GUIDE TO APPLICATION FOR EXPORT CERTIFICATE

This e-Application at MEDICS@HSA (Medical Device Information & Communication System) allows a Registrant to apply for a Export Certificate for medical device products that have been notified via Export Notification.

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

4. **Approved Export Notification(s)** for the relevant devices

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. Export Certificates are issued based on the name of the Product Owner / Brand Owner.

2) The softcopy of the following support documents need to be prepared. Please submit these documents as attachments in the application:
   - Device Label for the importing country
   - Instructions of Use (for verification of intended use)
   - Schedule and Appendix for inclusion in the Certificate (Please email to hsa_md_info@hsa.gov.sg for the templates)
   - Copies of updated QMS/ISO documentation e.g. ISO 13485 certificate

PAYMENT

Please refer to the following page for information on fee and payment modes:
https://www.hsa.gov.sg/medical-devices/fees.

ONLINE APPLICATION FORM

This online application form consists of 6 Sections.

For Sections 1 to 4, click on **"Add/Edit Info"** to access that section of the form.

For Section 5, clock on **"Attach/Remove Document"** to attach relevant supporting documents.

At the end of the application form, there are 3 button options for the you to select:

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.

Acknowledgement page will be shown once the applicant has submitted the form. The Job Reference number will be given in this acknowledgement page and will be used for future reference. If required, the applicant can print this acknowledgement page.

The submitted Application Form can be retrieved from *"Inbox"* in the Workbench@MEDICS.

The job of this application form will be indicated as
- 'pending' after submission to MDB,
- 'input request' if any further information required by MDB,
- 'approved' for approval by MDB,
- 'rejected' for rejection by MDB,
- 'withdrawn' if applicant submitted a withdrawal application to MDB.

MDB will send an email notification to applicant (and cc. to Registrant's account contact person) if there is any update on its status.

Button – Close
Closes the application form without saving any changes made.

SECTION 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.

SECTION 2 – Product Owner Info

This section requires you to fill in the following Product Owner Informaiton:
1) *Company Name*
2) *Address Type*
3) *Postal Code*
4) *Block/No*
5) *Street Name*
6) *Building Name*
7) *Level-Unit*
8) *Country*
9) *Main Telephone No.*
10) *Fax No.*
11) *Contact Person*
12) *Contact Telephone No.*
13) *Contact Email*

Item 2: Address Type – to select Singapore (Local) or Foreign (Overseas) address.
Item 3: Postal Code – Only applicable for local addresses

If the Product Owner is a foreign company and item 2 is selected as "Overseas", items 3 to 8 will be replaced by:

3) *Address (If select Overseas)*
4) *Country*
5) *City*
6) *State*
7) *Province*

SECTION 3 – Device Info

This section allows you to add devices to the application in 2 Steps:

Step 1: Selection of medical device

Input the following information:

- **Device Proprietary/Brand Name** - selected from the list of medical devices notified to HSA as export only (via Export Notification)
- **Description of Intended Use**

Click "Add" to include the device

To edit the details after adding the medical device, click on the corresponding **[Edit]** hyperlink.

To remove a medical device from the "**List of Medical Device(s) Added**", select the corresponding checkbox and click "**Remove**".

Step 2: Selection of Manufacturing Site

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

Enter partial or full manufacturing site name and click on "**Search**" to find the manufacturing site.

The manufacturing sites available for selection are dealers holding valid Manufacturer's Licence.

Select the corresponding checkbox to select the manufacturing site and click "**Add**".

To remove a manufacturing site from the "**List of manufacturing site(s) selected**", select the corresponding checkbox and click "**Remove**".

Click the "**Update Form**" Button when all information are added.

SECTION 4 – Importing Country

This section requires the following fills to be completed:

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 information are added.

[NOTE: If applicable, MDB may request for evidence of informed consent from regulatory agencies of importing countries for the export of medical devices into their countries]

SECTION 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