

GUIDE TO APPLICATION FOR FREE SALES CERTIFICATE

This e-Application at MEDICS@HSA (Medical Device Information & Communication System) allows a Registrant to apply for a Free Sales Certificate (FSC) for medical device products listed on the Singapore Medical Device Register (SMDR) for local commerce.

The online [Free Sales Certificate Application](#) 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 marketing clearance and listed on the Singapore Medical Device Register (SMDR)

In the application, you will be required to provide with the following information:

- 1) Only ONE single Product Owner for devices to be included in each application. Free Sales Certificates are issued based on the name of the Product Owner / Brand Owner.
- 2) Softcopy of the following support documents need to be prepared. They are submitted as attachments in the application:
 - a. Device labels for the importing country
 - b. Schedule and Appendix for inclusion in the Certificate
(Please email to hsa_md_info@hsa.gov.sg for relevant templates)

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

ONLINE APPLICATION FORM FOR CANCELLATION

This online application form consists of 6 parts

1. Applicant Info
2. Product Owner Information
3. Device Info
4. Importing Country
5. Supporting Documents
6. Remarks

For Parts 2 to 4, click on “Add/Edit Info” to access this section of the online form.

For Parts 5, click on “Attach/Remove Document” to attach relevant supporting documents.

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 proceed to the confirmation page to verify the information in the completed form and make relevant declarations. All information in the current page will be auto-saved.

To amend any mistake from the Confirmation page, click on the “<< Previous” Button to return to the Application Form. Before the application is submitted, you may print a copy the application for your record.

Upon submission, an acknowledgement containing the Job Reference number will be displayed. This Job Reference number will be used for future reference in all communications. If required, you may wish to print this acknowledgement page.

Button – Close

Closes the application form without saving any changes made. You will be brought to [Workbench@MEDICS](#).

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 – Product Owner Info

This section requires you to select the product owner of the product.

The Product Owner is selected from a list of Product Owners that the Registrant is representing in Singapore and whose medical device products are registered and listed on the Singapore Medical Device Register. Once the Product Owner is selected, click on “Populate” to populate the form.

Note:

- The lists of devices available in “PART 3 – Device Info” are devices that belong to the selected Product Owner.

Click the “**Update Form**” Button when this part is completed

PART 3 – Device Info

This section allows you to select medical device products of a product owner selected in Part 2 to be included in the FSC. The selection is made through the following two steps:

1. Selection of medical device:

Enter partial or full device name and click on the “Search”.

A list of devices belonging to the Product Owner selected will be shown. Check the corresponding checkbox to select any of the devices and click “Add”

To remove a medical device from the “List of Device(s) Selected”, select the corresponding checkbox and click “Remove”.

2. Select Manufacturing Site

For each selected device, click on “[Add Mfr Site]” to select the manufacturing site required for the certificate.

The list of manufacturing sites is according to information registered with MDB. Select the corresponding checkbox to select the manufacturing site and click “Add”.

To remove a manufacturing site from the “List of manufacturing sites selected”, select the corresponding checkbox and click “Remove”.

Click the “**Update Form**” Button when this part is completed

PART 4 – Importing Country

This section requires you to fill in the following:

1. *Name of Importing Country*
2. *Consignee Name*
3. *Address*
4. *City*
5. *State*
6. *Province*

After completing the above fields, click on “**Add**” to add the country details.

To edit the details after adding the country and consignee info, click on the corresponding **[Edit]** hyperlink.

To remove a country from the “List of Importing Countries and Consignees Added”, select the corresponding checkbox and click “**Remove**”.

Click the “**Update Form**” Button when all this part is completed

PART 5 – Supporting Document(s)

The supporting documents are attached by browsing the local storage devices for the documents using the “**Browse**” button, and attaching these documents by clicking on the “**Add Attachment**”.

To remove documents from the “**list of documents attached**”, select the corresponding checkbox and click “**Remove Attachment**”.

Click the “**Update Form**” Button when all required documents are attached.

SECTION 6 – Remarks

You may insert any remarks here to MDB regarding the application.

END OF DOCUMENT