GUIDE TO APPLICATION REGISTRANT ACCOUNT

This e-Application at MEDICS@HSA (Medical Device Information & Communication System) allows a company to apply for a Registrant Account.

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. The recommended computer and network configurations are at the following URL: 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

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.

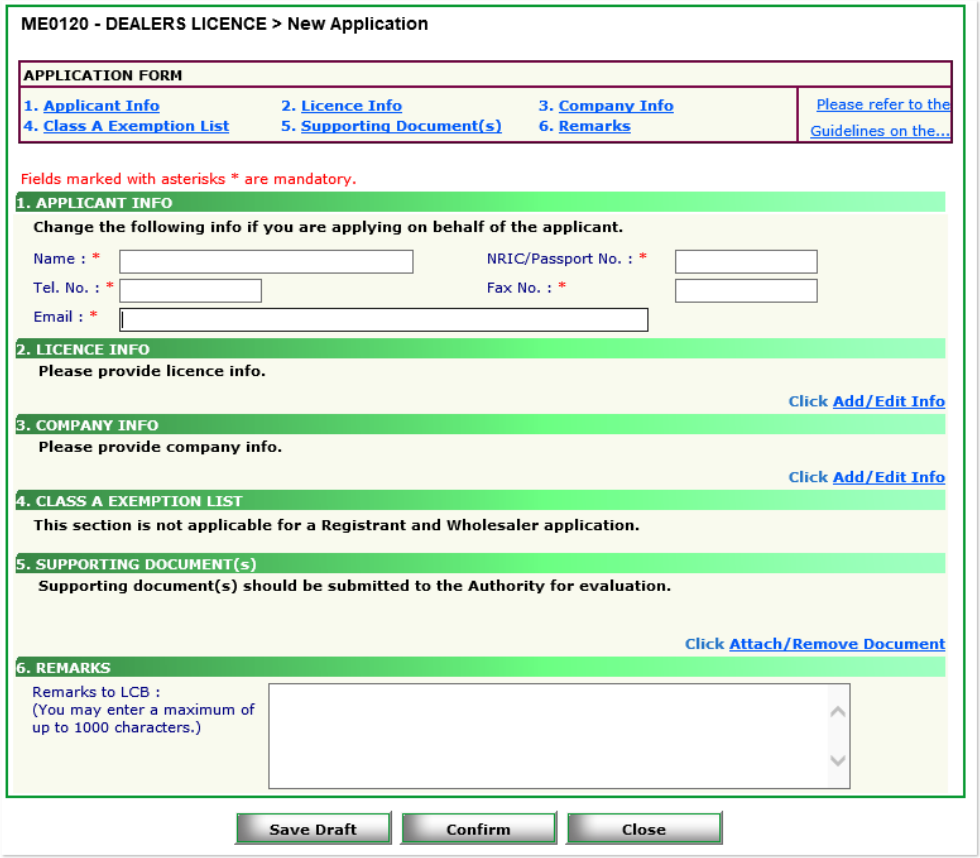
PAYMENT

There is no charge to the application for Registrant Account.

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



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 amend any mistake, click on the **"<< Previous"** Button to return to the Application Form. Before the application is submitted, the applicant may print a copy 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 that are relevant:

1) Dealer Type
2) Device Type

1) Dealer Types

Select Registrant as “Dealer Type” from a drop-down list.

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)
d) Class B, Class C, Class D (Higher Risk IVD)

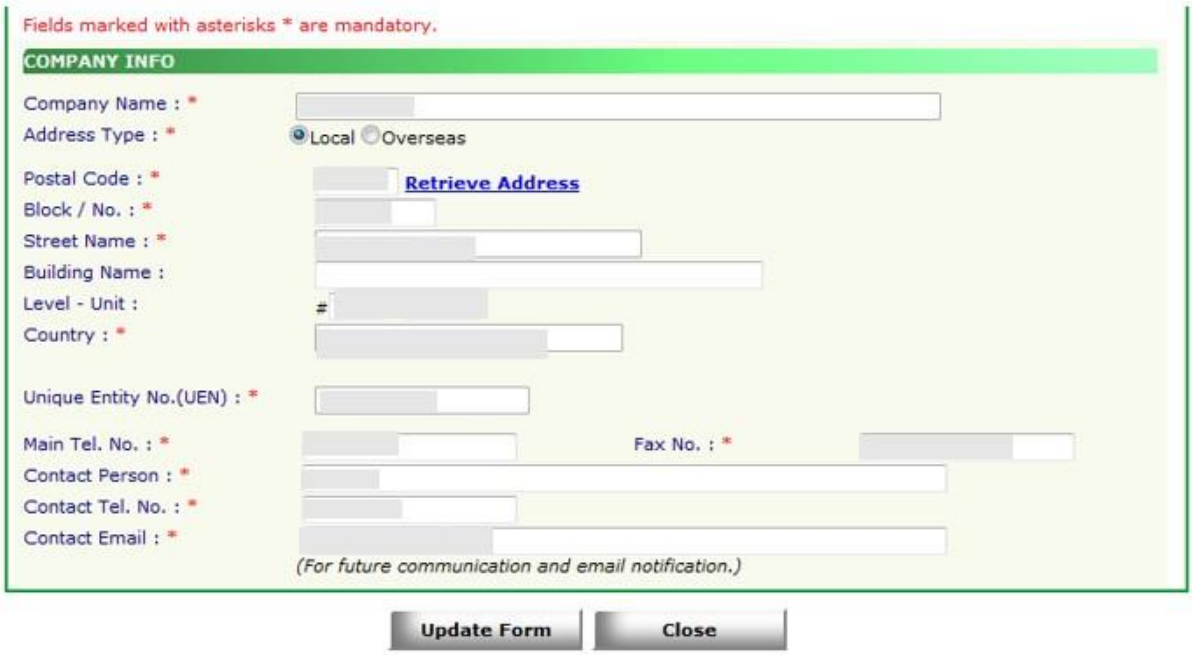
Note: With effect from 1 June 2018, Class A medical devices are exempted from product registration. Hence a Registrant account is not required if company is dealing with only Class A medical devices. However company should still adhere to the Dealers' Licences requirements based on the type of activities performed.

3) Certification

This section is not applicable for Registrant Account application.

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.

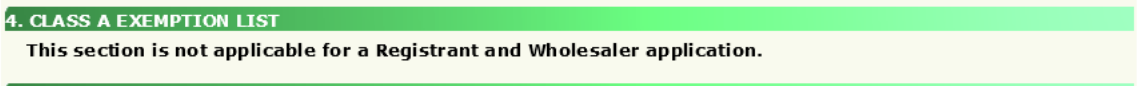
Item 8: Selection from a country list.

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

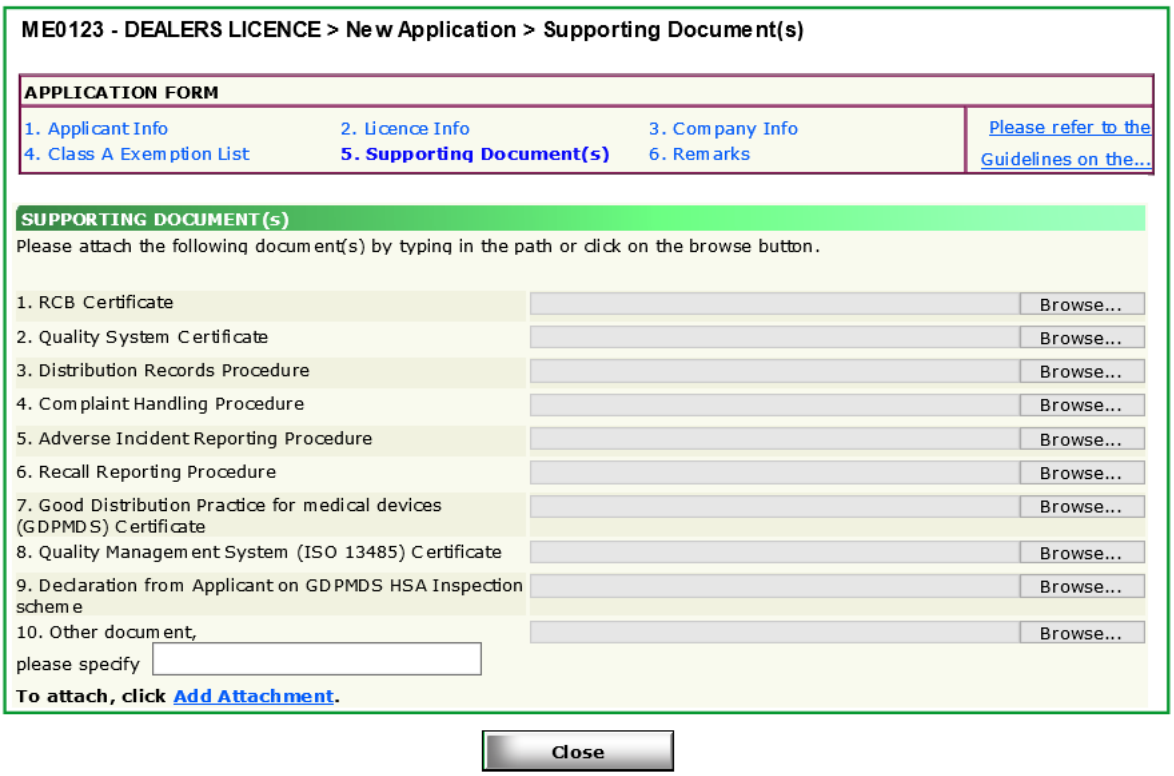
This section is not applicable for Registrant application.



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".**



PART 6 – Remarks

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

Click the "**Confirm**" followed by "Submit" button to submit the application.

END OF DOCUMENT