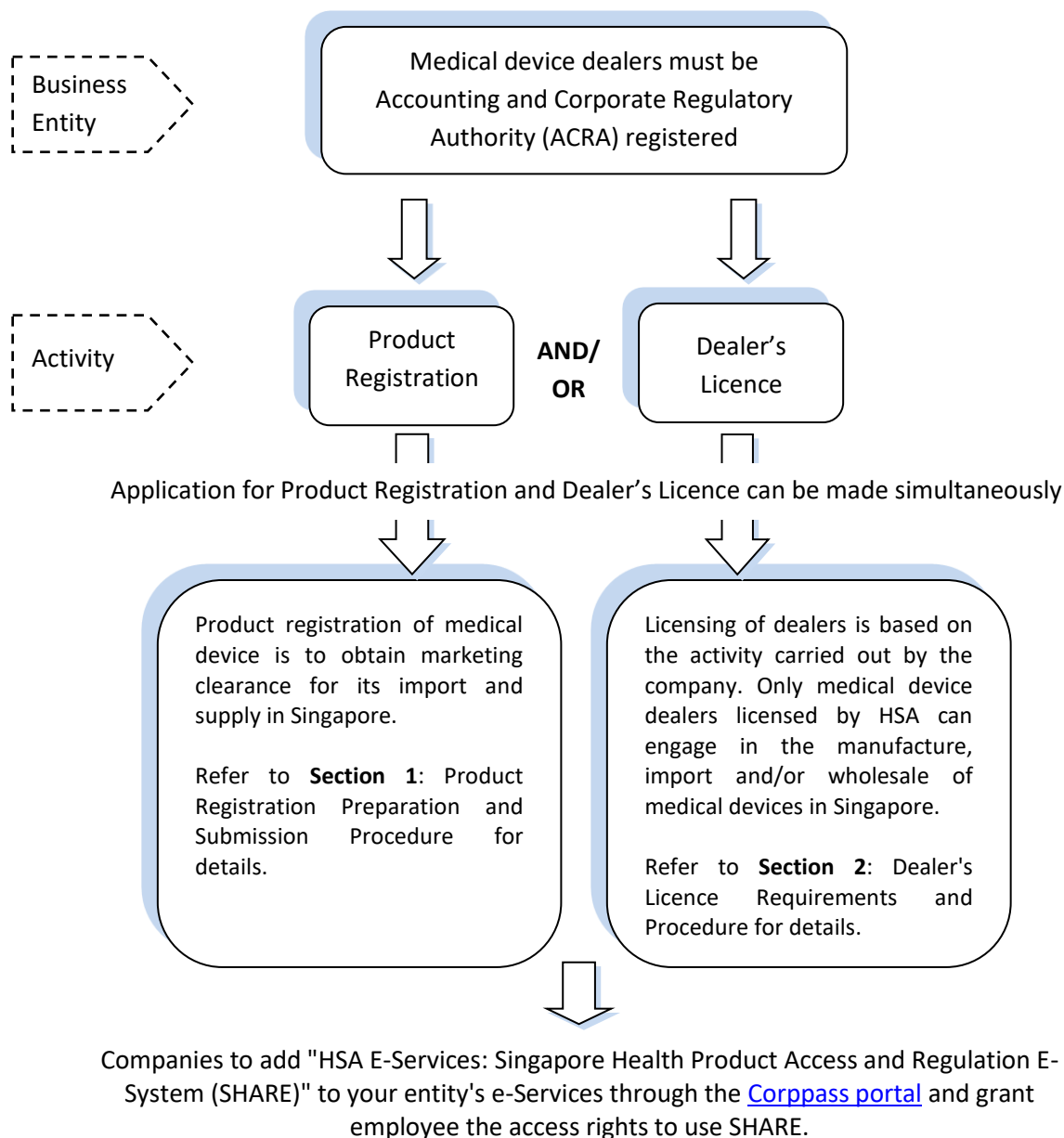


## QUICK GUIDE TO MEDICAL DEVICE PRODUCT REGISTRATION AND DEALER LICENSING

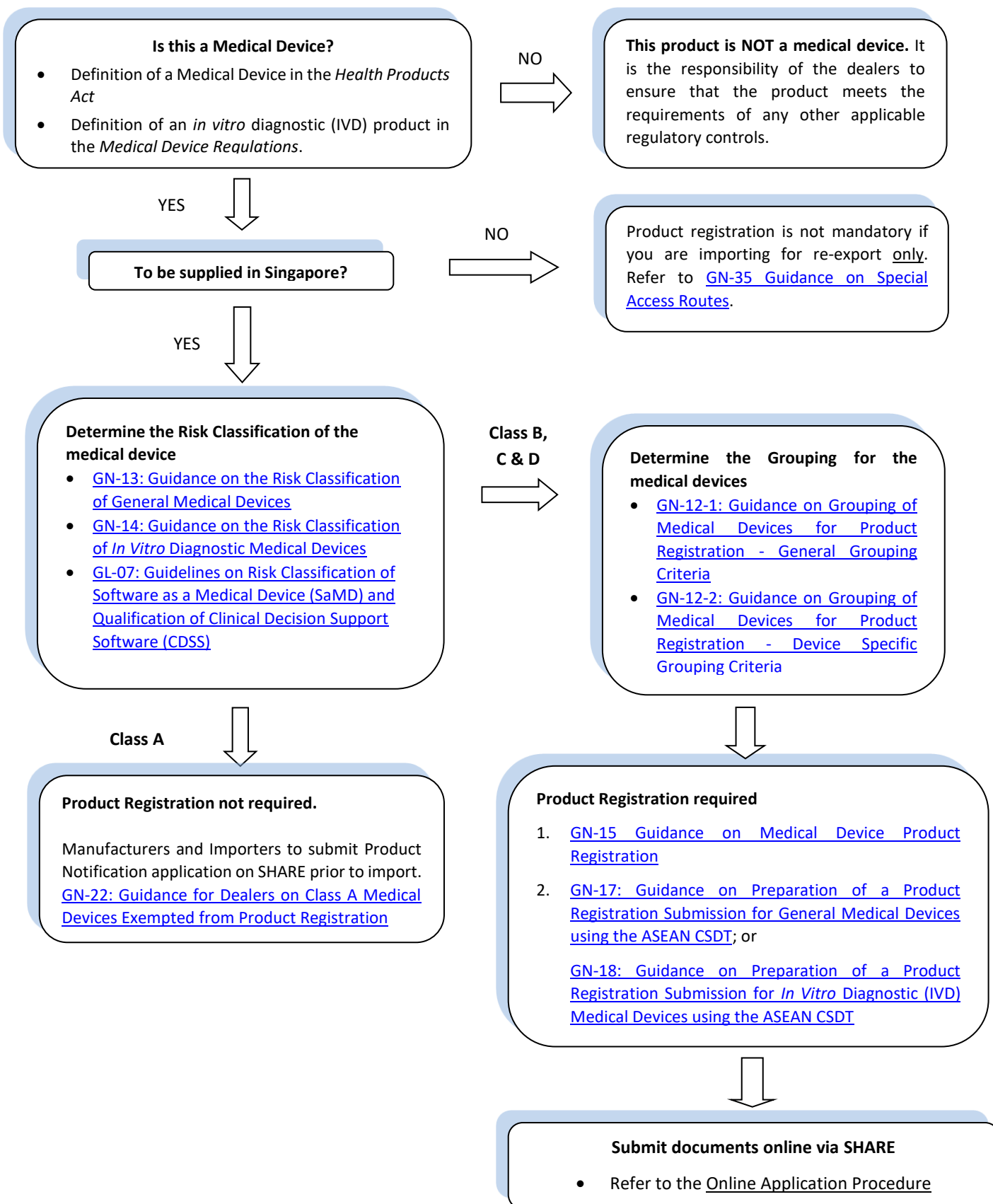


Payment modes available: GIRO or Online Payment (card or PayNow through STRIPE payment portal)

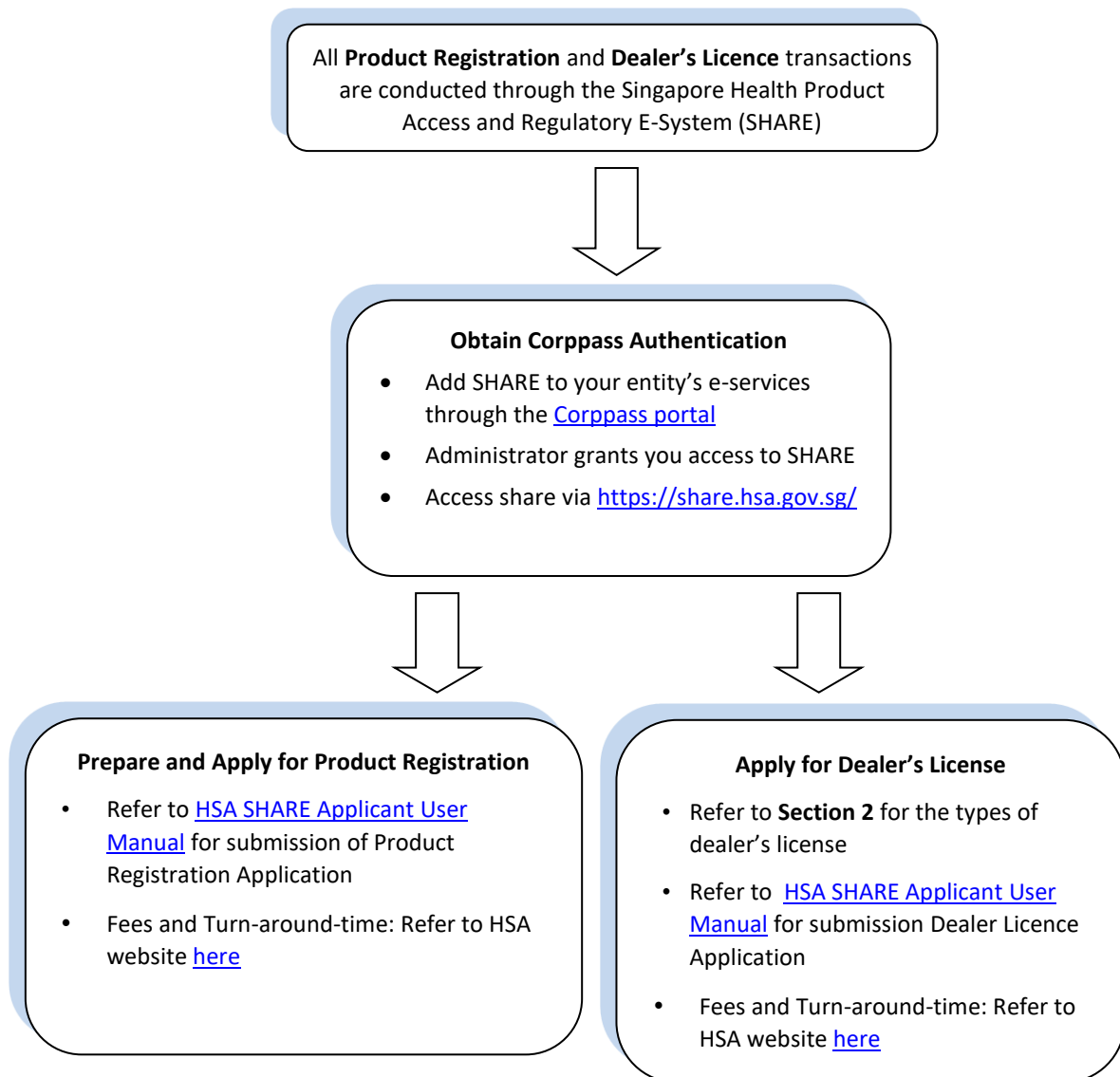
Cheques will not be accepted for any transaction.

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

**Section 1: Product Registration Guide:**



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

<sup>1</sup> 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.

<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](#). The QMS certificate, together with the audit report, should be submitted.

<sup>4</sup> GDPMDS certification is not required for Import for re-export only.