

HSA CIRCULAR FOR EXHIBITORS



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).

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. 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.

3. 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.

Medical Devices Cluster
Health Sciences Authority