

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 <u>Global Update of Applicant Details application</u> 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
 - <u>Corppass</u> (Singapore Corporate Access), a corporate digital identity for business and other entities to transact with Government online services, OR
 - <u>HSA PIN</u> (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 <u>cris@hsa</u>.
- 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 IO (HEX					
CR0002 CRI	S MANAGEMENT	MODULE > VIEW ADMIN	View Admin	Manage ches	
Client Info	1			E.	
Client Code Client Name	C09000955P FLOWERY FASHIO	N CHG 3			
ocation Code	1-HQ +				
Auto-renewal Scheme	🗷 (Note: Checked	Opt-in: Unchecked; Opt-out)	Save Preference		
List of CRIS Ad	Immistrators				
SingPasot0 / H	SA P91	User Name	Admin Status		
	REX	REXX TA (OSC)		Active	
\$2547610G		\$2547610G		Active	
525715620		82571562D		Active	
\$1234567G		Teo Xiong		Active	
S12	234567H	Tep Xiong		Active	
50	750212E	Tester (updated)		Active	
50	750213C	Tester_01		Active	
Ga	401234F	Wong Sai Seng		Active	

Click on "Manage Users" tab to see the list of currently registered employees

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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



CRODO3 CRIS I	MANAGEMENT MODULE > EDIT USER						
Client Info			tinia				
Client Code	0900085P						
Location Code	1-HQ						
ields marked with	an asterisk * are mandatory.						
Edit User Partic	ulars						
SingPass ID / HS	A PIN: SingPass ID S1474890C	SingPass ID 51474890C					
User Name *	Mr • Test_Staff	Nr • Test_Staff					
ID Number *	Pink • \$1474890C	Pink • \$1474890C					
Telephone No							
Designation							
Effective Date *	18-02-2013 (dd-mm-yyy)	18-02-2013 Edd-mm-ww)					
Expiry Date	(mm-yyy)	(dd-mm-ww)					
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Status *	Adive -						
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	Economic (Select atther Submitter/Direfter when you select on Economic	submitter	Draffer				
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	Change Applicant Info		0				
	Establishment Licence Application						
	Establishment Licence Application (test)						
	Free Sales Certificate Application						
	Licence Enguiry for MEDICS	C Licence Enguiny for MEDICS					
	E MEDICS Workbench	C MEDICS Workbanch					
	Management of Distributora						
	Management of View Access for Medical Devices						
	Notification for Import/Export						
	Online Enquiry on Incident Report/Recall						
	Pre-Market Application						
	Public Enquiry - SMDR						
	Recall Notification/Reporting	E Recall Notification/Reporting					
	Registration for Clinical Investigation	C Registration for Clinical Investigation					
	Becestration for Custom-made Devices						
	Registration for Higher Risk Medical Device	Registration for Higher Risk Medical Device					
	Registration for Low Disk Medical Device	Registration for Low Risk Medical Device					
	Department of Control Access Otheres (GAD)						
	Registration of special Access scheme (SAS)	-					
	L1 Renewal of Licence/Registration/Hothcation (Company with GIRC)	0					
	RenewauRetention of Licence/Registration	Renewal/Retention of Licence/Registration					
	Status Enquiry for MEDICS						
	Supplementary for Pre-Market Application						
	Voluntary Adverse Incident Notification						
	Withdrawal of Application						

Submit Cancel



SEARCH FORM

MD1410 - AMENDMENT OF LICENO	CE/REGISTRATION/NOTIFICATION
GLOBAL UPDATE OF APPLICANT DETA	AILS
Search Work Items	
Licence/Registration/Notification Type :	▼
Licence/Registration No. :	
Job Reference No. :	
Current Applicant NRIC/Passport. :	
Search Reset	
	Close Next

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.

Applicant Info 2 Remarks	Summary of a	ipulications/licences/registri	itions to be updated	Ennos refer to Guidelines on th
APPLICANT INFO				
Change the following info il	you are apply	ing on behalf of the applicant		
Name I * *********************************		NKIC/Passport No.	it's second second	
Frend - *		F4X NO. 1		
/No. Licence/Registration No.	Job Type	Dealer's Type/Device Proprietery/Brand Name	Registration Date	Expiry Date
		week and		and the second second
and the second s	101100			
	100.000	And the second second second		
REMARKS				
Remarks to MDB : You may enter a maximum of up to 1000 characters.)				
				1.41



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:

Name
NRIC/Passport No
Contact Telephone Number
Contact Fax Number
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