HEALTH SCIENCES AUTHORITY

REGULATORY GUIDANCE

22 March 2021

MEDICAL DEVICE GUIDANCE

GN-24: Guidance on the Change of Registrant

Revision 1.4

HSA
Health Sciences Authority

CONTENTS

PREFACE

R1.1 ►This document is intended to provide general guidance. Although we have tried to ensure that the information contained here is accurate, we do not, however, warrant its accuracy or completeness. The Health Sciences Authority (HSA) accepts no liability for any errors or omissions in this document, or for any action/decision taken or not taken as a result of using this document. The information contained in this document should not be a substitute for professional advice from your own professional and healthcare advisors. ◄

REVISION HISTORY

Guidance Version (Publish Date) *[3 latest revisions]*	Revision
GN-24: Revision 1 (01 April 2014)	R1
R1.1 ►GN-24: Revision 1.1 (25 April 2014)	R1.1
R1.2 ►GN-24: Revision 1.2 (01 December 2017)	R1.2
R1.3 ►GN-24: Revision 1.3 (21 August 2018)	R1.3
R1.4 ►GN-24: Revision 1.4 (22 March 2021)	R1.4

**Where applicable, changes and updates made in each document revision are annotated with or within the arrow symbol "►". Deletions may not be shown.*

1. INTRODUCTION

1.1. Purpose

This document is meant to provide general guidance on the change of registrant and the accompanying documents required by the Authority.

1.2. Background

A registrant, in relation to a registered medical device, is the person who applied for and obtained the registration of the medical device under the Health Products Act (*Act*).

A registrant of a medical device has to fulfill the duties and obligations prescribed under the *Act* and Health Products (Medical Devices) Regulations (*Regulations).* The key responsibilities are as follows:

- Comply with the conditions applicable to the registered medical device and conditions imposed on the registrant;
- Submit applications to the Authority for changes made to the registered medical device;
- Maintain records of supply;
- Maintain records of complaints;
- Report defects and adverse effects to the Authority; and
- Notify the Authority concerning field safety corrective action (FSCA), including recalls.

A change of registrant application has to be made to HSA, when there is a change of registrant for a registered medical device. The *Relinquishing Company* and *Accepting Company* should clearly define their duties and obligations to the Authority before the change of registrant can take effect. The Authority reserves the right to approve or reject the application.

1.3. Scope

This document applies to all registered medical devices where a change of registrant is to be made.

1.4. Definitions

Definitions that do not indicate they are set out in the *Act* or *Regulations* are intended as guidance in this document. These definitions are not taken verbatim from the above-mentioned legislation and should not be used in any legal context. These definitions are meant to provide guidance in layman terms.

ACCEPTING COMPANY: in relation to a change of registrant for a registered medical device, means the newly appointed registrant by the product owner.

FIELD SAFETY CORRECTIVE ACTION *(as set out in the Regulations)*: any action taken to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device, including

- the return of the medical device to its product owner;
- replacement or destruction of the medical device;
- any action regarding the use of the medical device that is taken in accordance with the advice of its product owner;
- the clinical management of any patient who has used the medical device;
- the modification of the medical device;
- the retrofitting of the medical device in accordance with any modification to it or any change to its design by its product owner;
- the making of any permanent or temporary change to the labelling or instructions for use of the medical device; or
- any upgrade to any software used with the medical device, including any such upgrade carried out by remote access.

PRODUCT OWNER (*as set out in the Regulations*): in relation to a health product, means a person who —

- supplies the health product under his own name, or under any trade mark, design, trade name or other name or mark owned or controlled by him; and
- is responsible for designing, manufacturing, assembling, processing, labelling, packaging, refurbishing or modifying the health product, or for assigning to it a purpose, whether those tasks are performed by him or on his behalf.

REGISTRANT *(as set out in the Act)*: in relation to a registered health product, means the person who applied for and obtained the registration of the health product under the *Act*.

RELINQUISHING COMPANY: in relation to a change of registrant for a registered medical device, means the registrant that has obtained the registration of the medical device and that shall be relinquishing the product registration for the medical device to the *Accepting Company*.

SUPPLY (*as set out in the Act*): in relation to a health product, means to transfer possession of the health product by any means whether or not for reward, and includes the following:

(a) to sell the health product, whether by retail, wholesale or auction;

(b) to expose or display the health product as an invitation to treat;

(c) to transfer possession of the health product by exchange, gift, lease, loan, hire or hire-purchase;

(d) to supply the health product in connection with:-

  (i) a contract for the provision of any goods or the performance of any service; or

  (ii) any advertising, sponsorship or promotional activity;

(e) to supply the health product by way of administration to or application in any person in the course of any diagnosis, treatment or test;

(f) to offer, agree or attempt to supply the health product in any of the ways described in paragraphs (a) to (e) or to cause or permit the health product to be so supplied; and

(g) to keep or possess the health product for the purpose of supplying it in any of the ways described in paragraphs (a) to (f).

2. APPLICATION REQUIREMENTS FOR THE CHANGE OF REGISTRANT

A request to change the registrant should only be made after the medical device is listed on the Singapore Medical Device Register (SMDR) and there should be no pending applications in the system for the registered medical device; such as Change Notification applications, cancellation of medical device listing, etc; if any, they would be required to be completed or withdrawn. A separate application should be made for each product owner involved.

The change of registrant application is to be made by the *Accepting Company*, and only duly completed application forms should be submitted to HSA. The target turn-around-time (TAT) for an application for the change of registrant is 40 working days. R1.4 ► *Accepting company* is to ensure that the SMDR device listing(s) are valid for at least the next two months before the next retention due date. . The target turn-around-time (TAT) for change of registrant applications commences from the date of receipt of the application and does not include 'stop-clock time' due to input requests for clarifications and additional information. ◄ The effective date of the change of registrant is the date of approval of the application by HSA.

The following is required for the application for the change of registrant:

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- A letter of authorisation to appoint the *Accepting Company* as the registrant. The Letter of Authorisation Template is found in GN-15 Guidance on Medical Device Product Registration.
- **A letter of request (Annex 1), addressed to HSA for the request for the change of registrant from the *Relinquishing Company* to the *Accepting Company*.**
- Annex 2 Relinquishing Company Declaration Form, duly completed and signed by *Relinquishing company.* ◄

The *Relinquishing Company* shall retain proper records of supply and records of complaints for the devices. These records can either be:

- maintained by the *Relinquishing Company* for the periods stipulated in the *Health Products (Medical Devices) Regulations; or*
- transferred to the *Accepting Company.*

3. APPLICATION PROCEDURE

The *Accepting Company* is responsible for making the application for the change of registrant. R1.4 ► All change of registrant application is to be submitted through the Medical Device Information and Communication System (MEDICS). ◄ Companies with an existing HSA Client Registration and Identification Service (CRIS) Company Account and registrant's account may proceed directly to step 3.

1. Apply for the HSA Client Registration and Identification Service (CRIS) Company Account.

2. Apply for the registrant's account.

3. Obtain **all** required supporting documents as described in Section 2 of this guidance document, including the Annex 2 Relinquishing Company Declaration Form duly completed by the *Relinquishing Company*.

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4. Submit application through MEDICS. Turn-around-time: 40 working days.◄

4. COMPLETION OF CHANGE OF REGISTRANT

The *Accepting Company and Relinquishing Company* will be notified of the outcome of the application for the change in registrant.

The effective date of the change of registrant is the date of approval of the application by HSA. Upon the successful change of registrant, information of the registered medical device in the Singapore Medical Device Register (SMDR) will be updated to reflect the new registrant. The access rights of the *Relinquishing Company* to the device listing will cease with immediate effect.

From the effective date of the change of registrant, the *Accepting Company* shall fulfill the duties and obligations under the *Act* and *Regulations*:

- Comply with the conditions applicable to the registered medical device and conditions imposed on the registrant;
- Notify the Authority for changes made to the registered medical device;
- Maintain records of supply;
- Maintain records of complaints;
- Report defects and adverse effects to the Authority; and
- Notify the Authority concerning FSCA, including recalls.

Should the *Relinquishing Company* decide to continue maintaining the records of supply and records of complaints for the device(s) up to the effective date of the change of registrant, it is obliged to provide these records to the *Accepting Company* or the Authority in the event of an FSCA or when requested by the Authority.

There will be no refund of the annual retention fee to the *Relinquishing Company*. The *Accepting Company* will be required to pay annual retention fee(s) from the next annual retention exercise from the effective date of the change of registrant. R1.4 ► *Accepting* company is to ensure that the SMDR device listing(s) are valid for at least the next two months before the next retention due date. ◄

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ANNEX 1

Letter of Request Template

[To be printed on Company Letterhead of Product Owner]

Medical Devices Branch
Medical Devices Cluster
Health Products Regulation Group
Health Sciences Authority

[Date]

Dear Sir/Madam,

Subject: Letter of Request for the change of registrant from *[Relinquishing Company name]* to *[Accepting Company name]*

We, *[name of Product Owner (Company name)]*, as the Product Owner, hereby request the change of Registrant from *[Relinquishing Company name]*, as the Relinquishing Company to *[Accepting Company name]*, as the Accepting Company for the following medical devices:

[List containing SMDR listing name and number]

In this letter, we declare that:

- the effective date of appointment of *[Accepting Company name]* as the new registrant is *[effective date (dd/mm/yyyy - this date should be before the date of submission of the change of registrant application to the HSA)]*
- there are *[changes/no changes]* made to the registered medical device(s) above that require a change notification to HSA, such as change in instructions for use (IFU) or addition of models.

  [List of changes made requiring change notification submission, if applicable]

Yours sincerely,

[Signature]

[Full name and Title of Senior Company Official]
[Name and address of company]

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ANNEX 2

RELINQUISHING COMPANY DECLARATION FORM

Important Notes:

1. This form should be duly completed and signed by a Company Director or senior officer of the *Relinquishing Company*.
2. If the space provided in the form is insufficient, please provide the information as an attachment.

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Relinquishing Company			
Name of company			
Company address			
Contact person's name			
Job title			
Tel no.		Fax no.	
Email Address			
Product Owner			
Name of company			
Company address			
Contact person's name			
Job title			
Tel no.		Fax no.	
Email Address			

Please tick one of the following:

☐ I, _____ (Name of Relinquishing *Company)* will retain all records of supply and complaints of the following registered medical device(s). I am obliged to maintain these records for the period stipulated in

the *Health Products (Medical Devices) Regulations* and provide such records to the *Accepting Company* or the Authority in the event of a field safety corrective action or when requested by the Authority.

☐ I, _____ (Name of Relinquishing Company) attest that I will transfer all records of supply and complaints of the following registered medical device(s) up to the date of approval of this Change of Registrant application by the Authority, HSA to _____ (Name of *Accepting Company).*

No.	Device Name	SMDR Device Registration No.

** If there are more than 5 medical devices to be transferred, please attach a list to this page*

The effective date of this change of *Registrant* is the date of approval of this Change of *Registrant* application by the Authority, HSA.

Signature	
Full Name of Applicant (as it appears in the NRIC or Passport)	
Designation	
Company Name and address	
Date (DD/MM/YYYY)	

HEALTH SCIENCES AUTHORITY

Health Products Regulation Group
Blood Services Group
Applied Sciences Group

www.hsa.gov.sg

Contact Information:

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Health Sciences Authority

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