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MEDICAL DEVICE GUIDANCE DOCUMENT

NOTIFICATION OF LISTING FOR ORPHANED MEDICAL DEVICE

Medical Device Authority
MINISTRY OF HEALTH MALAYSIA

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1. 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 endeavour.

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 to ensure 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.

CONTACT INFORMATION

For further information, please contact:

MEDICAL DEVICE AUTHORITY
Ministry of Health Malaysia
Aras 6, Prima 9, Prima Avenue II
Block 3547, Persiaran APEC
63000 Cyberjaya, Selangor
MALAYSIA
Fax: (03) 82300200
Email: mda@mda.gov.my
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NOTIFICATION OF LISTING FOR ORPHANED MEDICAL DEVICE

1. Introduction

According to section 5 of Act 737, all medical devices must be registered before being imported, exported or placed in Malaysia market. An existing medical device placed in healthcare facilities and/or related facilities before the implementation of Act 737 also need to be registered in accordance with Section 80 of Act 737. However, there are orphaned medical devices that are still required for use by hospitals or healthcare facilities. Since the manufacturer or authorized representative of these medical devices are no longer available, these medical devices could not be registered under the Act 737.

The Circular Letter of Medical Device Authority No. 2 Year 2018, *Control of orphaned, obsolete and discontinued medical device in hospital or healthcare and related facilities,* was published to enable the continued use of orphaned medical devices to ensure that medical services in hospital or healthcare and related facilities are uninterrupted. Nevertheless, all local healthcare and related facilities which has orphaned medical devices shall identify and provide the notification/listing to the Medical Device Authority (MDA). In line with the requirements of the circular, this Guidance Document is developed to assist the healthcare and related facilities in providing notification/listing to the Authority for orphaned medical device.

This Guidance Document also specifies the responsibilities and obligations of the healthcare and related facilities when dealing with this category of medical device. The risk of using orphaned, obsolete and discontinued medical device is under the responsibility of healthcare facilities or related facilities.

2. Scope and application

This guidance document specifies requirements for notification/ listing of orphaned medical devices to the Authority.

This document applies to all products that fall within the definition of medical device, as defined in MDA/GD/0006: Definition of Medical Device, including in vitro diagnostic (IVD) medical devices.

3. Terms and definitions

For the purposes of this document, the terms and definitions in Act 737, the regulations under it and the following terms and definitions apply.

3.1 applicant

Applicant can be either local government, private healthcare facilities and related facilities (example: saloons or wellness centre).

3.2 authority

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

3.3 beyond economical repair (BER)

As defined in MS 2058, *Code of practice for good engineering maintenance management of active medical devices*, beyond economical repair is when:

a) cost of repair exceeds depreciated value; or

b) accumulated maintenance cost plus the estimated cost of impending upcoming repairs exceeds the depreciated value of the equipment.

3.4 establishment

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

3.5 government healthcare facility

Any facilities used or intended for use to provide established healthcare services, maintained, operated or provided by the Government but excluding government healthcare facilities privatized or incorporated;

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

3.6 healthcare facility

Any premise 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 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 healthcare 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 orphaned medical device

An existing medical device in a hospital, healthcare facilities, or related facilities that is not registered under this Act as it no longer has the manufacturer or authorized representative to register the medical device or where the manufacturer or authorized representative has ceased operation.

[Source: Circular Letter No. 2/2018 Control of Orphaned, Obsolete and Discontinued Medical Device in Hospital or Healthcare Facilities Institution]

3.10 person responsible

Person responsible is the person who is responsible for all legal obligations and implications under Act 737 and its subsidiary legislations.

3.11 place in the market

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

3.12 private healthcare facility

Any premises, used or intended for use in providing services healthcare or services related to health, such as hospital, hospice, ambulatory care center, home nursing care, maternity home, psychiatric hospital, home psychiatric care, community mental health centers, centers hemodialysis, medical clinics, private dental clinics and anything else healthcare premises or health-related premises other than as may be determined by the Minister from time to time by notification in the Gazette;

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

3.13 related facilities

Any facilities used or intended for use, other than hospitals or healthcare facilities to provide services by using medical devices, for example saloons and wellness centre.

4. Criteria to be eligible as orphaned medical device for notification/listing

The criteria for orphaned medical device for notification/listing are:

(a) The medical device has been placed in the healthcare and/or related facilities (placed/ installed and not categorised as decommissioned).

(b) No manufacturer/ authorized representative/ distributor of the medical device in Malaysia.

For example, where the manufacturer has gone into liquidation, has ceased operation or where the manufacturer is not known.

5. Person responsible

Criteria for person responsible:

(a) Shall be from top management;

i) Person responsible shall have the overall control and have the authority to make decision;

ii) Depending on the organisational structure of the healthcare facilities and related facilities, person responsible may include Proprietor, President, Vice President, Director, Chief Executive Officer (CEO), Managing Director, General Manager or Manager;

(b) Domiciled in Malaysia;

i) Malaysian citizen;

ii) Non-Malaysian, who has an employment pass or residential address in Malaysia.

6. Obligations of hospitals/ healthcare and related facilities

6.1 Hospitals/healthcare and related facilities shall identify and provide notification/listing to the Authority.

6.2 The applicant is responsible to confirm that the products are medical devices. Such products which do not meet the medical device definition are not eligible for this requirement.

6.3 The applicant is responsible to confirm that the products are orphaned medical devices. Such products which do not meet the orphaned medical device criteria are not eligible for this requirement.

6.4 Hospitals/ healthcare and related facilities shall provide declaration of orphaned medical device.

6.5 The risk of using orphaned medical device is under the responsibility of hospitals and healthcare and related facilities giving notification.

7. Submission of Notification of listing

7.1 Notification of orphaned medical device shall be made by hospitals/healthcare facilities/ related facilities. Notification of listing shall be submitted to the Authority by using the 'Notification Listing of Orphaned Medical Device Form' in Annex A by email to Chief Executive Medical Device Authority at email address *orphaned@mda.gov.my*.

7.2 The form for 'Notification/Listing of Orphaned Medical Device' is published in the Authority website at mda@mda.gov.my.

7.3 Each notification submitted can be for more than one medical device and locations.

7.4 The explanations for filling in the application for notification of listing form is presented in Table 1.

Table 1 notification/listing of orphaned medical device application

Particulars	Explanation	Supporting document
Part 1 Hospitals/ healthcare facilities/ related facilities details		
a. Name of hospital/healthcare facility/ related facility/ healthcare professional	Please provide full name of Hospital/ healthcare facility/related facility applying for notification or full name of healthcare professional	-
b. Address of Hospital/ healthcare facility/ related facility	Please provide full address	-
c. City	Please provide name of city	-
d. State	Please provide name of state	-
e. Postcode	Please provide postcode number	-
f. Telephone No	Please provide general telephone number	-
g. Email Address	Please provide email address of the Hospitals/ healthcare facilities/ related facilities	-
Part 2 Contact Person Details		
a. Name	Please provide full name of person responsible for medical device or appointed by the person responsible	Letter of appointment by person responsible for notification of listing.
b. Designation	Please provide the designation of person responsible for medical device	-
c. Division/Unit	Please provide full name of the division/unit of the person responsible.	-
d. Telephone No	Please provide direct phone line number.	-
e. Mobile phone No.:	Please provide mobile phone number (if applicable)	-
f. Email Address	Please provide email address of the person responsible.	-
Part 3 Medical Device Details		
a. General information		
i) Medical Device Name	Please provide the general name of medical device (e.g wheelchair)	If the notification involves more than one (1) type of medical device, please complete Appendix A. Submit Appendix A (if applicable)
ii) Brand	Please provide the brand name of the medical device	
iii) Model No.	Please provide the model number of the medical device	
iv) Serial No.	Please provide the serial number of the medical device	
v) Intended purpose	Please provide description of medical device with intended purpose and indication for use.	

Particulars		Explanation	Supporting document
vi)	Date of purchase/placement	Please state the date the medical device was procured in the healthcare facility.	
vii)	Location(s) e.g operation theatre, Intensive Care Unit	Please state the location(s) where the medical device is to be used.	
viii)	Beyond Economic Repair (BER) Yes/No?	Is this BER medical device which is pending disposal?	
ix)	PPM report or machine report	Please submit PPM report or machine report for the medical device.	
b. Manufacturer/Authorized representative Details (if available)			
i)	Manufacturer/Authorized representative Name	Please state the manufacturer name of the medical device.	-
ii)	Address	Please state the full address of the manufacturer.	-
c. Supplier/Distributor Details (if available)			
i)	Supplier/Distributor Name	Please state the name of supplier/distributor of the medical device.	-
ii)	Address	Please state the full address of the supplier/distributor.	-
d. Person In-Charge Details			
i)	Name	Please state the full name of the person in charge who is responsible for the orphaned medical device.	-
ii)	Designation	State designation of person in charge in the organisation.	-
iii)	Division/Unit	Please state the division/unit of the person in charge.	-
Part 4 Attestations & Declaration			
i)	Signature	Attestation to be signed by person responsible for this application or appointed personnel by top management	-
ii)	Name		-
iii)	Designation		-
iv)	Date		-
v)	Company stamp		-

8. Administrative charge

Each notification shall be submitted together with a RM XXX administrative charge, with the following conditions:

(a) Administrative charge shall be paid through bank draft. CASH WILL NOT BE accepted. The Authority will not be responsible for the cash sent or brought to MDA.

(b) The bank draft must be made payable to “KUMPULAN WANG PIHAK BERKUASA PERANTI PERUBATAN” and sent to:

KETUA EKSEKUTIF

Medical Device Authority (MDA),
Ministry of Health Malaysia,
Level 6, Prima 9, Prima Avenue II,
Block 3547, Persiaran APEC,
63000 Cyberjaya, Selangor, MALAYSIA
U/P: UNIT KHIDMAT PENGURUSAN

(c) Name, Telephone No. of the applicant and application for 'Notification/listing for orphaned medical device' must be written at the back of the bank draft but not in the table section.

9. Conditions of the Notification/ Listing

9.1 Provision of inaccurate information or making false declaration shall render this notification null and void.

9.2 The hospitals, healthcare facilities or related facilities shall be required to attest that its medical device is/are orphaned medical device according to the definition.

9.3 Orphaned medical device shall not be sold/loaned/provided for free/donated/used in research to third party.

Excluding:

i) for teaching/education which is not to be used on patient; required to inform MDA on change of location; or

ii) if the medical device is sold to a third party for the purpose of disposal as scrap material or as e-waste.

9.4 The notification letter shall not be used for the purpose of promoting or advertising the device.

9.5 Applicant shall ensure the device is used in accordance with the requirement of Section 43, Medical Device Act 2012:

(1) A person using or operating a medical device on a third party shall:
   a) ensure that the medical device is safe and efficacious,
   b) used in according with its intended purpose,
   c) used in accordance with manufacture's instruction and properly installed, tested, commissioned and maintained;

(2) A person-
   a) using or operating a medical device on a third party; or
   b) installing, testing, commissioning, maintaining, and disposing of a medical device, shall have the qualification and competency as prescribed by the Minister.

(3) A person using or operating a medical device on a third party shall take the medical device out of operation when it is no longer safe and effective for use.

(4) A medical device which has been taken out of operation under subsection (3) shall be removed and disposed of in a safe manner which eliminates or reduce any-
   a) danger of injury;
   b) danger of contamination with biological material or other contaminants;
   c) danger of environmental damage; and
   d) danger of it being re-used.

9.6 Applicant shall monitor the safety and performance of the medical device.

9.7 Applicant shall ensure that any incidents involving its medical device is properly recorded and reported to the Authority according to the Act 737 using MDA Feedback Management System (FEMES) at https://femes.mda.gov.my/.

9.8 When the medical device is no longer safe and effective, it shall be removed and disposed in a safe manner and the Authority shall be notified as in Annex B.

9.9 Applicant shall establish and implement documented procedures and maintain records of reported problems or complaints relating to the safety and the performance of its medical device.

9.10 Applicant shall provide any document or record upon request and may be subjected to inspection by the Authority.

ANNEX A

(normative)

		PIHAK BERKUASA PERANTI PERUBATAN *Medical Device Authority* KEMENTERIAN KESIHATAN MALAYSIA *Ministry of Health Malaysia* Portal: www.mda.gov.my Email: mdb@mda.gov.my

BORANG PERMOHONAN BAGI NOTIFIKASI PENYENARAIAN PERANTI PERUBATAN *ORPHANED*

NOTIFICATION LISTING OF ORPHANED MEDICAL DEVICE FORM

For MDA Office use			
Application serial No. :			
Particulars (Please tick X if completed)		**[Signature and Name]**	**Date**
	Application received		
	CE office		
	Head of Division		
	Evaluation Officer		

KETERANGAN *EXPLANATION*

Berdasarkan Surat Pekeliling PBPP Bilangan 2 Tahun 2018: Kawalan terhadap peranti perubatan 'orphaned', 'obsolete' dan 'discontinued' di Hospital atau Institusi Kemudahan Kesihatan. Institusi kemudahan kesihatan dan institusi berkaitan yang mempunyai peranti perubatan orphaned hendaklah mengenalpasti dan memberikan notifikasi/penyenaraian kepada Pihak Berkuasa Peranti Perubatan (PBPP).

In accordance with Circular Letter of Medical Device Authority No. 2 Year 2018: Control of orphaned, obsolete and discontinued medical device in hospitals, healthcare facilities or related facilities. Facilities/institutions which have orphaned medical devices shall identify and provide the notification/listing to the Medical Device Authority (MDA)

Sila lengkapkan maklumat di ruangan yang disediakan

All fields are mandatory unless stated otherwise

PART 1 **HOSPITALS/HEALTHCARE FACILITIES/ RELATED FACILITIES DETAILS**		
a.	Name of hospitals/healthcare facilities/ related facilities or healthcare professional:	
b.	Address of hospitals/healthcare facilities/ related facilities:	
c.	City:	
d.	State:	
e.	Postcode:	
f.	Telephone No.:	
g.	Email Address:	
PART 2		

CONTACT PERSON DETAILS		
a.	Name:	
b.	Designation:	
c.	Division/Unit:	
d.	Telephone No.:	
e.	Mobile phone No.:	
f.	Email Address:	

PART 3 MEDICAL DEVICE DETAILS		
** If the notification involves more than one (1) device, please complete Appendix A		
a.	**GENERAL INFORMATION**	
	i. Name of medical device:	
	ii. Brand:	
	iii. Model No.:	
	iv. Intended purpose:	
	v. Date of purchase:	
	vi. Location: e.g operation theatre, Intensive Care Unit	
	vii. Beyond Economic Repair (BER): Yes/No?	
	viii. PPM report or machine report (if applicable) (Please tick if document is attached)	
b.	**MANUFACTURER/AUTHORIZED REPRESENTATIVE DETAILS (if available)**	
	i. Name of manufacturer:	
	ii. Address:	
c.	**SUPPLIER/DISTRIBUTOR DETAILS (if available)**	
	i. Supplier/Distributor Name:	
	ii. Address:	
d.	**PERSON IN-CHARGE DETAILS**	
	i. Name:	
	ii. Designation:	
	iii. Division/Unit:	

PART 4 ATTESTATIONS & DECLARATION
I, the undersigned, hereby attest and declare that: The product(s) indicated on this application is/are:

i) medical device(s) according to the definition of “medical device” set out in Section 2, Medical Device Act 2012 (Act 737); and
ii) orphaned medical device according to the definition set out in Circular Letter of Medical Device Authority No. 2 Year 2018

I shall comply fully with the terms and conditions in the requirements of Notification/listing by the Authority.

I am aware that advertising of orphaned medical device is strictly prohibited under Section 44, Act 737.

I shall comply with any relevant competent authorities on any other law or regulations in Malaysia, if applicable (i.e. Atomic Energy Licensing Board, etc).

I shall ensure that the orphaned medical device(s) as in **PART 3 (Appendix A)** that is no longer safe and effective shall be removed and disposed according to Act 737.

The information provided on this application is accurate, correct, complete and current to this date. I understand and acknowledge that it is an offence 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: (person responsible or appointed personnel by top management)	
Name:	
Designation:	
Date:	
Company stamp:	

Please return this form to:

Chief Executive Medical Device Authority
Email : *orphaned@mda.gov.my*

APPENDIX A
MEDICAL DEVICE DETAILS

A. General Information									B. Manufacturer /Authorized representative Details (if available)		C. Supplier /Distributor Details (if available)		D. Person In-Charge Details		
No.	**Particulars**														
	Medical Device Name:	**Brand:**	**Model Number:**	**Intended purpose:**	**Date of purchase :**	**Location: e.g operation theatre, Intensive Care Unit**	**BER: Yes/ No**	**PPM report / machine report (if applicable)**	**Manufacturer /Authorized representative Name:**	**Address:**	**Supplier/ Distributor Name:**	**Address:**	**Name:**	**Designation:**	**Division/ Unit:**
i.															

* Repeat as Needed
** This Appendix A is part of the notification to be submitted together with the Notification/listing Application Form.

ANNEX B
(normative)

PIHAK BERKUASA PERANTI PERUBATAN
Medical Device Authority
KEMENTERIAN KESIHATAN MALAYSIA
Ministry of Health Malaysia
Portal: www.mda.gov.my
Email: mdb@mda.gov.my

DISPOSAL OF ORPHANED MEDICAL DEVICE NOTIFICATION FORM

Please complete all information requested in this form

Please state Notification letter reference number information:

Notification ID:	

PARTICULARS OF MEDICAL DEVICE(S) (Repeat as needed)

Name of Device	Brand	Model	Serial number	Location(s) e.g operation theatre, Intensive Care Unit	Manufacturer /Authorized representative Name
1.					
2.					
3.					
4.					

DECLARATION
(Please read carefully & tick the boxes)

I, the undersigned, hereby declare that:

☐	The orphaned medical device(s) are properly disposed.
☐	The information provided on this application is accurate, correct, complete and current to this date. I understand and acknowledge that it is an offence 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:	
Designation:	

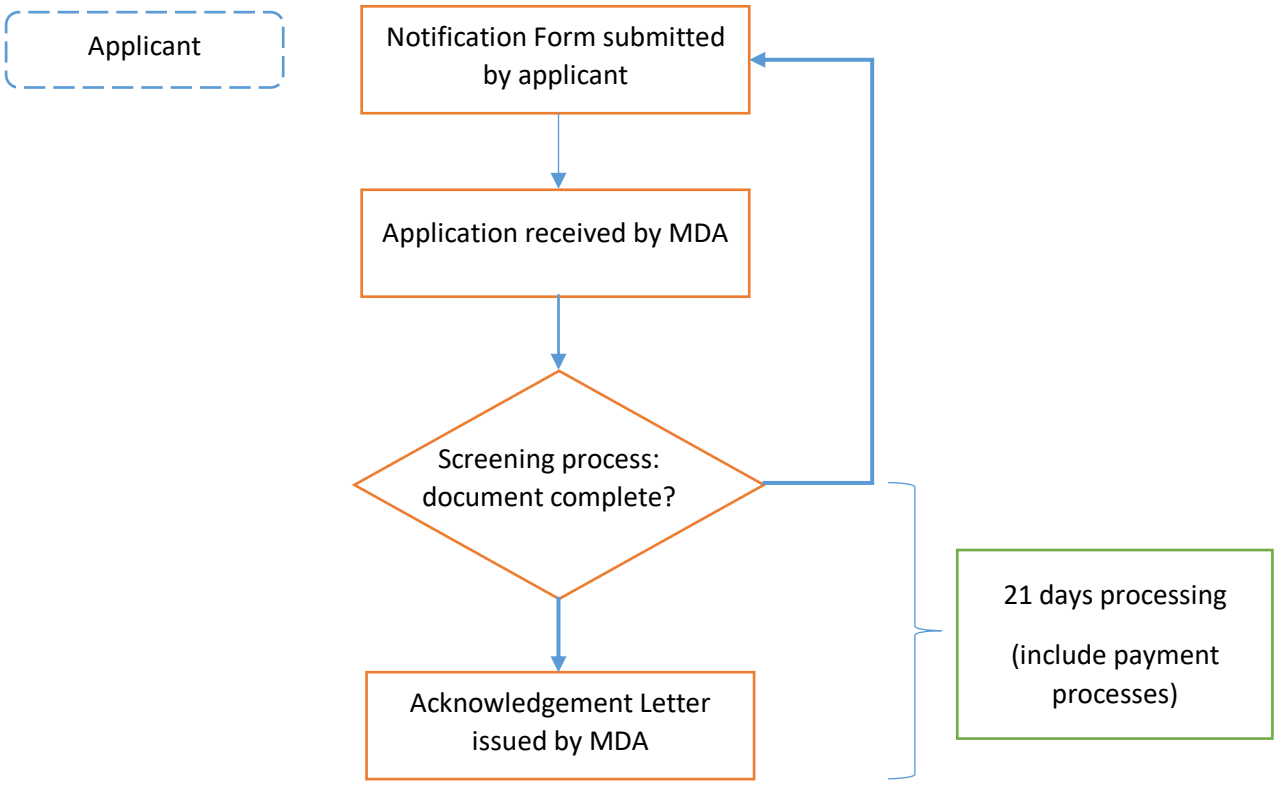
Hospitals/Healthcare Facilities
and Related Facilities stamp:

Date:

Please return this form to:
Chief Executive Medical Device Authority
Email : *orphaned@mda.gov.my*

ANNEX C
(informative)

FLOWCHART OF APPLICATION FOR NOTIFICATION OF LISTING OF ORPHANED MEDICAL DEVICE.



MEDICAL DEVICE AUTHORITY

MINISTRY OF HEALTH, MALAYSIA

Contact Information:

MEDICAL DEVICE AUTHORITY
Ministry of Health Malaysia
Level 6, Prima 9, Prima Avenue II,
Block 3547, Persiaran APEC,
63000 Cyberjaya, Selangor,
MALAYSIA
T: (03) 8230 0300
F: (03) 8230 0200
Website: http://www.mda.gov.my