

GUIDE TO APPLICATION FOR CHANGE OF REGISTRANT

This e-Application at MEDICS@HSA (Medical Device Information & Communication System) allows a Registrant (Accepting Company) to apply for a Change of Registrant (COR) to transfer medical device product(s) listed on the Singapore Medical Device Register (SMDR) from the current Registrant (Relinquishing Company).

The online [Change of Registrant 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**
 - [Corppass](#) (Singapore Corporate Access), a corporate digital identity for business and other entities to transact with Government online services, OR
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 your locally registered company as the **Accepting Company** of the transferred devices as authorised by the Product Owner.
4. **Medical Device(s)** with marketing clearance and listed on the Singapore Medical Device Register (SMDR) registered under the Relinquishing Company and not involved in a pending application.

In the application, you will be required to provide with the following information and ensure that the application satisfies the following requirements:

- 1) All devices to be transferred in each application must be
 - a. registered under the same Registrant (same Relinquishing Company) and
 - b. from ONE single Product Owner
- 2) Softcopy of the following support documents need to be prepared. They are submitted as attachments in the application:
 - a. **Letter of Authorisation** issued by the Product Owner (as per template in Annex 1 of GN-15 Guidance on Medical Device Registration)
 - b. **Letter of Request** issued by the Product Owner (as described in Annex 1 of GN-24 Guidance on the Change of Registrant)
 - c. **Annex 2 Relinquishing Company Declaration Form** issued by the Relinquishing Company (as per template in Annex 2 of GN-24 Guidance on the Change of Registrant)

Please refer to GN-24 Guidance on the Change of Registrant for further information on the application requirements.

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 FOR CHANGE OF REGISTRANT

This online application form consists of 6 parts

1. Applicant Info
2. Relinquishing Company
3. Product Owner
4. Devices to be Transferred
5. Supporting Documents
6. Remarks
7. Declaration

For Parts 2 to 4, click on “Add/Edit Info” to access this section of the online form.

For Parts 5, click on “Attach/Remove Document” to attach relevant supporting documents.

At the end of the application form, there are 3 button options:

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 proceed to the confirmation page to verify the information in the completed form and make relevant declarations. All information in the current page will be auto-saved.

To amend any mistake from the Confirmation page, click on the “<< Previous” Button to return to the Application Form. Before the application is submitted, you may print a copy the application for your record.

Upon submission, an acknowledgement containing the Job Reference number will be displayed. This Job Reference number will be used for future reference in all communications. If required, you may wish to print this acknowledgement page.

Button – Close

Closes the application form without saving any changes made. You will be brought to Workbench@MEDICS.

PART 1 – Applicant Info

Fields marked with asterisks * are mandatory.

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 : *

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 2 – Relinquishing Company

This section requires the applicant to search and select one of the registrant for relinquishing company.

MD4003 - CHANGE OF REGISTRANT > New Application > Relinquishing Company Info

APPLICATION FORM

1. Applicant Information	2. Relinquishing Company	3. Product Owner	Please refer to the Guidelines on the...
4. Devices To Be Transferred	5. Supporting Document(s)	6. Remarks	

Fields marked with asterisks * are mandatory.

RELINQUISHING COMPANY INFO

Company Name : Starts With [Click Search](#)

List of Registrant(s)

Total 3 records of 1 [Go](#) [\[first\]](#) | [\[previous\]](#) | [\[next\]](#) | [\[last\]](#)

S/No.	Select	Dealer No	Company Name	Address
1.	<input checked="" type="radio"/>	ES00000000
2.	<input type="radio"/>	ES00000000
3.	<input type="radio"/>	ES00000000

To select a registrant, select the option button and click [Add](#).

[Update Form](#) [Close](#)

Click on “Add” and click “Update Form” to proceed.

MD4003 - CHANGE OF REGISTRANT > New Application > Relinquishing Company Info

APPLICATION FORM			
1. Applicant Information	2. Relinquishing Company	3. Product Owner	Please refer to the Guidelines on the...
4. Devices To Be Transferred	5. Supporting Document(s)	6. Remarks	

Fields marked with asterisks * are mandatory.

RELINQUISHING COMPANY INFO

Relinquishing Company selected

To remove a registrant and click [Remove](#).

Company Name : *

Address Type : *

Postal Code : *

Block / No. : *

Street Name : *

Building Name :

Level - Unit :

Country : * Singapore

Contact Person : *

Contact Email : *

(For future communication and email notification.)

Applicant is required to input the Contact Person and Contact Email and click “**Update Form**” to proceed.

This contact information will be used when sending final notification email of successful Change of Registrant application upon approval.

PART 3 – Product Owner

This section requires the applicant to select the product owner of the product.

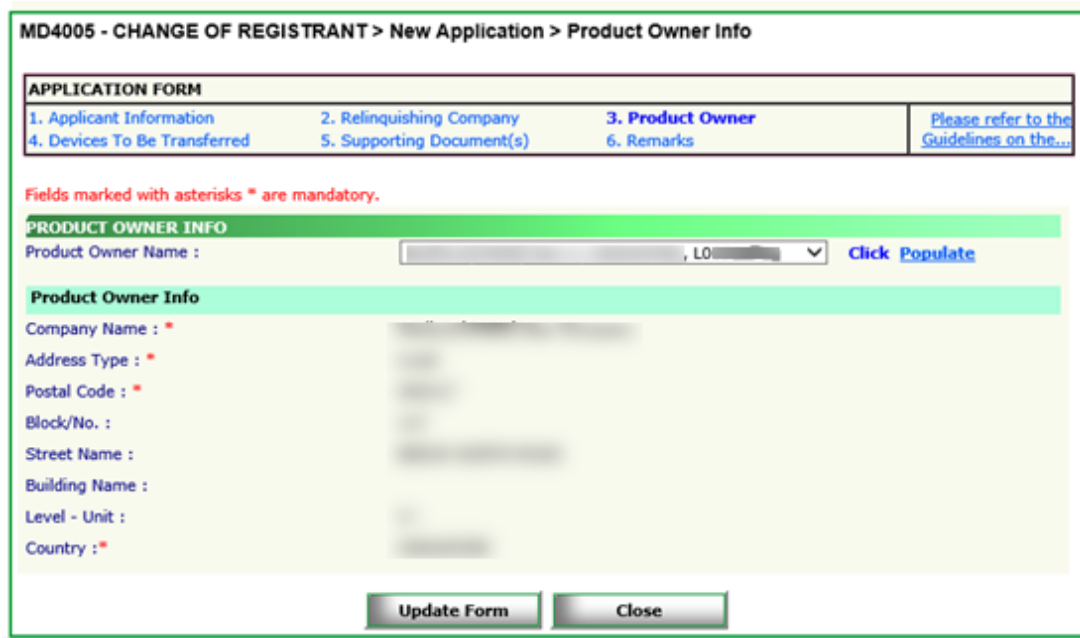
The Product Owner is to be selected from a list of Product Owners that the Relinquishing Company selected in Part 2 is representing in Singapore, and whose medical device products are registered and listed on the Singapore Medical Device Register (SMDR).

Once the Product Owner is selected, click on “Populate” to populate the form.

Note:

- The lists of devices available in the next section “PART 4 – Device To Be Transferred” are devices are listed on SMDR under the selected Product Owner.

Click the “**Update Form**” when this part is completed.



PART 4 – Device To Be Transferred

This section requires the applicant to select medical device products of a product owner selected in Part 3 to be included in the Change of Registrant.

Selection of medical device:

A list of devices belonging to the Product Owner selected will be shown. Check the corresponding checkbox to select any of the devices and click “Add”

Enter licence number or partial or full device name and click on the “Search” to find particular device listings.

To remove a medical device from the “Selected Device(s) for Change of Registrant for Registered Device”, select the corresponding checkbox and click “Remove”.

Click the “**Update Form**” when this part is completed.

MD4007 - CHANGE OF REGISTRANT > New Application > Device to be Transferred Info

APPLICATION FORM			
1. Applicant Information	2. Relinquishing Company	3. Product Owner	Please refer to the Guidelines on the...
4. Devices To Be Transferred	5. Supporting Document(s)	6. Remarks	

Fields marked with asterisks * are mandatory.

DEVICE TO BE TRANSFERRED INFO

Search Device(s) for Change of Registrant

Licence No :

Device Proprietary/Brand Name : Starts With [Search](#)

Total 3 record(s) Page 1 Of 1 [GO](#) [first] | [previous] | [next] | [last]

<input type="checkbox"/>	Licence No.	Risk Class	Device Proprietary/Brand Name
<input type="checkbox"/>	DE	CLASS B	
<input type="checkbox"/>	DE	CLASS B	

Legend:

* Please note that Change of Registrant application cannot be submitted for device listings that are involved in a pending application.
 ^ The IBR Pre-Market application for the device is still under post-approval review.

Total 3 record(s) Page 1 Of 1 [GO](#) [first] | [previous] | [next] | [last]

To add device(s) for Change of Registrant, check the checkbox(es) and click [Add](#).

Selected Device(s) for Change of Registrant

Total 2 record(s) Page 1 Of 1 [GO](#) [first] | [previous] | [next] | [last]

<input type="checkbox"/>	Licence No.	Risk Class	Device Proprietary/Brand Name
<input type="checkbox"/>	DEC	CLASS B	
<input type="checkbox"/>	DEC	CLASS B	

Total 2 record(s) Page 1 Of 1 [GO](#) [first] | [previous] | [next] | [last]

To remove device(s), check the checkbox(es) and click [remove](#).

PART 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.

MD5000 - CHANGE OF REGISTRANT > New Application > Supporting Document(s)

APPLICATION FORM			
1. Applicant Information	2. Relinquishing Company	3. Product Owner	Please refer to the Guidelines on the...
4. Devices To Be Transferred	5. Supporting Document(s)	6. Remarks	

SUPPORTING DOCUMENT(S)

Please attach the following document(s) by typing in the path or click on the browse button.

1. Letter of Authorization (mandatory)		Browse...
2. Letter of Request (mandatory)		Browse...
3. Annex 2 Relinquishing Company Declaration Form (mandatory)		Browse...
4. Other documents		Browse...

To attach, click [Add Attachment](#).

Close

PART 6 – Remarks

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

6. REMARKS

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

PART 7 – Declaration

This section requires for the applicant to acknowledge on the declaration for the submission.

7. DECLARATION

a. I acknowledge and accept the appointment by the Product Owner as the new Registrant for the registered medical device(s) submitted in this application and duly acknowledge and accept my duties and obligations as a Registrant;

b. I shall comply with all the conditions of approval applicable to the registered medical device(s) submitted in this application and conditions imposed on the Registrant; and

c. **Please tick if applicable:**
I attest that I will take possession of all records of supply and complaints of the above medical devices(s) previously held by the relinquishing company up to the date of approval of this Change of Registrant application by HSA. I am obliged to maintain these records for the period stipulated in the Health Products (Medical Devices) Regulations and provide such records to the Authority in the event of a field safety corrective action or when requested by the Authority.

Accept Decline

Click on “**Previous**” button to review the application and amend accordingly.

Click on “**Submit**” button the Change of Registrant application.

END OF DOCUMENT