

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

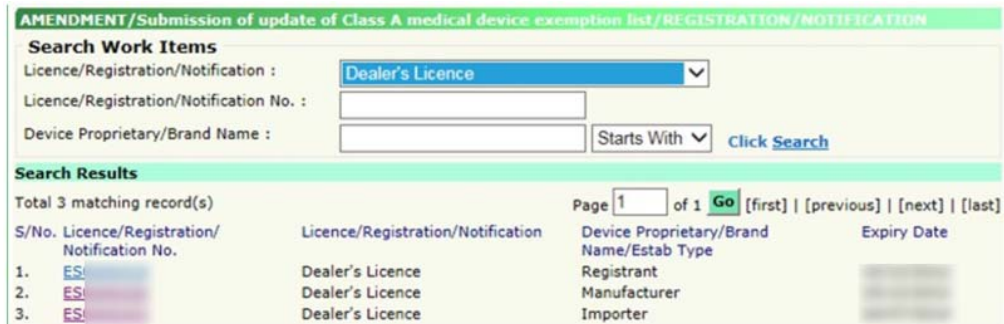
PAYMENT

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.



The screenshot shows a search interface with the following fields and results:

Search Work Items

Licence/Registration/Notification : **Dealer's Licence** (dropdown menu)

Licence/Registration/Notification No. : [Empty text box]

Device Proprietary/Brand Name : [Empty text box] Starts With [Empty dropdown menu] [Click Search](#)

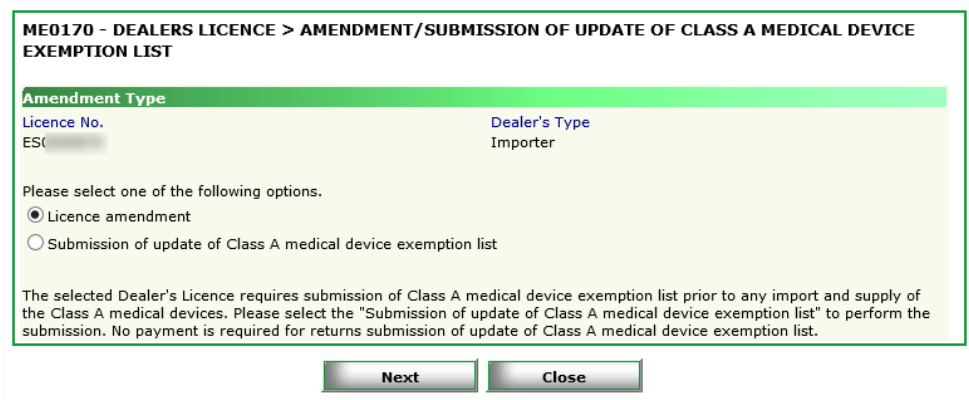
Search Results

Total 3 matching record(s) Page 1 of 1 [Go](#) [first] | [previous] | [next] | [last]

S/No.	Licence/Registration/Notification No.	Licence/Registration/Notification	Device Proprietary/Brand Name/Estab Type	Expiry Date
1.	ES	Dealer's Licence	Registrant	[Redacted]
2.	ES	Dealer's Licence	Manufacturer	[Redacted]
3.	ES	Dealer's Licence	Importer	[Redacted]

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.



The screenshot shows the following information:

ME0170 - DEALERS LICENCE > AMENDMENT/SUBMISSION OF UPDATE OF CLASS A MEDICAL DEVICE EXEMPTION LIST

Amendment Type

Licence No. ES([Redacted]) Dealer's Type Importer

Please select one of the following options.

Licence amendment

Submission of update of Class A medical device exemption list

The selected Dealer's Licence requires submission of Class A medical device exemption list prior to any import and supply of the Class A medical devices. Please select the "Submission of update of Class A medical device exemption list" to perform the submission. No payment is required for returns submission of update of Class A medical device exemption list.

[Next](#) [Close](#)

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

ME0170 - DEALERS LICENCE > Amendment

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

Registration No. : ES0004833
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.

Wholesaler (CLASS A)
Certification Quality Systems Certification Body Expiry Date
Cold-chain Management
Approved Site Address(es)
Approved Scope of Operations

[Click Add/Edit Info](#)

3. COMPANY INFO
Please provide company info.

Medics New Company

Main Tel. No. :
Contact Person : , Contact Tel. No. :
Contact Email :

[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.)

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



The screenshot shows a web form titled "LICENCE INFO" with a green header. A red note at the top states "Fields marked with asterisks * are mandatory." The form contains several sections:

- Dealer Type :** * (dropdown menu)
- Device Type :** * (dropdown menu)
- Importer Medical Device Class:** CLASS A (LOW RISK), CLASS B, CLASS C, CLASS D (HIGHER RISK)
- In Vitro Diagnostic (IVD):** CLASS A IVD (LOW RISK), CLASS D IVD, CLASS C IVD, CLASS B IVD (HIGHER RISK)
- Approved Site Address(es) *:** 1. [text input field] [Click Add/Edit Info](#)
- Certification *:** ISO13485, Declaration of Conformity to Quality Management System (QMS): ISO13485, GDPMDS (Certification Body) [dropdown menu: --Select Certification Body--], Secondary Assembly, Cold-chain Management, Declaration of Conformity to Quality Management System (QMS): GDPMDS, Exempted from GDPMDS (Medical devices solely for non-clinical and/or import for re-export only)
- Expiry Date:** [calendar icon], (dd/mm/yyyy)
- Approved Scope of Operations *:** [text input field]

At the bottom of the form are two buttons: "Update Form" and "Close".

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”.

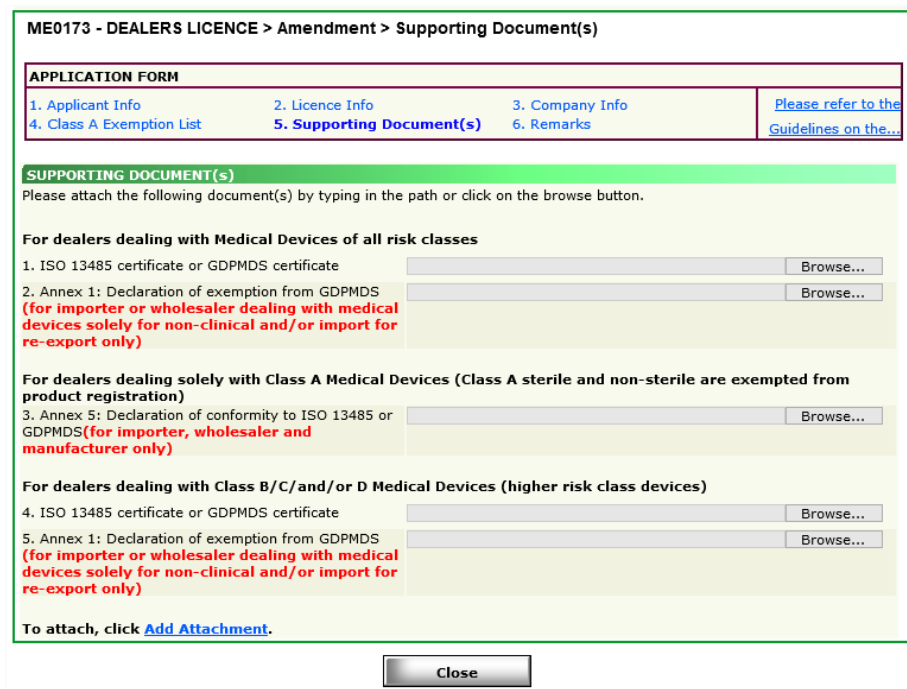
PART 4 – Class A Exemption List

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”.



The screenshot shows a web application window titled "ME0173 - DEALERS LICENCE > Amendment > Supporting Document(s)". It features a navigation menu with six items: 1. Applicant Info, 2. Licence Info, 3. Company Info, 4. Class A Exemption List, 5. Supporting Document(s) (highlighted), and 6. Remarks. A link "Please refer to the Guidelines on the..." is also present. The main content area is titled "SUPPORTING DOCUMENT(S)" and contains instructions: "Please attach the following document(s) by typing in the path or click on the browse button." Below this, there are three sections for different dealer types, each with numbered requirements and "Browse..." buttons:

- For dealers dealing with Medical Devices of all risk classes**
 1. ISO 13485 certificate or GDPMDS certificate
 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)
- 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)
- For dealers dealing with Class B/C/and/or D Medical Devices (higher risk class devices)**
 4. ISO 13485 certificate or GDPMDS certificate
 5. 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)

At the bottom, it says "To attach, click [Add Attachment](#)." and a "Close" button is visible.

PART 6 – Remarks

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

END OF DOCUMENT