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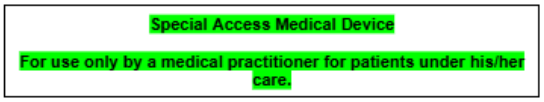
Third Edition

MEDICAL DEVICE GUIDANCE DOCUMENT

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

Medical Device Authority
MINISTRY OF HEALTH MALAYSIA

REVISION HISTORY

No	Edition no.	Section	Description of changes	Published date
	Second	All	Revised release	May 2020
1	Third	Title	Changed title to IMPORT AND/OR SUPPLY OF UNREGISTERED MEDICAL DEVICES UNDER SPECIAL ACCESS EXEMPTION APPLICATION	November 2025
2		1. Introduction	Rephrase the contents of clause 1. Introduction to provide better clarity	February 2026
3		i. Scope and application	Added Medical Device ~~Device~~ (Exemption) Order 2024 as the provisions of law for special access medical device.	
4		ii. Terms and definitions	Changed definitions of applicant to "The applicant is either the person responsible from the local manufacturer or an Authorized Representative (AR)."	
5			Added new definitions for 3.4 import and 3.8 validity period. Rephrase the definition for 3.6 medical practitioners.	
6		iii. Criteria for Special Access Medical Device	Removed Route A and B in Table 1: Situations that require special access for medical devices. Rephrase sentences to provide better clarity.	
7		iv. Application process	Changed submission process from manual form to Medcast.	
8			Changed Administrative charge and Reviewing Process from bank draft to online payment via BayarNow.	
9		5. Labelling of Special Access Medical Device	Added sample of labelling requirements for special access medical device as per stated in the Medical Device Regulations (MDR) 2012 	
10		6. Validity Period of Exemption	Added validity period of exemption for 6 months.	

		Application		
11		7. Post handling of medical devices after Validity Period Ended / Termination	Rephrase the sentence to Proper Management options: i. Disposal of the medical device. i. Export Out of the medical device. ii. Proceed with Medical Device Registration.	
12			Added new requirement of Record Keeping: The applicant shall maintain relevant records as proof of the actions taken, which may include: i. Disposal records of the medical device. ii. Documentation of export out of the medical device. iii. Copies of registration certificates and the names of the medical devices.	
13		8. Duties and responsibilities of applicant	Rephrase the whole requirements for Duties and responsibilities of applicant and added new sentence below:	
14		ANNEX C (normative) TEMPLATE HEALTHCARE PROFESSIONAL REQUEST LETTER	Added in new template for healthcare professional request letter	

Contents

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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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 emergency situations or in the event that conventional medical treatment has failed, is unavailable or unsuitable. It is essential to ensure the availability of these devices when special access provisions are intended to address exceptional clinical circumstances by providing a regulated framework for the controlled access and use of unregistered medical devices, while ensuring appropriate regulatory oversight and patient safety.

Under the Medical Device (Exemption) Order 2024, the Minister has exercised Section 77 of the Act 737, to exempt 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 applications for exemption for special access medical devices, ensuring that such devices are handled in accordance with the exemption provisions and regulatory requirements.

2. Scope and Application

This guidance outlines the regulatory framework for the importation and use of Special Access medical devices as defined by the *Medical Device (Exemption) Order 2024*. It provides a definitive eligibility of personnel qualified for exemptions, details of procedures for notifying authorities and the responsibilities of applicants regarding the handling of unregistered medical devices.

The application for exemption must be obtained prior to the importation and/or supply of medical devices and serves to facilitate their importation or placement for 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 local manufacturer or an Authorized Representative (AR).

3.2 Authority

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

3.3 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)]

3.4 medical device

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

3.5 medical practitioner

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

3.6 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]

3.7 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 is eligible for a 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	A. **Lack of Viable Treatment Alternatives**: There must be a demonstrated absence of alternative treatment options available. 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. C. **Clinical Imperative**: It must be established that the patient's health would suffer significant clinical compromise in the absence of the requested treatment.
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

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

NOTES:

1. The applicant is responsible to confirm that the product is a medical device. Such product which does not meet the medical device definition is not under the purview of the Authority.

2. The applicant who requires confirmation if their product is a medical device may refer to guidance document MDA/GD/0006 Definition of Medical Device or apply for product classification as detailed out in the Guideline on How to Apply for Product Classification. The information, guideline and form to apply for product classification are available in the MDA Portal as per the link, https://portal.mda.gov.my/index.php/industry/classification/product-classification.

5.2 The applicant must complete the online application form as shown in Annex B via the MeDC@St system. All required sections, including details about the medical practitioner, medical device, and justification for special access, must be accurately filled.

5.3 The application must be accompanied with supporting documents as follows:

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 & Manufacturer)
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)

5.4 The applicant may submit the application once all required information has been completed and all supporting documents have been uploaded to the system. Applicants are encouraged to submit their applications as early as possible, particularly for urgent requests, to allow sufficient time for MDA's review and processing.

5.5 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. The instructions to make payment 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.

5.6 Once the application is submitted, the Authority will review the provided information within the 7 working days, upon submission of complete documents. 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 3 working days from the date of the Authority's request.

5.7 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.

5.8 The Authority will issue an Exemption letter, if satisfactory that all requirements have been complied. Additionally, the Authority reserves the right to revoke an Exemption letter if there is a breach or non-compliance with the terms and conditions, or the duties and responsibilities of the applicant. This letter should be retained as proof of application and will be required for any further correspondence with the Authority.

6. Validity Period of Exemption Letter

The validity period of the exemption granted is 6 months. The exemption will no longer be applicable once the medical device has been fully registered with the MDA. No extension shall be granted beyond the six (6)-month validity period.

7. Handling of medical devices after expiry or termination of Special Access Exemption

Upon the expiration of the validity period of the special access exemption, and where 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 in accordance with one of the following options:

I. Disposal of the medical device;
II. Export Out of the medical device; or
III. Proceed with Medical Device Registration.

The applicant shall submit a Post-Handling Notice to the Authority as 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.

8. Duties and responsibilities of applicant

The granting of a special access exemption is conditional upon the applicant's compliance with the following duties, responsibilities, and obligations:

a) The applicant shall not import or supply any unregistered medical device prior to obtaining the Exemption Application from the Authority.

b) The medical device shall be used solely for the purpose specified in the special access exemption letter. The applicant must ensure that the device is not repurposed for any other use.

c) **Labelling Compliance**:
The applicant shall ensure that all medical devices are properly labelled in accordance with regulatory requirements, including the following:

I. a statement indicating that the medical device is a special access medical device;
II. a statement specifying that the device is to be used solely by a medical practitioner for patients under his/her care.

Special Access Medical Device **For use only by a medical practitioner for patients under his/her care.**

d) **User Guidance and Post-Market Monitoring**:

The applicant shall provide adequate information on the use, operation, and maintenance of the special access medical device, including the furnishing of instructions for use (IFU), user manuals, and, where applicable, on-site training to medical practitioners, users, or technical personnel on the correct use, handling, and maintenance of the device.

In the event of any adverse incidents during the special access period, the applicant shall take immediate corrective actions. Furthermore, the applicant shall manage post-market issues in compliance with the Medical Device (Duties and Obligations of Establishments) Regulations 2019 and other relevant guidance documents.

e) **Installation and User Support for Active Devices**:

For active medical devices requiring installation, the applicant shall ensure that installation, testing, commissioning, and acceptance are carried out by trained personnel appointed or certified by the manufacturer, in accordance with the manufacturer's prescribed instructions. Adequate information on warranties, technical support, and maintenance shall be provided. The user manual shall accompany the device, and spare parts shall be made readily available to healthcare facilities, as required.

f) **Record Maintenance and Availability**:

The applicant shall maintain records as evidence of all actions taken in relation to the exempted special access medical device, including the evidence of handling the devices after the expiry or termination of special access exemption (refer to Clause 8).

All records shall be kept at the applicant's premises and be readily available for review by the Authority upon request.

g) **Continued Market Placement and Registration**:

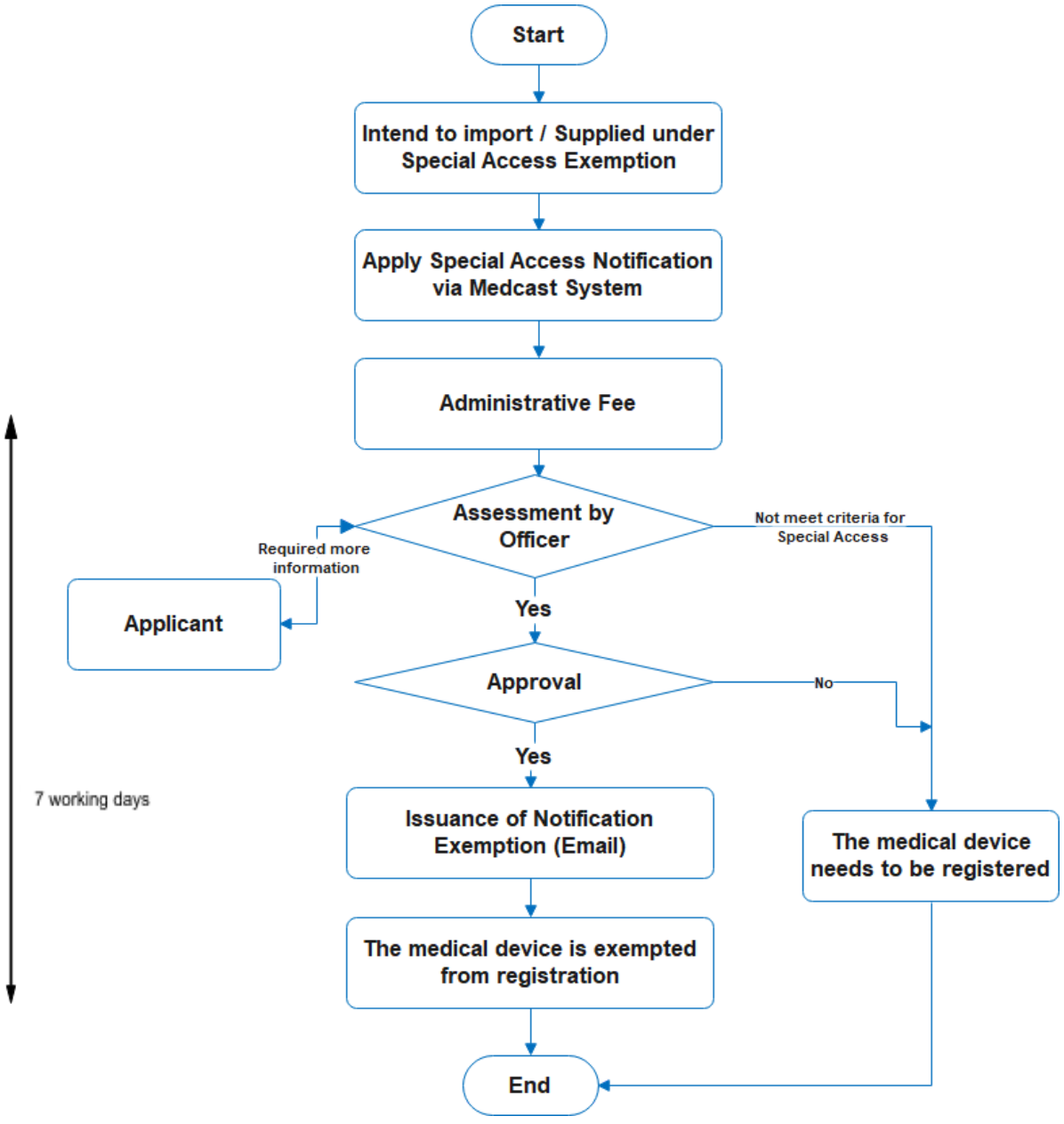
If the applicant intends to continue placing the medical device on the market after the expiry of the exemption validity period, the applicant shall apply for medical device registration in accordance with Section 5 of Act 737.

h) **Adherence to Terms and Conditions**:

The applicant shall strictly comply with all terms and conditions specified by the Authority in the Special Access Exemption letter. Any breach of these conditions may lead to revocation of the exemption and may constitute a violation of Section 5 in Act 737**.**

ANNEX A
(normative)

PROCESS FLOW FOR SPECIAL ACCESS MEDICAL DEVICE APPLICATION



ANNEX B
(normative)

Information requirements are as outlined in the MeDC@St

NO	MEDCAST APPLICATION FORM	EXPLANATION
SECTION A : Applicant Details		
1.	**Applicant Type :**	Applicant is either: - 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 Hold Establishment License?**	If there is no establishment license, the application is not eligible
SECTION B : Medical practitioners Details (*This Section Is for The Healthcare Professional Who or Which Takes Responsibilities for The Importation And/or Supply the Unregistered Medical Devices in Malaysia)*		
1.	**Name**	The identity of the medical professional who initiated or acknowledged the device request.
2.	**Title**	➢ 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		

1.	**Name Of Medical Device Grouping** **Brief Description** **Brand** **Identifier Intended use** **Manufacturer's information** **Risk-Based Classification** **Quantity to be Imported**	· 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.

NO	MEDCAST APPLICATION FORM	EXPLANATION
2.	**Marketing Approval Status in other country(-ies)**	· The quantities are not for future supply.
3.	**Supporting Documents**	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 & Manufacturer) 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)		
1.	**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:**	

□	**Medical devices on compassionate use basis**	A. Lack of Viable Treatment Alternatives: There must be a demonstrated absence of alternative treatment options available. 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. C. Clinical Imperative: It must be established that the patient's health would suffer significant clinical compromise in the absence of the requested treatment.

NO	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 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 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.

2.	**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
3.	**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.
4.	**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)

NO	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.
5.	**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.
6.	**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.
7.	**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.
8.	**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 MEDICAL PRACTITIONER'S 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 provided for the user	

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.

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 state exemption application letter ID information: -

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 & Method used: i) Disposal of the medical device. ii) Export Out of the medical device. iii) Proceed with Medical Device Registration. Please Specify	
			Qty	Method

ATTESTATIONS & DÉCLARATION

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: Name:	Company Stamp:

Date:

Designation:

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

MEDICAL DEVICE AUTHORITY

MINISTRY OF HEALTH, MALAYSIA

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