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# MEDICAL DEVICE GUIDANCE DOCUMENT

# APPLICATION FOR CONFIRMATION STATUS OF ORPHANED MEDICAL DEVICE



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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# APPLICATION FOR CONFIRMATION STATUS OF ORPHANED MEDICAL DEVICE

## 1. Introduction

The healthcare sector relies heavily on a wide array of medical devices to provide safe and effective patient care. However, there are instances where certain medical devices become "orphaned." This situation presents unique challenges for healthcare providers and regulators, particularly regarding compliance with existing medical device regulations under Section 5(1) and Section 15(1) of the Medical Device Act 2012 [Act 737].

These orphaned medical devices are still required for use by Government and private healthcare facilities and services, wellness centers or any related facilities and cannot be registered under Act 737 due to the absence of their manufacturers or authorized representatives. By exercising Section 77, the Minister has issued the MEDICAL DEVICE (EXEMPTION) ORDER 2024. This order exempts orphaned medical devices from the registration and establishment requirement under Section 5 and Section 15 of the Act. The exempted devices, however, must be managed in a form and manner determined by the Authority to ensure continued safety and efficacy in their use.

This guidance document aims to provide comprehensive instructions for the control and management of orphaned medical devices within Government and private healthcare facilities and services, wellness centres or any related facilities. It outlines the necessary procedures to notify on the placement of the orphaned medical device, despite the absence of their manufacturers or authorized representatives. By adhering to this guidance, healthcare or related facilities providers can maintain compliance while ensuring that patient care is not compromised.

## 2. Scope and application

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

This guidance document specifically outlines the eligibility criteria, notification procedures, the responsibilities and obligations of healthcare or other facilities 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 person or entity which acknowledges the operation or use of orphaned medical device.

### 3.2 Authority

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

### 3.3 Establishment

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

### 3.4 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]

### 3.5 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]

### 3.6 Manufacturer

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

### 3.7 Medical device

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

### 3.8 Orphaned medical device

an existing medical device in a Government and private healthcare facilities and services, wellness centres or any related facilities where the manufacturer or authorized representative has ceased operation.

[Source: Medical Device Exemption Order 2024]

### 3.9 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]

### 3.10 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) the existing medical device in the healthcare facilities;

ii) it has been declared as orphaned by the; and

iii) this declaration shall be confirmed by the Authority.

## 5. Criteria for Application of Confirmation of Orphaned Medical Device Status

MDA has outlined specific criteria and conditions under which these devices may be exempted and will confirm a medical device as orphaned if it meets the criteria specified in the table below:

**Table 1. Category and criteria of orphaned medical devices**

| No | Category of Exemption | Description |
|---|---|---|
| **1.** | Orphaned medical device Type 1 | 1. An existing medical device in the facility* where the manufacturer or authorized representative is no longer **an officially recognized entity** to ensure that the medical device meets regulatory requirements, provide necessary support, or address compliance issues in the market.<br>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. |

| | | |
|---|---|---|
| | | 3. The medical device is still in use in the facility* and in well-functioned and maintained condition. |
| **2.** | Orphaned medical device Type 2 | 1. An existing medical device in the facility* that has **lacked an authorized representative since its initial placement**. (e.g. donation device)<br>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 facility.

## 6. Manner of Application

If the above criteria are met, the facility shall apply for confirmation of the device's status using the Google Form for Confirmation of Medical Device Status. The overall process is summarized in **Annex A**.

### 6.1 Completion of Confirmation of Medical Device Status form

#### 6.1.1 Submission Requirements

The applicant shall submit the application for verification of the medical device' status to the Authority as follows:

i) **Application Form:** The application shall be made using the Google Form, based on Annex B Confirmation of Medical Device Status form.

ii) **Supporting Documents:** Attach the following documents:

a) Search results for the assuming company from the Medical Device Authority Register (MDAR);
b) Search results for the assuming company from relevant websites; and
c) Any other documents requested by the Authority.

iii) **Attestation and Declaration:** Complete the attestation and declaration as per Annex B-II.

**Submission Method:**

The submission of the application form via Google Form requires the applicant to have a Google account. If the applicant does not have a Google account, they will need to create one in order to access and complete the form.

Steps for Google Form Submission:

1. **Access the Form:** Click on the provided link to access the Google Form.
   **Link :** https://forms.gle/qWm74qbkDzKPL2QW6
2. **Complete the Form:** Fill in all required fields, ensuring that all information is accurate and complete. For Medical Device details, please follow the Template as per Annex B-I.
3. **Upload Supporting Documents:** Upload the necessary supporting documents directly within the form.
4. **Submit:** Review your information and submit the form. You will receive a confirmation email once your submission is received.

### 6.2 Reviewing Process

a. The Authority will evaluate the application to verify/ confirm that the medical device meets the criteria for being classified as orphaned. If any information is missing or incomplete, the application will be notified and requested to provide the necessary details.

b. Once the review is complete and the device is confirmed to meet the criteria, the Authority will issue the confirmation status letter.

c. The device will be added to the official registry of orphaned medical devices maintained by the Authority.

## 7. Obligations of Applicant

### A. Usage:

a) The orphaned medical device utilized within the facility shall not be sold, loaned, provided for free, donated, or used in research by or to a third party, except under the following circumstances:

- The device is used for teaching or educational purposes, provided it is not used on patients. In such cases, we will notify in writing to demo.edu@mda.gov.my.
- The medical device is sold to a third party for disposal as scrap material or e-waste.

b) The facility commits to adhering to the provisions of Section 43 of Act 737, ensuring that medical devices used on third parties are:

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.

**B. Risk Accountability and Post-Market Responsibility:**

a) The facility acknowledges that the risk associated with using orphaned medical devices lies with the facility itself. The facility commits to monitoring the safety and performance of the medical device in use within the facility.

b) The facility is responsible for managing post-market issues related to orphaned medical devices during their usage period.

c) The facility will ensure that any incidents involving orphaned medical devices are properly recorded and reported to the Authority using the MDA Feedback Management System (FEMES) at https://femes.mda.gov.my.

**C. Maintenance Compliance:**

The active medical devices, which require maintenance or PPM, shall comply with MS 2058, Code of Practice for Good Engineering Maintenance Management of Active Medical Devices.

**D. Decommissioning and Disposal:**

If a medical device is deemed no longer safe and effective for use or Beyond Economical Repair (BER), the facility shall promptly decommission, remove or dispose of it in a safe manner. The facility **shall comply with the MS 2650 Guidance on the safe disposal procedure**

**E. Inspection and Document Provision:**

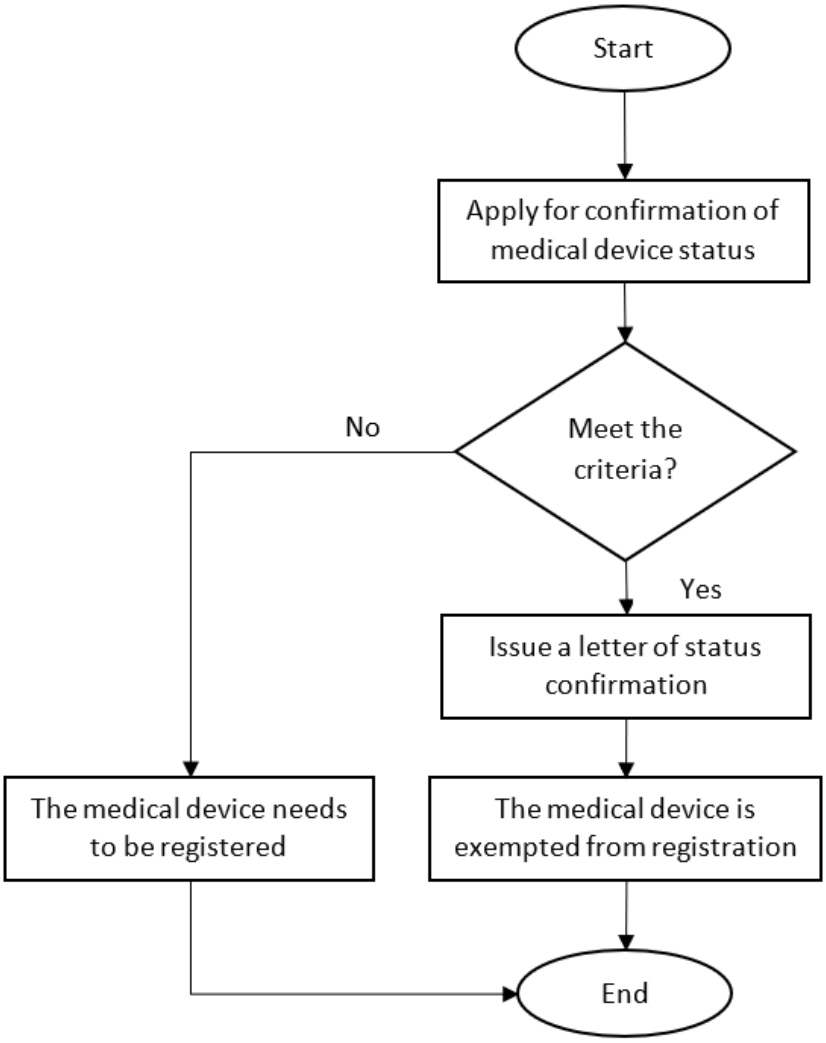
Users may be subject to inspection by the Authority and must produce any requested documents or records.

**F. Importation and/or supply of spare parts and components**

The importation and/or supply of spare parts and/or components are allowed using the confirmation status letter provided by the Authority to maintain its service and performance.

## ANNEX A
(Informative)

### PROCESS FLOW OF EXEMPTION FOR ORPHANED 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 ORPHANED MEDICAL DEVICE STATUS** |
| **Category of exemption:** | |
| ☐ Type 1: | An existing medical device in the facility where the manufacturer or authorized representative is no longer an officially recognized party to ensure that the medical device meets regulatory requirements, provide necessary support, or address compliance issues in the market. |
| ☐ Type 2 : | An existing medical device in the facility that has lacked an authorized representative since its initial placement. |
| **Section A : Applicant Information**<br>(The person or entity which acknowledge for the operation or use of orphaned medical device) | |
| **Name :** | |
| **NRIC/Passport No. :** | **Designation :** |
| **Department Name :** | |
| **Facility Name and Address :** | |
| **Contact Person Information:** (for effective communication) | |
| **Name :** | |
| **Email Address :** | |
| **Telephone No. :** | |
| **Section B : Facility Information**<br>(The location responsible for the operation and use of orphaned medical devices) | |
| Please provide the details in Appendix 1. | |
| **Section C : Medical Device Information**<br>(Allow for multiple medical devices) | |
| Please ensure that the product meets the definition of a medical device. Notification applies to medical devices only. | |
| Please provide other information in **ANNEX B-I** | |
| Supporting Document : | |

1. Search results for the assuming company from the Medical Device Authority Register (MDAR), and
2. Search results for the assuming company from relevant websites
3. Any other documents requested by the Authority.

## ANNEX B-I

## TEMPLATE OF MEDICAL DEVICE DETAILS

| No. | Previous Registration No. | Device Name | Brand | Model | Manufacturer | Facility Name |
|---|---|---|---|---|---|---|
| | | | | | | |
| | | | | | | |
| | | | | | | |

**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 D : Attestation & Declaration**

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

On behalf of my Facility, I shall comply with the terms and conditions imposed by the Authority from time to time and affirm the following:

1. The orphaned 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.

2. We acknowledge that the risk associated with using orphaned medical devices lies with our facility and we commit to monitoring the safety and performance of the medical device in use within our facility.

3. In the event that a medical device is deemed no longer safe and effective for use, we shall promptly remove and dispose of it in a safe manner. We will inform the Authority using the prescribed disposal form.

4. We will be responsible for post-market issues related to orphaned medical devices during the usage period.

5. We will ensure that any incidents involving these medical devices are properly recorded and reported to the Authority using the MDA Feedback Management System (FEMES) at https://femes.mda.gov.my/.

6. We commit 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.

7. 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.

I hereby declare that the above statements are true and accurate to the best of my knowledge and belief. I understand and acknowledge that it is an offense to make signs or furnish any declaration, or other document which is untrue, inaccurate or misleading as required by Section 76 of Medical Device Act 2012 (Act 737).

[Signature]

Name :

Official Stamp :

Date :

# MEDICAL DEVICE AUTHORITY

# MINISTRY OF HEALTH, MALAYSIA



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