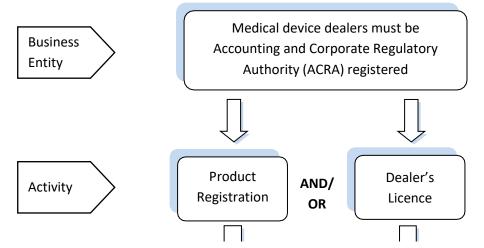
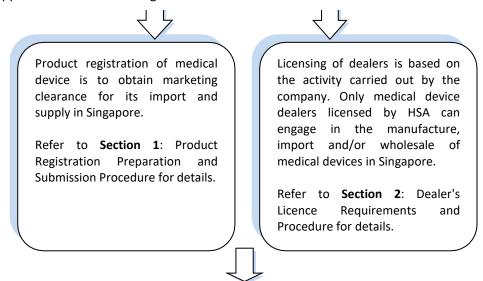
# QUICK GUIDE TO MEDICAL DEVICE PRODUCT REGISTRATION AND DEALER LICENSING



Application for Product Registration and Dealer's Licence can be made simultaneously



Companies to authorise employees or service providers to carry out electronic transactions with HSA on companies' behalf via **cris@hsa** (Client Registration and Identification Service)

Payment modes for all medical device applications: GIRO and credit card

Cheques will not be accepted for any transaction.

Refer to Fees and Charges on HSA website for further details.

Please download the GIRO Application Form here.

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#### **Section 1: Product Registration Guide:**

#### Is this a Medical Device?

- Definition of a Medical Device in the Health Products Act
- Definition of an in vitro diagnostic (IVD) product in the Medical Device Regulations.



This product is NOT a medical device. It is the responsibility of the dealers to ensure that the product meets the requirements of any other applicable regulatory controls.

YES NO
To be supplied in Singapore?

YES

Product registration is not mandatory if you are importing for re-export only. Refer to Guidance on Special Access Routes for import for re-export of unregistered medical devices (Special Access Route).

### Determine the Risk Classification of the medical device

- GN-13: Guidance on the Risk Classification of General Medical Devices
- GN-14: Guidance on the Risk Classification of
- In Vitro Diagnostic Medical Devices



## C & D

Class B,

## Determine the Grouping for the medical devices

- GN-12-1: Guidance on Grouping of Medical Devices for Product Registration - General Grouping Criteria
- GN-12-2: Guidance on Grouping of Medical Devices for Product Registration - Device Specific Grouping Criteria



#### Product Registration not required.

## Declare in the Class A exemption list (under manufacturer/importer licence)

GN-22: Guidance for Dealers on Class A Medical Devices Exempted from Product Registration

#### **Product Registration required**

- 1. GN-15 Guidance on Medical Device Product Registration
- GN-17: Guidance on Preparation of a Product Registration Submission for General Medical Devices using the ASEAN CSDT; or
  - GN-18: Guidance on Preparation of a Product Registration Submission for In Vitro Diagnostic (IVD) Medical Devices using the ASEAN CSDT



#### **Submit documents online via MEDICS**

• Refer to the Online Application Procedure

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#### **Online Application Procedure:**

All **Product Registration** and **Dealer's Licence** transactions are conducted through the Medical Device Information and Communication System (MEDICS)



#### **Apply for CRIS Company Account**

- A CRIS account allows companies to carry out electronic transactions with HSA
- Refer to Client Registration and Identification Service - cris@hsa
- Created upon submission





#### **Apply for Registrant's Account**

- A Registrant's account allows companies to register medical devices on behalf of product owners.
- Turn-around-time: 7 working days



Apply for Dealer's License

- Refer to **Section 2** for the types of dealer's license applicable
- Refer to MEDICS application guide for Dealer's Licence & Registrant's Account
- Turn-around-time: 10 working days



#### **Prepare and Apply for Product Registration**

- Refer to MEDICS application guide for Product Registration
- Turn-around-time: Refer to HSA website here

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#### **Section 2: Dealer's Licence Requirements:**

	Dealer Licensing (Refer to GN-02: Guidance on Licensing for Manufacturers, Importers and Wholesalers of Medical Devices)			
	Manufacturer's Licence	Importer's Licence	Wholesaler's Licence	
•	Manufacture of medical devices in Singapore	Import of medical devices into Singapore	Wholesale of medical devices in Singapore (including export)	



Requirements					
	Manufacturer's Licence	Importer's Licence	Wholesaler's Licence		
Type of QMS Certification	ISO 13485 certificate <sup>1</sup>	ISO 13485 certificate <sup>1</sup>	ISO 13485 certificate <sup>1</sup>		
	Or	Or	Or		
	Declaration of conformity to a QMS <sup>2</sup>	GDPMDS certificate (Good Distribution Practice for Medical Devices) <sup>3</sup>	GDPMDS certificate (Good Distribution Practice for Medical Devices) <sup>3</sup>		
		Or	Or		
		Declaration of exemption from GDPMDS <sup>4</sup>	Declaration of exemption from GDPMDS <sup>4</sup>		
		Or	Or		
		Declaration of Conformity to a QMS <sup>2</sup>	Declaration of Conformity to a QMS <sup>2</sup>		
Other document	Or	Or			
where applicable	Declaration letter on non- dealing in Class A medical devices	Declaration letter on non- dealing in Class A medical devices			

 $<sup>^{1}\</sup>mbox{The scope}$  of ISO 13485 certificate shall include activities performed at the facility.

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<sup>&</sup>lt;sup>2</sup> Declaration of conformity to a QMS is applicable for companies who deal with Class A medical devices only.

<sup>3</sup> GDPMDS certification to requirement of Singapore Standard for GDPMDS (SS 620). Certification is performed by GDPMDS certification bodies listed on Singapore Accreditation Council (SAC) website.

<sup>4</sup> GDPMDS certification is not required for the following activities: - Import for re-export only, -Import for non-clinical use only.