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

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

The online Amendment 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.

3. **An active Importer, Wholesaler or Manufacturer Licence.**

REFERENCES

The information in the following Regulatory Guidance details the requirements to submit an amendment of dealer licence application.

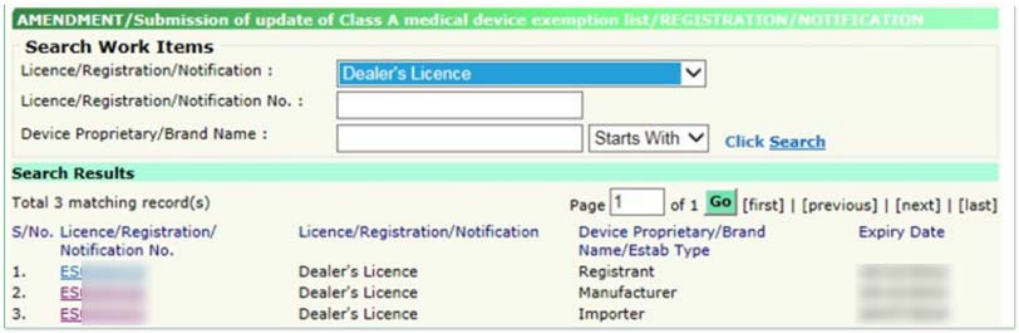
- GN-02: Guidance on Licensing of Manufacturers, Importers and Wholesalers of Medical Devices

PAYMENT

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

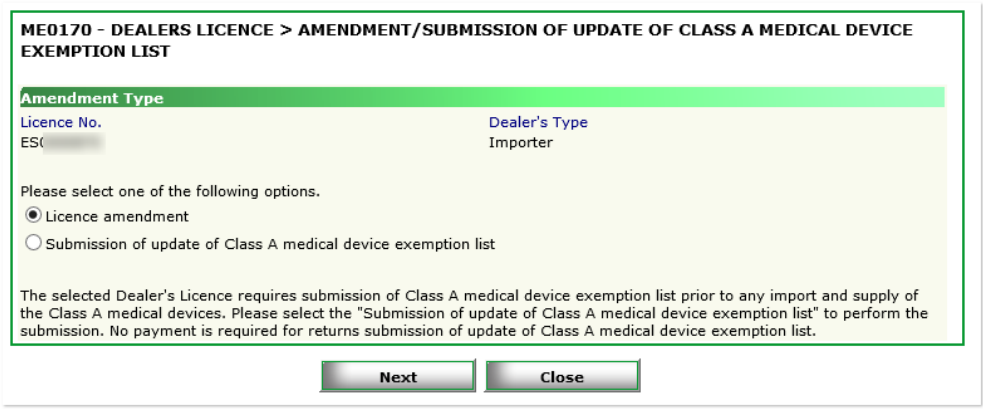
SEARCH SCREEN

This search screen allows you to search for dealer's licence under your company. Eligible dealer's licence will be listed under the search result.



Select **"Dealer's Licence"** from the Licence/Registration Type drop-down list and click **"Search"** to retrieve the dealer's licence accordingly.

After retrieving the dealer's licence, click on the appropriate licence no. to proceed.

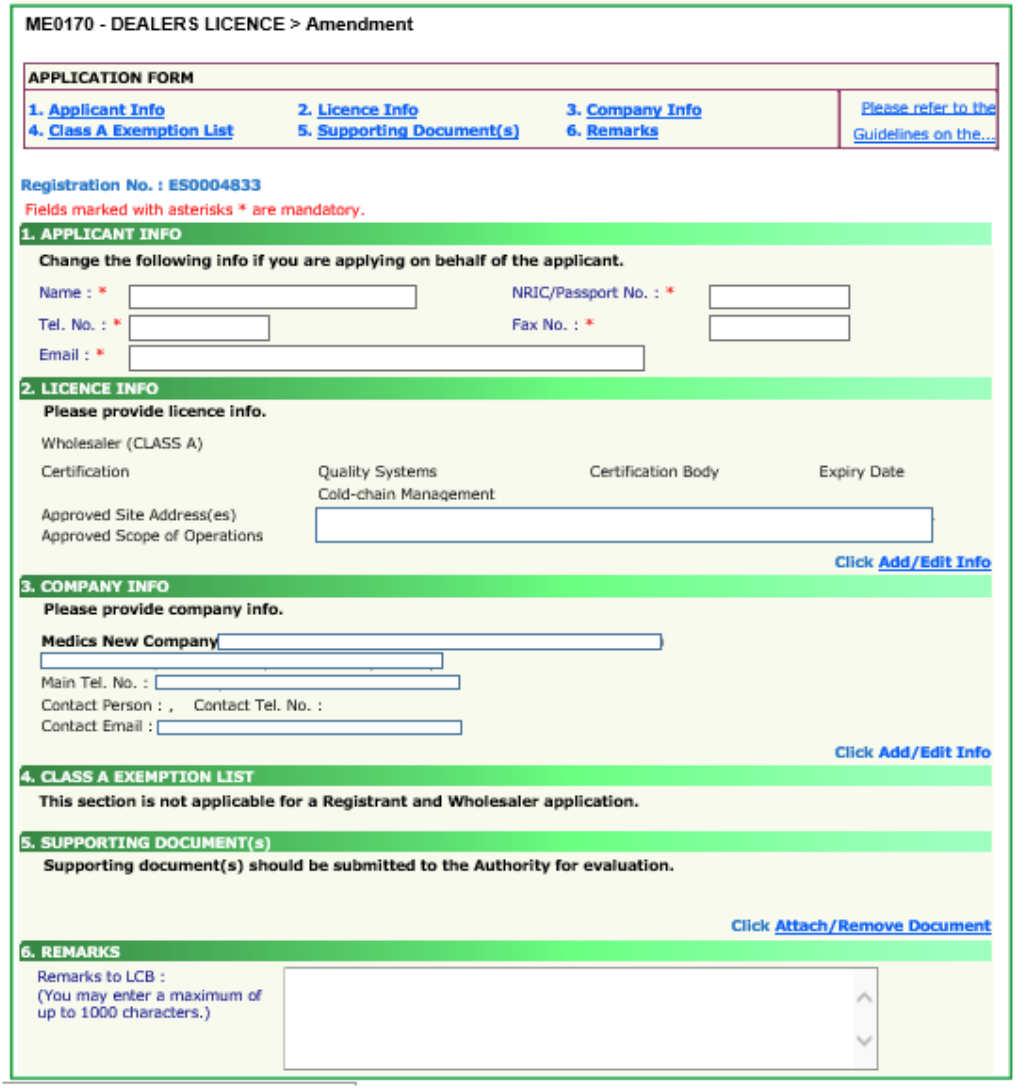


Select "**Licence amendment"** and click "**Next**" to proceed to the online application form.

ONLINE APPLICATION FORM

The online application form consists of 6 parts.

To make an amendment, 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 make any amendments, 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 allows the applicant to update the following fields:

1) Device Type
2) Approved Site Address(es)
3) Certification
4) Approved Scope of Operations

Click the **"Update Form"** Button when the changes are completed.

Amendment fees will be triggered for any change in the following fields:

1) Quality Systems
2) Certification Body
3) Approved Scope of Operations

PART 3 – Company Info

The details in this section can only be changed via MEDICS E-service, Change@medics, "Change of Business Information".

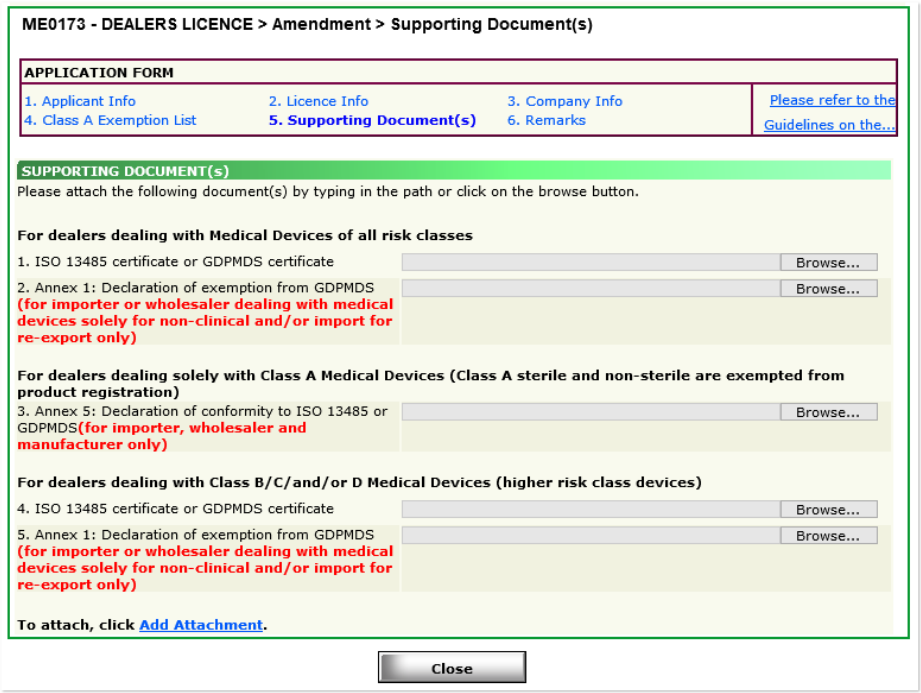
PART 4 – Class A Exemption List

This section is not applicable for amendment applications.

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.

END OF DOCUMENT