HSA Circular to Exhibitors and Importers

1. Regulatory Control for Medical Devices in Singapore

In Singapore, medical devices are subject to regulation under the Health Products Act. Under this law, the import and supply of all medical devices, including *in vitro* diagnostic devices (IVD), are required to be licensed and registered, respectively, by HSA before any of such activities can be legally carried out, unless otherwise exempted under the provisions of the law. Currently, only Class A medical devices do not require product registration in Singapore. Whereas, registered medical devices are listed in the Singapore Medical Device Register (SMDR).

For the importation of unregistered medical devices for exhibition purposes, the importing party shall seek approval via GN32 from HSA prior to importing the specific consignment. Details for GN32 is published in www.hsa.gov.sg

The Health Sciences Authority would like to remind all that any unregistered medical device which is permitted for display at the exhibition:

- **Shall not be supplied for use locally, which includes distribution of free samples or the use of such medical devices on a human for demonstration purpose, and**
- **Shall be exported out of Singapore or destroyed after the exhibition.**

The supply of an unregistered medical device is an offence under Singapore's law and is liable on conviction to a fine not exceeding $50,000 or to a jail term not exceeding 2 years or to both.

2. Authorisation for Import of Unregistered Medical Devices for Exhibitions

There are two options for importation of unregistered medical devices for exhibition purposes:

1. Import as cargo goods
2. Import via hand-carry by exhibitor

2.1. Import as Cargo Goods

All importation of unregistered medical devices for exhibition should be carried out by a Singapore registered entity. An application shall be submitted with the following:

- **FORM 32-A**
- **Information of event (Name, Period and Venue)**

An approval for importation of unregistered medical devices for exhibition purposes will be issued to the Singapore registered company. 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.

2.2. Import via Hand-Carry by Exhibitor

All applications for importation of unregistered medical devices for exhibition via hand-carry shall be supported with the following details such as:

- **FORM 32-A**
- **Information about the exhibition (Name, Period and Venue)**
- **Passport Page with Personal Particulars of Importer**

2.3. When will you receive the approval?

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 is required upon submission of a complete application.

2.4. Local companies exhibiting their medical devices

Local companies exhibiting locally manufactured medical devices are not required to obtain any authorisation for displaying their products at the exhibition. However, local exhibitors are reminded that supply of unregistered medical devices at the exhibition is prohibited under the law.

3. Handling of medical devices during the exhibition

Exhibitors of unregistered medical devices are required to prominently indicate that the medical devices exhibited cannot be legally supplied locally. This shall be done in the following ways:

- Have prominent labels or signs at their display booths, with a statement to the effect of **"Solely for display purposes only. Not intended for supply."**
- Unregistered, medical devices are to bear a label with a statement to the effect of **"Solely for display purposes only. Not intended for supply."**

HSA officers may be present during the exhibition to perform random checks for compliance with the regulatory and legal controls for medical devices in Singapore.

4. Post-Exhibition handling of 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.

For further queries on the process and regulatory requirements for importation of unregistered medical devices for exhibition in Singapore via GN-32, please contact:

Medical Devices Branch
Medical Devices Cluster
Health Sciences Authority

Email: hsa_md_info@hsa.gov.sg
Phone: (65) 6866 1111
Fax: (65) 6478 9028

Frequently Asked Questions

1. How do I tell if my product a medical device?

Medical devices contains a wide array of products, ranging from contact lenses, surgical tools, walking sticks, wheelchairs, through life maintaining implantable devices, equipment to screen and diagnose diseases and health conditions (e.g. pregnancy test kit), to the most sophisticated diagnostic imaging and minimal invasive surgery equipment.

Definition of a medical device, as found in the First Schedule of the Health Products Act (https://sso.agc.gov.sg):

"Medical device" —
(a) means 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 any 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) includes 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.

It is the responsibility of the exhibitor to determine if their product is a medical device in accordance with local regulations prior to import.

2. How do I determine if my product is a medical device and its associated risk classification in Singapore?

Exhibitors who require confirmation if their product is a medical device can complete the Health Product Enquiry Form and upload all product information.

Alternatively, exhibitors (or applicants) may also do so via the online Medical Device Risk Classification tool via the below weblink,
https://www.hsa.gov.sg/medical-devices/registration/risk-classification

The outcome of this tool corresponds to the answers given during the online assessment by the user.

3. I am importing models*/demo units for exhibition. Do I need to apply for GN32?

** Replicas of actual device*

Products that are clearly intended by their manufacturer **not** to be for human use are not medical devices under the definition above. Such products will not be subject to medical device regulatory controls in Singapore.

Please be reminded that it is the responsibility of the exhibitors and applicants to ensure that the product meets the requirements of any other applicable regulatory controls in Singapore.