GUIDE TO CHANGE NOTIFICATION FOR REGISTERED DEVICES

This e-Application at MEDICS@HSA (Medical Device Information & Communication System) allows a Registrant to submit a Change Notification application to higher risk medical devices that have been given marketing clearance.

The online Change Notification for Registered Device in MEDICS may take an average of 5-15 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. 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.

4. Medical device(s) with market clearance and listed in the Singapore Medical Device Register (SMDR).

Please take note of the following when submitting a new change notification application:

1) The Change Notification Application is meant to notify HSA if there are any changes or proposed changes to any particulars provided in relation to the registration of medical device, and/or if there are any changes or proposed changes that may affect the safety, quality or efficacy of a registered medical device.
2) In general, any changes to the documents submitted in the original application would need to be submitted. Also any documents that support the changes being reported are required. These enclosures are to be submitted as attachments in the e-application for the purpose of evaluation of the device for marketing clearance.
3) The MEDICS system will not allow for another submission of a new change notification application for the same device listing, when there is a pending change notification application. The pending application needs to be approved before submitting a new change notification application.
4) The MEDICS system will not allow submission of a new change notification application for the device that is pending IBR Pre-Market post approval. The IBR application needs to be approved before submitting a new change notification application.

REFERENCES

The information in the following Regulatory Guidances is useful for the application.

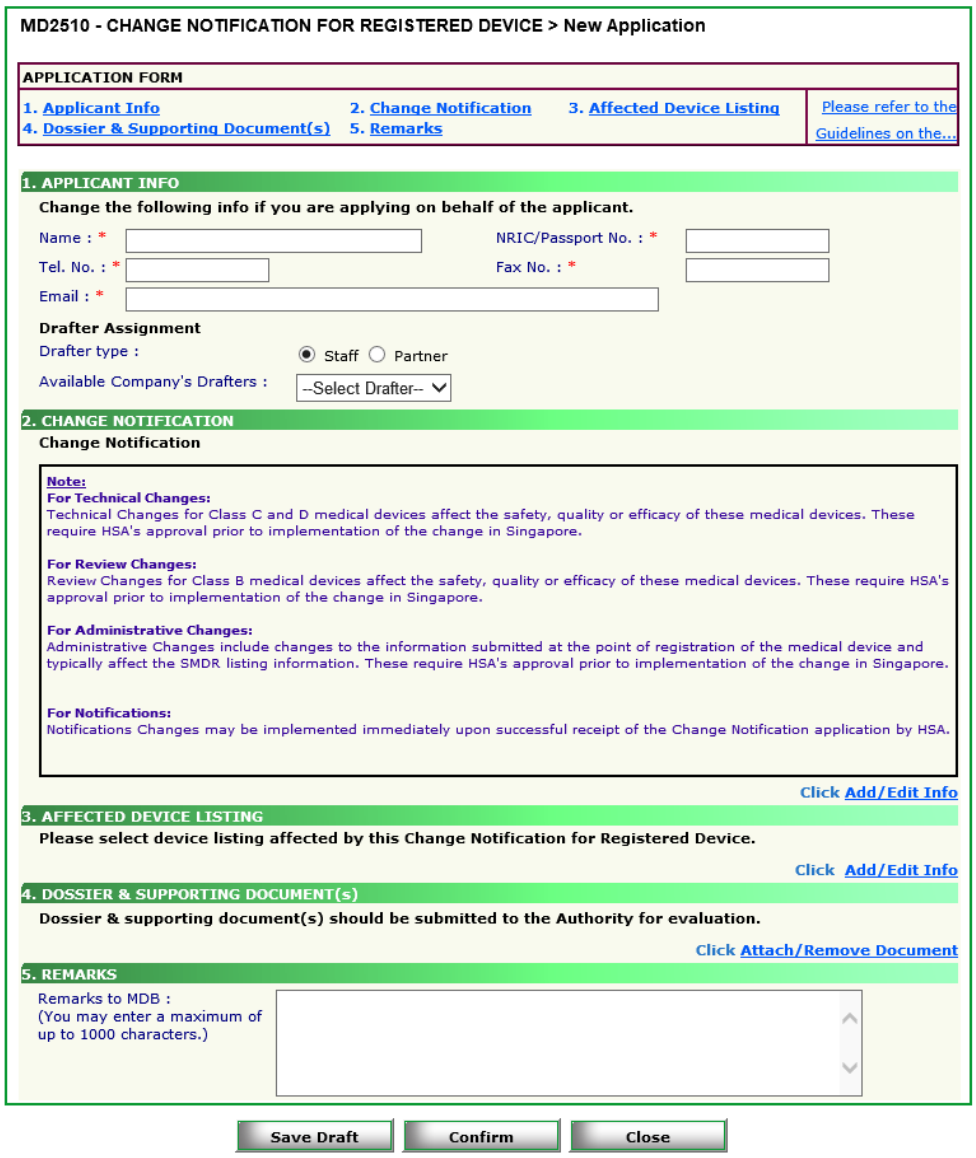
- GN-21: Guidance on Change Notification for Registered Medical Devices

PAYMENT

Please click here for the Tables of Fees for Change Notification for Medical Devices.

ONLINE APPLICATION FORM

This online Application Form consists of 5 parts (via Applicant Info; Change Notification; Affected Device Listing; Dossier and Supporting Document(s); Remarks)



For Part 2 and 3, click on "**Add/Edit Info**" to access that section of the on-line form.
For Part 4, click on "**Attach/Remove Document**" to attach relevant supporting documents.
At the end of the application form, there are 3 button options:

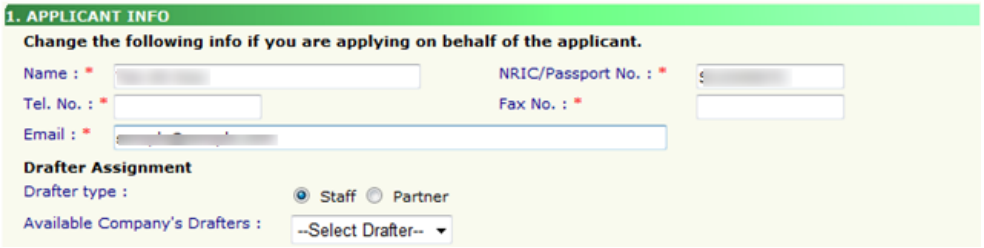
Button - Save Draft
Allows the applicant to save the Application Form for retrieval and submission at a later time. A transaction number will be assigned.

The saved Application Form can be retrieved from "My Drafts" in the Workbench@MEDICS.

Button – Confirm
Allows the applicant to 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

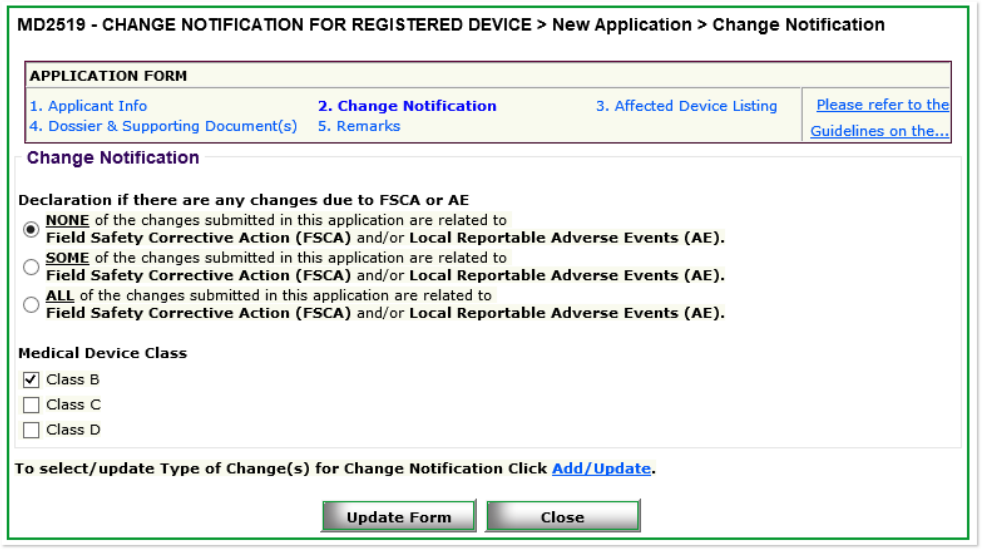
This is to allow designated staff or external partner to prepare the application form as a drafter. Note that the completed application will then need to be submitted by someone authorised as a submitter.

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 – Change Notification



Item 1: Declaration of FSCA and AE

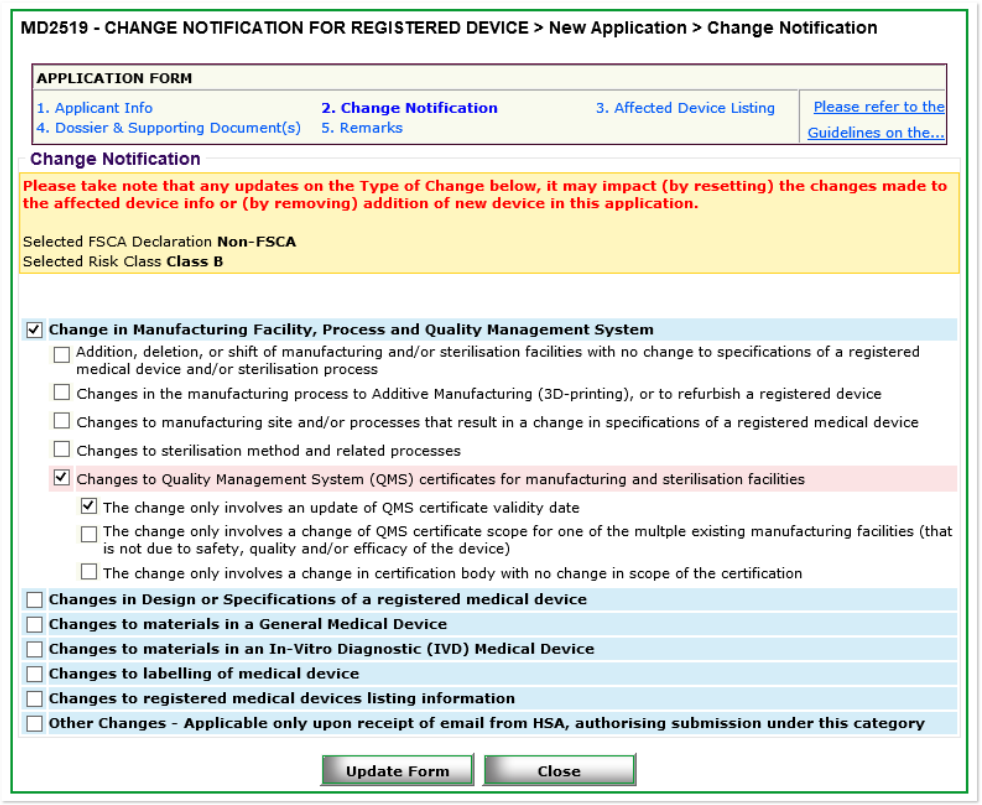
Select the applicable description of Field Safety Corrective Action (FSCA) and Reportable Adverse Events (AE) relating to the change submitted in this Change Notification.

Item 2: Medical Device Class

Select the relevant risk class(es) of the devices involved in the changes to be submitted in this Change Notification.

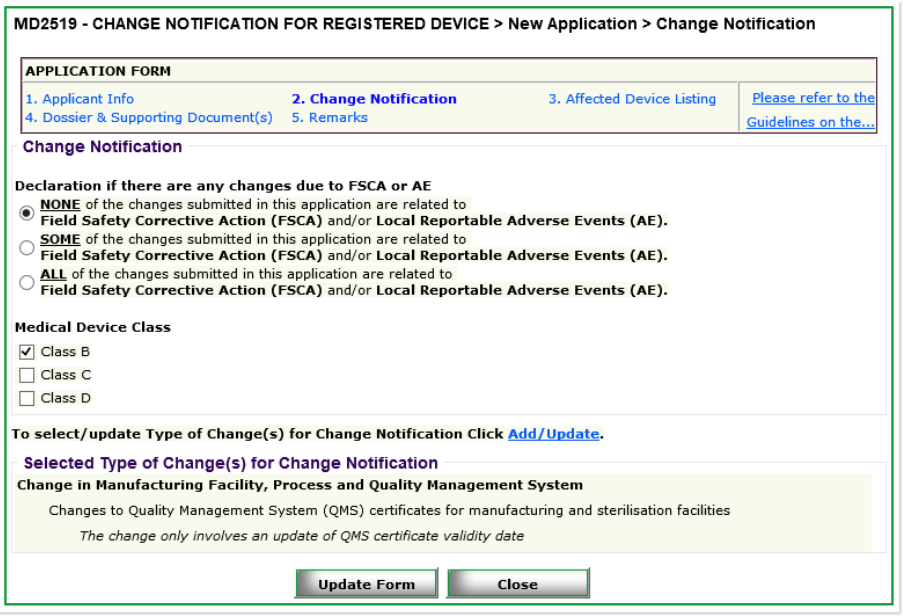
Please note that if multiple risk classes are selected for changes not due to FSCA or AE, only selected categories of change will be allowed. Please refer to GN-21 Guidance on Change Notification for Registered Medical Devices Section 4 for further information.

Click the **"Add/Update"** Button to select the Type of Changes



Please refer to *GN-21 Guidance on Change Notification for Registered Medical Devices Section 3 Change Type Assessment Flowcharts* to determine the applicable Type of Change to be selected for your proposed change.

Select the applicable Type of Change and click **"Update Form"**

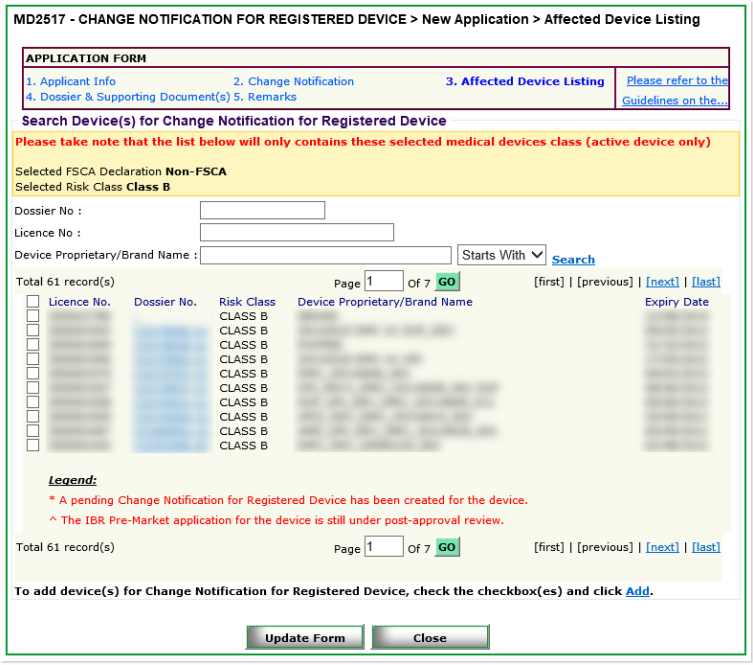


The selected type of change will be displayed under "Selected Type of Change(s) for Change Notification".

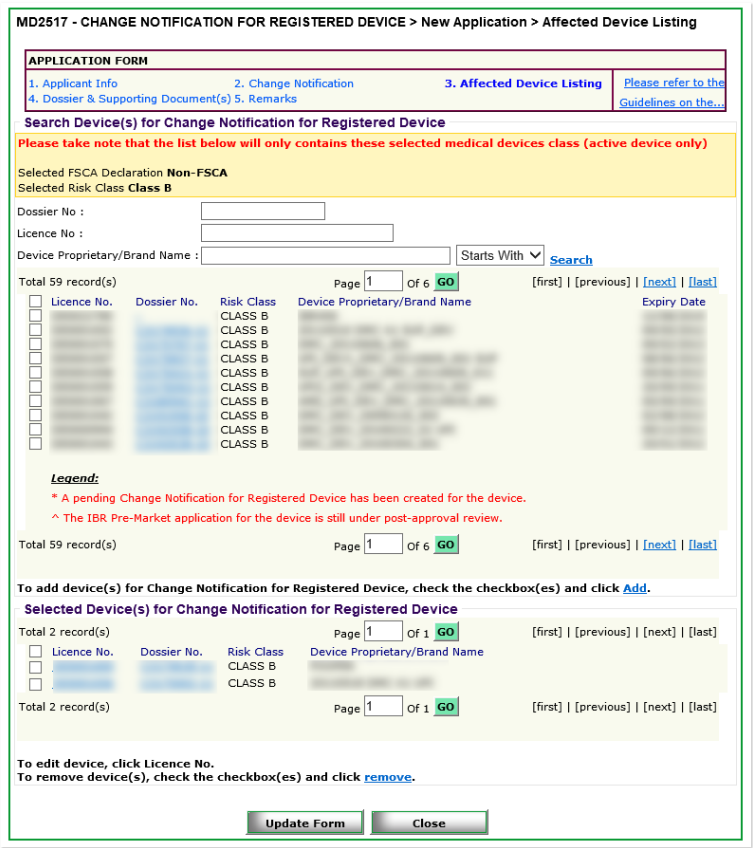
Please verify and click **"Update Form"**

A summary of the type of change and overall category of change (i.e. Technical, Review, Administrative or Notification) will be indicated in the main application form.

PART 3 – Affected Device Listing



Only ACTIVE devices of the risk class selected in PART 2 – Change Notification will be displayed. Select affected device listings and click “Add”; selected devices will be populated in a table below:



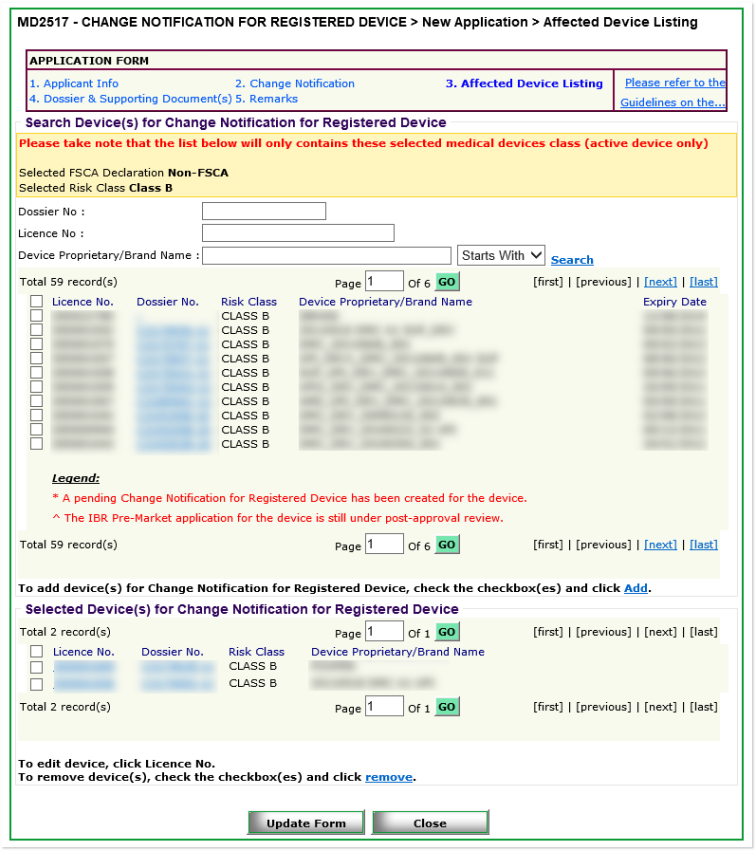
If the Type of Change selected in **PART 2 – Change Notification** involves a change in device listing information, click on the **Licence Number** of the relevant device listing to access the device information page to amend accordingly.

Click on **"Add/Edit Info"** to edit the relevant fields.

If the **"Add/Edit Info"** links are not available and you intend to make changes to the listing information, please review your Type of Changes selection in **PART 2 – Change Notification**.

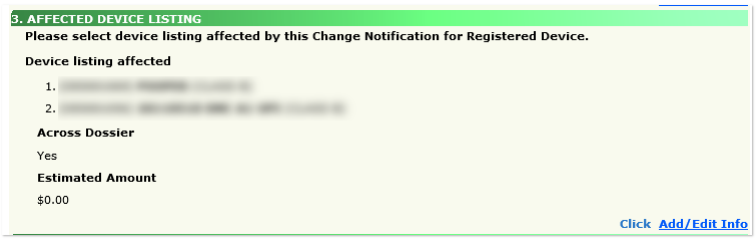
If in doubt of which Type of Change is applicable, please refer to *GN – 21 Guidance to Change Notification*, or send in an enquiry at hsa_md_info@hsa.gov.sg to verify the Type of Change to be selected.

Click **"Update Form"** to save changes and return to the device listing page.



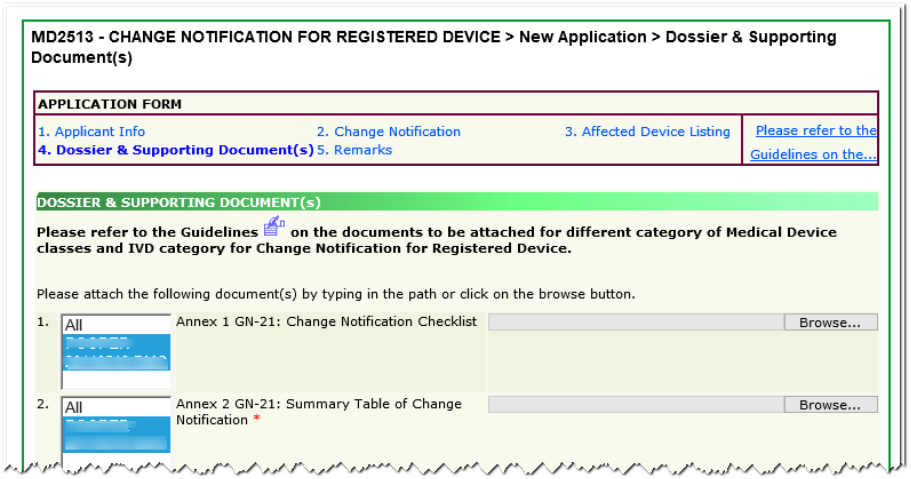
Click **"Update Form"** to save all changes and return to main application page.

A summary of the affected device listings selected and an estimated fee for the current application will be displayed.



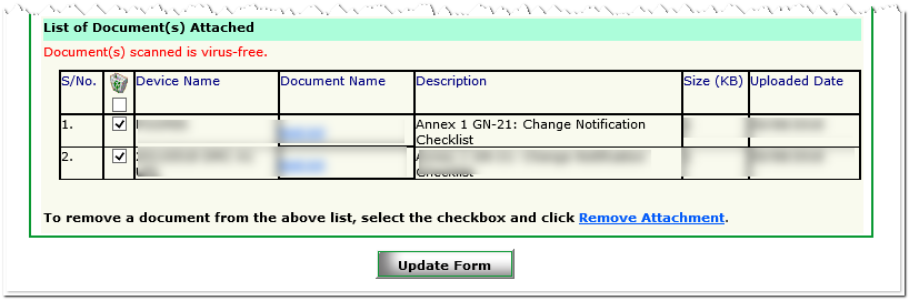
PART 4 – Dossier & Supporting Document(s)

This section requires the applicant to upload supporting documents for each device.



The supporting documents are attached by:

- selecting the device(s) from the selection box
- browsing the local storage devices for the documents using the "**Browse**" button
- attaching these documents by clicking on the "**Add Attachment**" after all documents have been selected



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.

Note:

- If a document is applicable for more than one device, you can select multiple devices from the selection box before browsing to the document and uploading it.
- If a document is applicable for ALL devices, you can select All from the selection box before browsing to the document and uploading it.
- If the device name is too long and you cannot distinguish them due to the limit of the section box, move the mouse over to the device name, the full name will be displayed below the mouse cursor.

PART 5 – Remarks

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

END OF DOCUMENT