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MEDICAL DEVICE GUIDANCE DOCUMENT

APPLICATION FOR CONFIRMATION STATUS OF OBSOLETE AND DISCONTINUED MEDICAL DEVICE



Medical Device Authority
MINISTRY OF HEALTH MALAYSIA

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Contents	Page
Preface	iii
1 Introduction	1
2 Scope and application	1
3 Term and definitions.....	1
4 General Requirements	4
5 Criteria for Application of Confirmation of Obsolete and Discontinued Medical Device.....	4
6 Manner of Application	5
7 Obligations of Applicant	6
Annex A Process flow of exemption for obsolete and discontinued medical device.....	7
Annex B Application for Confirmation of Obsolete or Discontinued Medical Device.....	8
Annex B-I Template of Medical Device Details	9
Annex B-II Template of Attestation and Declaration	10
Annex C Template for Declaration Letter of Obsolete or Discontinued Medical Device..	11

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 endeavor.

This Guidance Document shall be read in conjunction with the current laws and regulations used in Malaysia, which include but not limited to the following:

- a) Medical Device Act 2012 (Act 737); and
- b) Medical Device Regulations 2012

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

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

Irrespective of the requirements of this Guidance Document, MDA has the right to request for information or material, or define conditions not specifically described in this document that is deemed necessary for the purpose of regulatory control.

MDA has put much effort into ensuring the accuracy and completeness of this guidance document. In the event of any contradiction between the contents of this document and any written law, the latter should take precedence.

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

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APPLICATION FOR CONFIRMATION STATUS OF OBSOLETE AND DISCONTINUED MEDICAL DEVICE

1. Introduction

The landscape of healthcare technology is continuously evolving, accelerated by rapid technological advancements. However, amidst this progress, certain categories of medical devices present unique challenges, particularly those that are orphaned, obsolete, or discontinued. These devices may still be actively used within government and private healthcare facilities, wellness centers, or related settings, necessitating careful management to ensure patient safety and compliance with regulatory requirements.

The medical devices that are obsolete or discontinued face difficulties in the registration process especially in meeting requirements of EPSP and CSDT which are the compulsory requirements of registration. According to the Medical Device Act 2012 [Act 737] Section 5, no medical device shall be imported, exported, or placed on the market unless it is registered under this Act.

Therefore, in order to ensure no disruption to the healthcare services, the Minister through the Medical Device (Exemption) Order 2024 exempts obsolete and discontinued medical devices from the registration requirements and establishment license, ensuring healthcare services continue without disruption.

To address careful management to ensure patient safety, this guidance document focuses on the control of obsolete and discontinued medical devices. It provides a structured approach for establishment and healthcare providers to handle these devices, ensuring they meet safety standards and operational requirements.

2. Scope and application

This guidance document applies to all types of obsolete and discontinued medical devices that meet the definitions provided in the Medical Device (Exemption) Order 2024.

It outlines the eligibility criteria, application process and responsibilities related to the continued use of these devices within healthcare facilities.

This guidance applies only to devices that:

- were previously registered with the Authority;
- can no longer be eligible for registration due to obsolescence or discontinuation, and
- remain in use within healthcare facilities in a well-functioning and properly maintained condition.

3. Terms and definitions

For the purposes of this document, the terms and definitions in Act 737, the regulations, the order and circular letter under it and the following terms and definitions apply. Additional terms used in this guidance are defined below:

3.1 Applicant

The applicant may be 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 Discontinued medical device

An existing medical device in a government or private healthcare facility, wellness centers or related facility that is no longer in the distribution.

[SOURCE: Medical Device Exemption Order 2024]

3.4 Establishment

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

3.5 End of Support (EOS)

The point at which the manufacturer ceases all service support activities for a medical device, including technical assistance, maintenance, and provision of spare parts or software updates.

3.6 Government healthcare facility

Any facility used or intended to be used for the provision of healthcare services established, maintained, operated or provided by the Government but excludes privatized or corporatized Government healthcare facilities.

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

NOTE: Hereinafter referred to as 'facility'

3.7 Healthcare facility

Any premises 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 any healthcare services provided;

MDA/GD/0071

- 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 health care paraprofessional;
- 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]

NOTE: Hereinafter referred to as 'facility'

3.8 Intended use

The objective intent of the manufacturer regarding the use of a product, process or service as reflected in the specifications, instructions and information provided by the manufacturer.

[SOURCE: Medical Device Regulation 2012]

3.9 Manufacturer

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

3.10 Medical device

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

3.11 Obsolete medical device

An existing medical device in a Government and private healthcare facilities and services, wellness centers or any related facilities which is outdated and no longer being manufactured due to design changes or evolution of new technologies.

[SOURCE: Medical Device Exemption Order 2024]

3.12 Person responsible

The person responsible has the overall control and authority to make decisions. Depending on the setup of an establishment/ company, examples of a person responsible may include the chief executive officer, managing director or general manager for a company.

3.13 Private healthcare facility

Any premises, other than a Government healthcare facility, used or intended to be used for the provision of healthcare services or health-related services, such as a private hospital, hospice, ambulatory care center, nursing home, maternity home, psychiatric hospital, psychiatric nursing home, community mental health center, haemodialysis center, medical clinic, dental clinic and

MDA/GD/0071

such other healthcare or health-related premises as the Minister may from time to time, by notification in the Gazette.

NOTE: Hereinafter referred to as the 'Facility'.

3.14 Related facilities

Healthcare institutions or infrastructures that provided medical services other than government and private hospitals or clinics.

NOTE 1 : Hereinafter referred to as the 'Facility'.

NOTE 2: Wellness centres are included under "Facility". Examples of wellness centers are spa and rehabilitation centers.

4. General requirements

In accordance with Subparagraph 3(2)(b) of the Medical Device (Exemption) Order 2024, a medical device may be exempted from the registration requirements specified in Act 737, Section 5, if it meets the following conditions:

- I. The medical device has been declared obsolete by the manufacturer; or
- II. The medical device has been declared discontinued by the manufacturer; and
- III. The Authority has confirmed the declared status.

Confirmation of the device's status must be obtained through an application submitted to the Authority.

5. Criteria for applying for confirmation of medical device status

Application for confirmation of the medical device status can be made if the criteria below has been met;

Table 1. Status and criteria of the medical device

No	Status	Eligibility Criteria
1.	Obsolete medical device	<ol style="list-style-type: none">1. The medical device was previously registered with the MDA but can no longer be registered or have its registration maintained because the legal manufacturer has declared it obsolete, and the required technical documents are no longer available for registration purposes; or2. The production of accessories has ceased or has been declared discontinued; and3. The medical device remains in use at the facility and in well-functioning and properly maintained condition. <p>Note: Healthcare facilities should inform the establishment if they are using obsolete medical devices.</p>

<p>2.</p>	<p>Discontinued medical device</p>	<p>1. The medical device was previously registered with the MDA but can no longer be registered or have its registration maintained because the legal manufacturer or AR has stopped the distribution in Malaysia; and</p> <p>2. The medical device remains in use at the facility and is in well-functioning and maintained condition.</p> <p>Note: Healthcare facilities should inform the establishment if they are using discontinued medical devices.</p>
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6. Manner of Application

6.1 Form filling and submission process

The application for confirmation for obsolete or discontinued medical device status shall be submitted via the linked [Form](#) by taking the following action:

1. **Access the linked [Form](#)**

Note: To access the form the applicant must have a Google Account.

2. **Complete the form by providing information in all required fields** accurately.

3. **Upload the following supporting documents:**

- Declaration letter from the legal manufacturer (Annex C)
- Declaration letter from the healthcare facility agreeing to use the device (Annex D)
- Estimated timeline or transition plan for continued maintenance support.
- Completed and signed Attestation & Declaration Form with official company stamp (Annex E)

4. Review all information and submit the form

Upon submission, an acknowledgement email will be issued to the applicant.

NOTE: All required documents must be uploaded at the time of submission. All declarations must be duly signed and stamped.

6.2 Administrative charge and payment method

A processing fee of RM300 will be charged for each application. This fee is non-refundable, regardless of rejection or withdrawal of the application.

Upon submission of the application, the following steps will occur:

1. **Invoice Generation:** A payment invoice will be generated within 1 to 7 working days on the BayarNow platform (<http://bayarnow.mda.gov.my>).

MDA/GD/0071

2. **Notification:** The applicant will be notified via email once the invoice is available.
3. **Payment Deadline:** Payment must be completed within 3 working days from the date the invoice is issued.

Failure to make the required payment within the specified 3-working-day timeframe will result in the application being automatically considered withdrawn.

Note:

Detailed instructions for payment can be found in the BayarNow Customer Portal and Payment Gateway user manual. Please refer to the [User Manual BAYAR NOW CUSTOMER PORTAL & PAYMENT GATEWAY](#).

6.3 Reviewing Process

Upon receiving a complete application and cleared payment, the Authority will assess the submission against the exemption criteria set out in the Medical Device (Exemption) Order 2024. Subsequent action will be determined by the specific conditions of the application;

- **Incomplete or Unclear Applications:** If the application is incomplete or unclear, the applicant will be contacted to supply additional information.
- **Meeting the Criteria:** If the criteria are met, the Authority will issue an Exemption Letter, which confirms that the medical device is exempted from registration under Section 5 of the Medical Device Act 2012 (Act 737).

The total turnaround time (TAT) for this process is 10 working days, calculated from the date a complete application is received and payment is cleared.

7. Issuance of Obsolete and Discontinued Exemption Letter

A Letter of Exemption granted for a medical device that is obsolete or discontinued shall remain valid for a period of three (3) years. No extension will be granted beyond this validity period.

If the medical device continues to be used after the expiry of the Exemption Letter, the applicant must submit a new application in accordance with the prevailing requirements.

8. Obligations of applicants

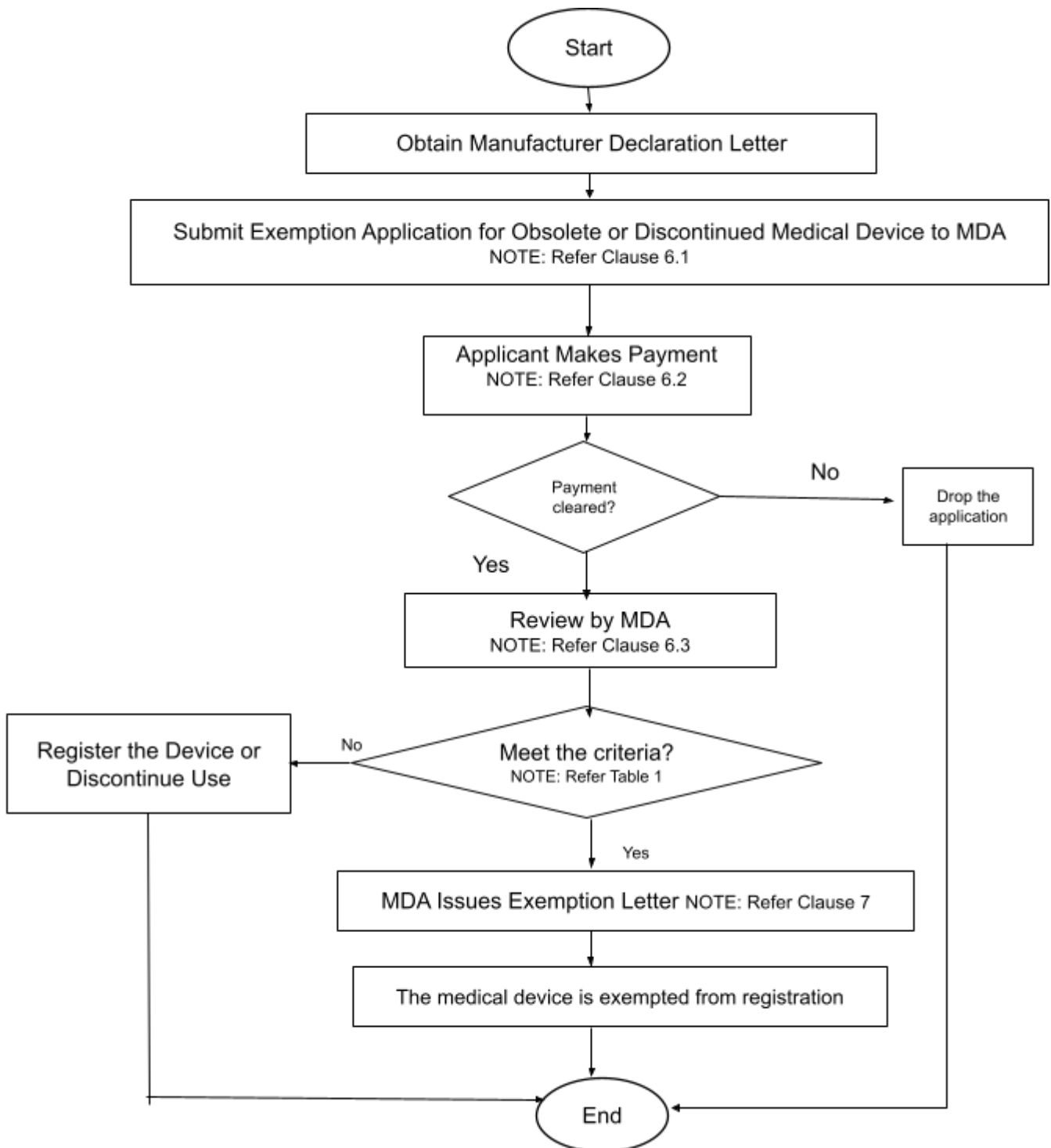
- a. Medical devices officially confirmed as obsolete or discontinued are exempt from the requirement for registration and must not be imported or distributed within the market. However, the import and export of these specific devices, or their associated accessories, are permissible exclusively for the purpose of maintenance or repair. Such activities must be supported by a valid Exemption Letter granted by the Authority.
- b. The establishment shall provide technical assistance and maintenance support as required by the facility.

MDA/GD/0071

- c. The establishment shall fulfil all post-market duties and obligations under the Medical Device (Duties and Obligations of Establishments) Regulations 2019 for a minimum period of at (5) years from the date of confirmation of the device's obsolete or discontinued status.
- d. The establishment shall maintain all records related to the medical device, including distribution, complaints, Mandatory Problem Reporting (MPR), Field Corrective Actions (FCA), and recalls. These records shall be retained for five (5) years from the date of End of Support (EOS) and must be provided to the Authority upon request.
- e. The Authority reserves the right to instruct users to stop the use of obsolete or discontinued medical devices if they are deemed unsafe or ineffective.

Annex A
(Informative)

PROCESS FLOW FOR EXEMPTION OF OBSOLETE AND DISCONTINUED MEDICAL DEVICES



**Annex B
(Normative)**

**Explanation on the information/particular required for application for confirmation of
obsolete or discontinued medical device status**

No.	Information/Particulars	Explanation and Documents to be submitted
1.0	Type of Exemption	
1	<p>Applicant must select one:</p> <ul style="list-style-type: none"> ● Obsolete: Device is outdated and no longer manufactured due to design changes or technological evolution. ● Discontinued: Device is no longer available in the distribution market, but still in use at healthcare facilities. 	
2.0	Section A: Applicant Information Details of the establishment (manufacturer or AR) responsible for market	
2	Name of Applicant:	Name of the person responsible from the manufacturer or AR
3	NRIC/Passport No.:	ID of applicant
4	Designation:	Job title of applicant
5	Telephone No.:	Applicant's contact number
6	Email Address	Applicant's email address
7	Company Name:	Name of the establishment
8	Company Address:	Full business address including postcode, city and state
9	Type of Establishment:	Manufacturer or Authorized representative
10	Establishment License No.	License number issued by MDA

3.0	Section B: Medical Device Information (Restricted to device(s) under the same registration)	
11	Device Previous Registration No.:	MDA Registration No (e.g., GCxxxx...)
12	Last Registration Validity period:	DD/MM/YYYY – DD/MM/YYYY
13	Effective date for Obsolete/Discontinued:	Date officially declared by legal manufacturer

<p>14</p>	<p>(Appendix 1) Device Condition & Usage Status</p>	<p>Provide details for each device:</p> <ul style="list-style-type: none"> ● Name of healthcare facility ● Functionality status (in use/not in use) ● Confirmation of safety and performance <p>Link: https://docs.google.com/spreadsheets/d/1c5ny2yXCQAgx44hRNBdsOR8SG6fSqRo4hviJ7UE27KA/edit?usp=sharing</p>
<p>15</p>	<p>Supporting Document 1</p>	<p>Certificate and report confirming the device's safety and performance for its intended use</p>
<p>16</p>	<p>Supporting Document 2</p>	<p>Declaration letter from the legal manufacturer (Annex C), signed and stamped</p>
<p>17</p>	<p>Supporting Document 3</p>	<p>Declaration letter from the healthcare facility (Annex D).</p>
<p>18</p>	<p>Supporting Document 4</p>	<p>Estimated timeline of transition plan for continued maintenance support</p>
<p>19</p>	<p>Attestation & Declaration Form</p>	<p>Completed and signed form with official company stamp (Annex E)</p>

ANNEX C
(normative)

**TEMPLATE FOR DECLARATION LETTER OF OBSOLETE OR DISCONTINUED
MEDICAL DEVICE**

[To be filled in by the manufacturer and printed on manufacturer's letterhead]

Medical Device Authority
Ministry of Health, Malaysia

[Date]

Dear Sir/ Madam,

Subject: Declaration for [Obsolete/ Discontinued] Medical Device

We, [name of manufacturer] hereby declare that the mentioned medical device below is:

Medical Device name	
Model/ identifier	
Brand	
Date of Obsolescence/ Discontinuation	

Note: Please repeat the table if there are multiple devices or accessories

(Please select 1)

- The device is **officially obsolete** and no longer manufactured.
- The device has been **officially discontinued** and no longer available for distribution* in Malaysia.

Reason(s) for the discontinuation

(Please tick where applicable):

- The manufacturer has withdrawn the medical device from global market.
- The registration is no longer valid and the device is not allowed to be imported and placed in the market.
- The Authority has instructed to withdraw the medical device from the market due to non compliance issues.
- The manufacturer ceased production or distribution.

MDA/GD/0071

- The manufacturer discontinued support, including accessories, software updates or parts.
- The manufacturer has shifted its focus to other products and is no longer involved in the medical device business.
- The manufacturer has recalled the medical device, resulting in its discontinuation.
- Others: Please state

***NOTES :**

- 1) Upon discontinuation of the medical device, the medical device and its related accessories will no longer be available for distribution.
- 2) Accessories that remain available must be registered and comply with Act 737 and its subsidiary legislation

We agree to provide support for the device, including accessories and software updates, until **[Insert End of Support Date]**.

We confirm our commitment to fulfill all post-market surveillance obligations under Act 737 and its regulations for 5 years from the date of confirmation of obsolete or discontinued status.

We confirm that no further registration of this medical device by any Authorized Representative (AR) in Malaysia.

We agree that the devices shall not be imported or placed on the market except for maintenance or repair purposes, supported by the Exemption Letter issued by the Authority.

The list of Authorized Representative (AR) of the mentioned medical devices is as follows (if applicable):

No.	Company Name/ Authorized Representative (AR)

Note: Please add an additional row if space is insufficient.

Signature:

[Person Responsible Name]

[Position]

[Company Name]

[Date]

ANNEX D
(normative)

**TEMPLATE FOR DECLARATION LETTER TO USE OBSOLETE OR
DISCONTINUED MEDICAL DEVICE**

[To be filled in by the user in the healthcare facilities and printed on healthcare facility letterhead]

I, on behalf of **[healthcare facility name]**, hereby declare and confirm the continued use of the obsolete or discontinued medical devices:

MEDICAL DEVICE NAME (Restricted to devices within the same registration)	
STATUS OF THE DEVICE (OBSOLETE/DISCONTINUED)	

We understand and acknowledge the regulatory requirements outlined by the Medical Device Authority (MDA) regarding the use of such devices.

We hereby affirm the following:

1. The obsolete or discontinued medical device utilized within our facility **shall not** be sold, loaned, provided for free, donated, or used in research to or by a third party, except:
 - (i) For teaching or education purposes, provided it is not used on patients. In such cases, we will notify in writing to demo.edu@mda.gov.my;
 - (ii) When sold to a third party for the purpose of disposal as scrap or e-waste.

We shall notify the establishment of any changes, including;

- Permanent decommissioning or cessation of use;
- Transfer to another department or facility for non-clinical use;
- Physical disposal or scrapping

2. We acknowledge that the risks associated with continued use lie with the facility. We commit to continuous monitoring the safety and performance. Maintenance shall comply with MS 2058.
4. We will ensure that any incidents involving these medical devices are properly documented and reported to the Authority via the MDA Feedback Management System (FEMES) at <https://femes.mda.gov.my/>.
5. We shall ensure compliance with Section 43 of Act 737, including:
 - (i) Safe and efficacious use
 - (ii) Use according to intended purpose
 - (iii) Use according to manufacturer's instructions
 - (iv) Proper installation, testing, commissioning, and maintenance
6. We understand that the Authority may conduct inspections at any time and that all requested documents must be produced upon request

MDA/GD/0071

[Signature]

[Name]

[Official Stamp]

[Date]

Note : This declaration must be signed by users at each facility.

ANNEX E
(normative)
TEMPLATE OF ATTESTATION & DECLARATION

Attestation & Declaration

I, the undersigned, hereby declare and affirm that:

- 1) All information provided in this application is true, complete, and accurate.
- 2) I shall be responsible for addressing post-market issues related to obsolete or discontinued medical devices, for a period of 5 years from the date of confirmation of status
- 3) I commit to complying with the all applicable requirements under Medical Device (Duties and Obligations of Establishments) Regulations 2019.
- 4) I shall comply fully with the terms and conditions imposed by the Authority.
- 5) I understand that the establishment shall provide any document or record requested by the Authority within the stipulated timeframe.
- 6) I understand that the Exemption Letter shall not be used for promotion, commercialization, or advertising.
- 7) I acknowledge the legal consequences and liabilities associated with making a false declaration or providing misleading information. I understand that any such actions may render me and my company liable under the Medical Device Act 2012 [Act 737] and any other applicable laws for dishonestly or fraudulently making, signing, sealing, or executing any declaration or any other documents which are false, inaccurate, or misleading.

I hereby declare that the above statements are true and accurate to the best of my knowledge and belief.

[Signature]

Name :

Official Stamp :

Date :

MDA/GD/0071

MEDICAL DEVICE AUTHORITY

MINISTRY OF HEALTH, MALAYSIA

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