or non-compliance with the terms and conditions, or the duties and responsibilities of the applicant.

6. Labelling of Medical Devices for Special Access

For medical devices granted special access, labelling is essential. The label must include 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.

7. Validity Period of Exemption Application

The validity period of this application is 6 months. However, the application given will not be valid when the Special Access Medical Device has been completely registered with MDA.

8. Post handling of medical devices after Validity Period Ended / Termination

Upon the expiration of the validity period of the special access exemption application, and if the medical device has not been installed, placed in the market, or registered with the Authority, the applicant is required to manage the medical devices using one of the following methods:

- a) Proper Management Options:
 - a) Disposal of the medical device.
 - b) Export Out of the medical device.
 - c) Proceed with Medical Device Registration.

d) Submit a New Special Access Medical Device Application.

b) Post-Handling Application:

The applicant must submit a Post-Handling Notice to the Authority via email, no later than 30 days from the end of the special access validity period. Please refer to Annex D for the submission form.

c) Record Keeping:

The applicant must maintain relevant records as proof of the actions taken, which may include:

- a) Disposal records of the medical device.
- b) Documentation of export out of the medical device.
- c) Copies of registration certificates and the names of the medical devices.
- d) Proof of any new submission of Special Access Medical Device Application.

9. Duties and responsibilities of applicant

The exemption application granted for special access is contingent upon the applicant's adherence to the following duties, responsibilities, and obligations:

1. The applicant is prohibited from importing or supplying any unregistered medical device before receiving the Exemption Application from the Authority.
2. The medical device must only be used for the specific purpose stated in the special access application submission. The applicant must ensure that the device is not repurposed for any other use.
3. **Labelling Compliance:**
It is the applicant's duty to ensure that all medical devices are properly labelled in accordance with regulatory requirement.
4. **User Guidance and Post-Market Monitoring:**
The applicant must advise the user or healthcare facility on the correct handling and usage of the medical device. In case of any adverse incidents during the special access period, the applicant is responsible for taking immediate corrective actions. Additionally, the applicant must manage post-market issues, ensuring compliance with the **Medical Device (Duties and Obligations of Establishments) Regulations 2019** and other relevant requirements.
5. **Record Maintenance and Availability:**
The applicant is responsible for keeping thorough records of all information related to the unregistered medical device at their premises. These records must be readily available for review by the Authority upon request.
6. **Continued Market Placement and Registration:**
If the applicant wishes to continue placing the medical device on the market after the

validity period of exemption expires, they must apply for medical device registration under **Act 737**.

7. Installation and User Support for Active Devices:

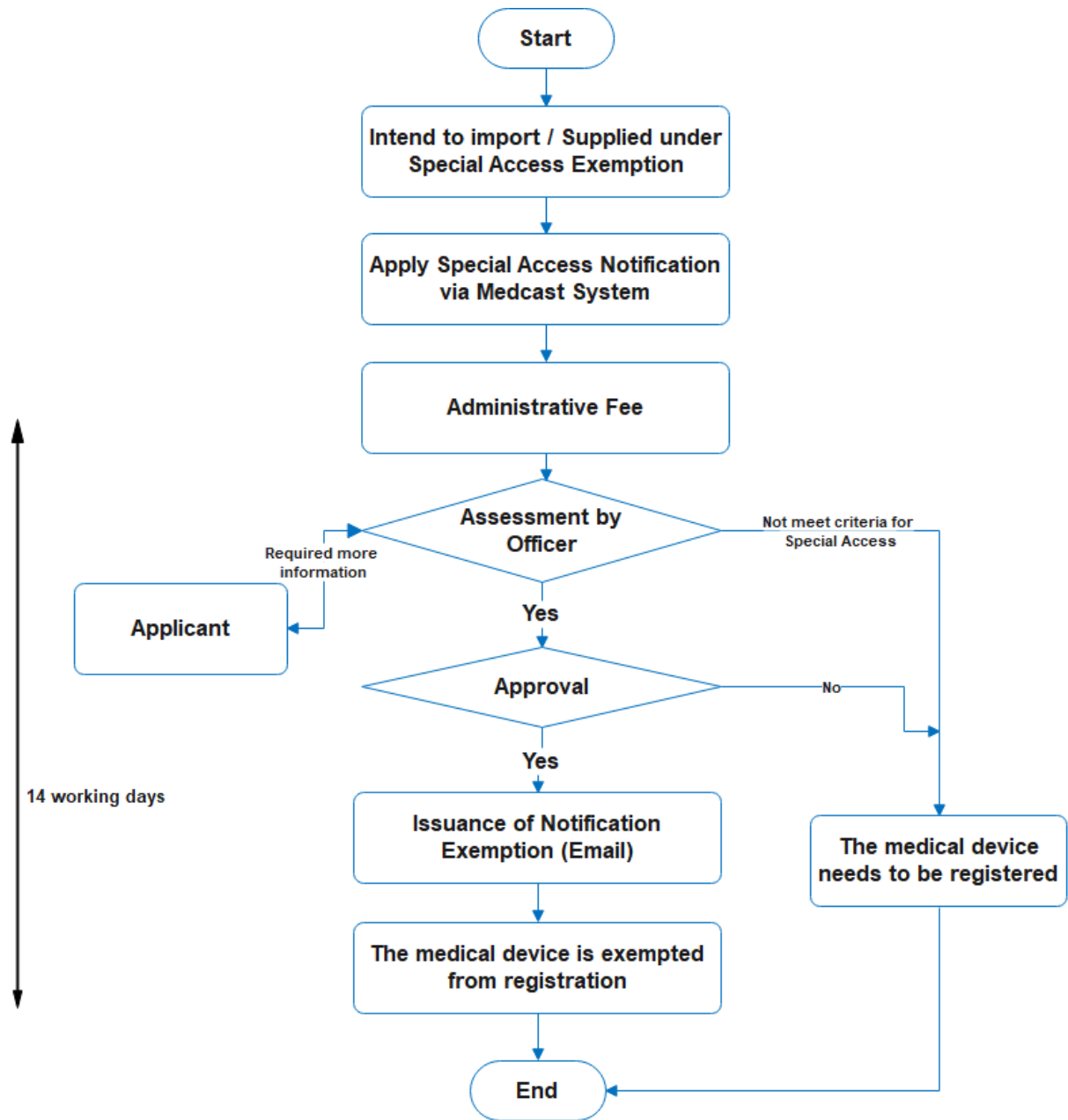
For active medical devices requiring installation, the applicant must ensure that proper installation, testing, commissioning, and acceptance are completed by the manufacturer. Adequate on-site training for healthcare personnel, as well as information on warranties, technical support, and maintenance, must be provided. The user manual must accompany the device, and spare parts must be readily available to healthcare facilities when required.

8. Adherence to Terms and Conditions:

The applicant must strictly comply with all terms and conditions specified by the Authority in the Special Access Application. Any violation of these conditions may lead to revocation of the exemption.

**ANNEX A
(normative)**

PROCESS FLOW FOR SPECIAL ACCESS MEDICAL DEVICE APPLICATION



ANNEX B
(normative)

Information requirements are as outlined in the MeDC@St

N O	MEDCAST APPLICATION FORM	EXPLANATION
SECTION A : Applicant Details		
1.	Applicant Type :	Applicant is either: <ul style="list-style-type: none"> - Local manufacturer license with Authority - An authorised representative license with Authority
2.	Name of Applicant	Person responsible name
3.	NRIC No. / Passport	
4.	Designation	
5.	Organisation Details	Including Name & Address
6.	Telephone No.	Contact person number for efficient communication
7.	Email Address	Contact person email for efficient communication
8.	Does The Company Already Holds Establishment License?	If there is no establishment license, the application is not eligible
SECTION B : Healthcare Professional Details <i>(This Section Is for The Healthcare Professional Who or Which Takes Responsibilities for The Importation And/or Supply the Unregistered Medical Devices in Malaysia)</i>		
1.	Name	The identity of the medical professional who initiated or acknowledge the device request.
2.	Title	<ul style="list-style-type: none"> ➤ Hospital Director ➤ Head of Department ➤ Specialist /Physicians ➤ Medical Officer
3.	Annual Practicing Certificate Number	Unique identification number issued to registered medical practitioners in Malaysia
4.	Telephone No.	-
5.	Email Address	-
6.	Healthcare Facility	The site where the Special Access medical device will be placed or utilized. *Each application corresponds to a single site.
SECTION C : Medical Device Details		
	Name Of Medical Device Grouping Brief Description Brand Identifier Intended use Manufacturer's information Risk-Based Classification Quantity to be Imported	<ul style="list-style-type: none"> ➤ A single application represents one group of medical devices only. ➤ The imported quantity solely pertains to the number intended for supply to the healthcare facility within the context of this application.

N O	MEDCAST APPLICATION FORM	EXPLANATION
	Marketing Approval Status in other country(-ies)	➤ The quantity are not for future supply.
	Supporting Documents	<ol style="list-style-type: none"> 1) Manufacturer's QMS ISO 13485 Certificate 2) Pre-market Approval / Registration Certificate in other countries 3) Instruction for Use (IFU), Operations Manual or Product Brochure by Manufacturer 4) Clinical evidence demonstrating the device's safety and effectiveness for the intended use, if relevant. 5) Special Access Medical Device Label 6) Establishment License (AR & Importer) 7) Letter of Authorization (LOA) from Legal Manufacturer. (if applicable) 8) A letter from the requesting medical practitioner detailing the clinical justification for the special access request and statement of undertaking.
SECTION C : Grouping List (for System, Family or Set)		
	Name of Device, Accessories as per label. Intended Use Identifier / Model Brief description Quantity to be imported.	
SECTION D : Medical Rationale		
1	Please tick the appropriate box:	
<input type="checkbox"/>	Medical devices on compassionate use basis	<p>A. Lack of Viable Treatment Alternatives: There must be a demonstrated absence of alternative treatment options available.</p> <p>B. Failure or Unsuitability of Alternatives: Available alternative treatments should either have failed to produce the desired results or have been deemed ineffective or unsuitable based on the clinical judgment of the attending medical practitioner.</p> <p>C. Clinical Imperative: It must be established that the patient's health would suffer significant clinical compromise in the absence of the requested treatment.</p>

N O	MEDCAST APPLICATION FORM	EXPLANATION
		D. In the context of medical devices intended for use in emergency situations that present an imminent threat to a patient's life or long-term well-being, particularly in scenarios where the required medical equipment is unavailable within the Malaysian healthcare system. Such situations encompass individuals facing severe illness with a prognosis of imminent death within a few months or a heightened risk of premature death without prompt intervention. Additionally, this pertains to instances of declared health emergencies, including pandemic situations.
□	Alleviation of stock-out situation	Medical device which essential to prevent any interruptions in the ongoing availability of a similar device. MDA will consider such requests when specific situations, like certain cases in registration process, ongoing change notifications or post-market actions, are in progress.
□	Design and/or operation that is likely to support or enhance the outcomes of the procedure or treatment for the patient.	This pertains to the design and operation of a medical device, which should have the potential to positively influence and improve the results of a patient's procedure or treatment.
1.	Provide the diagnosis, treatment or prevention for which the unregistered device is requested and the reasons why this unregistered device was chosen.	Please include following information : (1) Diagnosis / Medical Condition: (2) Treatment / Procedure that involve: (3) Reason why these products are to be exempted: (4) Reason not used alternative treatment (5) Registration Status ➤ Registration issue ➤ Medcast Submission ID (in draft/evaluation) ➤ CAB Assessment status ➤ Previous registration number and validity. If applicable
2.	List the registered devices considered and provide a rationale as to why these registered devices would not adequately meet the requirements of the patient (registered with MDA).	List any similar medical devices that are registered with MDA and were considered for use. Provide reasons why these registered devices are not sufficient or suitable for the patient's needs, and why the unregistered device is necessary for better treatment.
3.	Identify and list the risks and benefits associated with the use of the unregistered device and	Identify the potential risks and benefits associated with using the unregistered device. Explain how the expected benefits (e.g., improved patient outcomes)

N O	MEDCAST APPLICATION FORM	EXPLANATION
	indicate how the benefits obtained would outweigh the risks.	outweigh any potential risks involved in using a device that has not been officially registered.
4.	Summarize the known safety and effectiveness information in respect of the device.	Provide a summary of any known information regarding the safety and effectiveness of the unregistered device. This can include clinical data, research findings, or manufacturer information that demonstrates the device's reliability and suitability for the intended purpose.
5.	In the event that conventional medical treatment has failed, is unavailable or unsuitable, Describe the condition for the treatment	If conventional medical treatments have failed, are unavailable, or are unsuitable, describe the patient's condition and why these standard treatments are not effective.
6.	In the case of emergency situation, Number of devices required for one month	In case of an emergency, specify the number of devices required to treat the patient for a one-month period . This ensures that the correct number of devices is supplied during the special access period.
7.	Please define quantity for batch release (if required).	If batch release is needed for the unregistered device, define the total quantity of devices required for the release, ensuring it aligns with the needs of the treatment or procedure.
SECTION E : (Not Applicable)		
SECTION F : Attestation & Declaration		

**ANNEX C
(normative)**

TEMPLATE HEALTHCARE PROFESSIONAL REQUEST LETTER
(To be printed on the healthcare facility's letterhead)

[Date]

To:
Medical Device Authority
Ministry of Health.

Subject: **Justification for Special Access Request and Statement of Undertaking**

Dear Sir/Madam,

I, hereby submit a formal request for special access to the unregistered medical device as follows:

Device Name (as per device label)	
Brand	
Quantity	

Justification (in brief):

(1) Diagnosis / Medical Condition:	
(2) Treatment / Procedure that involve:	
(3) Reason why these products are to be exempted:	
(4) Reason not used alternative treatment:	
(5) Training	

As the requesting medical practitioner, I hereby undertake the following responsibilities:

1. The requested medical device will be used solely for the purpose outlined in this letter.
2. In accordance with Section 43 of the Medical Device Act 2012 [Act 737], I will ensure that the medical device is used in a safe and appropriate manner, and/or I will provide the necessary supervision during its use.
3. I will immediately report any adverse events or safety concerns related to the Authority immediately, as required under the Medical Device (Duties and Obligations of Establishments) Regulations 2019.

MDA/GD/0065

I acknowledge that MDA does not assess the Technical File safety and performance of the device during the application review. Consequently, the responsibility for prescribing an unregistered medical device lies solely with the qualified healthcare professional. It is also the duty of the qualified healthcare professional to obtain informed consent from the patient prior to the undergoing treatment.

Thank you for your consideration.

Yours sincerely,

(Signature)

Dr. [Full Name]

[Professional Title]

[Medical Registration Number]

[Official Stamp]

**ANNEX D
(normative)**

Disposal Form of Medical Device for Special Access

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

Please list out all Application ID:

- 1) MDA/SA/
- 2) MDA/SA/

PARTICULARS OF MEDICAL DEVICE(S) (Repeat as needed)

Name of Device (incl. accessories, components, etc)	Device details (i.e Manufacturer, Brand and Model)	Qty Import	Qty & Mode used:	
			Disposed or destroyed locally/ Exported out of Malaysia / Others. Please Specify	

ATTESTATIONS & DECLARATION

I, the undersigned, hereby declare that:

- 1) All unregistered medical devices related to the above application have been properly disposed of, destroyed, or exported out of Malaysia.
- 2) The information provided on this application form is accurate, correct and complete to the best of my knowledge;
- 3) I am aware that the placement of any unregistered medical device in the market is strictly prohibited under the Medical Device Act 2012 [Act 737];
- 4) I agree to comply with all relevant provisions of the Medical Device Act 2012 (Act 737) and Medical Device Regulations 2012.

Signature:

Company Stamp:

Name:

Designation:

Date:

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