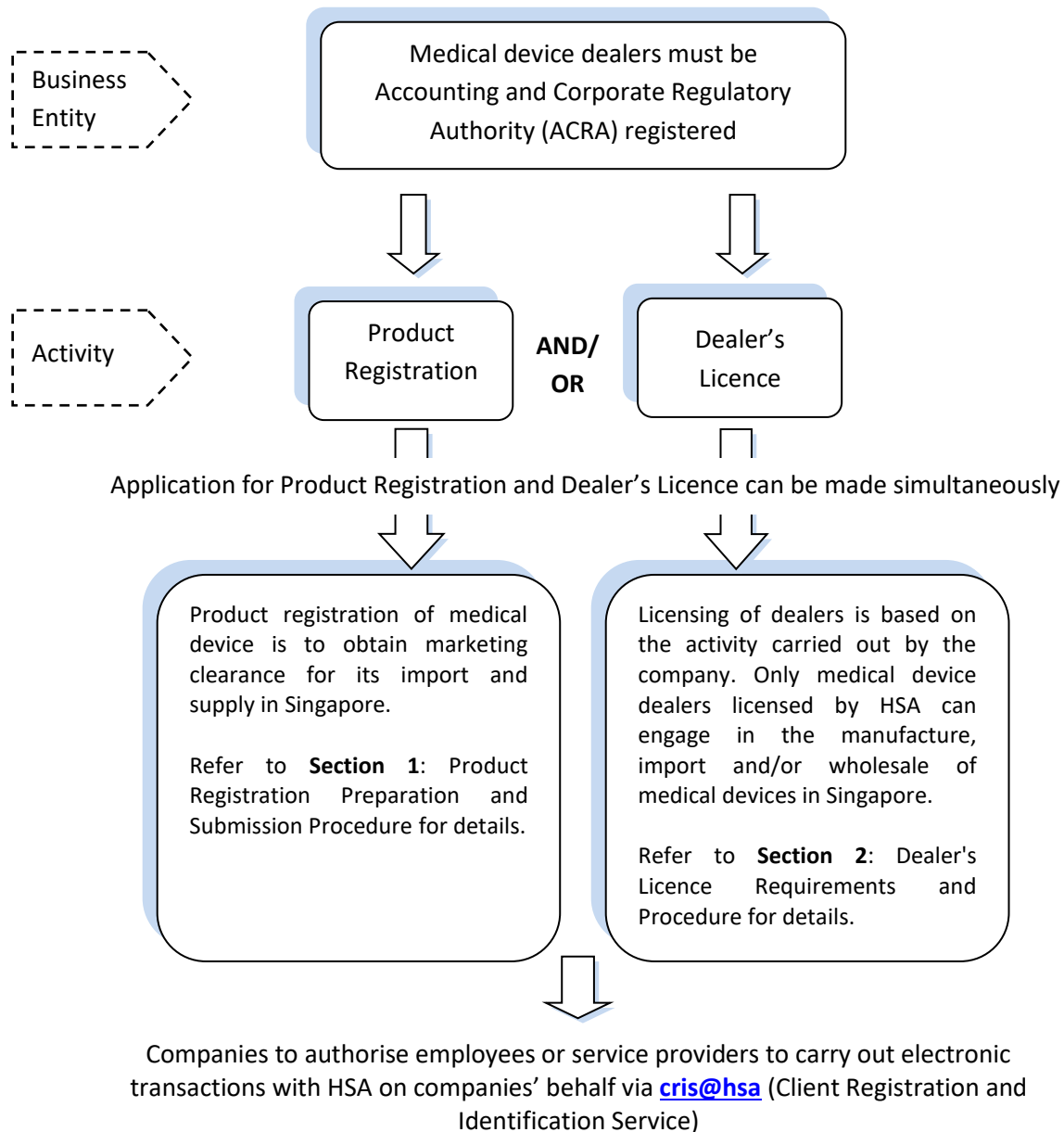


## QUICK GUIDE TO MEDICAL DEVICE PRODUCT REGISTRATION AND DEALER LICENSING

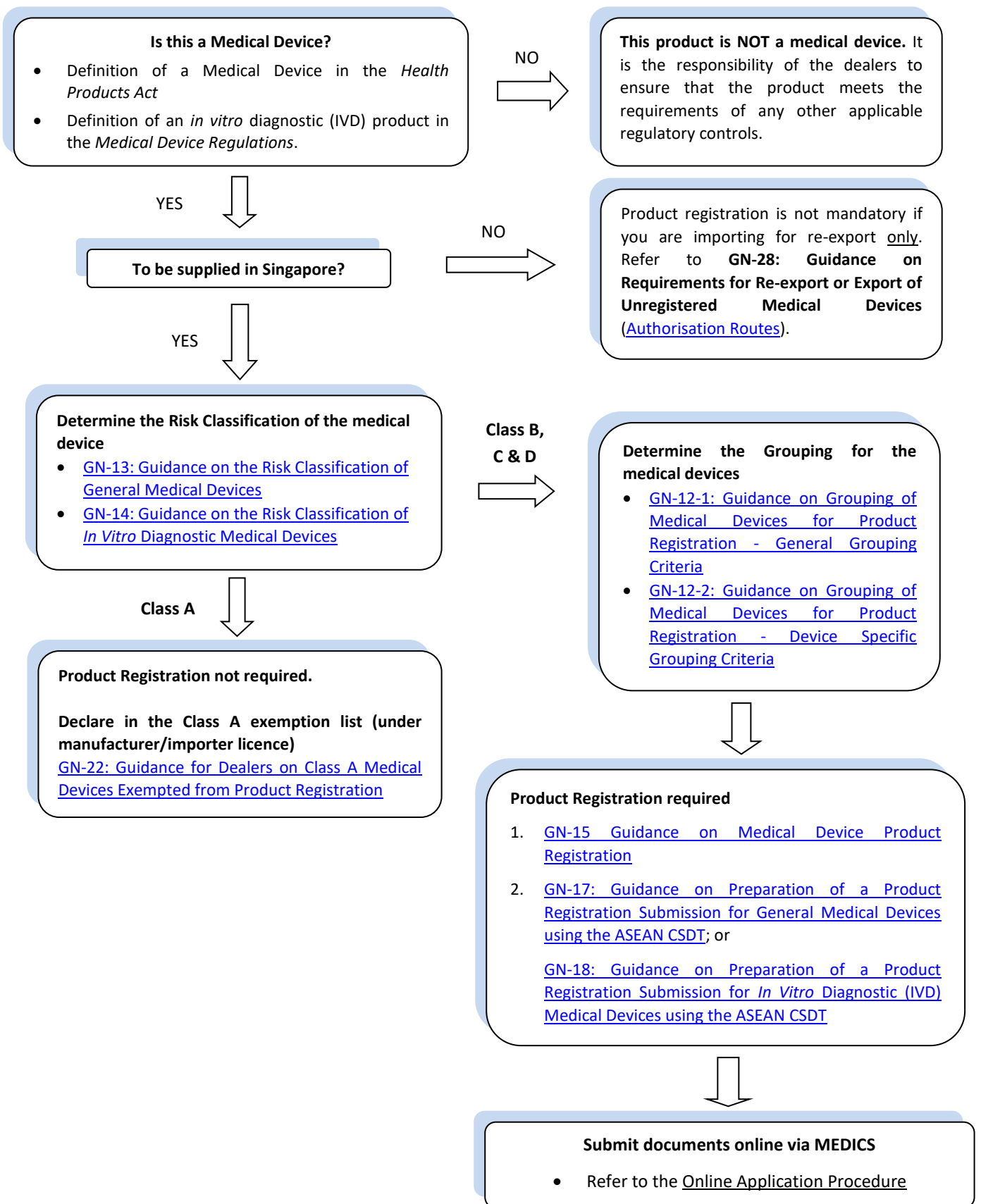


Payment modes for all medical device applications: GIRO and credit card

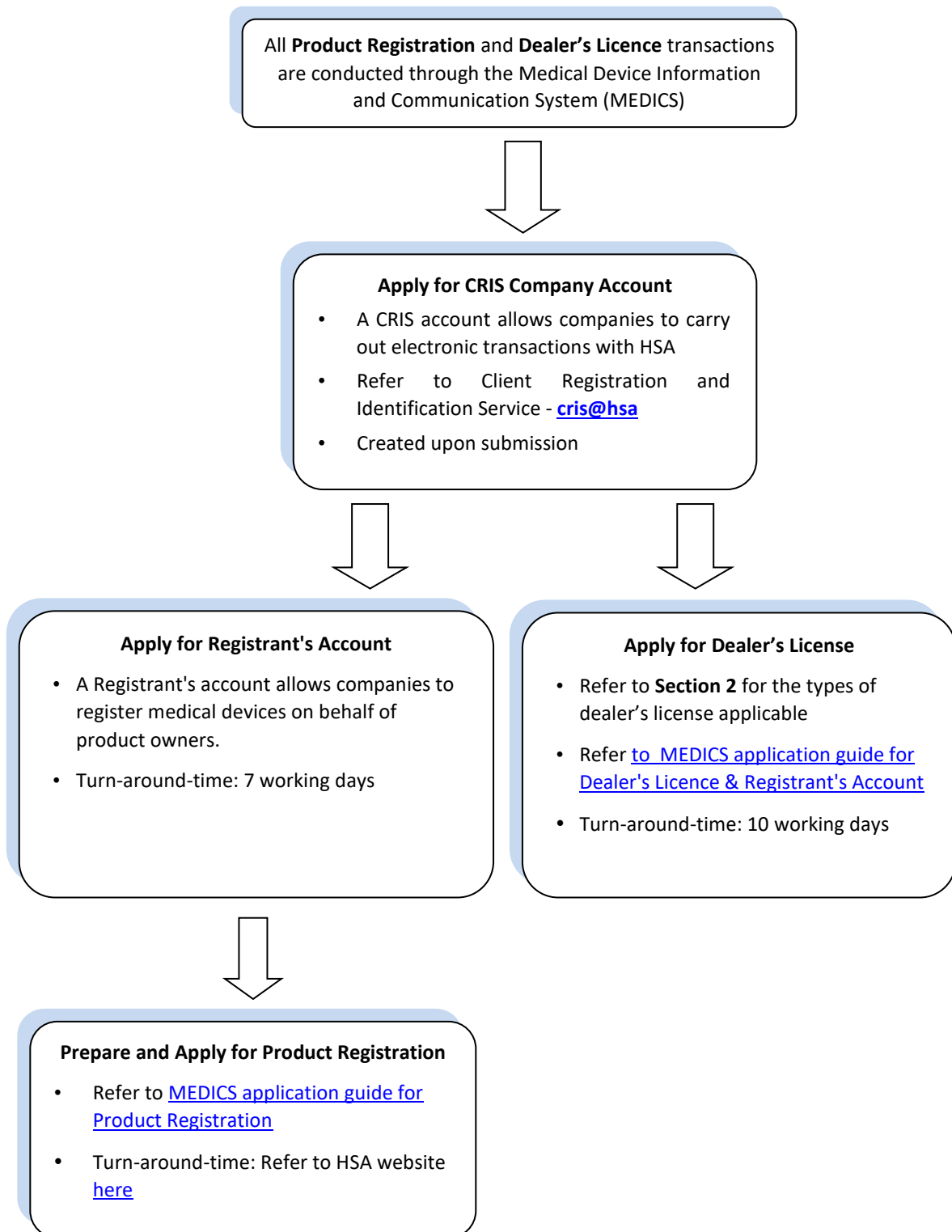
Cheques will not be accepted for any transaction.

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

### Section 1: Product Registration Guide:



**Online Application Procedure:**



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

Dealer Licensing (Refer to <a href="#">GN-02: Guidance on Licensing for Manufacturers, Importers and Wholesalers of Medical Devices</a> )		
Manufacturer's Licence	Importer's Licence	Wholesaler's Licence
<ul style="list-style-type: none"> <li>Manufacture of medical devices in Singapore</li> </ul>	<ul style="list-style-type: none"> <li>Import of medical devices into Singapore</li> </ul>	<ul style="list-style-type: none"> <li>Wholesale of medical devices in Singapore (including export)</li> </ul>



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

<sup>1</sup> The scope of ISO 13485 certificate shall include activities performed at the facility.

<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 [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](#).

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