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MEDICAL DEVICE GUIDANCE DOCUMENT

CHANGE OF OWNERSHIP FOR MEDICAL DEVICE REGISTRATION

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.

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 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
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CHANGE OF OWNERSHIP FOR MEDICAL DEVICE REGISTRATION

1 Introduction

Section 5(1) Act 737, no medical device shall be imported, exported or placed in the market unless the medical device is registered under this Act.

Section 6(1) requires an application for the registration of a medical device be made by an establishment to the Authority in the prescribed manner. In this context, the registration of medical device is the responsibility of local manufacturer or an authorized representative (AR) appointed by manufacturer having a principle place of business outside Malaysia.

Change ownership of medical device registration is required for reasons such as:

a) Manufacturer outside Malaysia who has set up a company in Malaysia and intends to obtain the ownership of medical device registration from AR.

b) Replacing of existing AR to new AR by the manufacturer to place the medical device in the market

c) Merging and acquisition activities

d) Existing AR closed its business

This guidance document is intended to provide guidance on the above circumstances, in complying with the Medical Device Act and Regulations. This document is made pursuant to Medical Device Authority (MDA) Circular Letter No. 3 Year 2016.

2 Scope and application

This guidance document specifies requirements for the change of ownership of medical device registration in Malaysia and applies to the persons responsible for registering a medical device under Act 737 as follows–

(a) the manufacturer of medical device as defined in Section 2 of Act 737; and

(b) authorized representative of the foreign manufacturer in the case of a medical device manufactured in foreign country, as defined in Section 2 of Act 737.

3 Terms and definitions

For the purposes of this document, the terms and definitions in Act 737, Medical Device Regulations and the following apply:

3.1 Authority

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

3.2 authorized representative (AR)

An authorized representative appointed by a manufacturer having a principal place of business outside Malaysia and such person and authorized representative being –

a) A person domiciled or resident in Malaysia; or

b) A firm or company constituted under the laws of Malaysia,

and carrying on business or practice principally in Malaysia.

3.3 establishment

Establishment means –

a) A person who is either a manufacturer, importer, or distributor who is responsible for placing any medical device in the market but does not include a retailer; and

b) An authorized representative appointed by a manufacturer having a principal place of business outside Malaysia,

and such person and authorized representative being –

a) A person domiciled or resident in Malaysia; or

b) A firm or company constituted under the laws of Malaysia,

and carrying on business or practice principally in Malaysia.

3.4 manufacturer

Manufacturer means –

a) a person who is responsible for –

(i) the design, production, fabrication, assembly, processing, packaging and labelling of a medical device whether or not it is the person, or a

subcontractor acting on the person's behalf, who carries out these operations; and

(ii) assigning to the finished medical device under his own name, its intended purpose and ensuring the finished product meets the regulatory requirement; or

b) any other person who –

(i) assembles, packages, processes, fully refurbishes, reprocesses or labels one or more ready-made medical devices; and

(ii) assigning to the ready-made medical device under his own name, its intended purpose and ensuring the finished product meets the regulatory requirement,

but shall not include the following persons:

a) any person who assembles or adapts medical devices in the market that are intended for individual patients; and

b) any person who assembles, packages or adapts medical devices in relation to which the assembling, packaging or adaptation does not change the purpose intended for the medical devices.

3.5 MeDC@St

MeDC@St is a web-based Online Application System to submit applications for registration of medical devices and licensing of establishment under Act. Its enables submissions to be made from anywhere in the world, which also provides features that enable access by multiple users.

4 General requirements

A request to change of ownership for medical device registration shall be made after the medical device is registered with the Authority and there shall be no pending applications in the system. Otherwise, the applications would be required to be completed or withdrawn.

The application for change of ownership for medical device registration shall be made by the new AR, and only duly completed application forms shall be submitted to the Authority. The effective date of the change is the date of approval of the application by the Authority.

The target turn-around-time (TAT) for an application for change of ownership for medical device registration is approximately 30 working days. All turn-around-time are estimated and based on complete submissions with all the necessary accompanying information and documents.

4.1 New AR

The new AR shall provide the following documents:

a) *Change Of Ownership For Medical Device Registration Application Form* that is duly completed and signed (please refer Annex A);

b) Establishment license;

c) Letter of Authorisation (LOA) from foreign manufacturer. LOA template may be refer in MDA/GD/0027; and

d) Official letter from manufacturer to request the change of ownership for medical device registration from current AR to the new AR. In this letter, the manufacturer is to provide:

- The effective date of appointment of the new AR. Date should be before the date of submission of the change application to the Authority;

- The list of applicable registered medical devices;

4.2 Current AR

The current AR shall provide the following documents:

a) *Current AR Declaration Form* that is duly completed and signed (please refer Annex B);

b) Surrender of all applicable medical device certificates to the Authority; and

c) The current AR shall transfer all distribution and complaints records of the applicable medical devices up to date of approval of the application by the Authority to the new authorized representative.

5 Application process

The new AR is responsible for making the application for the change of ownership for medical device registration. The general application procedure is described below. AR which is already licensed with the Authority with an existing MeDC@St account may proceed directly to Step 6.

1. Go to www.mdb.gov.my and click MeDC@St

2. An applicant need to complete *MeDC@St Account Creation Form* and must provide information required in *MeDC@St Account Creation Form* which includes business registration, establishment name and a valid email address.

3. A validation email will be sent to the email address provided in the form to activate the account. Applicant needs to log in to his/her email account to validate the email address provided in the *MeDC@St Account Creation Form*.

4. After the email is validated, applicant must login to the system by providing the User Name and Password given in the *MeDC@St Account Creation Form* during account creation.

5. An applicant needs to apply for establishment license by submitting required documents through the system. Please refer to MDA/GL No 2 for more information.

6. Obtain all required supporting documents as described in Clause 4 of this Guidance Documents, including *Current AR Declaration Form* duly completed by the current AR. Email or fax the documents to the Authority:

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Level 6, Prima 9, Prima Avenue II,
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63000 Cyberjaya, Selangor,
MALAYSIA
Tel: (03) 8230 0300
Fax: (03) 8230 0200
Email: mdb@mdb.gov.my

6 Completion

The new AR and current AR will be notified of the outcome of the application for the change of ownership for medical device. The effective date of the change is the date of approval of the application by the Authority. The access rights of the current AR to the device listing will cease with immediate effect.

The new AR shall fulfil the duties and obligations under the Act 737 and Medical Device Regulations.

The current AR shall not be entitled to any refund of the prescribed registration fee paid. The new AR will be required to pay the service/processing fee RM 500 per medical device registration ID. The validity of registration certificate shall continue from the initial date of registration of the medical device unless the registration is cancelled by the Authority before its expiry.

Annex A
(normative)

Change Of Ownership For Medical Device Registration Application Form

Change Of Ownership For Medical Device Registration Application Form (In accordance with Circular Letter of Medical Device Authority No. 3 Year 2016 : Change of Ownership for Medical Device Registration)		
Please complete all fields		
NEW AUTHORIZED REPRESENTATIVE		
Name Of Establishment:		
Address :		
City:	State:	
Establishment License Number:		
Name of Contact Person:		Designation:
Telephone No.:	Mobile Phone No.:	Email Address:
CURRENT AUTHORIZED REPRESENTATIVE		
Name Of Establishment:		
Address :		
City:	State:	
Role :		Establishment License Number:
Name of Contact Person:		Designation:
Telephone No.:	Mobile Phone No.:	Email Address:
MANUFACTURER		
Name Of Establishment:		
Address :		
City:	State:	
Role :		Establishment License Number:
Name of Contact Person:		Designation:
Telephone No.:	Mobile Phone No.:	Email Address:

DETAILS OF MEDICAL DEVICE(S)		
NO	MEDICAL DEVICE NAME	REGISTRATION NO.
1		
2		
3		
4		
5		

Change Of Ownership For Medical Device Registration Application Form

(In accordance with Circular Letter of Medical Device Authority No. 3 Year 2016 : Change of Ownership for Medical Device Registration)

**Please attached list of medical devices if there are more than 5 medical devices*

CHECKLIST

☐ Change of Ownership for Medical Device Registration Application Form
☐ Establishment License (New AR)
☐ Letter Of Authorization (LOA)
☐ Official Letter from Manufacturer
☐ Current AR Declaration Form
☐ Bank Draft Of RM 500 per medical device registration ID
(The bank draft must be made payable to "KUMPULAN WANG PIHAK BERKUASA PERANTI PERUBATAN")

I, < Name of responsible person >, ID <IC No. or Passport No.> hereby declare that:

i. Accept the appointment by the manufacturer as the new authorized representative for the following registered medical device(s) and duly acknowledge and accept my duties and obligation as an authorized representative; and

ii. Comply with all the conditions of approval applicable to the following registered medical device(s) and conditions imposed;

iii. Will take possession of all distribution and complaints records of the following registered medical device(s) previously held by current authorized representative up to the date of approval of this change application by the Authority. I am obliged to maintain these records for the period stipulated in the regulatory requirements for medical devices safety and performance, Good Distribution Practice for Medical Device (GDPMD) and provide such records to the Authority in the event of a field safety corrective action or when requested by the Authority; and

iv. Will fulfil the duties and obligations under the Act 737 and medical device regulations

I hereby attest that the information and attachment provided on this application are accurate, correct, complete and current to this date.

I understand and acknowledge that it is an offence under Section 76, Medical Device Act 2012 (Act 737) to make signs or furnish any declaration, or other document which is untrue, inaccurate or misleading.

Signature:

Person Responsible Name:

Designation

Date :

Company stamp :

Annex B
(normative)

Current Authorized Representative Declaration Form

Current Authorized Representative Declaration Form

(In accordance with Circular Letter of Medical Device Authority No. 3 Year 2016 : Change of Ownership for Medical Device Registration)

Please complete all fields		
CURRENT AUTHORIZED REPRESENTATIVE		
Name Of Establishment:		
Address :		
City:	State:	
Establishment License Number:		
Name of Contact Person:		Designation:
Telephone No.:	Mobile Phone No.:	Email Address:
MANUFACTURER		
Name Of Establishment:		
Address :		
City:	State:	
Role :		Establishment License Number:
Name of Contact Person:		Designation:
Telephone No.:	Mobile Phone No.:	Email Address:

DETAILS OF MEDICAL DEVICE(S)		
NO	MEDICAL DEVICE NAME	REGISTRATION ID.
1		
2		
3		
4		
5		

**Please attached list of medical devices if there are more than 5 medical devices*

Current Authorized Representative Declaration Form

(In accordance with Circular Letter of Medical Device Authority No. 3 Year 2016 : Change of Ownership for Medical Device Registration)

DECLARATION BY CURRENT AUTHORIZED REPRESENTATIVE

I, < Name of responsible person >, ID <IC No. or Passport No.> hereby declare that:

i. Will transfer all distribution and complaints records of the following medical device(s) up to date of approval of this change application by the Authority to the new authorized representative; and

ii. Will surrender all the applicable medical device certificates to the Authority.

I hereby attest that the information and attachment provided on this application are accurate, correct, complete and current to this date.

I understand and acknowledge that it is an offence under Section 76, Medical Device Act 2012 (Act 737) to make signs or furnish any declaration, or other document which is untrue, inaccurate or misleading.

Signature:

Person Responsible Name:

Designation

Date :

Company stamp :

MEDICAL DEVICE AUTHORITY

MINISTRY OF HEALTH, MALAYSIA

Contact Information:

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