

September 2018

MEDICAL DEVICE GUIDANCE

GN-29: Guidance on the Requirements for Import and
Supply of Unregistered Medical Devices for Non-Clinical
Purpose

Revision 2.2

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

<u>Guidance Version (Publish Date) [3 latest revisions]</u>	<u>Revision</u>
GN-29: Revision 1 (June 2010)	R1
R1.1 ► GN-29: Revision 1.1 (April 2014)	R1.1
R2 ► GN-29: Revision 2.0 (21 June 2016)	R2
R2.1 ► GN-29: Revision 2.1 (3 March 2017)	R2.1
R2.2 ► GN-29: 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*

INTRODUCTION

1.1. Purpose

This document provides guidance on the special authorisation route requirements to obtain approval to import and/or supply unregistered medical devices for non-clinical purpose.

1.2. Background

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

Supply for non-clinical purpose includes any form of use other than use or administration on humans. Examples of such uses include:-

- training equipment (i.e. Not for use on humans);
- use on animals; or
- use of in-vitro diagnostic medical devices for research-use only.

In order to supply a medical device which is not registered for non-clinical purpose, approval has to be first obtained from the Authority.

1.3. Scope

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

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.

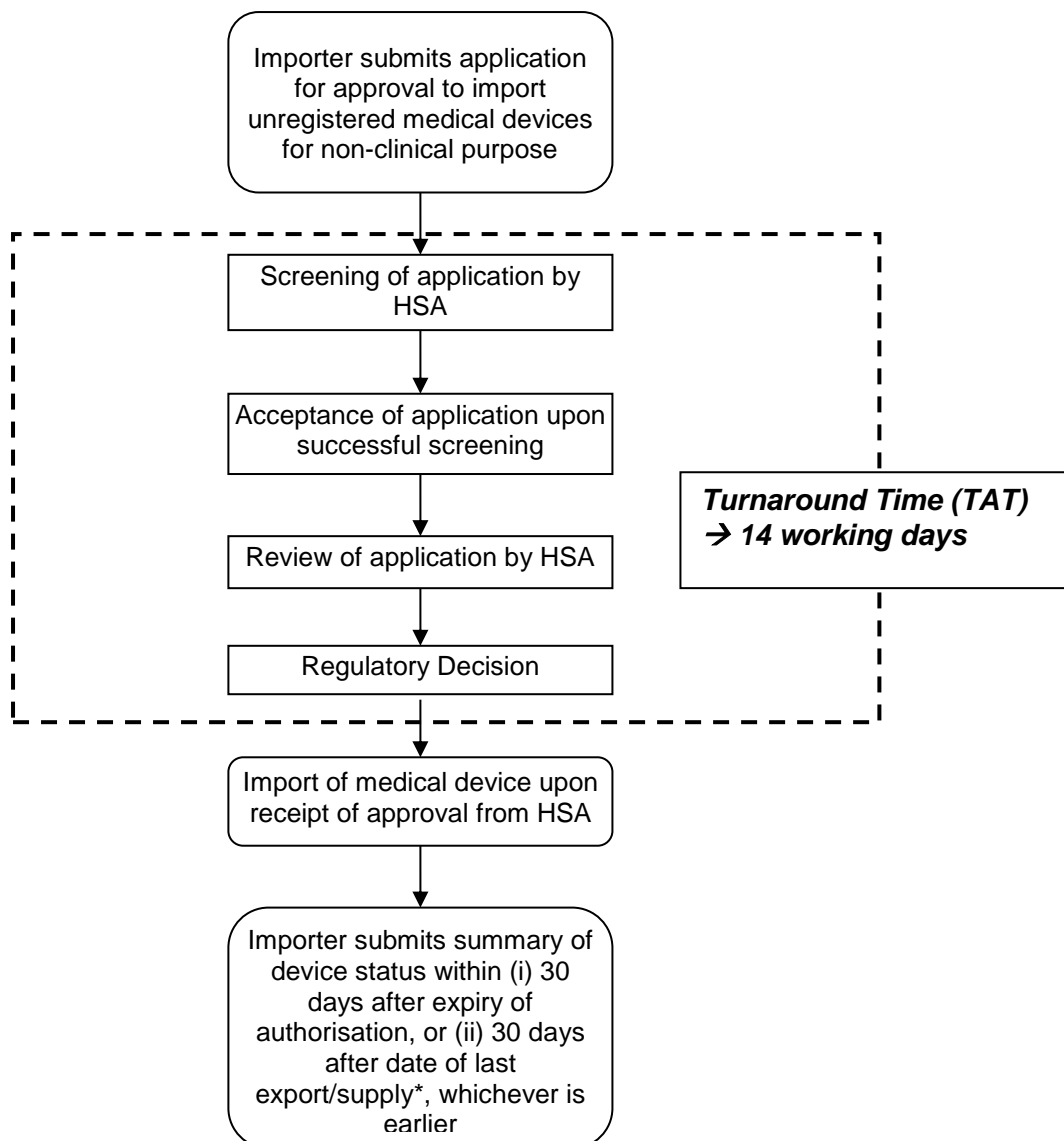
MEDICAL DEVICE: means a medical device as described in the First Schedule of the Act. This includes *IN VITRO* DIAGNOSTIC (IVD) PRODUCT (as set out in the *Regulations*).

NON-CLINICAL PURPOSE (*as set out in the Regulations*): means any purpose other than a purpose described in the second column of item 1 of the First Schedule to the Act.

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 supply of medical device to the consignee who shall be using it for non-clinical purpose.*

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

R2 ► Upon receipt of approval, the unregistered medical device shall only be imported by the importer authorised in the approval. ◀

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

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.

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:

- Application Form (Ref number: MDSA-NC)
- Annex 2 List of Devices (*if applicable*)
- A copy of Instructions for Use, Product Insert, or Operations Manual by the product owner
- A copy of the medical device label, including a statement to the effect 'for supply for non-clinical purpose only'.

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 unregistered 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. ◀

NOTE Any unauthorised modifications to the submitted application form shall render the application rejected. The applicant would be added to a blacklist and shall no longer be eligible to obtain future authorisations to import and supply unregistered medical devices.

Multiple devices may be submitted under each application.

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*. Medical devices imported through this authorisation route shall not be supplied for clinical use, including use on humans in the process of demonstration or during free trials.
- 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.
- **R2** ► In the event of occurrence of a FSCA for the device authorised under this licence within the validity period of this licence, the 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.

NOTE The unregistered medical device shall not be used for demonstration on humans. Such a use is deemed as a use for clinical purpose.

5. POST-MARKET OBLIGATIONS

R2 ► The responsibility for reporting field safety corrective actions (FSCA) and adverse events 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

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

The non-clinical purpose of the medical device shall be specifically indicated.

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 1

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:

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

11 Biopolis Way, #11-03 Helios
Singapore 138667
www.hsa.gov.sg
Email: hsa_md_sa@hsa.gov.sg

