GUIDE TO APPLICATION FOR RETENTION OF REGISTERED DEVICE LISTING (CLASS B, C AND D)

This e-Application at MEDICS@HSA (Medical Device Information & Communication System) allows a Registrant to submit a retention application to extend the expiry date of a medical device that had been given marketing clearance.

This application is only relevant for

- (i)   companies who do not have an existing GIRO arrangement with HSA **OR**
- (i)   companies existing GIRO arrangement with HSA, and
  - a. GIRO deductions have failed during device listing Auto-Retention(s) and
  - b. relevant device listings has entered the show cause period.

The online Retention of Registered Device in MEDICS may take an average of 10-15 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.

4. Medical Device with market clearance and listed in Singapore Medical Device Register (SMDR).

PAYMENT

Online Payment (Credit Card) Only

RENEW@MEDICS SEARCH SCREEN

This search screen allows you to search for registered devices under your company. Eligible device listing will be listed under the search result and allow selection and submission of a Retention Application.

For companies with no GIRO arrangements with HSA:

Select "Registration for High Risk Medical Devices" under Licence / Registration Type and enter the relevant search criteria to retrieve the device listing(s) accordingly.

Please leave the checkbox for "searches registration(s) in show cause period" blank if your device listing is not in the show cause period.

MD1700 - RENEWAL OF DEALERS LICENCE / RETENTION OF DEVICE LISTING

Search Criteria

Fields marked with asterisks * are mandatory.

Licence/Registration Type : *	Registration for High Risk Medical Device ▾
	☐ searches registration(s) in show cause period.
Licence/Registration No. :	
Device Proprietary / Brand Name :	Begins with ▾
Expiry Date (dd/mm/yyyy) :	[ ] 🗓 to [ ] 🗓

Search   Reset

For companies with existing GIRO arrangements with HSA,

Select "Registration for High Risk Medical Devices" under Licence / Registration Type and tick the checkbox to search registration(s) in show cause period to retrieve relevant listings for retention.

MD1700 - RENEWAL OF DEALERS LICENCE / RETENTION OF DEVICE LISTING

Search Criteria

Fields marked with asterisks * are mandatory.

Licence/Registration Type : *	Registration for High Risk Medical Device ▾
	☑ searches registration(s) in show cause period.
Licence/Registration No. :	
Device Proprietary / Brand Name :	Begins with ▾
Expiry Date (dd/mm/yyyy) :	[ ] 🗓 to [ ] 🗓

Search   Reset

After retrieving the device listing(s), under the column **"To Renew"**, select **"Yes"** for the listing(s) you wish to renew and click **"Next"** to proceed to the Online Application Form for Retention.

You may refer to the Singapore Medical Device Register (SMDR) for the device listing as registered by your company at: http://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/MEDICS_e-Services/Singapore_Medical_Device_Register_smdr_MEDICS.html

ONLINE APPLICATION FORM FOR RETENTION

This online application form consists of 4 sections

At the end of the application form, there are 4 button options:

Button – Previous
Allows the applicant to go to the Renew@MEDICS search screen. All information in the current page is not saved will be lost.

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 proceed to the next section. All information in the current page will be auto-saved.

Button – Close
Closes the application form without saving any changes made. You will be brought to Workbench@MEDICS.

SECTION 1 – Applicant Info

The applicant refers to the individual designated by the company as contact point for any correspondence regarding this application.

Items 1 to 3 are pre-populated from CRIS Company Account database and can be updated or replaced.

SECTION 2 – Summary of Licence(s) to be Renewed

This section shows a summary of licences selected for renewal. If you wish to amend the list of licences, please go back to the previous page by clicking the "Previous" button at the end of the form.

SECTION 3 – LOA For Device Licences

Submission of LOA during retention is no longer required. No action is required in this section.

SECTION 4 – Remarks

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

CONFIRMATION PAGE

Upon clicking the **"Confirm"** button, you will be redirected to a confirmation page. This section allows you to review your selection of device listings and make attestations to proceed with the retention of the selected listing(s).

Please select **"Agree"** under **Section 5 – Attestation** and click the **"Submit"** button to proceed to the payment page.

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

APPLICATION FORM

| 1. Applicant Info | 2. Summary of Licence(s) to be renewed | 3. LOA for Device Licence(s) |
| 4. Remarks | 5. Attestation | |

1. APPLICANT INFO

Change the following info if you are applying on behalf of the applicant.

2. SUMMARY OF LICENCE(S) TO BE RENEWED

S/No.	Licence/Registration No.	Device Name	Device Class	Expiry Date
1				

3. LOA FOR DEVICE LICENCE(S)

LOA is no longer required for all device licences.

4. REMARKS

5. DECLARATION

All applicants under the Medicines Act (MA) / Health Products Act (HPA) / Poisons Act (PA) must comply where applicable, with the MA/HPA/PA and their corresponding regulations. This is to ensure that all health products in Singapore meet the required standards of safety, quality and efficacy. Applicants must also comply with all other applicable laws and their regulations.

6. ATTESTATION

In accordance to Section 30(10) of the Health Products Act, I, on behalf of the product owner and registrant, duly attest & undertake:
(i) that this registrant remains authorised by the product owner to be the registrant of medical devices under this listing,
(ii) that the registrant remains aware and complies with all product registration conditions issued for medical devices under this listing,
(iii) that all certifications (e.g. ISO 13485 certificate for manufacturing site) relating to the product registration remain valid and will be submitted to the Authority upon request, and
(iv) that all changes, as defined in GN-21 Guidance on Change Notification, made to medical devices registered under this listing have been notified to the Authority in the prescribed manner.

○ Agree ● Decline

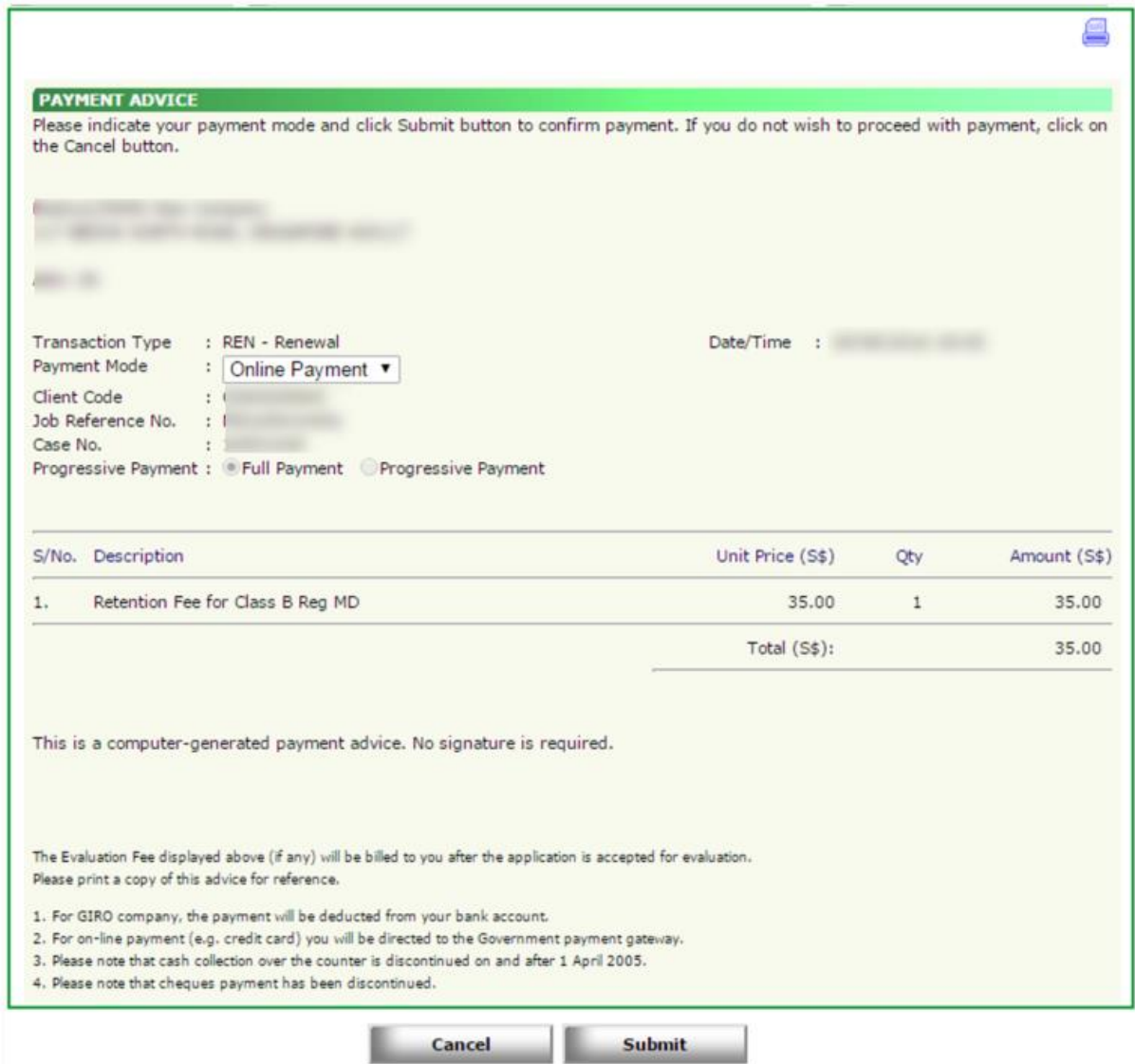[<< Previous]   [Submit]   [Close]

PAYMENT ADVICE

Upon submitting the Attestation, applicant will be prompted to make payment. Only Credit Card will be accepted for payment under "Online Payment".

The payment advise will be generated for your review before submitting for payment. The total amount to be charged for listings based on risk class will be tabulated in the advice.

You will be directed to the Government Payment Gateway for Online Payment.

To confirm the payment, click the **"Submit"** button.

To cancel the transaction, click the **"Cancel"** button.

Upon clicking the **"Submit"** button, you will be redirected to a payment acknowledgement page.

To complete the transaction, please click the **"Done"** button.

ACKNOWLEDGEMENT

Upon successful submission and payment of the retention application, the acknowledgement page will be displayed, and the expiry dates of the selected device listings will be extended upon approval.

END OF DOCUMENT