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MEDICAL DEVICE GUIDANCE DOCUMENT

CONTROL OF OBSOLETE AND DISCONTINUED MEDICAL DEVICE IN HEALTHCARE OR RELATED FACILITIES

Medical Device Authority
MINISTRY OF HEALTH MALAYSIA

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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.

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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CONTROL OF OBSOLETE AND DISCONTINUED MEDICAL DEVICE IN HEALTHCARE OR RELATED FACILITIES

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 para-professional;

f) any service for curing or alleviating abnormal conditions of the human body by the application of any apparatus, equipment, instrument or device or any other medical technology; or

g) any health-related services

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

3.7 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 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 centre, nursing home, maternity home, psychiatric hospital, psychiatric nursing home, community mental health centre, haemodialysis centre, 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]

3.11 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 Para 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.

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	Category of Exemption	Description
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 purpose; or 2. The device no longer has maintenance support (end of support) 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.
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: Facility* : Government and private healthcare facilities and services, wellness centers 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) 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 7 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 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.

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. Conditions of Exemption

a. Medical device that has 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.

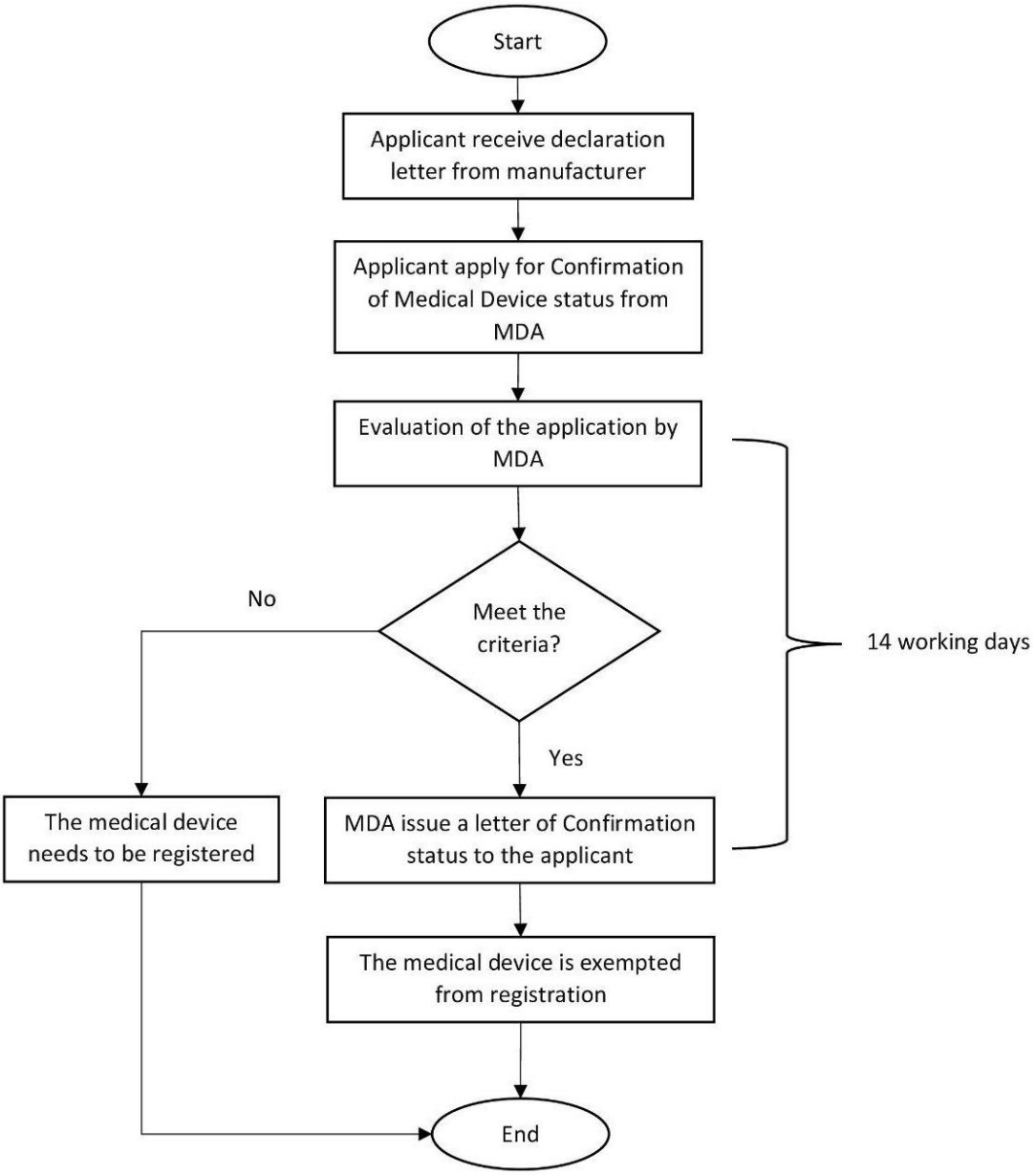
c. The establishment shall carry out post market duties and obligations as stipulated in the Medical Device (Duties and Obligations of Establishments) Regulations 2019 until the end of the life span of the medical device.

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.

ANNEX A
(Informative)

PROCESS FLOW OF EXEMPTION FOR OBSOLETE AND DISCONTINUED MEDICAL DEVICES



ANNEX B
(Normative)
(Information requirements are as outlined 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**
MDA Licensing 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. Timeline or transition plan for maintenance support 4. Previous Product Registration Certificate	

ANNEX B-I

TEMPLATE OF MEDICAL DEVICE DETAILS

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

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 projected useful life or support of the medical devices as determined by the manufacturer.
2) I commit to complying with the prescribed requirements as stated in the registration 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.
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 penal consequences and legal liabilities associated with making a false declaration or providing misleading information. I understand that any such actions may make me and my company punishable under the Penal Code [Act 574] for dishonestly or fraudulently making, signing, sealing, or executing any declaration or other document that is untrue, 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 update 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
……..

***Note** :

1) Upon discontinuation of the medical device production, 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 throughout the product's entire lifespan.

We commit that there will be no further re-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]

MEDICAL DEVICE AUTHORITY

MINISTRY OF HEALTH, MALAYSIA

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