

## **GUIDE TO RENEWAL OF MEDICAL DEVICE DEALER'S LICENCE (IMPORTER, WHOLESALER AND MANUFACTURER)**

This e-Application at MEDICS@HSA (Medical Device Information & Communication System) allows a company to submit a renewal application for dealer's licences.

The online [Renewal of Medical Device Dealer's Licence](#) in 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](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](mailto:cris@hsa).
- 3. An active Importer, Wholesaler or Manufacturer Licence.**

### **PAYMENT**

Please refer to the following page for information on payment options:

[http://www.hsa.gov.sg/content/hsa/en/Health\\_Products\\_Regulation/MEDICS\\_e-Services/Accessing\\_MEDICS/Payment\\_Options.html](http://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/MEDICS_e-Services/Accessing_MEDICS/Payment_Options.html)

### SEARCH SCREEN

This search screen allows the applicant to search for dealer's licence under the company. Eligible dealer's licence will be listed under the search result and allow the applicant to select and submit amendment application for their licence.

Select **<Dealer's Licence>** from the "Licence/Registration/Notification" drop-down list, then click **<Search>** to retrieve the dealer's licence(s).

**MD1700 - RENEWAL OF DEALER'S LICENCE / RETENTION OF DEVICE LISTING**

**Search Criteria**

Fields marked with asterisks \* are mandatory.

Licence/Registration Type : \*

Licence/Registration No. :

Dealer's Type :

Expiry Date (dd/mm/yyyy) :  to

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**RENEWAL OF DEALER'S LICENCE / RETENTION OF DEVICE LISTING**

The following Dealer's Licence(s) / Device Listing(s) are due for renewal. If you wish to renew, please select the appropriate radio button(s) for the corresponding Dealer's Licence(s) / Device Listing(s) and click on Next Button.  
Please submit your renewal application before the expiry date, failing which, your Dealer's licence(s) / Device Listing(s) will not be able to be renewed / retained and will be suspended and eventually, cancelled. Please be reminded that payment is required for successful renewal / retention of the licence(s).

**List of Dealer's Licence(s) / Device Listing(s) due for Renewal / Retention**

Total 3 record(s) Page 1 of 1  [First] | [Previous] | [Next] | [Last]

S/No. Licence / Registration No.	Dealer's Type / Device Proprietary / Brand Name	Registration Date	Expiry Date	To Renew
1.	Manufacturer			<input type="radio"/> All Yes <input type="radio"/> All No
2.	Wholesaler			<input type="radio"/> Yes <input type="radio"/> No
3.	Wholesaler			<input type="radio"/> Yes <input type="radio"/> No

**Acknowledgement**

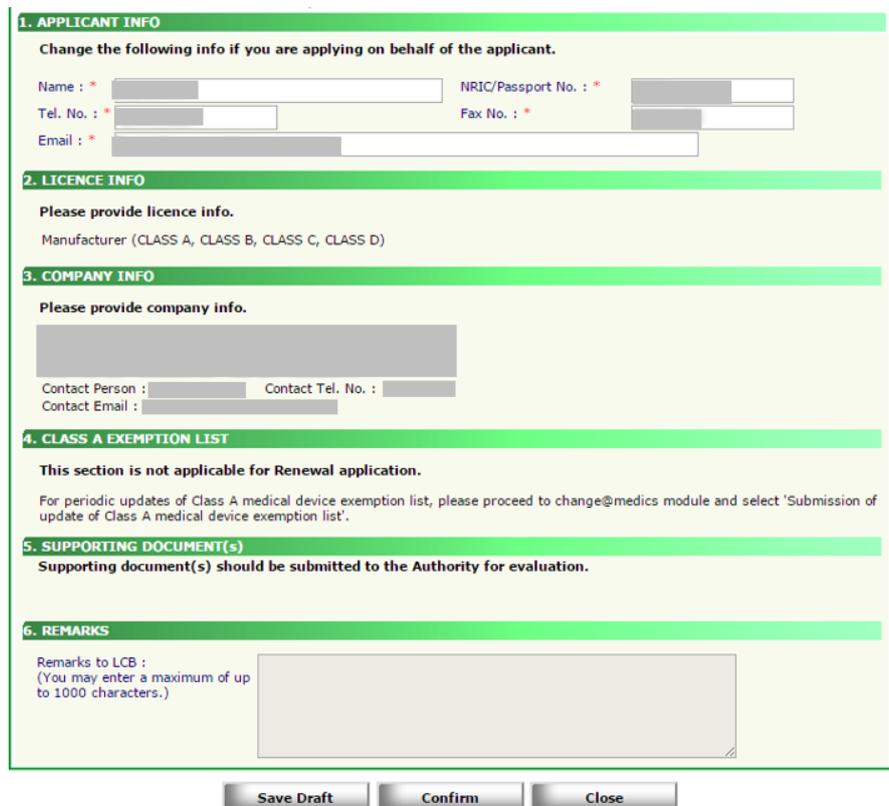
I have read and acknowledge the following:  
I am aware that the following information could be updated during the renewal process for dealer's licences

- a. Particulars of Company's Contact:
  - i. Contact Person, Contact Telephone No. & Contact Email
- b. Particulars of Applicant's Information:
  - i. Telephone No., Fax No. & Email Address
- c. Particulars of Certification
  - i. Good Distribution Practice for Medical Devices (GDPMDS) Certificate
  - ii. Quality Management System Certificate
  - iii. GDPMDS HSA Inspection Scheme

Select **<Yes>** for licences intended for renewal and click **<Next>** to proceed to the Online Application Form for Renewal.

## ONLINE APPLICATION FORM

This online application form consists of 6 sections. Sections 2 to 6 are read-only.



The screenshot displays the online application form with the following sections:

- 1. APPLICANT INFO**: Includes fields for Name, NRIC/Passport No., Tel. No., Fax No., and Email. A note states: "Change the following info if you are applying on behalf of the applicant."
- 2. LICENCE INFO**: Includes a field for Manufacturer (CLASS A, CLASS B, CLASS C, CLASS D). A note states: "Please provide licence info."
- 3. COMPANY INFO**: Includes fields for Contact Person, Contact Tel. No., and Contact Email. A note states: "Please provide company info."
- 4. CLASS A EXEMPTION LIST**: A note states: "This section is not applicable for Renewal application." It also includes a note about periodic updates: "For periodic updates of Class A medical device exemption list, please proceed to change@medics module and select 'Submission of update of Class A medical device exemption list'."
- 5. SUPPORTING DOCUMENT(S)**: A note states: "Supporting document(s) should be submitted to the Authority for evaluation."
- 6. REMARKS**: Includes a text area for Remarks to LCB with a note: "Remarks to LCB : (You may enter a maximum of up to 1000 characters.)"

At the bottom of the form, there are three buttons: "Save Draft", "Confirm", and "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](mailto: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.

## CONFIRMATION PAGE

Upon clicking <Confirm>, the applicant will be redirected to a confirmation page

**1. APPLICANT INFO**  
[ ] (NRIC/Passport No. : [ ]), Tel. No. : [ ] Fax No. [ ] Email : [ ]

**2. LICENCE INFO**  
Manufacturer (CLASS A, CLASS B, CLASS C, CLASS D)

**3. COMPANY INFO**  
[ ]  
Contact Person : [ ] Contact Tel. No. : [ ]  
Contact Email : [ ]

**4. CLASS A EXEMPTION LIST**  
This section is not applicable for Renewal application.

**5. SUPPORTING DOCUMENT(s)**

**6. REMARKS**

**7. ATTESTATION**  
In accordance to Section 24(6) of the Health Products Act, I, on behalf of the licence holder, duly attest & undertake:  
(i) that the information provided in this application to renew the licence is correct and complete, and  
(ii) that all changes, as defined in GN-02 Guidance on Licensing for Manufacturers, Importers and Wholesalers of Medical Devices, made to this licence have been notified to the Authority in the prescribed manner.

Accept  Decline

<< Previous      Submit      Close

### Attestation

The applicant has to read the attestation text in this section and indicate the decision. If the applicant accepts the attestation, the Accept radio button has to be chosen in order for the application to proceed for submission. If the applicant declines the attestation, the application cannot proceed for submission.

Click <Submit> to proceed with submission and payment.

## END OF DOCUMENT