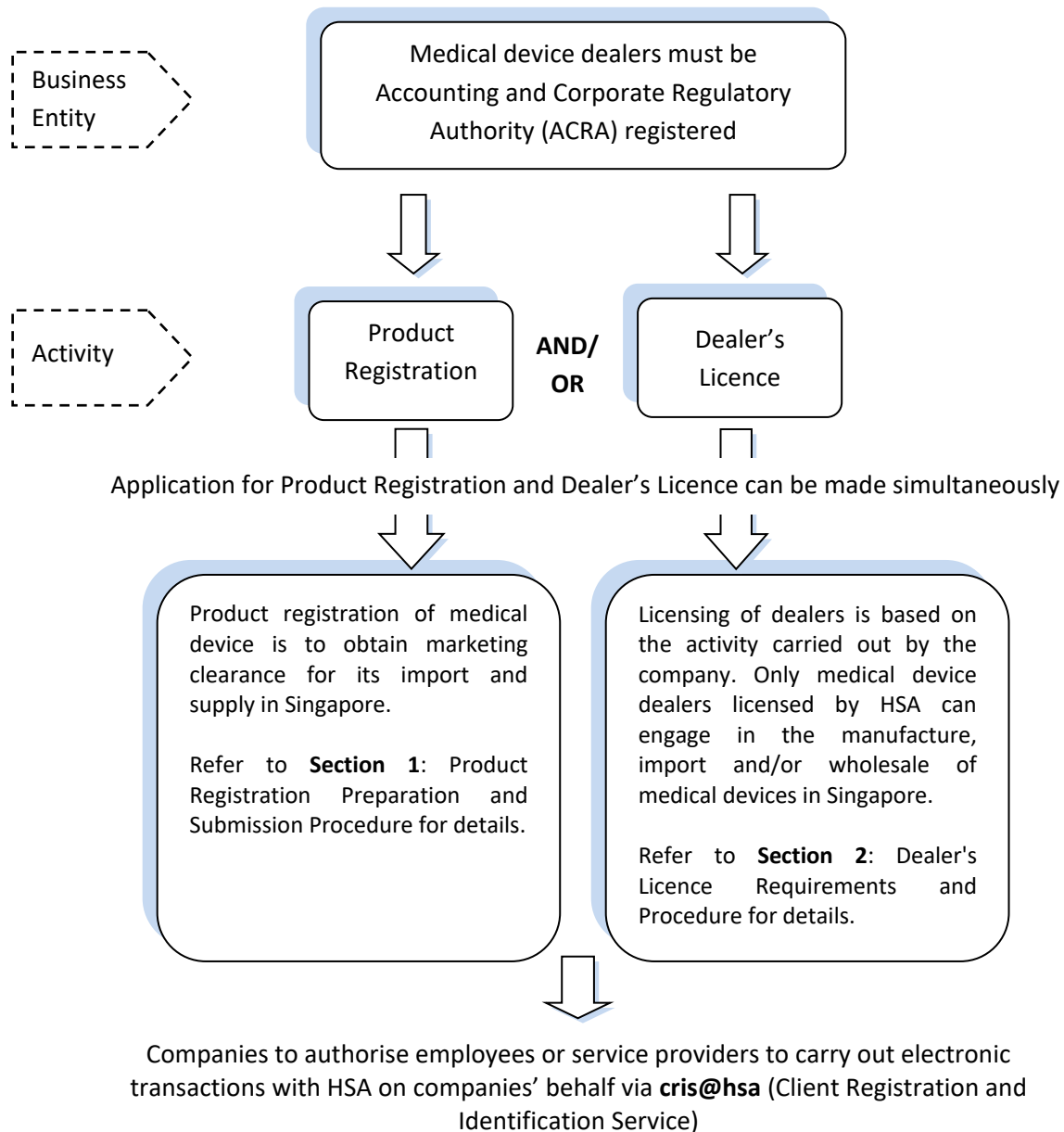


QUICK GUIDE TO MEDICAL DEVICE PRODUCT REGISTRATION AND DEALER LICENSING



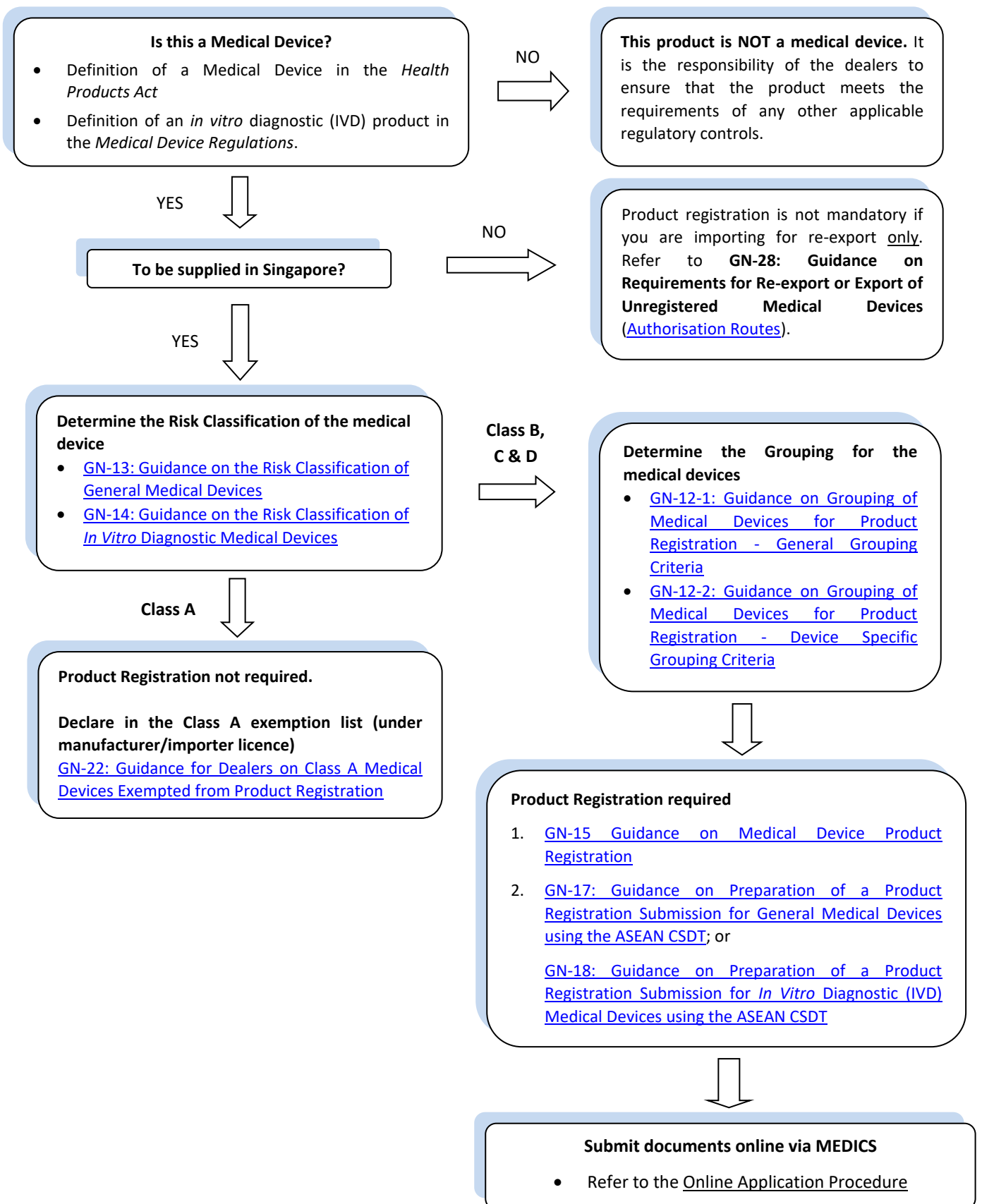
Payment modes for all medical device applications: GIRO and credit card

Cheques will not be accepted for any transaction.

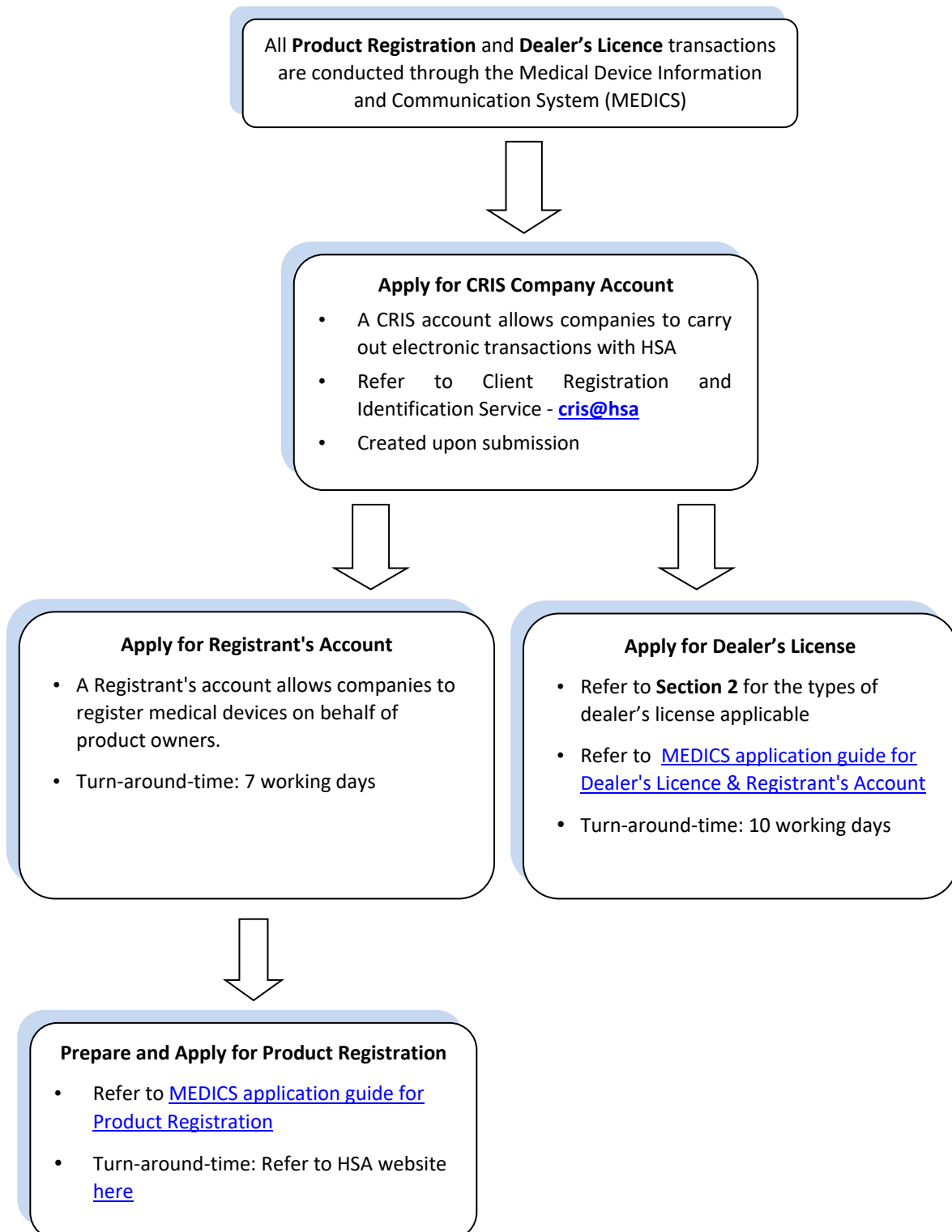
Refer to [Fees and Charges](#) on HSA website for further details.

Please download the GIRO Application Form [here](#).

Section 1: Product Registration Guide:



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
<ul style="list-style-type: none"> Manufacture of medical devices in Singapore 	<ul style="list-style-type: none"> Import of medical devices into Singapore 	<ul style="list-style-type: none"> 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 Declaration of conformity to a QMS ²	ISO 13485 certificate ¹ Or GDPMDS certificate (Good Distribution Practice for Medical Devices) ³ Or Declaration of exemption from GDPMDS ⁴ Or Declaration of Conformity to a QMS ²	ISO 13485 certificate ¹ Or GDPMDS certificate (Good Distribution Practice for Medical Devices) ³ Or Declaration of exemption from GDPMDS ⁴ Or Declaration of Conformity to a QMS ²
Other document where applicable	Or Declaration letter on non-dealing in Class A medical devices	Or Declaration letter on non-dealing in Class A medical devices	

¹ The scope of ISO 13485 certificate shall include activities performed at the facility.

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 [TS-01 GDPMDS](#) or Singapore Standard for GDPMDS (SS 620). From 9 Nov 2020, only GDPMDS certification to SS 620 will be accepted. Certification is performed by GDPMDS certification bodies listed on [Singapore Accreditation Council \(SAC\) website](#).

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