HEALTH SCIENCES AUTHORITY

REGULATORY GUIDANCE

December 2017

MEDICAL DEVICE GUIDANCE

GN-25: Guidance on the Cancellation of Medical Device Listing

Revision 1

HSA
Health Sciences Authority

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PREFACE

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-25: Revision 1 (01 December 2017)	R1

**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 cancellation of medical device listing(s) and the accompanying documents required by the Authority.

1.2. Background

When a medical device is no longer supplied in Singapore, and/or the registrant is no longer a business entity registered with the Accounting and Corporate Regulatory Authority of Singapore (ACRA), an application to cancel the medical device listing from the Singapore Medical Device Register (SMDR) should be made.

After the medical device listing is cancelled, the registrant still has to fulfill the following duties and obligations under the Health Products Act (*Act*):

- 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.

If the registrant is no longer registered with the Accounting and Corporate Regulatory Authority of Singapore (ACRA) as a business entity, all records of supply and records of complaints should be transferred to the product owner.

NOTE If the medical device listing is to be transferred to a newly appointed registrant, an application for Change of Registrant should be made to the Authority. Relevant forms are found in GN-24 Guidance for the Change of Registrant.

1.3. Scope

This document applies to all registered medical devices where a cancellation of medical device listing(s) is to be made.

1.4. Definitions

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

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*.

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

An application for the cancellation of medical device listing should be made after the medical device is no longer supplied. A separate application should be made for each product owner involved. There should be no pending applications in the system for the registered medical device listing; such as Change Notification applications, cancellation of medical device listing, etc; if any, they would be required to be completed or withdrawn.

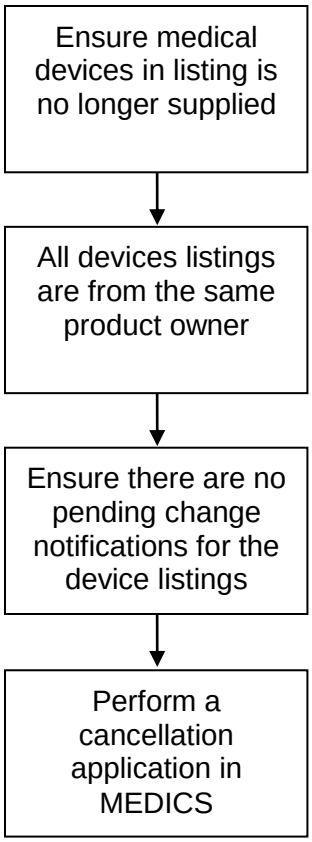
Records of supply and records of complaints, up to the cancellation date of the medical device listing, must be properly kept. The registrant shall maintain these records for the periods stipulated in the *Regulations*.

If the registrant is no longer registered with Accounting and Corporate Regulatory Authority of Singapore (ACRA) as a business entity, all records of supply and records of complaints should be transferred to the product owner.

3. APPLICATION PROCEDURE

To apply for the cancellation of medical device listing, the registrant may make a submission through the e-Services module on HSA's webpage or through their MEDICS account.

Flowchart on Cancellation of Medical Device Listing Application



4. CANCELLATION OF MEDICAL DEVICE LISTING

When the cancellation of a medical device listing is effected, the medical device will be removed from the SMDR.

Once a medical device is removed from the SMDR, supply of the medical device in Singapore is prohibited.

There will be no refund of annual retention fee to the registrant.

It is important to note that after a medical device is no longer supplied or after a medical device listing is cancelled, the registrant still has to fulfill the following responsibilities:

- Maintain records of supply;
- Maintain records of complaints;
- Report defects and adverse effects to the Authority; and
- Notify the Authority concerning FSCA, including recalls.

HEALTH SCIENCES AUTHORITY

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Blood Services Group
Applied Sciences Group

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