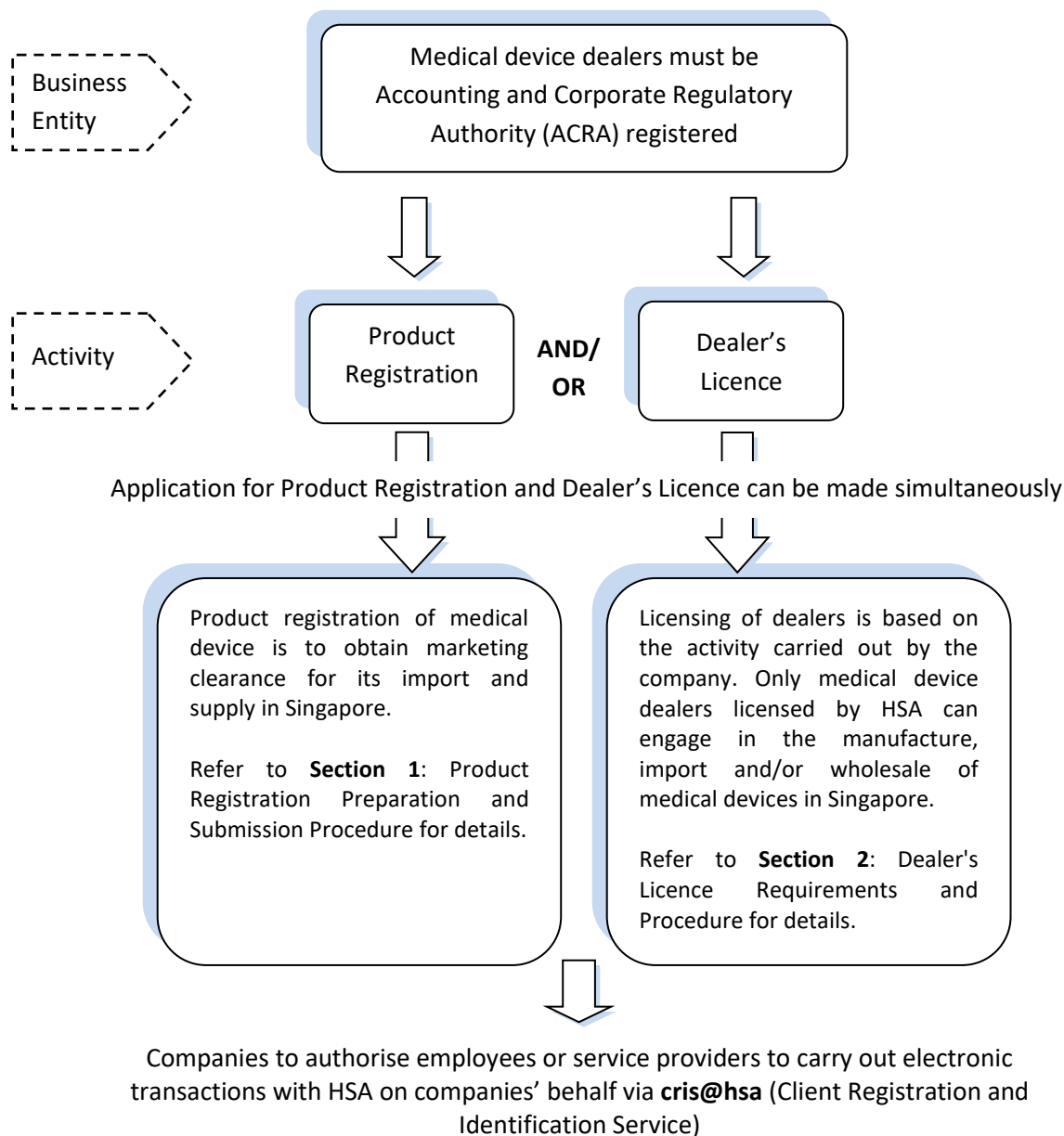


QUICK GUIDE TO MEDICAL DEVICE PRODUCT REGISTRATION AND DEALER LICENSING



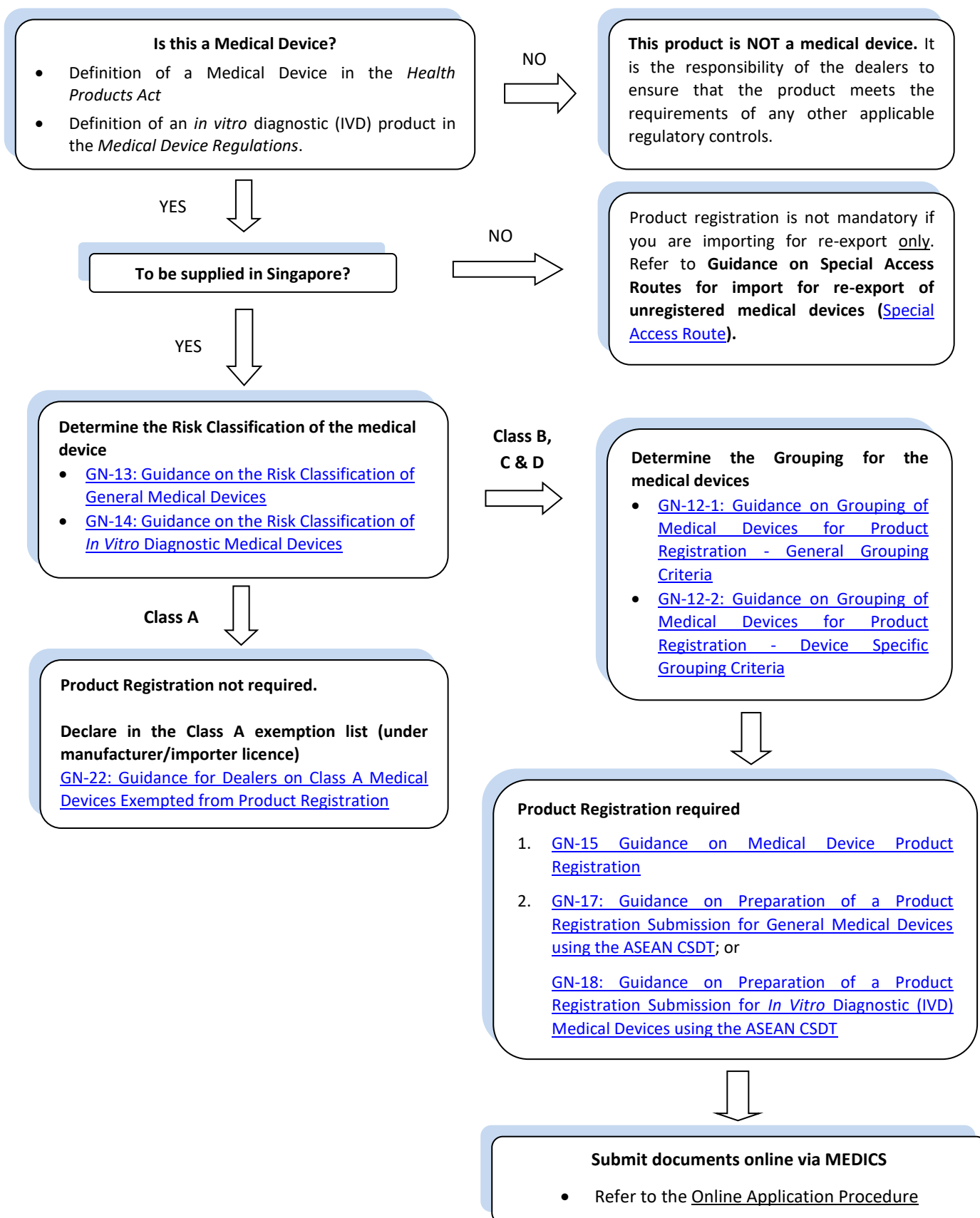
Payment modes for all medical device applications: GIRO and credit card

Cheques will not be accepted for any transaction.

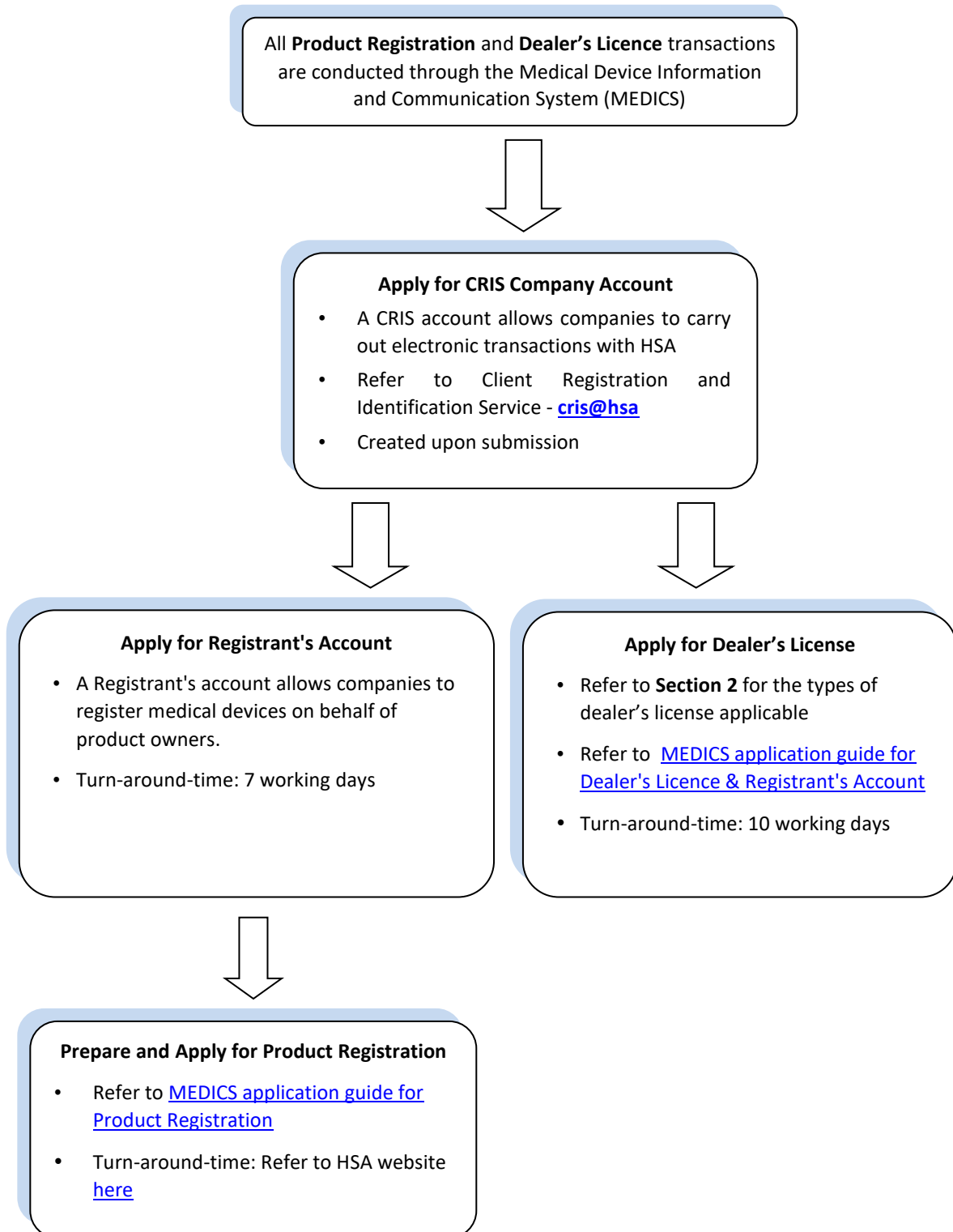
Refer to [Fees and Charges](#) on HSA website for further details.

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 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 of exemption from GDPMDS 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 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 or MDSAP certificate must include distribution of the categories of medical devices and the activities performed at the facility, where applicable.

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](#).

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