

GUIDE TO APPLICATION FOR AMENDMENT OF REGISTRANT

This e-Application at MEDICS@HSA (Medical Device Information & Communication System) allows a Registrant to make amendments to the Registrant Account.

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

http://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/MEDICS_e-Services/Accessing_MEDICS/System_Requirement_for_accessing_MEDICS.html

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. A Registrant Account** that is held by a local company who registers medical devices on behalf of a Product Owner.

Please note that this Amendment of Registrant application is not applicable for changes in UEN number.

PAYMENT

No fees are applicable for this application

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 - Registrant, click on the licence no. for amendment.

MD1410 - AMENDMENT/Submission of update of Class A medical device exemption list/REGISTRATION/NOTIFICATION

AMENDMENT/Submission of update of Class A medical device exemption list/REGISTRATION/NOTIFICATION

Search Work Items

Licence/Registration/Notification : ▼

Licence/Registration/Notification No. :

Device Proprietary/Brand Name : Starts With ▼ [Click Search](#)

Search Results

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

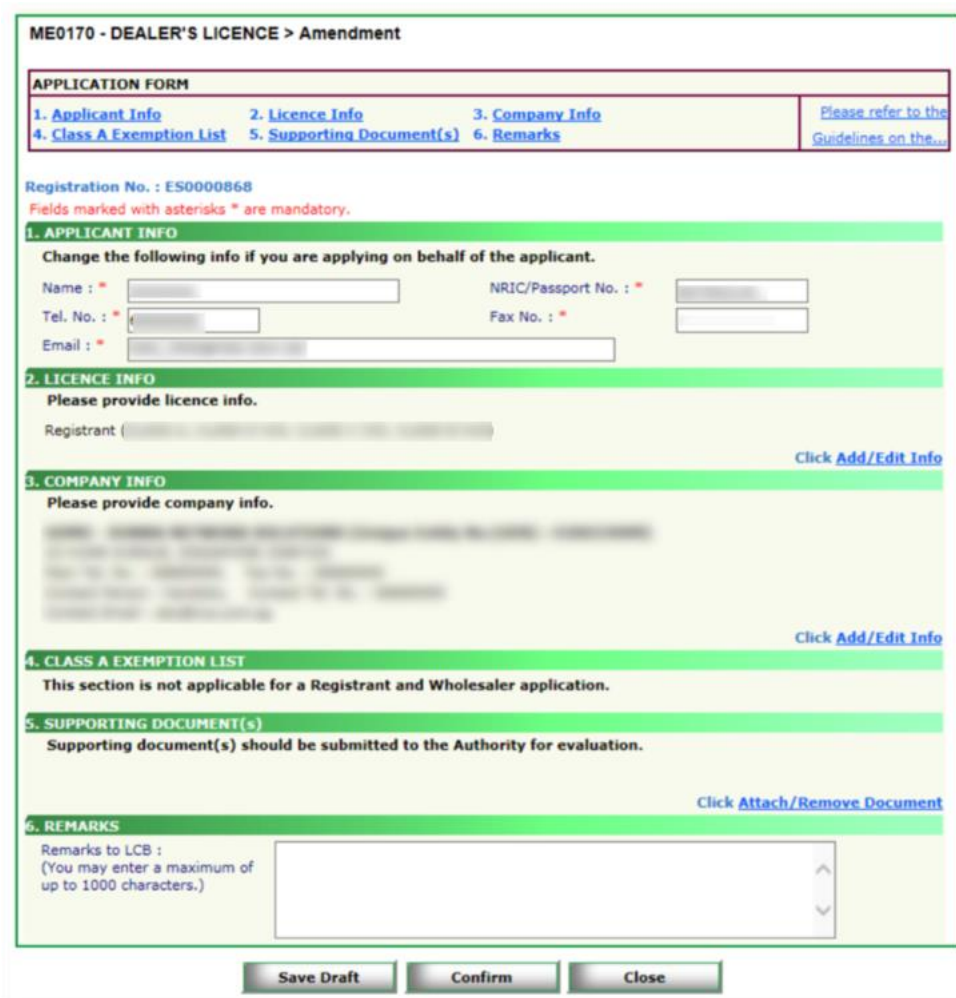
S/No.	Licence/Registration/Notification No.	Licence/Registration/Notification	Device Proprietary/Brand Name/Estab Type	Expiry Date
1.	ES ←	Dealer's Licence	Registrant	
2.	ES	Dealer's Licence	Importer	
3.	ES	Dealer's Licence	Manufacturer	

[Close](#)

ONLINE APPLICATION FORM

The online application form consists of 6 parts. For amendment of Registrant account, Part 4 is not applicable.

To make an amendment, click on “**Add/Edit Info**” to access that section of the form



ME0170 - DEALER'S 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. : ES0000868
 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.

Registrant () [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.)

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:

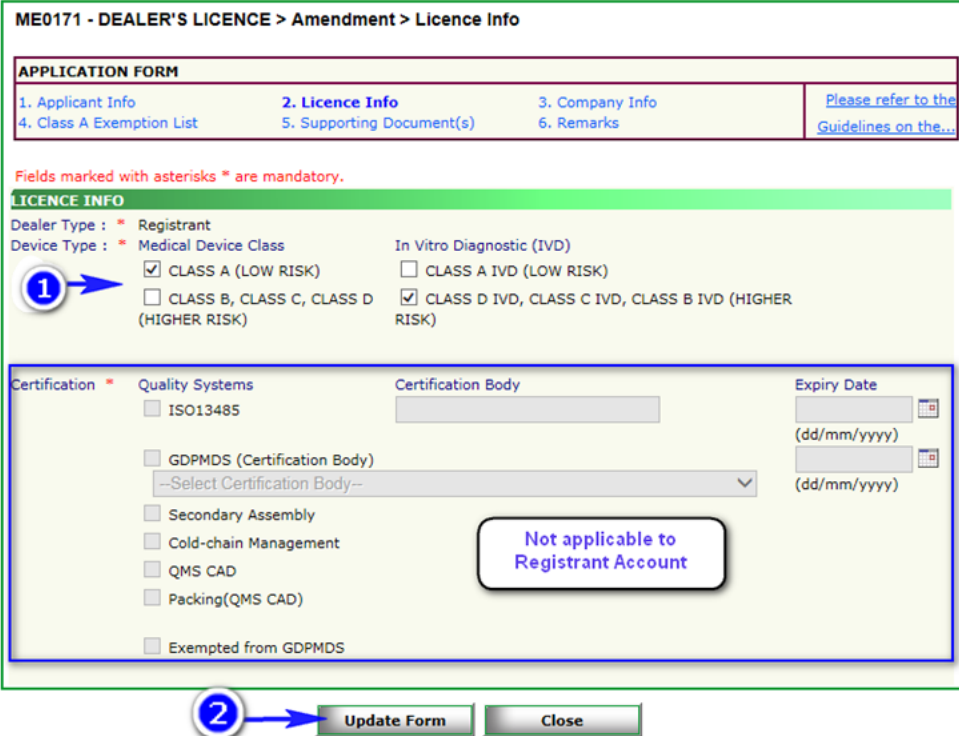
- 1) Name
- 2) NRIC/Passport No
- 3) Contact Telephone Number
- 4) Contact Fax Number
- 5) Contact E-mail

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 update the Licence information.

Click the “**Update Form**” Button when the changes are completed.



ME0171 - DEALER'S LICENCE > Amendment > Licence Info

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.

LICENCE INFO

Dealer Type : * Registrant
 Device Type : * Medical Device Class In Vitro Diagnostic (IVD)

1 → CLASS A (LOW RISK) CLASS A IVD (LOW RISK)
 CLASS B, CLASS C, CLASS D (HIGHER RISK) CLASS D IVD, CLASS C IVD, CLASS B IVD (HIGHER RISK)

Certification * Quality Systems Certification Body Expiry Date

ISO13485 (dd/mm/yyyy)
 GDPMDS (Certification Body) (dd/mm/yyyy)
 --Select Certification Body--
 Secondary Assembly
 Cold-chain Management
 QMS CAD
 Packing(QMS CAD)
 Exempted from GDPMDS

2 → **Update Form** **Close**

Not applicable to Registrant Account

PART 3 – Company Info

This section allows the applicant to update the following fields with no change in the UEN number:

- 1) Company Name
- 2) Postal code and Address
- 3) Main Tel Number
- 4) Fax number
- 5) Contact person
- 6) Contact Tel Number
- 7) Contact email address

Click the “**Update Form**” Button when the changes are completed.

PART 4 – Class A Exemption List

This section is not applicable for Amendment to Registrant.

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**”.

ME0173 - DEALER'S LICENCE > Amendment > Supporting Document(s)

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	

SUPPORTING DOCUMENT(S)

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

1. RCB Certificate	Browse...
2. Assessment form for Class A Medical Device Dealer (form 31 A)	Browse...
3. Factory Licence	Browse...
4. Quality System Certificate	Browse...
5. Distribution Records Procedure	Browse...
6. Complaint Handling Procedure	Browse...
7. Adverse Incident Reporting Procedure	Browse...
8. Recall Reporting Procedure	Browse...
9. Other document, please specify <input style="width: 150px;" type="text"/>	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