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

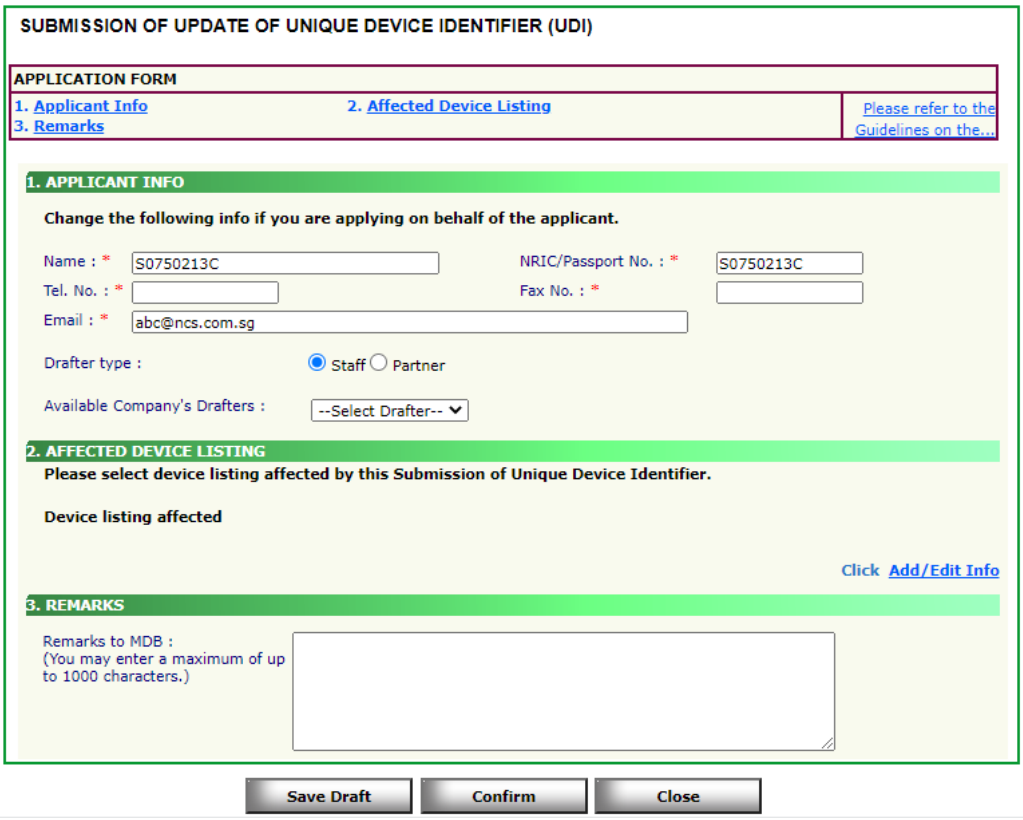
There is no charge for the Submission of Update of Unique Device Identifier (UDI).

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.



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.

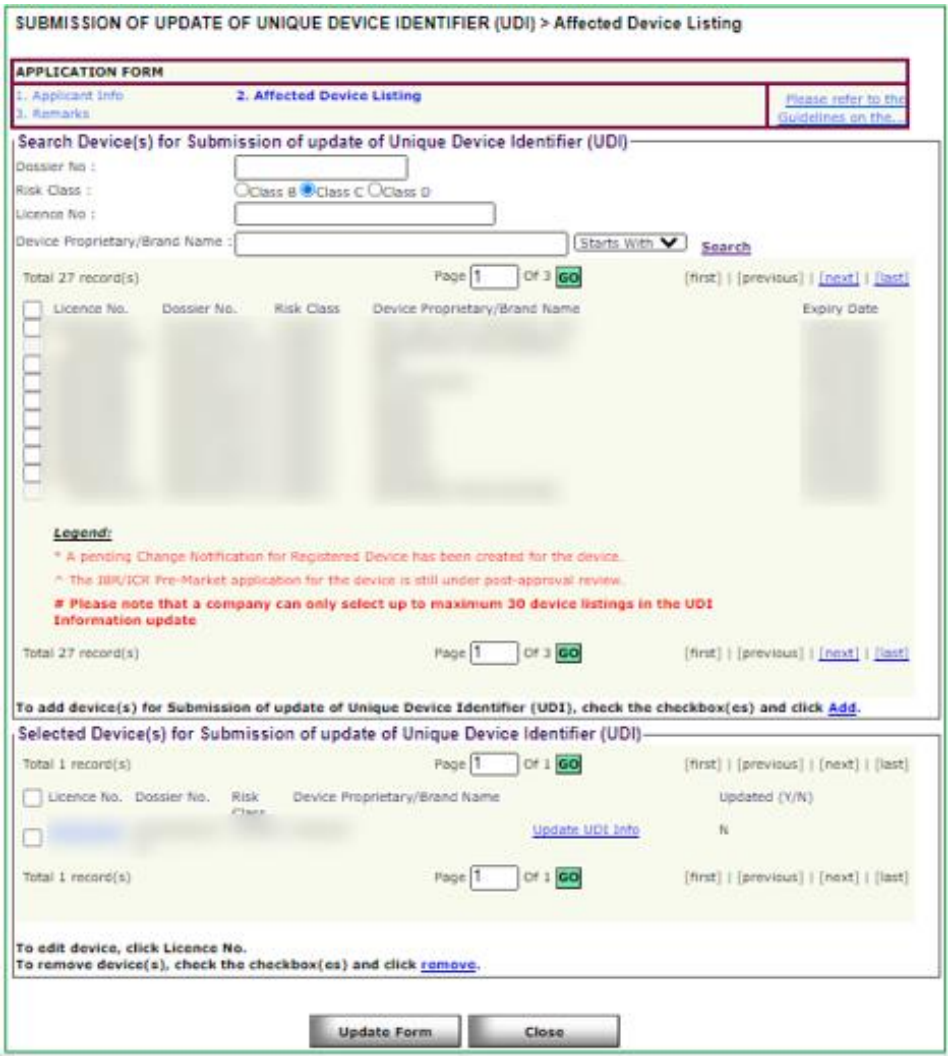
1) Drafter type: The applicant can select either a “Staff” or “Partner”.

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.

PART 2 – Affected Device Listing

This section requires the applicant to search and select devices for which the Model Info need to be updated.

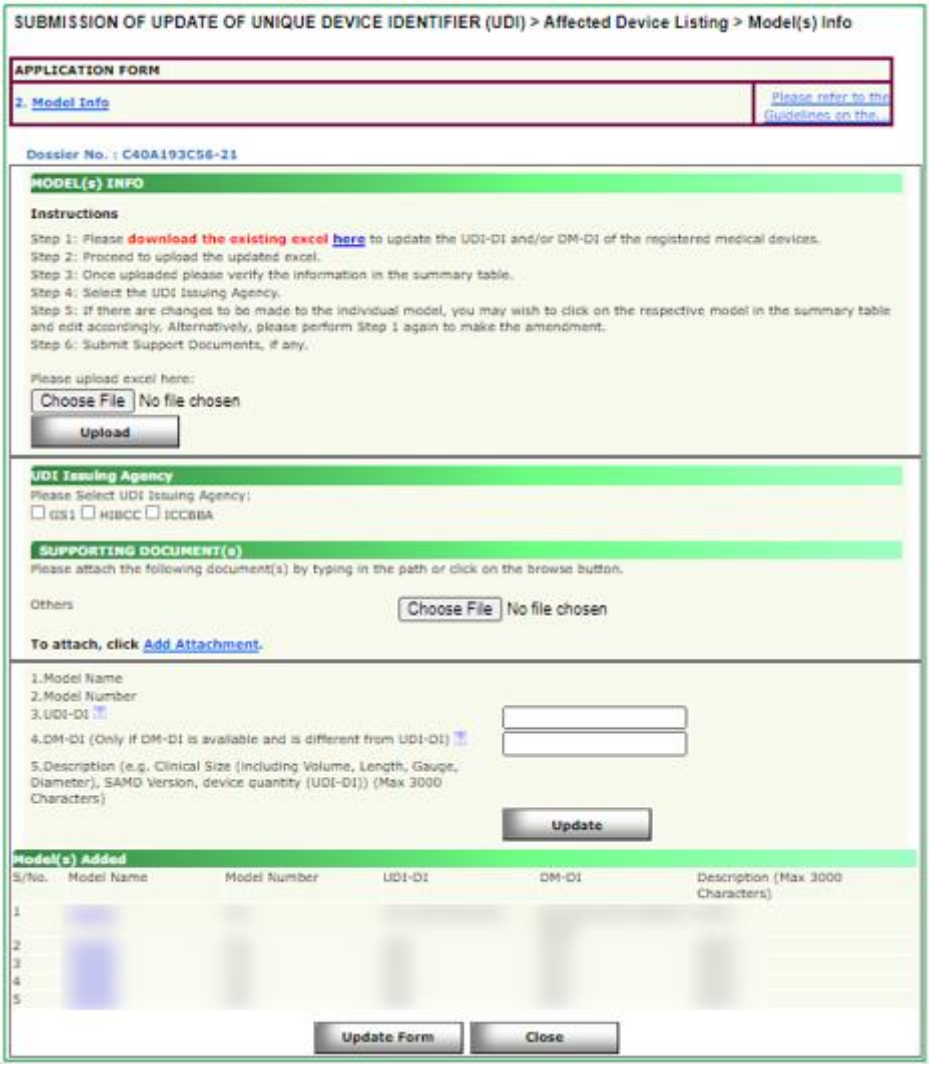


Select device listings and click on "**Add**". The selected devices will appear in the section "Selected Device(s) for Submission of update of Unique Device Identifier (UDI).

To view the latest SMDR information related to licence click on the hyperlink of licence number.

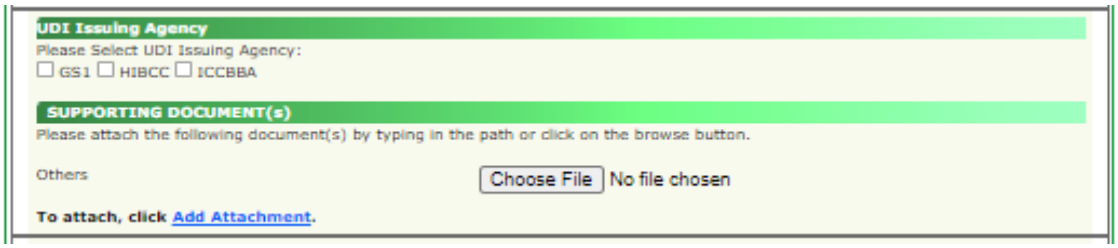
To update the UDI information, click on the Update UDI Info hyperlink.

In this section user can follow the instructions present in the page to download the excel file, edit the UDI-DI, DM-DI information related to the model and upload the excel.



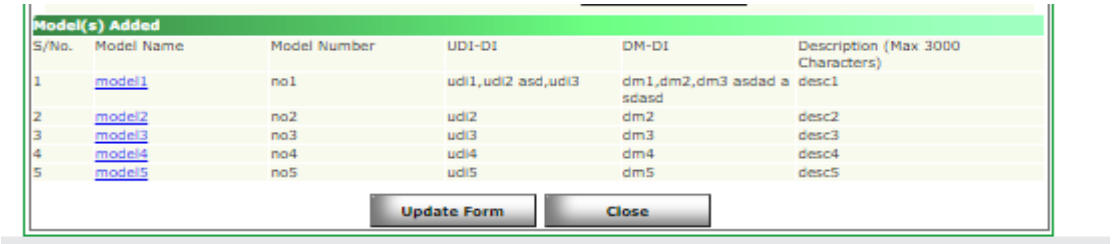
Verify the information in the summary table. In case of any modifications to individual model data, click on the model name hyperlink and the data appears as in the section below.

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



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.



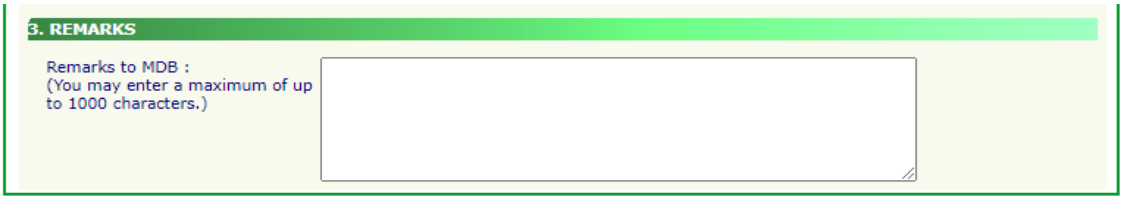
All the devices for which UDI data is updated will be marked as 'Y' as shown below.

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

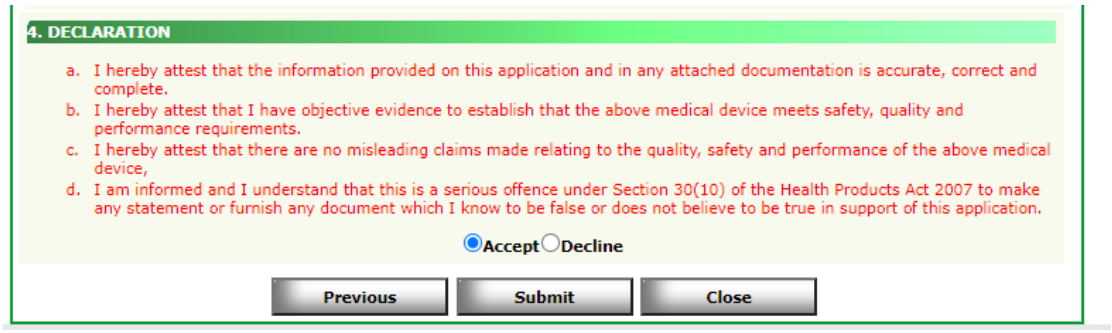
Click the "Update Form" button on Affected Device Listing page when all the devices are updated.

PART 3 – Remarks

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



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



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

Click on "**Submit**" button to submit the UDI application

END OF DOCUMENT