

GUIDE TO APPLICATION FOR WITHDRAWAL OF APPLICATION

This e-Application at MEDICS@HSA (Medical Device Information & Communication System) allows a Registrant to withdraw applications that have been submitted to MDB but yet to be approved or rejected.

The online Withdrawal of 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. 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
 - <u>Corppass</u> (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.
- An application has been submitted via MEDICS that has not yet been approved or rejected.

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

- 1) The following type of applications can be withdrawn
 - Dealer's Licence and Registrant Account
 - Product Registration Application for Higher Risk Medical Device
 - Change Notification for Higher Risk Medical Device
 - Free Sales Certificate Application
 - Export Certificate Application

These applications should have a job status of Pending or Input Request.

- 2) The following types of applications CANNOT be withdrawn:
 - Withdrawal of Application
 - Amendment of Licence
 - Cancellation of Licence

ONLINE APPLICATION FORM

This online application form consists of 2 Steps.

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At the end of the application form, there are 2 button options for the you to select:

Button - Confirm

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.

Button - Close

Closes the application form without saving any changes made.

STEP 1 - Search Work Items

This section allows you to search for and select the relevant application for withdrawal.

The applicant can select the type of application from a drop-down list:

- 1) Job Type:
 - a) All
 - b) Pre-Market Application
 - c) Supplementary for Pre-Market Application
 - d) Establishment Licence
 - e) Registration for Higher Risk Medical Device
 - f) Registration for Low Risk Medical Device
 - g) Free Sales Certificate
 - h) Export Certificate

The applicant can also search by:

- a) Job Reference No.
- b) Device Proprietary/Brand Name

Click on "Search" to commence the search.

Search Results

The search results will be displayed as follows:

- 1) S/No.
- 2) Submission Date
- 3) Job Reference No
- 4) Job Type
- 5) Job Status

Click on the job reference number of the relevant application to proceed with withdrawal.

STEP 2 - Withdrawal Form

This part has two buttons:

Button - Submit



A pop-up window will ask the applicant to "Click OK to proceed with withdrawal or Cancel to abort the withdrawal application". Clicking "**OK**" will submit the application to MDB and present the applicant an acknowledgement page with a job reference number for the cancellation application.

Button - Close

Will close the application form without saving any changes made.

The Withdrawal Form consists of 3 sections:

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.

2) Application Info

The display of information details for the application to be withdrawn as follows:

- 1) Job Type
- 2) Job Reference No
- 3) Submission Date
- 4) Status

Item 2: Click on this item to fully view the application that was to be withdrawn

Item 4: Shows the status of the application

3) Remarks

In this Section, the applicant can enter the "Reason for withdrawal" in the space provided.

END OF DOCUMENT

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