GUIDE TO APPLICATION FOR DEALER'S LICENCE
(IMPORTER, WHOLESALER AND MANUFACTURER)

This e-Application at MEDICS@HSA (Medical Device Information & Communication System) allows a company to apply for an Importer, Wholesaler and Manufacturer's licence.

The online Dealer's Licence Application in MEDICS may take an average of 5 - 10 minutes to fill in.

The time taken varies depending on the number and sizes of the file attachments, configurations of your computer and network system, Internet performance, etc. For more information, please refer to https://www.hsa.gov.sg/e-services/medics.

Please note that the time stated above excludes time taken for preparatory work in relation to filing the online form (e.g. scanning documents for file attachments.)

INSTRUCTIONS

In order to use this e-Service in MEDICS, you must have all of the following:

1. **Personal Access Authentication to log on**
   - Corppass (Singapore Corporate Access), a corporate digital identity for business and other entities to transact with Government online services, OR
   - HSA PIN (HSA Personal Identification Number), password for overseas individual, supplied by HSA

2. **A CRIS Company Account for MEDICS** (Client Registration & Identification Services), an account to enable a local company to gain access to MEDICS. See details at cris@hsa.
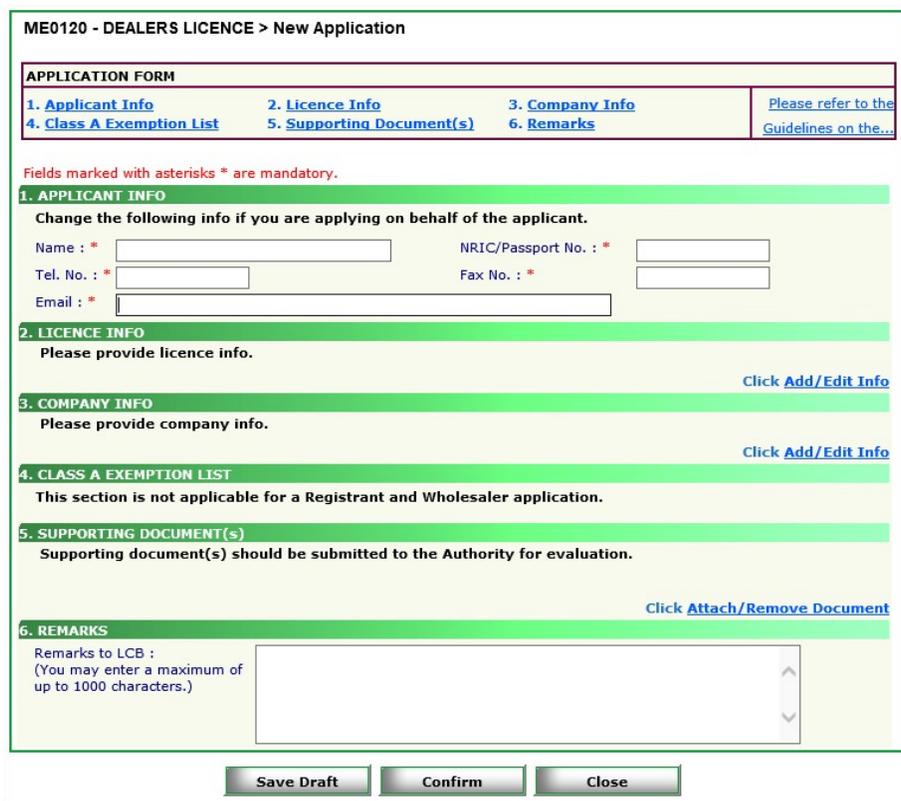
PAYMENT

Please refer to the following page for information on fee and payment modes: https://www.hsa.gov.sg/medical-devices/fees.

ONLINE APPLICATION FORM

The online application form consists of 6 parts.

To fill in the relevant information, click on **"Add/Edit Info"** to access that section of the form

---

ME0120 - DEALERS LICENCE > New Application

APPLICATION FORM

1. **Applicant Info**	2. **Licence Info**	3. **Company Info**	Please refer to the
4. **Class A Exemption List**	5. **Supporting Document(s)**	6. **Remarks**	Guidelines on the...

Fields marked with asterisks * are mandatory.

1. APPLICANT INFO

Change the following info if you are applying on behalf of the applicant.

Name : *   NRIC/Passport No. : *

Tel. No. : *   Fax No. : *

Email : *

2. LICENCE INFO

Please provide licence info.

Click **Add/Edit Info**

3. COMPANY INFO

Please provide company info.

Click **Add/Edit Info**

4. CLASS A EXEMPTION LIST

This section is not applicable for a Registrant and Wholesaler application.

5. SUPPORTING DOCUMENT(s)

Supporting document(s) should be submitted to the Authority for evaluation.

Click **Attach/Remove Document**

6. REMARKS

Remarks to LCB :
(You may enter a maximum of
up to 1000 characters.)

[Save Draft]   [Confirm]   [Close]

At the end of the application form, there are 3 button options:

Button - Save Draft
Allows the applicant to save the Application Form for retrieval and submission at a later time. A transaction number will be assigned.

The saved Application Form can be retrieved from "My Drafts" in the Workbench@MEDICS.

Button – Confirm
Allows the applicant to confirm the completed Application Form and the company's declaration on the form before submitting it to MDB. To make any amendment, click on the **"<< Previous"** Button to return to the Application Form. Before the application is submitted, the applicant may print a copy of the application for his record.

Button – Close
Closes the application form without saving any changes made.

PART 1 – Applicant Info

The applicant refers to the individual designated by the company as contact point for any correspondence regarding this application. This section requires the applicant to fill in the following:

      1) Name
      2) NRIC/Passport No
      3) Contact Telephone Number
      4) Contact Fax Number
      5) Contact E-mail

Items 1 to 3 are pre-populated from CRIS Company Account database and can be updated or replaced.

PART 2 – Licence Info

This section requires the applicant to complete the following fields
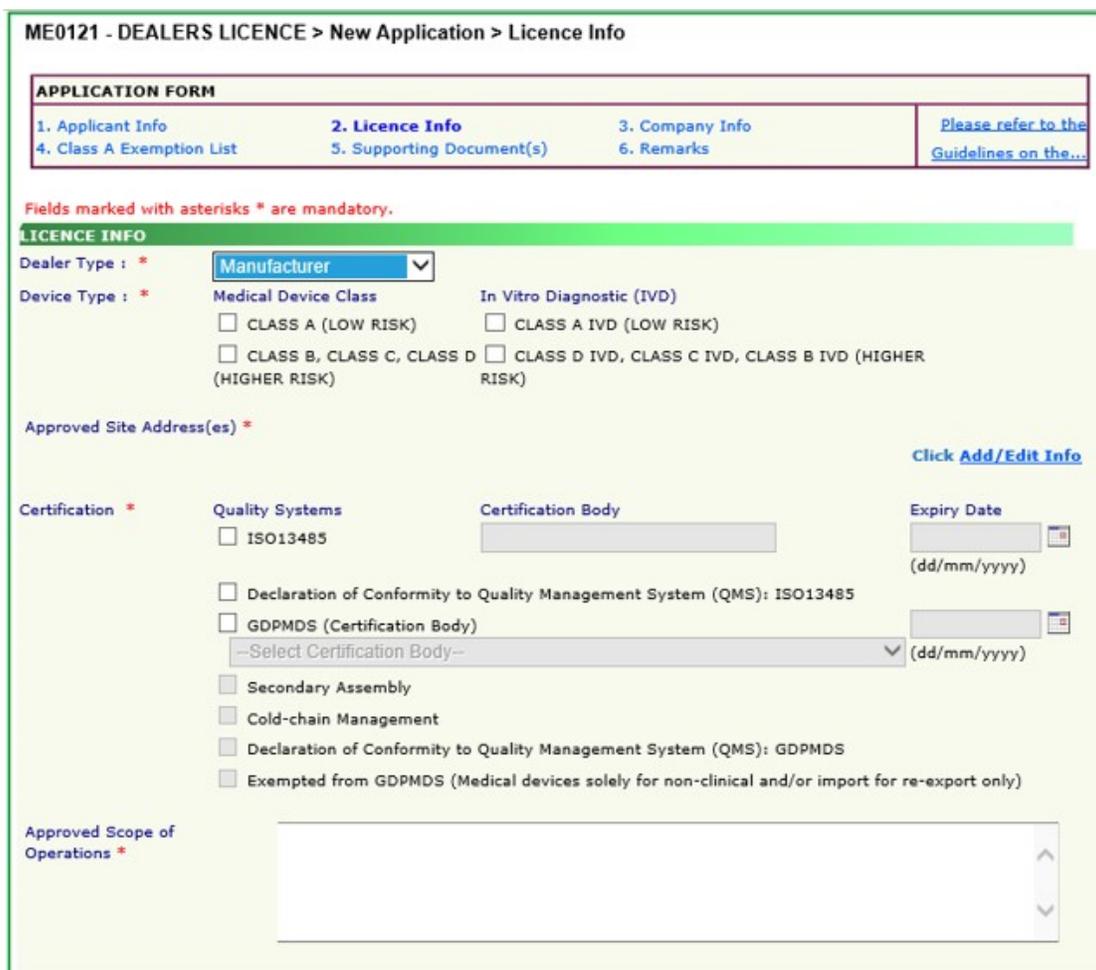
1) Dealer Types
    Select the "Dealer Type" from a drop-down list:

        a) Manufacturer's Licence
        b) Importer's Licence
        c) Wholesaler's Licence

Only 1 dealer type can be selected for each application. A new separate application has to be submitted if company intends to apply for more than 1 dealer's licence.

2) Device Types
Select the "Device Type" that the company is dealing in (more than 1 type can be selected):

   a) Class A (Low Risk Medical Device)
   b) Class B, Class C, Class D (Higher Risk Medical Device)
   c) Class A IVD (Low Risk IVD)
   d) Class B, Class C, Class D (Higher Risk IVD)

3) Approved Site Address(es)
Site address(es) listed in the QMS certificate have to be included in the application.

   a) Click <Add/ Edit Info> and click <Retrieve Address>. The Blk/House No, Street Name and Building Name will be populated on screen.
   b) Fill in Level-Unit information if applicable.

4) Certification
Please include information in relation to certifications obtained by the company.

   a) Select the type of "Quality Systems" that the company has and include the "Certification Body", as well as the "Expiry Date" of the certificate.
   b) If "Cold Chain" or "Secondary Assembly" is involved in the Scope of Certification, the option should be selected by checking the radio button beside the description.
       i) "Cold-Chain Management": select this checkbox if the GDPMDS scope includes cold-chain management. This selection is only applicable to importers and wholesalers.
       ii) "Secondary Assembly": select this checkbox if the GDPMDS scope includes secondary assembly. This selection is only applicable to importers and wholesalers.
   c) Manually enter the scope of certification into "Approved Scope of Operations".

Click **"Update Form"** to proceed.

PART 3 – Company Info

This section requires the applicant to fill in the following:
1) Company Name
2) Address Type
3) Postal Code
4) Block/Number
5) Street Name
6) Building Name
7) Level-Unit
8) Country
9) Unique Entity Number
10) Main Telephone Number
11) Fax Number
12) Contact Person
13) Contact Telephone Number
14) Contact Email

Item 1 and 9: Pre-populated from CRIS Company Account database.

Item 2: Address Type. The applicant is required to select whether it is a Singapore (local) or foreign (overseas) address.

Item 3: Postal Code. After completing the postal code for a local address, the applicant may click on "retrieve address" and the street address (items 4, 5, 6 & 8) will be populated with data from SingPost.

Item 8: Selection from a country list.

Item 14: Upon the approval of this application, a notification of its approval and all future correspondence with the company regarding this dealer's licence will be via the email address that is entered at item 14.

Click **"Update Form"** to proceed.

PART 4 – Class A Exemption List

This section is only applicable for the submission of manufacturer's or importer's licence applications.

Companies manufacturing or importing Class A medical devices that are exempted from product registration, please select "I declare that this application has Class A Exemption List" and/or "I declare that the sterilization process for all Class A sterile medical devices in this Class A Exempted List submitted conform to international standards for sterilization of medical devices or equivalent", if applicable.

Click "**Add / Edit Info**" to proceed to the following screen.

Click "**here**" link to download the empty excel template to fill up the required information for Class A Exemption list.

Note

1. Excel Columns B, C, D, E, I, J, K, L, M are mandatory fields relating to the Class A medical devices being imported/manufactured in Singapore. Excel Columns F, G, H are optional fields relating to UDI. Should information be entered in either column F or G, column H would be mandatory.

2. No input from the applicant is required for the first column (Record ID) and the last column (Time Stamp).

After completing the Class A Exemption list, click "**Browse**" to select the excel file and click "**Upload**".

Once the excel file is successfully uploaded, a table on the declared Class A medical devices exempted from product registration will be displayed.

Note: The table only shows the new / updated device info.

Class A Exemption List :

Product Owner	Name as per Device label	Intended purpose	Device Identifier/(Model No.)	UDI-DI	DM-DI	UDI Issuing Agency	Name of Manufacturer	Address of Manufacturing Site	Country of Manufacturer	Sterile/ Non-sterile	Status	Time Stamp (To be generated by HSA System)
PO1	MD1	Intended use 1	1111	UDI 1		GS1	name 1	add 1	Australia	Non-sterile	Active	
PO2	MD2	Intended use 2	2222		DM2	HIBCC	name 2	add 2	Brazil	Sterile	Active	
PO3	MD3	Intended use 3	3333				name 3	add 3	South Africa	Non-sterile	Active	

Click "**Update Form**" to proceed.

PART 5 – Supporting Documents

The supporting documents are attached by browsing the local storage devices for the documents using the **"Browse"** button. Then click the **"Add Attachment"** button to attach these documents.

To remove documents from the **"list of documents attached",** select the corresponding checkbox and click **"Remove Attachment".**

NOTE: "***ANNEX 6: Declaration of Non-Dealing of Class A Medical Devices***" of GN-02 is mandatory if companies are not dealing in Class A medical devices which are exempted from registration.

ME0123 - DEALERS LICENCE > New Application > Supporting Document(s)

APPLICATION FORM

| 1. Applicant Info | 2. Licence Info | 3. Company Info | Please refer to the |
| 4. Class A Exemption List | 5. Supporting Document(s) | 6. Remarks | Guidelines on the... |

SUPPORTING DOCUMENT(s)
Please attach the following document(s) by typing in the path or click on the browse button.

For dealers dealing with Medical Devices of all risk classes
1. ISO 13485 certificate or GDPMDS certificate [Browse...]
2. Annex 1: Declaration of exemption from GDPMDS **(for importer or wholesaler dealing with medical devices solely for non-clinical and/or import for re-export only)** [Browse...]

For dealers dealing solely with Class A Medical Devices (Class A sterile and non-sterile are exempted from product registration)
3. Annex 5: Declaration of conformity to ISO 13485 or GDPMDS**(for importer, wholesaler and manufacturer only)** [Browse...]

For dealers dealing with Class B/C/and/or D Medical Devices (higher risk class devices)
4. Annex 6: Declaration letter of non-dealing in Class A medical devices**(for importer and manufacturer only)** [Browse...]
5. ISO 13485 certificate or GDPMDS certificate [Browse...]
6. Annex 1: Declaration of exemption from GDPMDS **(for importer or wholesaler dealing with medical devices solely for non-clinical and/or import for re-export only)** [Browse...]

To attach, click Add Attachment.

PART 6 – Remarks

This section is for you (the applicant) to insert any remarks to MDB regarding the application.

END OF DOCUMENT