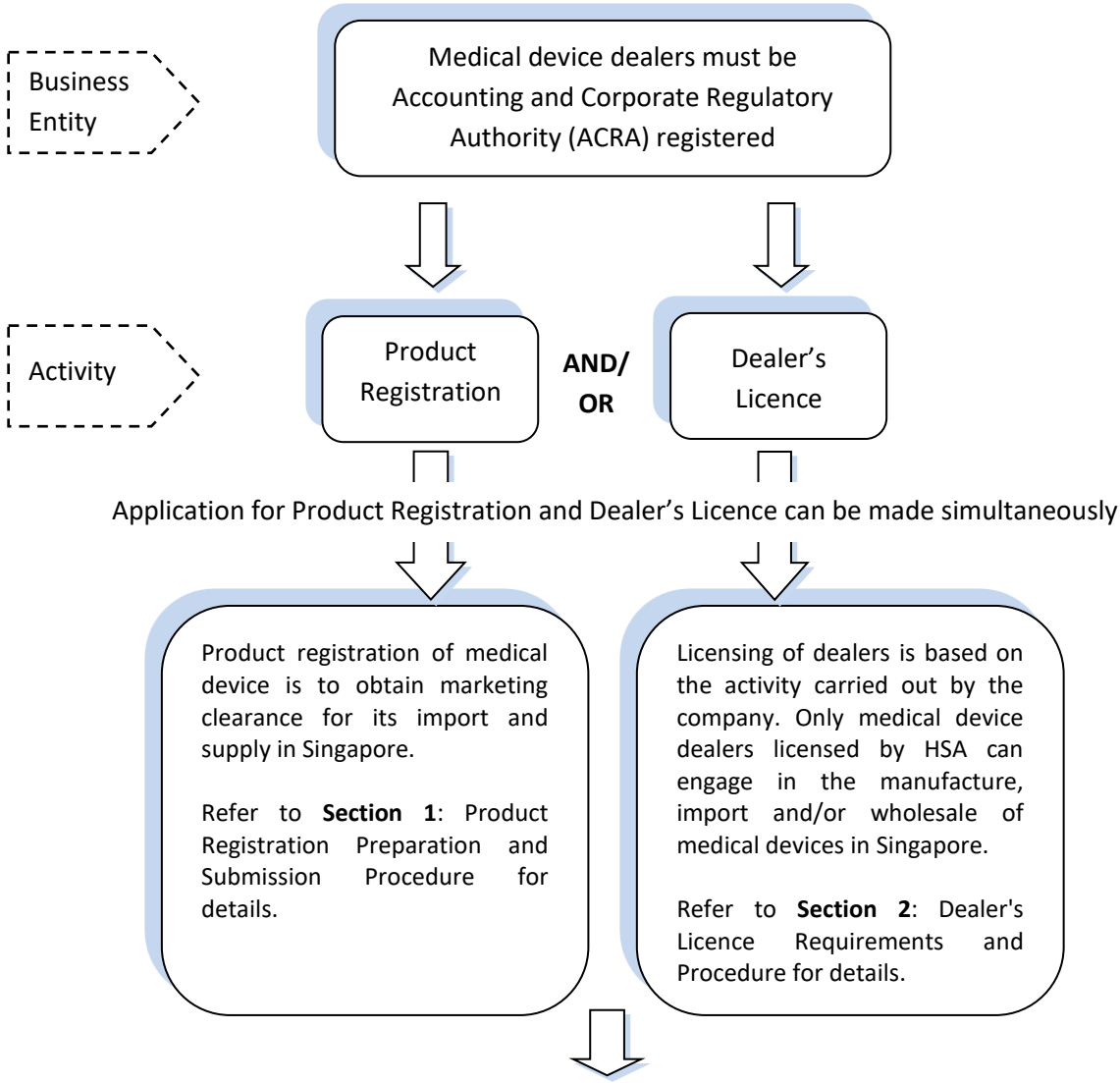
QUICK GUIDE TO MEDICAL DEVICE PRODUCT REGISTRATION AND DEALER LICENSING



Companies to add "HSA E-Services: Singapore Health Product Access and Regulation E-System (SHARE)" to your entity's e-Services through the Corppass portal and grant employee the access rights to use SHARE.

Payment modes available: GIRO or Online Payment (card or PayNow through STRIPE payment portal)

Cheques will not be accepted for any transaction.

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

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*.

NO → **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 ↓

To be supplied in Singapore?

NO → Product registration is not mandatory if you are importing for re-export only. Refer to GN-35 Guidance on Special Access Routes.

YES ↓

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
- GL-07: Guidelines on Risk Classification of Software as a Medical Device (SaMD) and Qualification of Clinical Decision Support Software (CDSS)

Class B, C & D → **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

Class A ↓

Product Registration not required.

Manufacturers and Importers to submit Product Notification application on SHARE prior to import. GN-22: Guidance for Dealers on Class A Medical Devices Exempted from Product Registration

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Product Registration required

1. GN-15 Guidance on Medical Device Product Registration
2. GN-17: Guidance on Preparation of a Product Registration Submission for General Medical Devices using the ASEAN CSDT; or

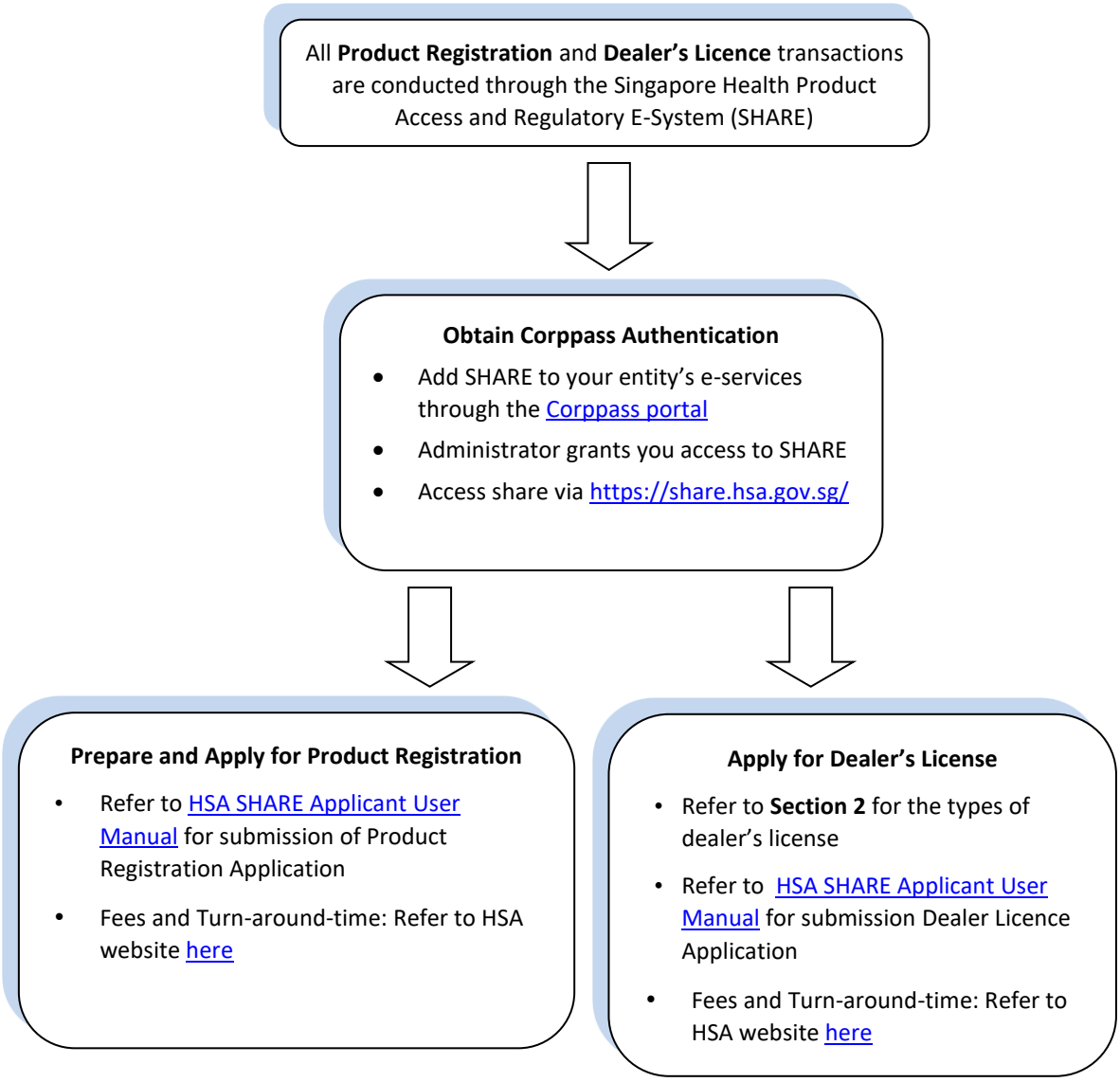
   GN-18: Guidance on Preparation of a Product Registration Submission for *In Vitro* Diagnostic (IVD) Medical Devices using the ASEAN CSDT

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Submit documents online via SHARE

- Refer to the Online Application Procedure

Online Application Procedure:



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[1] **Or** MDSAP[1] **Or** Declaration of conformity to a QMS[2]	ISO 13485 certificate[1] **Or** MDSAP[1] **Or** GDPMDS certificate (Good Distribution Practice for Medical Devices)[3] **Or** Declaration for dealing with medical devices that are solely for export or re-export purposes [4] **Or** Declaration of Conformity to a QMS[2]	ISO 13485 certificate[1] **Or** MDSAP[1] **Or** GDPMDS certificate (Good Distribution Practice for Medical Devices)[3] **Or** Declaration for dealing with medical devices that are solely for export or re-export purposes [4] **Or** Declaration of Conformity to a QMS[2]

[1] The scope of ISO 13485 or MDSAP certificate must include distribution of the categories of medical devices and the activities performed at the facility, where applicable. Only ISO13485 certificates issued by Singapore Accreditation Council (SAC) accredited certification bodies (CBs) will be accepted. The list of SAC accredited CBs can be referred on SAC's website. The QMS certificate, together with the audit report, should be submitted.
[2] Declaration of conformity to a QMS is applicable for companies who deal with Class A medical devices only.
[3] 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. The QMS certificate, together with the audit report, should be submitted.
[4] GDPMDS certification is not required for Import for re-export only.