

GUIDE TO APPLICATION FOR GLOBAL UPDATE OF APPLICANT DETAILS

This e-Application at MEDICS@HSA (Medical Device Information & Communication System) allows a Registrant to make amendments to the Importer, Wholesaler and Manufacturer's licence.

The online [Global Update of Applicant Details application](#) 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. 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.

PAYMENT

No fees are applicable for this application.

GRANTING OF ACCESS RIGHTS FOR E-SERVICE

This CRIS Management Module can only be accessed by the company's CRIS Admin. This can be accessed via cris@hsa.

Login ID: REX

View Admin Manage Users

CR0002 CRIS MANAGEMENT MODULE > VIEW ADMIN

Client Info Help	
Client Code	C09000955P
Client Name	FLOWERY FASHION CHG 3
Location Code	1 - HQ
Auto-renewal Scheme	<input checked="" type="checkbox"/> (Note: Checked:Opt-in; Unchecked:Opt-out) Save Preference

[HSA Pin - CT Protocol Mapping](#)
[Grant drafter access to specific applications](#)

8 Records Page 1 Of 1 Pages

List of CRIS Administrators		
SingPassID / HSA PIN	User Name	Admin Status
REX	REXX TA (OSC)	Active
S2547610G	S2547610G	Active
S2571562D	S2571562D	Active
S1234567G	Teo Xiong	Active
S1234567H	Teo Xiong	Active
S0750212E	Tester (updated)	Active
S0750213C	Tester_01	Active
G8401234F	Wong Sai Seng	Active

Click on **“Manage Users”** tab to see the list of currently registered employees






Login ID: REX

View Admin Manage Users

CR0001 CRIS MANAGEMENT MODULE > MANAGE USERS

Client Info Help	
Client Code	C09000955P
Client Name	FLOWERY FASHION CHG 3
Location Code	1 - HQ
Auto-renewal Scheme	<input checked="" type="checkbox"/> (Note: Checked:Opt-in; Unchecked:Opt-out) Save Preference

5 Records Page 1 Of 1 Pages

List of Authorised Users							
Select All	SingPassID/HSA PIN	User Name	Role	Status	Effective Date	Expiry Date	Edit
<input type="checkbox"/>	H0000612	ANDREA SUSAN OWEN	Staff	Active	14-09-2012		
<input type="checkbox"/>	H0000203	Law		Active	01-08-2011		
<input type="checkbox"/>	S6842925J	RAM (OSC)	Staff	Active	06-09-2012		
<input type="checkbox"/>	S1474890C	Test_Staff	Staff	Active	18-02-2013		
<input type="checkbox"/>	H0000211	8019912770	Staff	Suspended	01-08-2011		

Add User Delete User

To grant Submitter role for the Global Update of Applicant Details eService to a particular employee, click on the **yellow edit icon** of that employee

Select **“Medical Devices”** from the **“Available Rights”** drop-down list to see the list of all MEDICS eServices

Check **“Change Applicant Info”**

Click on the radio button under the **“Submitter”** column

Click **“Submit”** to save the changes in access right of the employee

CR0003 CRIS MANAGEMENT MODULE > EDIT USER

Client Info		Help
Client Code	C09000955P	
Client Name	FLOWERY FASHION CHG 3	
Location Code	1 - HQ	

Fields marked with an asterisk * are mandatory.

Edit User Particulars			
SingPass ID / HSA PIN : *	SingPass ID S1474890C		
User Name *	Mr	Test_Staff	
ID Number *	Pink	S1474890C	
Telephone No			
Designation			
Effective Date *	18-02-2013	(dd-mm-yyyy)	
Expiry Date		(dd-mm-yyyy)	
Role *	Staff		
Status *	Active		
Available Rights *	Medical Device		
	Eservices (Select either Submitter/Drafter when you select an Eservice)	Submitter	Drafter
	<input type="checkbox"/> Adverse Incident Notification/Reporting		
	<input type="checkbox"/> Amendment of Licence/Registration/Notification		
	<input type="checkbox"/> Cancellation of Licence/Registration/Notification		
	<input checked="" type="checkbox"/> Change Applicant Info	<input checked="" type="radio"/>	<input type="radio"/>
	<input type="checkbox"/> Establishment Licence Application		
	<input type="checkbox"/> Establishment Licence Application (test)		
	<input type="checkbox"/> Free Sales Certificate Application		
	<input type="checkbox"/> Licence Enquiry for MEDICS		
	<input type="checkbox"/> MEDICS Workbench		
	<input type="checkbox"/> Management of Distributors		
	<input type="checkbox"/> Management of View Access for Medical Devices		
	<input type="checkbox"/> Notification for Import/Export		
	<input type="checkbox"/> Online Enquiry on Incident Report/Recall		
	<input type="checkbox"/> Pre-Market Application	<input type="radio"/>	<input type="radio"/>
	<input type="checkbox"/> Public Enquiry - SMDR		
	<input type="checkbox"/> Recall Notification/Reporting		
	<input type="checkbox"/> Registration for Clinical Investigation		
	<input type="checkbox"/> Registration for Custom-made Devices		
	<input type="checkbox"/> Registration for Higher Risk Medical Device		
	<input type="checkbox"/> Registration for Low Risk Medical Device		
	<input type="checkbox"/> Registration for Special Access Scheme (SAS)		
	<input type="checkbox"/> Renewal of Licence/Registration/Notification (Company with GIRO)		
	<input type="checkbox"/> Renewal/Retention of Licence/Registration	<input type="radio"/>	<input type="radio"/>
	<input type="checkbox"/> Status Enquiry for MEDICS		
	<input type="checkbox"/> Supplementary for Pre-Market Application		
	<input type="checkbox"/> Voluntary Adverse Incident Notification		
	<input type="checkbox"/> Withdrawal of Application		

Submit Cancel

SEARCH FORM

MD1410 - AMENDMENT OF LICENCE/REGISTRATION/NOTIFICATION

GLOBAL UPDATE OF APPLICANT DETAILS

Search Work Items

Licence/Registration/Notification Type :

Licence/Registration No. :

Job Reference No. :

Current Applicant NRIC/Passport. :

All search criteria are optional

- To retrieve some particular licences and/or registrations and/or pending applications to update the applicant information, specify the search criteria accordingly.
- To transfer all licences, registrations and pending applications from one employee to another, enter the NRIC/Passport No. of the current employee holding the licences, registrations and pending applications to the Current Applicant NRIC/Passport. and click Search

Upon clicking Search, the list of applicable licences, registrations and pending applications will be displayed.

Select the licences, registrations and/or pending applications that you wish to update by selecting the relevant checkbox(es) and click **"Next"**

ONLINE APPLICATION FORM

The online application form consists of 3 parts.

MD1412 - GLOBAL UPDATE OF APPLICANT DETAILS> New Application

1. [Applicant Info](#) 2. [Summary of applications/licences/registrations to be updated](#) [Please refer to the Guidelines on the...](#)
3. [Remarks](#)

1. APPLICANT INFO

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

Name : * NRIC/Passport No. : *

Tel. No. : * Fax No. : *

Email : *

2. SUMMARY OF APPLICATIONS/LICENCES/REGISTRATION TO BE UPDATED

S/No.	Licence/Registration No.	Job Type	Dealer's Type/Device Proprietary/Brand Name	Registration Date	Expiry Date
1					
2					
3					
4					

3. REMARKS

Remarks to MDB :
(You may enter a maximum of up to 1000 characters.)

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

Button – Previous

Bring the applicant back to the search form to amend the selection. If the Global Update of Applicant Details draft is accessed from Workbench, this button will not be available.

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.

Button – Close

Closes the application form without saving any changes made.

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 update the following to the new applicant information:

- 1) Name
- 2) NRIC/Passport No
- 3) Contact Telephone Number
- 4) Contact Fax Number
- 5) Contact E-mail

PART 2 – Summary of Applications / Licences / Registration to be updated

This section is read-only. If you intend to make amendments to this list, please click “Previous” to go back to the Search Form.

PART 3 – Remarks

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

END OF DOCUMENT