## 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.

You may verify whether the product falls under the definition of a medical device, as found in the First Schedule of the Health Products Act 2007 (http://statutes.agc.gov.sg/):

*"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.*

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 forward it together with the list of required product information to hsa_prod_class@hsa.gov.sg for further advice.

Alternatively, exhibitors (or applicants) may also do so via the online Medical Device Risk Classification tool via the below weblink,
http://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/Medical_Devices/risk-classification-tool.html

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?** 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.**