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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

REVISION HISTORY

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Preface

This Guidance Document was prepared by the Medical Device Authority (MDA) to help the industry and healthcare professionals in their quest to comply with the Medical Device Act (Act 737) and the regulations under it, 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.

This guidance document specifically outlines the eligibility criteria, application procedures, the responsibilities and obligations of establishments when managing these devices.

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.

3.1 applicant

The applicant can 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 and private healthcare facilities and services, wellness centers or any related facilities 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 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]

3.6 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;

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]

3.7 manufacturer

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

3.8 medical device

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

3.9 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]

3.10 person responsible

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

3.11 place in the market

To make available a medical device in return for payment or free of charge with a view to distributing, using, supplying or putting it into service, in Malaysia, regardless of whether it is new or reprocessed, but does not include to make available for use for clinical research or for performance evaluation of a medical device

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

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

3.13 related facilities

Healthcare institutions or infrastructures that fall under the scope of the ministry's service. These include hospitals, clinics, specialized medical centers and other health-related facilities that provide medical services to the public.

4. General requirements

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

I. its status has been declared by the manufacturer as obsolete medical device; or
II. its status has been declared by the Authorized Representative/manufacturer as discontinued medical device; and
III. The declaration of the status has been confirmed by the Authority.

The status of the medical device can be confirmed by applying 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	Criteria
1.	**Obsolete medical device**	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 necessary technical documents are no longer available for registration purposes; or 2. The device no longer has maintenance support (end of support) from the manufacturer and the production of the spare parts and/or accessories have been discontinued to support maintenance and repair of the medical device; and 3. The medical device is still in use in the facility* and in well-functioned and maintained condition. Note: Healthcare facilities may need to inform the establishment if they are using obsolete medical devices.
2.	**Discontinued medical device**	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 2. The medical device is still in use in the facility* and in well-functioned and maintained condition. Note: Healthcare facilities may need to inform the Establishment if they are using obsolete medical devices.

NOTE: Facility* : Government and private healthcare facilities and services, wellness centres or any related facilities

6. Manner of Application

6.1 Form filling and submission process

Application for confirmation of the medical device status shall be made by the manufacturer or AR using a form as stated in the Annex B and B-I. This form is placed in the platform linked at the following URL;

https://forms.gle/RmTrf9y2JkBwdxmu8

The complete application form shall be accompanied with supporting documents as follows;

a. Declaration letter for obsolete medical device from Legal manufacturer as per Annex C; or
b. Declaration letter for discontinued medical device from Legal manufacturer as per Annex C;
c. Previous medical device registration certificate; and
d. Estimated timeline or transition plan for maintenance support of obsolete or discontinued medical devices.

The applicant shall complete, sign and put an official company stamp on the Attestation & Declaration form as per Annex B-II and enclose the document together with the complete application form.

All supporting documents, including the completed Attestation and Declaration Form, shall be uploaded to the platform. Once all required information is provided, the form shall be submitted by clicking the <Submit> button. The applicant will be notified via email regarding the receipt of the application.

6.2 Administrative charge and payment method

A processing charge of RM300 will be charged for each application. This fee will not be refunded if the application is rejected or withdrawn.

After submission of the application, the payment invoice will be ready within 1-7 working days on the online payment platform (http://bayarnow.mda.gov.my). An email will be sent to inform the applicant that the payment invoice is ready and payment can be made via the platform.

The administrative fee shall be made within 30 working days. If the payment is not made within that time frame, the application shall be deemed to be withdrawn and shall not be processed further.

Instructions for making payments through the BayarNow system are provided 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

The application will be assessed by the Authority to verify that the medical device meets the criteria of the status of obsolete or discontinued. If the information provided is insufficient or incomplete, the applicant will be notified and requested to provide the necessary details.

The turn-around time per application is 14 working days upon submission of complete form and supporting documents.

A letter will be issued to inform the applicant of the confirmation of the medical device status and the exemption from the registration requirement if the Authority determines that all criteria have been met and requirements have been complied with.

The medical device will be listed in the Registry of Obsolete and Discontinued Medical Devices and will be published on MDA portal for public reference.

7. Obligations of applicants

a. Medical devices that have been confirmed obsolete or discontinued and exempted from registration requirements are not allowed to be imported or distributed in the market.

b. The establishment shall provide the technical assistance and maintenance support if needed by the healthcare institution.

c. The establishment shall carry out post market duties and obligations as stipulated in the Medical Device (Duties and Obligations of Establishments) Regulations 2019 until the end of the life span of the medical device.

d. The establishment shall maintain all records pertaining to the medical device including post market records (distribution, complaint, MPR, FCA or Recall) and provide the records if requested by the Authority.

e. The confirmation status letter shall not be used for the purpose of promoting, marketing or advertising the medical device.

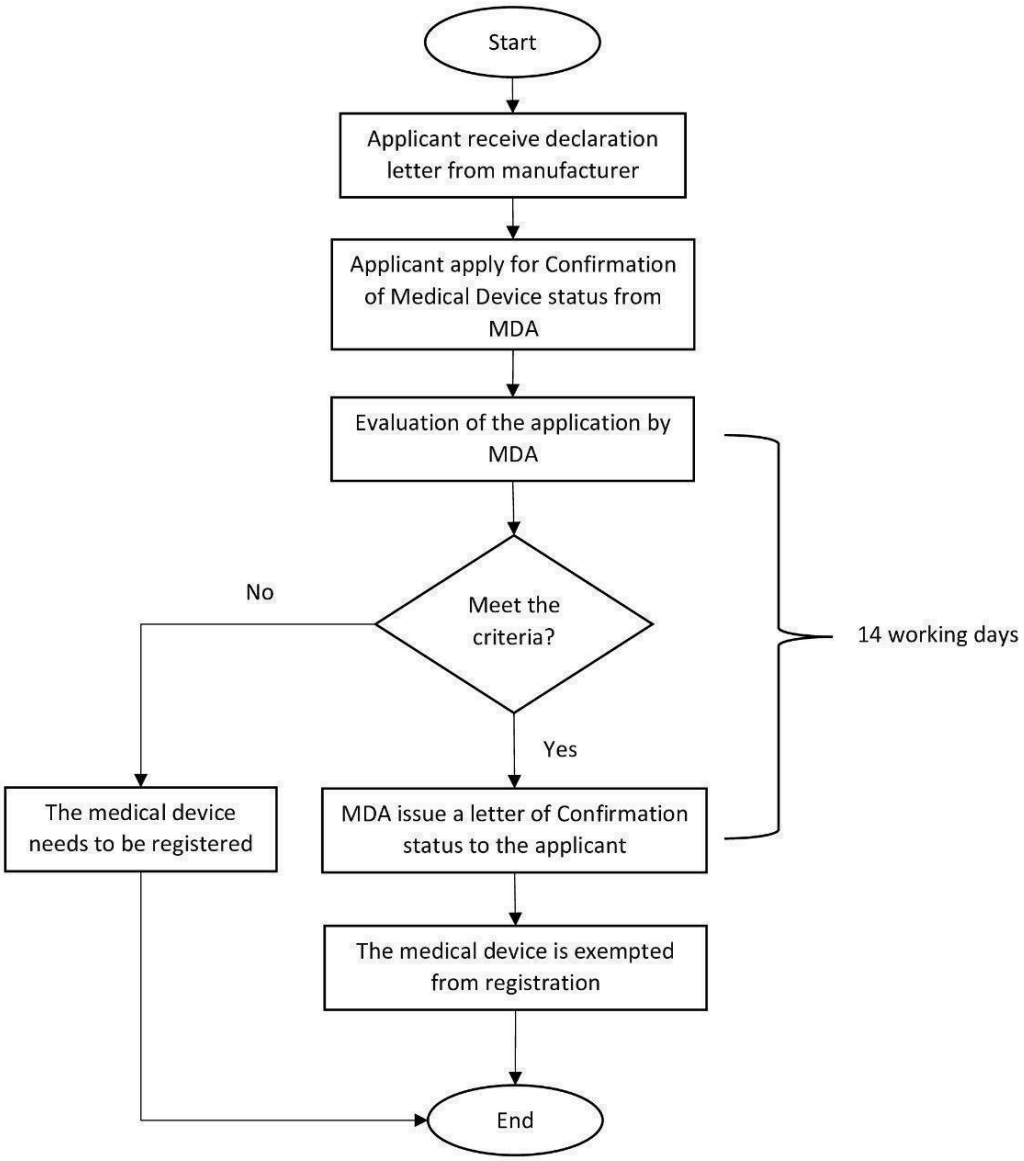
f. All the relevant documents to maintain the safety and performance of medical devices including but not limited to the performance evaluation plan and maintenance report shall be kept at the healthcare facility and submitted to the Authority,upon request.

g. The manufacturer or Authorized Representative (AR) shall submit the relevant maintenance report to the Authority, if requested by the Authority.

h. MDA 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 OF EXEMPTION FOR OBSOLETE AND DISCONTINUED MEDICAL DEVICES



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ANNEX B
(Normative)

The required information is detailed in the Google Form.

Medical Device AUTHORITY MALAYSIA	**MEDICAL DEVICE (EXEMPTION) ORDER 2024** **APPLICATION FOR CONFIRMATION OF OBSOLETE OR DISCONTINUED MEDICAL DEVICE STATUS**
Type of Exemption:	
☐ Obsolete:	An existing medical device in healthcare or any related facilities which is outdated and no longer being manufactured due to design changes or evolution of new technologies
☐ Discontinued:	An existing medical device in healthcare or any related facilities that is no longer in the distribution
Section A: Applicant Information (The AR or manufacturer who responsible for distributing a medical device that later declared obsolete or discontinued, but remains available in the market)	
Name of Applicant:	
NRIC/Passport No.:	**Designation:**
Company Name:	
Company Address:	
Type of Establishment:	☁ **Manufacture** ☁ **Authorized representative**
Establishment License No.	
Contact Person Information: (for effective communication)	
Name:	
Email Address:	
Telephone No.:	

Section B: Medical Device Information (Restricted to one medical device or devices within the same registration)	
Device Previous Registration No.:	
Last Registration Validity period:	
Effective date for Obsolete/Discontinued:	
Please provide other information in **Annex B-I**.	
Supporting Document: 1. Legal manufacturer declaration letter for Obsolete Medical Device, or 2. Legal manufacturer declaration Letter for Discontinued Medical Device 3. Estimated timeline or transition plan for maintenance support. 4. Previous medical device registration certificate. 5. Declaration from the healthcare facilities to use the obsolete and discontinued medical device as specified in Annex D.	

ANNEX B-I

TEMPLATE OF MEDICAL DEVICE DETAILS

No.	Status (OB/DC)	Previous Registration No.	Device Name/ Accessories Name	Brand	Model	Identifier	Manufacturer	Name and address of Healthcare facility	Obsolete/ Discontinued date	End of Maintenance support Date

Note : Please ensure that the information in this table is accurately and completely filled out. This information will be publicly displayed on the MDA Portal.

ANNEX B-II
TEMPLATE OF ATTESTATION & DECLARATION

Section C : Attestation & Declaration

I, the undersigned hereby attest and declare the following statements in relation to the submission of the Notification to the Authority:

1) I shall be responsible for addressing post-market issues related to obsolete or discontinued medical devices, at least in accordance with the end of the lifespan or support of the medical devices as determined by the manufacturer.
2) I commit to complying with the prescribed requirements as stated in any applicable conditions and the Medical Device (Duties and Obligations of Establishments) Regulations 2019.
3) I shall comply fully with the terms and conditions imposed by the Authority.
4) I understand that the establishment shall provide any document or record upon request by the Authority within the stipulated timeframe.
5) I understand that the confirmation status letter must not be used for the purpose of promoting, commercialization or advertising the device.
6) 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 :

ANNEX C
(normative)

TEMPLATE FOR DECLARATION LETTER OF OBSOLETE OR DISCONTINUED MEDICAL DEVICE

[To be filled in by the manufacturer and printed on company 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:

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

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

(Please choose 1 only)

- □ is **officially obsolete** and no longer being manufactured.
- □ has been **officially discontinued** and no longer available for further distribution* specifically in Malaysia.

  Reason(s) for the discontinuance *(Please tick where appropriate)*:

  - ☐ 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.
  - ☐ 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) If the accessory is still available for market placement, it shall be registered and comply with the requirements outlined in the Medical Device Act 2012 [Act 737] and its subsidiary legislation.

We agree that we will provide support for the device, including accessories or software updates etc., until **[Insert End of Support Date].**

We confirm our commitment to fulfill all post-market surveillance obligations as required under the Medical Device Act 2012 [Act 737] and its regulations, until the end of the product's lifespan.

We commit that there will be no further registration of this medical device by any Authorized Representative (AR) and the obsolescence or discontinuation applies to all markets in Malaysia. This declaration is intended to ensure consistency in managing obsolete or discontinued medical devices nationally and to avoid any conflicting registrations within the Malaysia market.

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]

On behalf of the healthcare facility, I hereby declare and confirm the use of obsolete or discontinued medical devices within our facility with the information below:

MEDICAL DEVICE NAME (Restricted to one medical device or 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 under the circumstances specified below:

   (i) The device is used 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) If the medical device is sold to a third party for the purpose of disposal as scrap material or e-waste.

   We shall notify the establishment of any changes related to obsolete or discontinued medical devices, including but not limited to:

   - The device is permanently decommissioned or no longer in use.
   - The device is transferred to another department or facility for non-clinical use (e.g., training, demonstration).
   - The device has been physically disposed of or sent for scrapping/recycling.

2. We acknowledge that the risk associated with using obsolete or discontinued medical devices lies with our facility and we are committed to continuously monitoring the safety and performance of the medical device in use within our facility to ensure optimal patient care and compliance with regulatory requirements. The maintenance of active medical devices requiring servicing or preventive planned maintenance (PPM) shall be conducted in accordance with MS 2058.

3. If a medical device is deemed unsafe or ineffective, the user shall immediately discontinue its use, remove it from service, ensure its safe disposal, and inform the establishment, which shall notify the Authority in accordance with applicable regulatory requirements.

4. We will ensure that all 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 are committed to adhering to the provisions of Section 43 of Act 737, ensuring that medical devices used on third parties will be:
    (i) Safe and efficacious
    (ii) Used in accordance with their intended purpose
    (iii) Used in accordance with the manufacturer's instructions
    (iv) Properly installed, tested, commissioned and maintained.

6. We understand that the Users may be subject to inspection by the Authority and must produce any requested documents or records upon request by the Authority.

7. We understand that the Authority reserves the right to make a visit or inspection to our facility at any time without prior notice and we must produce any requested documents or records upon request by the Authority.

[Signature]

Name:_____

[Official Stamp]

[Date]

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

MEDICAL DEVICE AUTHORITY

MINISTRY OF HEALTH, MALAYSIA

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