HEALTH SCIENCES AUTHORITY

REGULATORY GUIDANCE

September 2022

MEDICAL DEVICE GUIDANCE

GN-32: Guidance for Importation of Unregistered Medical Devices for Exhibition in Singapore

Revision 5

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 (Effective Date) *[3 latest revisions]*	Revision
R3.1 ►GN-32: Revision 3.1 (11 July 2018)	R3.1
R3.2 ►GN-32: Revision 3.2 (19 September 2018)	R3.2
R4 ►GN-32: Revision 4 (29 June 2022)	R4
R5 ►GN-32: Revision 5 (5 September 2022)	R5

**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 to an importer or exhibitor in seeking approval from HSA to import unregistered medical devices into Singapore for exhibition purposes via cargo or hand-carry routes.

Exhibitors are also reminded that any unregistered medical device which is permitted for display at the exhibition shall not be supplied for use locally, including distribution of free samples or the use of such medical devices on a human for demonstration purpose. These unregistered products shall be destroyed, exported out of Singapore or returned to the overseas supplier within the timeframe stipulated by HSA after the exhibition.

1.2. Background

R4 ► The Health Products Act 2007 (*Act*) and Health Products (Medical Devices) Regulations 2010 (*Regulations)* require medical devices to be registered with HSA prior to being brought or imported into Singapore by HSA licensed dealers, unless otherwise exempted under the provisions of the law. The import and supply of an unregistered medical device is an offence under Singapore's law.

Products that are clearly indicated by their manufacturer not to be used on humans are not medical devices under the definition in the law. Such products will not be subject to medical device regulatory controls in Singapore and hence are excluded from the scope of this guidance note.

Exhibitors who require confirmation if their product is a medical device can use the Product Classification tool under the Medical Device Registration section [www.hsa.gov.sg > Products Regulation > Medical Devices > Register your Device] ◄

1.3. Scope

This document is applicable to all applicants who are importing unregistered medical devices of any risk classification into Singapore for exhibition purposes.

Local companies exhibiting locally-manufactured medical devices are not required to obtain any approval for displaying their products at exhibitions. However, the manufacturer is still required to display prominent labels or signage that the medical device is not allowed to be used on human nor supplied for use locally.

1.4. Making an application

R5 ► The applicant shall submit an online application FORM 32 to import unregistered medical devices for exhibition purposes.

Table 1. Documents / information required for the online submission

Mode of Importation	**Information of event** (Eg. Brochures, official website)	**Passport Page with Personal Particulars of Importer**	**Appoint a Singapore registered company on behalf of the exhibitor**
Cargo	✓	**N.A**	✓
Hand-carry	✓	✓	**N.A**

◄

Please submit your application early so that the approval for the importation can be issued in time for the exhibition event. A processing time of up to 10 working days may be needed upon submission of a complete application.

1.5. Definitions

R3.1 ►

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 legislation and should not be used in any legal context. These definitions are meant to provide guidance in layman terms. ◄

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

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

R3.1 ►

MEDICAL DEVICE: means —

(a) any instrument, apparatus, implement, machine, appliance, implant, reagent for *in vitro* use, software, material or other similar or related article that is intended by its manufacturer to be used, whether alone or in combination, for humans for one or more of the specific purposes of —

(i) diagnosis, prevention, monitoring, treatment or alleviation of disease;

(ii) diagnosis, monitoring, treatment or alleviation of, or compensation for, an injury;

(iii) investigation, replacement, modification or support of the anatomy or of a physiological process, mainly for medical purposes;

(iv) supporting or sustaining life;

(v) control of conception;

(vi) disinfection of medical devices; or

(vii) providing information by means of in vitro examination of specimens derived from the human body, for medical or diagnostic purposes,

and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means; and

(b) the following articles:

(i) any implant for the modification or fixation of any body part;

(ii) any injectable dermal filler or mucous membrane filler;

(iii) any instrument, apparatus, implement, machine or appliance intended to be used for the removal or degradation of fat by invasive means.

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

- to sell the health product, whether by retail, wholesale or auction;
- to expose or display the health product as an invitation to treat;
- to transfer possession of the health product by exchange, gift, lease, loan, hire or hire-purchase;
- to supply the health product in connection with a contract for the provision of any goods or the performance of any service, or any advertising, sponsorship or promotional activity
- to supply the health product by way of administration to or application in any person in the course of any diagnosis, treatment or test;
- to offer, agree or attempt to supply the ways described above, or to cause or permit the health product to be supplied; and
- to keep or possess the health product for the purpose of supplying it in any of the ways described above. ◄

2. VERIFICATION WITH OTHER CONTROLLING AGENCIES

For importation procedures into Singapore, please refer to the Singapore Customs website for more information.

For products containing X-ray, laser, ultraviolet or radiation emission characteristics, please refer to the National Environment Agency (Radiation Protection and Nuclear Science Department) website for further details.

3. AVAILABLE IMPORTATION ROUTES

3.1. Import as Cargo Goods

Importation of unregistered medical devices as cargo goods shall be carried out by a Singapore registered company on behalf of the exhibitor.

An approval for importation of unregistered medical devices for exhibition purposes will be issued to the Singapore registered entity. The approval permits the import of multiple consignments of unregistered medical devices for the specified event, within the validity period.

3.2. Import via Hand-Carry by Exhibitor

Limited quantities of unregistered medical devices for exhibition may be imported via hand-carry by the exhibitor on an individual basis. It is the exhibitor’s responsibility to ensure that it is in compliance with the relevant authorities such as the Singapore Custom’s regulations and any other aviation or shipping requirements.

An importer’s licence for importation of unregistered medical devices for exhibition purposes will be issued to the exhibitor.

4. HANDLING OF UNREGISTERED MEDICAL DEVICES DURING THE EXHIBITION

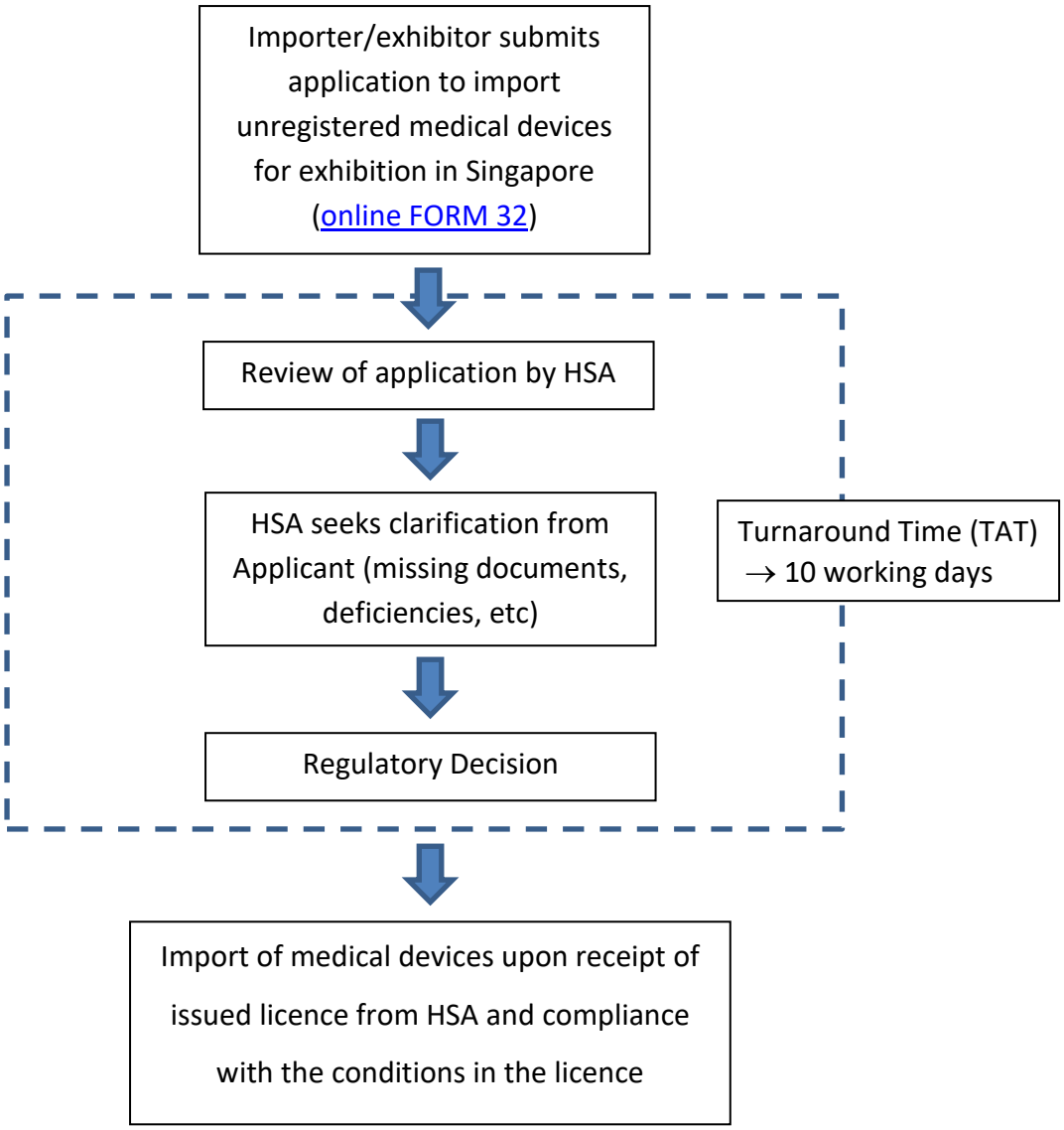
Exhibitors of unregistered medical devices are required to ensure that the medical devices exhibited are not supplied in Singapore. The exhibitor's display booth and unregistered medical devices shall be prominently indicated with labels or signage "SOLELY FOR DISPLAY PURPOSES ONLY. NOT INTENDED FOR SUPPLY".

Unregistered medical devices approved under this route shall not be used for clinical purposes or demonstrated on humans. There is no restriction for activating the devices at exhibitions provided it does not pose any safety issues to the public. However, the National Environment Agency (NEA) has prohibited the energizing or switching on of medical devices which can emit radiation such as X-ray equipment and lasers in the public, unless the appropriate radiation licences have been obtained from NEA.

5. POST EXHIBITION HANDLING OF UNREGISTERED MEDICAL DEVICES

After the exhibition, all importers and exhibitors must ensure that these unregistered medical devices are exported out of Singapore or destroyed, according to the stipulated licensing conditions in the importer's licence.

6. APPLICATION PROCESS FLOWCHART



HEALTH SCIENCES AUTHORITY

Health Products Regulation Group
Blood Services Group
Applied Sciences Group

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