HEALTH SCIENCES AUTHORITY

REGULATORY GUIDANCE

September 2018

MEDICAL DEVICE GUIDANCE

GN-28: Guidance on the Requirements for Import of Unregistered Medical Devices solely for Export or for the Re-export of Unregistered Medical Devices

Revision 2.2

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-28: Revision 1 (June 2010)	R1
R1.1 ► GN-28: Revision 1.1 (April 2014)	R1.1
R2 ► GN-28: Revision 2.0 (21 June 2016)	R2
R2.1 ► GN-28: Revision 2.1 (3 March 2017)	R2.1
R2.2 ► GN-28: Revision 2.2 (01 September 2018)	R2.2

**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 unregistered medical devices for the purposes of export or re-export.

1.2. Background

Supply of unregistered medical devices is prohibited under the Health Products Act (*Act*). In order to supply/export an unregistered medical device, prior approval from HSA shall be required.

Export is a form of supply by wholesale. In order to import and re-export a medical device, without the device in question having to undergo product registration, approval has to be first obtained from the Authority.

This guidance discusses the requirements in order to obtain such an approval.

1.3. Scope

This document is applicable to all persons who manufacture, import and supply by wholesale medical devices in Singapore solely for re-export.

1.4. Definitions

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*).

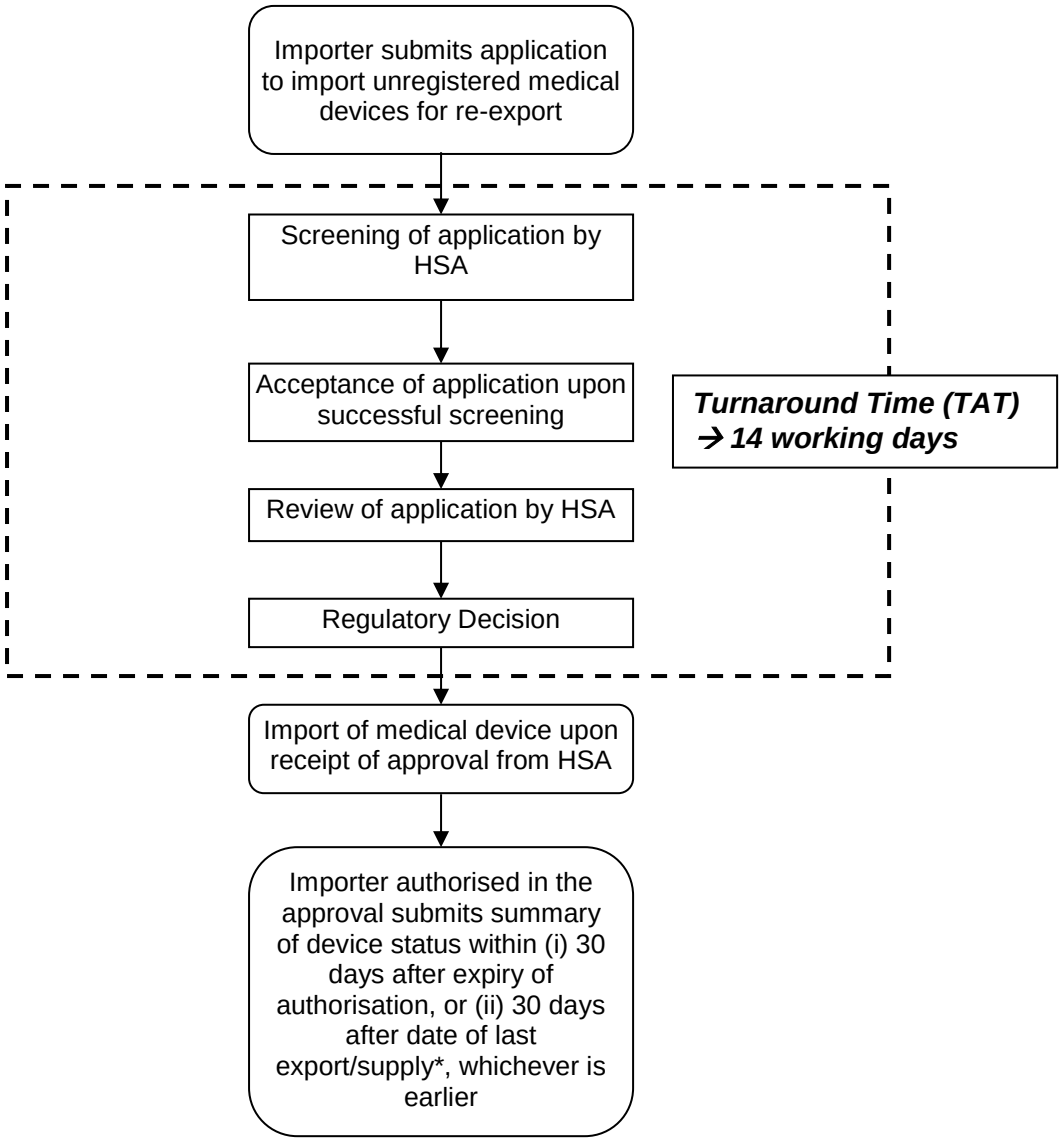
PRODUCT OWNER *(as set out in the Regulations)*:

in relation to a health product, means a person who —

(a) 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

(b) 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



**Export/supply – refers to export of medical devices out of Singapore*

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 be valid for a period of **12 months** from the date of approval.

This authorisation route permits **multiple** import consignments within the validity period of the authorisation.

If excess quantities of the medical devices are still in Singapore after expiry of the authorisation, the company shall apply for re-authorisation.

The safety and performance of the device is not assessed by HSA during application review.

Unauthorised supply of an unregistered medical device is an offence under the *Act* and penalties of a fine of up to $50,000 or imprisonment for a term not exceeding 2 years, or both will apply.

R2 ► Please note that it is the responsibility of the licence holder to ensure the medical device(s) complies with any other applicable regulatory requirements of other regulatory bodies in Singapore prior to its supply (e.g. for medical devices also subject to control under the Radiation Protection Act, a licence from the Radiation Protection and Nuclear Science Department (RPNSD) of the National Environment Agency (NEA) may be required). ◄

3. APPLICATION REQUIREMENTS

3.1. Data Requirements

An application shall be accepted for review by HSA if the following documents shall be submitted together with the application form (Ref number: MDSA-IR1):-

- Application form (Ref no. MDSA-IR)
- Annex 2 List of Device (*if applicable*)

Medical devices manufactured in Singapore and that are solely for export, shall not require authorisation from the Authority for their export by the licensed manufacturer.

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

R2 ► It is the duty of the applicant to verify that the medical device requires authorisation prior to supply. There shall be no amendments to the application or no refund of any application fees for incorrect applications once the application has been approved.◄

Multiple devices may be submitted under each application.

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. Submission mode and procedure

A Client Registration and Identification System (CRIS) account with HSA have to be set-up prior to application submission.

- To set-up your CRIS account with HSA, please submit an online application at the following webpage:
  R2.1►http://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/CRIS.html ◄
- The turn-around time: 4 working days

The applicant (i.e. 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

Please refer to the fee schedule and HSA website for the fees applicable.
ONLY fee payment by GIRO shall be accepted. The application is subject to a fee payment by the importer.

A GIRO account with HSA shall have to be set-up prior to payment via GIRO.

- The application form to set-up a GIRO account with HSA may be downloaded from the following webpage: R2.1►

http://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/MEDICS_e-Services/Accessing_MEDICS/Payment_Options.html ◄

4. CONDITIONS OF APPROVAL

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 unregistered medical devices shall only be permitted for import by the importer authorised in the approval.
- The 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.
- Any unauthorised supply would be a contravention of section 15 of the Health Products Act.
- The importer shall perform and observe all the Duties and Obligations under Part VIII of the *Health Products Act*.
- The 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 importer or product owner in accordance with the provisions specified in the *Health Products Act* and *Health Products (Medical Devices) Regulations.*
- Any promotional materials or presentation of the medical device that contains any statement to the effect, 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 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 export/supply, whichever is earlier.
- The quantity of the unregistered medical device approved for supply under this licence is as indicated in the attached application form.
- Health Sciences Authority shall not be held responsible for any defects in the medical device whatsoever, including defects related to manufacture, distribution and directions for use.
- All remaining unused supplies of the medical device shall be returned to the product owner or importer.
- 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. DECLARATION ON DISTRIBUTION RECORDS

R2 ►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 submission of documentary evidence (e.g. airway bill with proforma invoice) of export shall not be required.

However, 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.

Any balance medical devices that have not been exported out shall have to be authorised for re-export through a subsequent authorisation or destroyed locally within the timeframe specified by the Authority.

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

ANNEX 1

Form No.: Annex 1
Date of Revision: September 2018

Declaration on Distribution Records Template

[To be printed on Company Letterhead of Licensed Importer]

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

[Date]

Dear Sir/Madam,

Subject: Status of Medical Devices Imported under Authorisation Route – [*GN26 / GN27 / GN28 / GN29] [Reference number for CURRENT authorisation] – Expiry date (DD/MM/YYYY)

I, <Name >, on behalf of < Importing company name>, hereby declare that the information listed in the table below is complete and accurate.

Product Name	Identifier	Total Quantity approved	Total Quantity imported	Total Quantity consumed	Balance Quantity

I further declare that as at <date>, * the stock balance is zero / the continued supply of the balance stock is authorised under <Reference number for NEW authorisation>.

(*Delete accordingly)

[Signature]
[Full Name and Title of Company Representative]

HEALTH SCIENCES AUTHORITY

Health Products Regulation Group
Blood Services Group
Applied Sciences Group

www.hsa.gov.sg

Contact Information:

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