

GUIDE TO APPLICATION FOR NOTIFICATION OF EXPORT-ONLY UNREGISTERED MEDICAL DEVICES

This e-Application at MEDICS@HSA (Medical Device Information & Communication System) allows a registered company with an Export-Only Establishment Licence to notify the Authority on export of medical device not intended for Singapore market.

The online [Export Notification](#) 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.

REFERENCE

Not Applicable

PAYMENT

No fees are relevant to this application

ONLINE APPLICATION FORM

This online Application Form consists of 5 parts.

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.

PART 1 – Notification Type

This section requires the applicant to select the type of notification:

Notification for Export

PART 2 – 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 3 – Device Info

This section requires the applicant to fill in the Device information.

Devices can be added individually “online” or by “batch” upload of data file.

- A) If you wish to fill in the device information individually, please select the “**online**” option and complete the following field(s):

1) Device Proprietary/Brand Name

This refers to the name of the device as it appears on the product label.

- (i) To add more devices, enter the number of additional devices needed and then click “**Add**”.
- (ii) To remove a device from the list of devices added, select the corresponding checkbox and click “**Remove**”.



The screenshot shows a web form titled "MD0911 - NOTIFICATION FOR EXPORT > New Application > Add Device Info (Online)". It features a navigation bar with tabs for "1. Notification Type", "2. Applicant Info", "3. Device Info" (selected), "4. Supporting Document(s)", and "5. Remarks". A red note states "Fields marked with asterisks * are mandatory." The "ADD DEVICE INFO" section includes a text input for the number of additional devices, a "Device Proprietary/Brand Name*" field with a checkbox, and a "Symbol" field. A "Remove" instruction and a "Remove" button are also present. At the bottom, there are "Update Form" and "Close" buttons.

Click the “**Update Form**” Button when all devices are added.

- B) If you wish to fill in the device info by uploading of an excel spreadsheet, select the “batch” option and complete the following steps:
- i.* Download the template by clicking on the “download” hyperlink
 - ii.* Save the Microsoft Excel spreadsheet “**ImpExpNotfnBatch.xls**” to the local storage device
 - iii.* Open the spreadsheet. Please **ENABLE MACROS** for the template.
 - iv.* Enter the device Proprietary/Brand Name into the relevant fields.
 - v.* Once all the devices are added, generate the data file by clicking on the “**GenerateFile**” button in the Excel spreadsheet. A text file will be generated and save on the local storage device with the file name “**ImpExpNotfnBatch.txt**”
 - vi.* Return to the on-line form webpage and click “**upload**”. An upload file pop-up will appear. Use the “Browse” button to browse the local storage devices for the document and click on “Upload” to upload the file.

To remove a device from the “list of Medical Device(s) added”, select the corresponding checkbox and click “Remove”.

IMPORTANT: Once the list of Medical Device is populated, subsequent upload of file will overwrite the current list.

Click the “**Update Form**” Button when all devices are added.

PART 4 – 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.

PART 5 – Remarks

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

END OF DOCUMENT