HEALTH SCIENCES AUTHORITY

REGULATORY GUIDANCE

September 2018

MEDICAL DEVICE GUIDANCE

GN-30: Guidance on the Requirements for Approval to Import Medical Devices on Consignment Basis

Revision 3.1

HSA
Health Sciences Authority

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-30: Revision 1 (June 2010)	R1
R1.1 ► GN-30: Revision 1.1 (April 2014)	R1.1
R2 ► GN-30: Revision 2.0 (21 June 2016)	R2
R3 ► GN-30: Revision 3.0 (01 June 2018)	R3
R3.1 ► GN-30: Revision 3.1 (01 September 2018)	R3.1

**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 provides guidance on the special authorisation route requirements to obtain approval to import medical devices on a consignment basis.

1.2. Background

The importation of a medical device which is already registered on the Singapore Medical Device Register (SMDR) shall be performed by a licensed importer authorised by the Registrant only.

An act of import or wholesale of a registered medical device by a dealer neither authorised by the Registrant nor authorised by the import on consignment basis authorisation route would be an offence under the Health Products Act (*Act*) and the Health Products (Medical Devices) Regulations 2010 (*Regulations*).

A dealer who has not been authorised by the Registrant to import a registered medical device may seek authorisation from HSA to import the said registered medical device through the Consignment Registered (CR) Route.

HSA has a responsibility to maintain a balance between ensuring individuals gain access to essential therapeutic developments and maintaining broader public interest that medical devices available in Singapore are evaluated for quality, safety and efficacy.

1.3. Scope

R3 ► This document is applicable to dealers who are not authorised by the Registrant and would like to seek authorisation from HSA to import the said registered medical device on Consignment Registered (CR) basis. ◄

1.4. Definitions

Definitions that do not indicate they are set out in the *Act* and *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.

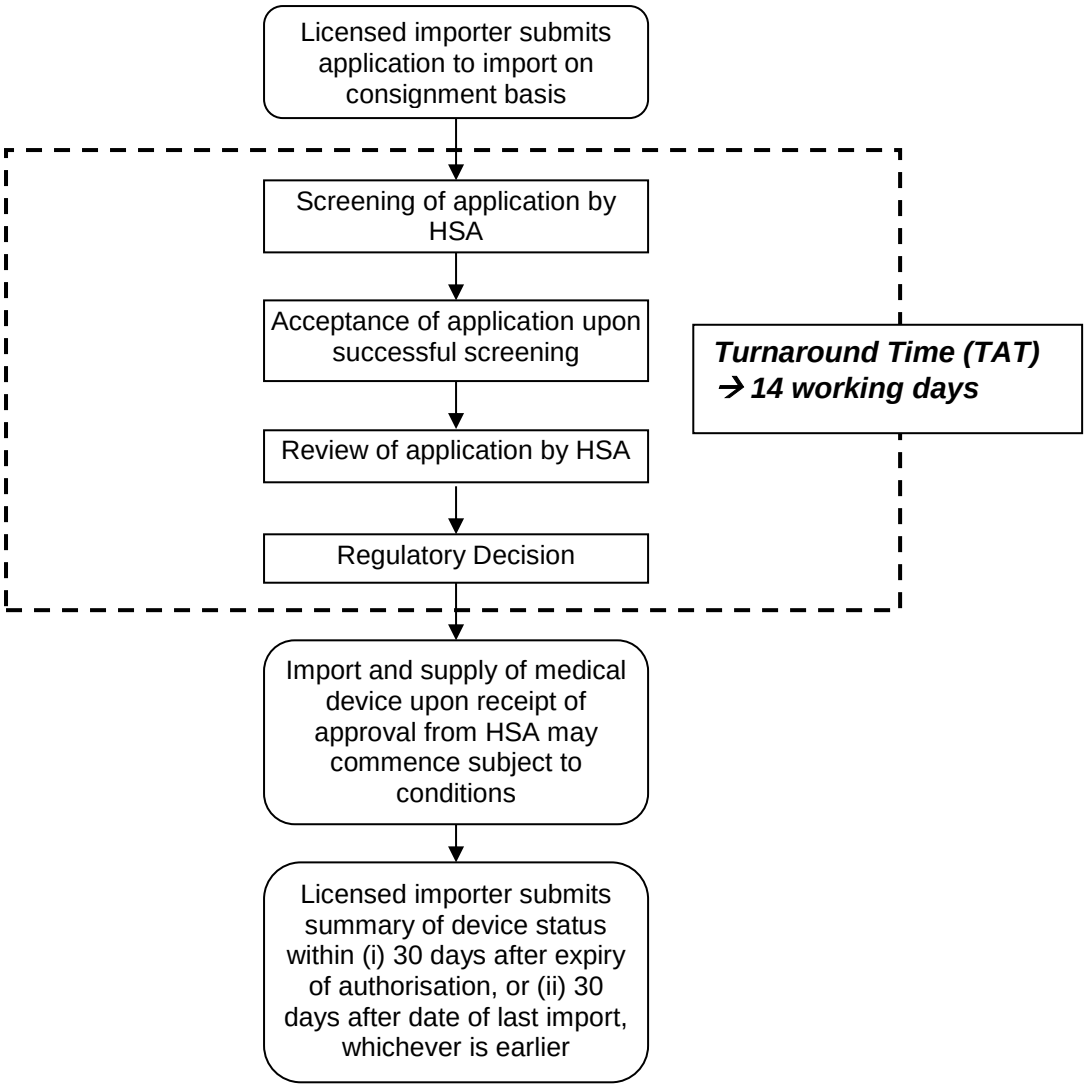
IMPORT: with its grammatical variations and cognate expressions, means to bring or cause to be brought into Singapore by land, sea or air.

MEDICAL DEVICE: means a medical device as described in the First Schedule of the Act. This includes *IN VITRO* DIAGNOSTIC (IVD) PRODUCT (as set out in the *Regulations*).

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.

2. APPLICATION PROCESS FOR CR ROUTE



R3 ► Dealers who are not authorised by the Registrant of the said registered medical device may seek authorisation from HSA for import of a single consignment of registered medical devices. ◄

A valid importer and wholesaler licence with Good Distribution Practice for Medical Devices (GDPMDS) or ISO 13485 is a pre-requisite for application under this authorisation route.

The medical device shall only be imported after the application is approved. A letter of approval would be sent to the applicant via email.

The authorisation shall only be valid for:

- A period of **12 months** from the date of approval subject to R3 ►the medical devices being listed on the Singapore Medical Device Register (SMDR), and◄
- The quantity approved for import under this authorisation shall only be imported on a **single import** consignment.

An act of import or wholesale of a registered medical device by a dealer who is not authorised by the Registrant or authorised under this authorisation route would be an offence under the *Regulations*.

3. APPLICATION REQUIREMENTS (CONSIGNMENT REGISTERED (CR) ROUTE)

One application is for a **single device listing**.

3.1. Data requirements for CR Route

An application shall be accepted for review by HSA if the following documents shall be submitted:

- Application form (Ref number: MDSA-CR)
- Annex 2 List of Devices (*if applicable)*
- Singapore Medical Device Register (SMDR) listing number of the original registered medical device
- A copy of Instructions for Use, Product Insert, or Operations Manual by the product owner
- A copy of the primary medical device label,
- Documentary evidence to show that the medical device is registered in the exporting country (e.g. Free Sale Certificate),
- Certified true copy of ISO 13485 certificate for each of the manufacturing sites of the medical device,
- Copy of invoice from exporting company indicating the lot number/serial number of each of the medical device to be imported,

- Attestation from product owner that the medical device is identical to registered medical device in Singapore, including the manufacturing site, packaging and labelling (refer to Annex 4), and
- Undertaking by importer to take responsibility for quality, safety and performance of the medical device to be imported.

Failure to submit any of the above documents shall render the application invalid and shall be rejected.

R2 ►There shall be no amendments to the application or no refund of any application fees for incorrect applications once the application has been approved. ◄

NOTE Any unauthorised modifications to the submitted application form shall render the application invalid and it shall be rejected. Thereafter, the applicant shall not be eligible to obtain approval to import medical devices through any of the authorisation routes.

3.2. Mode of submission for CR Route

The applicant (i.e. licensed importer) shall submit the application form by email to hsa_md_sa@hsa.gov.sg.

The application form shall be signed and be submitted to HSA by the applicant.

3.3. Fees for CR Route

Please refer to the fee schedule and HSA website for the fees applicable.

4. CONDITIONS OF APPROVAL FOR CR ROUTE

The authorisation would be subject to regulatory conditions of approval. Failure to comply with these conditions will render this authorisation invalid. The list (i.e. not exhaustive) of conditions may include the following:-

- The registered medical devices shall only be permitted for import by a licensed importer.
- The licensed importer shall be responsible for ensuring that the quality, safety and performance of the medical devices are not adversely affected during import, storage and distribution of the medical devices.
- The licensed importer shall perform and observe all the duties and obligations under Part VIII of the *Health Products Act*.
- The licensed importer or product owner shall inform the Health Sciences Authority of any product-related problems and/or adverse events arising from the use of the medical devices that become known to the licensed importer or product owner in accordance with the provisions specified in the *Health Products Act* and *Health Products (Medical Devices) Regulations 2010*.
- Any promotional material or presentation of the medical device that contains any statement which states, indicates or suggests, whether directly or indirectly, that the use of the medical device is being promoted or endorsed by the Health Sciences Authority, shall not be issued.
- The product presentation and/or advertisement, inclusive of brochures, pamphlet and others shall not contain any claims related to the following scheduled diseases and conditions: blindness, cancer, cataract, drug addiction, deafness, diabetes, epilepsy or fits, hypertension, insanity, kidney disease, leprosy, menstrual disorders, paralysis, tuberculosis, sexual function, infertility, impotency, frigidity and conception and pregnancy.
- R2 ►All medical devices intended for qualified professional use should not be advertised to public ◄
- The licensed importer shall submit a declaration on distribution records in accordance to the format prescribed by the Authority. This declaration shall

be submitted to the Authority within 30 days after the date of expiry of the authorisation or date of last import, whichever is earlier.

- The quantity of the registered medical device approved for supply under this licence is as indicated in the attached application form.
- The quantity approved for import under this authorisation shall only be imported on a single import consignment within the validity period of the authorisation (invoice number to be provided).
- All remaining unused supplies of the medical device shall be returned to the product owner or licensed importer.
- R2 ►In the event of occurrence of a FSCA for the device authorised under this licence within the validity period of this licence, the licensed importer shall undertake the following measures:
    - Inform all consignees and users included in this licence regarding the FSCA immediately.
    - Further supply of the medical devices authorised under this licence will be dependent on the advice provided by the Authority in the context of the FSCA review. ◄
- Once the authorisation has expired or has been cancelled, no further import and supply of the medical device, at any quantity, shall be permitted.

This authorisation may be cancelled by the Authority, by informing the applicant in writing. If the authorisation is cancelled, all unsupplied or balance medical devices imported under this authorisation shall be placed under quarantine by the applicant in their facility. The applicant shall not supply or remove medical devices under quarantine unless authorised by the Authority.

5. POST-MARKET OBLIGATIONS

R2 ►The responsibility for reporting field safety corrective actions (FSCA) and adverse events (AE) for medical devices that are supplied through the special authorisation route lies primarily with the importer who arranged for its supply. It is a condition of approval that the importer reports the details of any FSCA or adverse event to the Authority according to applicable timelines.

6. DECLARATION ON DISTRIBUTION RECORDS

The importer shall be required to submit a declaration (Annex 1) on the distribution records using the prescribed format in Annex 1 within 30 days after expiry of authorisation, or within 30 days after date of last import.

The document should be submitted by email to (hsa_md_sa@hsa.gov.sg).

Importer shall be required to maintain documentary evidence of supply (e.g. traceability records) as part of their mandatory device distribution records for the devices imported under this authorisation. This information shall be submitted to the Authority upon request. ◄

ANNEX 4

Letter of Authorisation 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 Authorisation for [name of Importer]

We, [name of Product Owner], as the Product Owner, hereby confirm that the medical devices listed below have been manufactured to the same safety, quality and performance specifications as the medical device listed under Singapore Medical Device Register (SMDR) listing number, [device listing number].

[List containing the following: (i) product names of medical devices for import, (ii) quantity for import, (iii) manufacturing site, (iv) ISO 13485:2003 certificate number, (v) SMDR listing number, (vi) invoice number (vii) invoice date]

We hereby acknowledge that we are aware of the import of the medical devices listed above into Singapore by [name of Importer] for the quantity specified. We shall keep [name of Importer] informed of any Field Safety Corrective Action (FSCA) that is applicable.

Yours Sincerely,

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

HEALTH SCIENCES AUTHORITY

Health Products Regulation Group
Blood Services Group
Applied Sciences Group

www.hsa.gov.sg

Contact Information:

Medical Device Branch
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