

GUIDE TO SUBMISSION OF UPDATE OF UNIQUE DEVICE IDENTIFIER (UDI)

This e-Application at MEDICS@HSA (Medical Device Information & Communication System) allows a company to submit an of update of Unique Device Identifier (UDI).

The online [Submission of Update of unique Device Identifier \(UDI\)](#) 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: <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
- [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.

PAYMENT

There is no charge for the Submission of Update of Unique Device Identifier (UDI).

ONLINE APPLICATION FORM

Submission of Update of Unique Device Identifier module will only allow companies to edit the UDI-DI, DM-DI and Issuing Agency (IA) information related to the device models. For amendment to other information (i.e. device name, identifier, and device description), please proceed to submit a Change Notification application instead.

This online application form consists of 3 parts.

To fill in the relevant information, click on “**Add/Edit Info**” to access that section of the form.

SUBMISSION OF UPDATE OF UNIQUE DEVICE IDENTIFIER (UDI)

APPLICATION FORM		
1. Applicant Info	2. Affected Device Listing	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 : *	<input type="text" value="S0750213C"/>	NRIC/Passport No. : *	<input type="text" value="S0750213C"/>
Tel. No. : *	<input type="text"/>	Fax No. : *	<input type="text"/>
Email : *	<input type="text" value="abc@ncs.com.sg"/>		

Drafter type : Staff Partner

Available Company's Drafters :

2. AFFECTED DEVICE LISTING

Please select device listing affected by this Submission of Unique Device Identifier.

Device listing affected

[Click Add/Edit Info](#)

3. REMARKS

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

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 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 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.

Drafter Assignment

This is to allow designated staff or external partner (i.e HSA Pin users) to prepare the application form as a drafter. Note that the completed application will then need to be submitted by someone authorised as a submitter.

A Submitter is allowed to prepare drafts and submit applications without the help of an intermediary drafter. The role of the current login user is displayed at the top of the screen under the Logon ID.

- 1) Drafter type: The applicant can select either a “Staff” or “Partner”.
- 2) Available Company’s Drafters: Once the above is selected, the corresponding list of drafters will then be selectable from the drop down list.

The list of available drafter depends on the user setting in the [CRIS Management Module](#). The CRIS Administrator is able to set up company users or service providers/partners to be drafter for this e-Service.

SUBMISSION OF UPDATE OF UNIQUE DEVICE IDENTIFIER (UDI) > Affected Device Listing > Model(s) Info

APPLICATION FORM

2. Model Info Please refer to the Guidelines on the...

Dossier No. : C40A193C56-21

MODEL(s) INFO

Instructions

Step 1: Please **download the existing excel** [here](#) to update the UDI-DI and/or DM-DI of the registered medical devices.
 Step 2: Proceed to upload the updated excel.
 Step 3: Once uploaded please verify the information in the summary table.
 Step 4: Select the UDI Issuing Agency.
 Step 5: If there are changes to be made to the individual model, you may wish to click on the respective model in the summary table and edit accordingly. Alternatively, please perform Step 1 again to make the amendment.
 Step 6: Submit Support Documents, if any.

Please upload excel here:

No file chosen

UDI Issuing Agency

Please Select UDI Issuing Agency:

GSI HSBCC ICCBA

SUPPORTING DOCUMENT(s)

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

Others No file chosen

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

1. Model Name
 2. Model Number
 3. UDI-DI
 4. DM-DI (Only if DM-DI is available and is different from UDI-DI)
 5. Description (e.g. Clinical Size (Including Volume, Length, Gauge, Diameter), SAMD Version, device quantity (UDI-DI)) (Max 3000 Characters)

Model(s) Added

S/No.	Model Name	Model Number	UDI-DI	DM-DI	Description (Max 3000 Characters)
1					
2					
3					
4					
5					

Verify the information in the summary table. In case of any modifications to individual model data, click on the model name hyperlink and the data appears as in the section below.

1. Model Name
 2. Model Number
 3. UDI-DI
 4. DM-DI (Only if DM-DI is available and is different from UDI-DI)
 5. Description (e.g. Clinical Size (Including Volume, Length, Gauge, Diameter), SAMD Version, device quantity (UDI-DI)) (Max 3000 Characters)

Update the information by clicking the Update button. Once updated, proceed to verify the information in the summary table under Model(s) Added section.

UDI Issuing Agency

Please Select UDI Issuing Agency:
 GS1 HIBCC ICCBBA

SUPPORTING DOCUMENT(S)

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

Others No file chosen

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

Select UDI Issuing Agency. Any supporting documents can be attached in this section. Note: Supporting documents are not Mandatory in the Model Info page.

Click on Update form and return to the Affected Device Listing page.

Model(s) Added					
S/No.	Model Name	Model Number	UDI-D1	DM-D1	Description (Max 3000 Characters)
1	model1	no1	udi1,udi2 asd,udi3	dm1,dm2,dm3 asdad a	desc1
2	model2	no2	udi2	dm2	desc2
3	model3	no3	udi3	dm3	desc3
4	model4	no4	udi4	dm4	desc4
5	model5	no5	udi5	dm5	desc5

All the devices for which UDI data is updated will be marked as 'Y' as shown below.

Selected Device(s) for Submission of update of Unique Device Identifier (UDI)

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

<input type="checkbox"/>	Licence No.	Dossier No.	Risk Class	Device Proprietary/Brand Name	Updated (Y/N)
<input type="checkbox"/>				Update UDI Info	Y
<input type="checkbox"/>				Update UDI Info	Y
<input type="checkbox"/>				Update UDI Info	N

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

To edit device, click Licence No.
 To remove device(s), check the checkbox(es) and click [remove](#).

To remove device, select a check box and click on remove hyperlink.

Click the "Update Form" button on Affected Device Listing page when all the devices are updated.

PART 3 – Remarks

This section is for the applicant to insert any remarks to MDB regarding the submission, if any.

3. REMARKS

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

Select Accept radio button in the Declaration section of the Confirmation page to submit the application.

4. DECLARATION

- a. I hereby attest that the information provided on this application and in any attached documentation is accurate, correct and complete.
- b. I hereby attest that I have objective evidence to establish that the above medical device meets safety, quality and performance requirements.
- c. I hereby attest that there are no misleading claims made relating to the quality, safety and performance of the above medical device,
- d. I am informed and I understand that this is a serious offence under Section 30(10) of the Health Products Act 2007 to make any statement or furnish any document which I know to be false or does not believe to be true in support of this application.

Accept Decline

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

Click on “**Submit**” button to submit the UDI application

END OF DOCUMENT