HEALTH SCIENCES AUTHORITY

REGULATORY GUIDANCE

AUGUST 2016

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

Revision 3

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. If you need specific legal or professional advice, you should consult your own legal or other relevant professional advisers.

In the event of any contradiction between the contents of this document and any written law, the latter should take precedence.

1. INTRODUCTION

1.1. Purpose

This document provides guidance to an importer in seeking approval from HSA to import unregistered medical devices into Singapore for exhibition purposes via cargo or hand-carry mode, and an overview of the regulatory control of these unregistered medical devices.

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 or exported out of Singapore within the timeframe stipulated by HSA after the exhibition.

1.2. Background

Under the Health Products Act, medical devices are subject to regulation in Singapore. The import and supply of all medical devices are required to be licensed by HSA before any of such activities can be legally carried out, unless otherwise exempted under the provisions of the law. The supply of an unregistered medical device is an offence under Health Products Act.

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 Medical Devices Risk Classification Tool or submit the Health Product Enquiry Form to hsa_prod_class@hsa.gov.sg, to determine the classification of the products. The tool and form are available at the HSA website: www.hsa.gov.sg > Health Products Regulation > Medical Devices > Overview.

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

The applicant shall submit the application form FORM 32A and required supporting documents by either fax or email. FORM 32A is published in HSA website www.hsa.gov.sg > Health Products Regulation > Medical Devices > Regulatory Guidances.

Mode of Importation	**FORM 32A**	**Information of event** (Eg.Brochures, official website)	**Passport Page with Personal Particulars of Importer**
Cargo	✓	✓	**N.A**
Hand-carry	✓	✓	✓

Table 1. Documents to be submitted

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

1.5. Definitions

MEDICAL DEVICE: Means any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, 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

(a) diagnosis, prevention, monitoring, treatment or alleviation of any disease;
(b) diagnosis, monitoring, treatment, alleviation of or compensation for an injury;
(c) investigation, replacement, modification, or support of the anatomy or of a physiological process;
(d) supporting or sustaining life;
(e) control of conception;
(f) disinfection of medical devices; or
(g) providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body, 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.

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

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

SUPPLY: (as set in the Health Products 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. 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.

All persons issued with an importer's licence under the Health Products Act (HPA) must comply with the HPA and their regulations. This is to ensure that all health products in Singapore meet the required standards of safety, quality and efficacy. Licensees must also comply with all other applicable laws and their regulations.

3. AVAILABLE IMPORTATION MODES

3.1 Import as Cargo Goods

Importation of unregistered medical devices as cargo goods should be carried out by a Singapore registered entity 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, and is valid for the period from the date of issuance to date of expiry.

3.2 Import via Hand-Carry by Exhibitor

Limited quantities of unregistered medical devices to be used for exhibitions may be imported via hand-carry by an overseas exhibitor on an individual basis. It is the exhibitor's responsibility to ensure that the importation is in compliance with the relevant authorities such as the Singapore Customs 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 cannot be 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 imported for exhibition purposes shall not be used for clinical purposes or demonstration 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. Please check with NEA for further details.

Anyone found to be supplying unregistered medical devices may be prosecuted under the Health Products Act, and shall be liable to be punished with a fine of up to $50,000 or imprisonment term not exceeding 2 years, or both. Please refer to Section 1.5 of this guidance notes for the meaning of "supply",

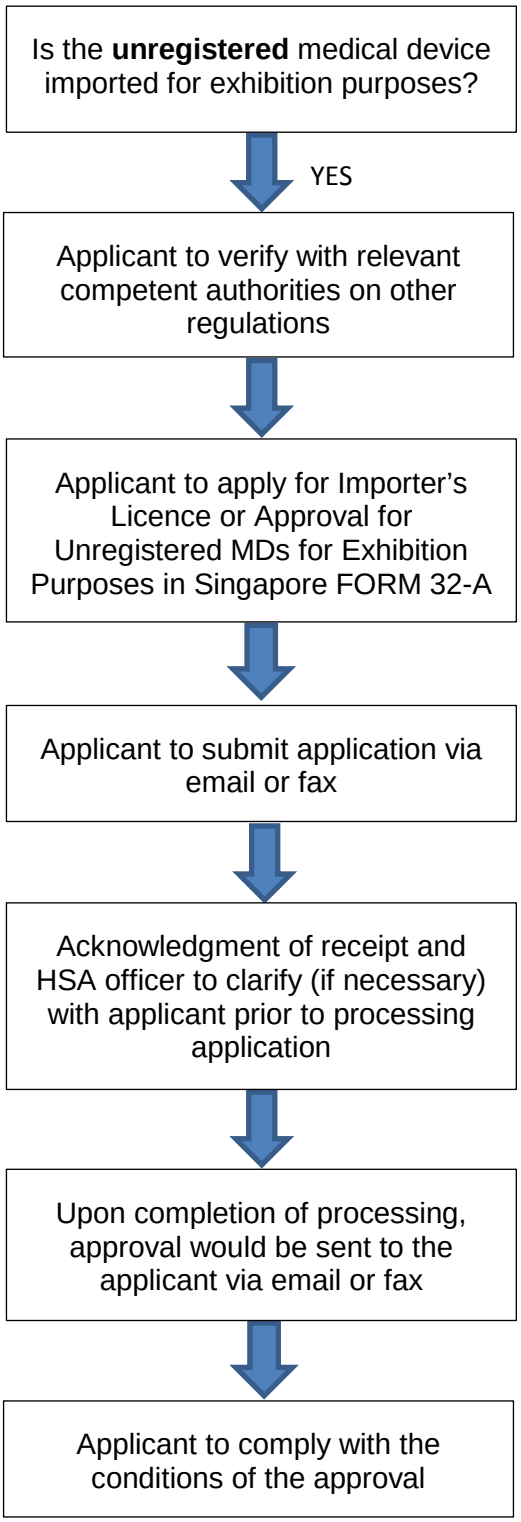
5. POST EXHIBITION HANDLING OF UNREGISTERED MEDICAL DEVICES

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

6. FLOWCHART

The process on the application for approval from HSA is summarized in Annex 1.

Annex 1: General workflow for application to import unregistered medical devices for exhibition purposes in Singapore



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HEALTH SCIENCES AUTHORITY

Health Products Regulation Group
Blood Services Group
Applied Sciences Group

www.hsa.gov.sg

Contact Information:

Ms. Lim Na/ Ms. Catherine Koh
Audit & Licensing Division
Health Products Regulation Group
Health Sciences Authority

150 Cantonment Road,
Cantonment Centre, Block A #01-02
Singapore 089762
www.hsa.gov.sg

E: HSA_LCB_MDEx@hsa.gov.sg
T: +65 6866 1072, +65 6304 5453
F: +65 6478 9068

HSA Health Sciences Authority