USER MANUAL FRONT END USER

Medical Device Centralised Online Application System (MeDC@St 2.0)

MODUL UTAMA - CHANGE NOTIFICATION CLASS A

DISEDIAKAN OLEH :

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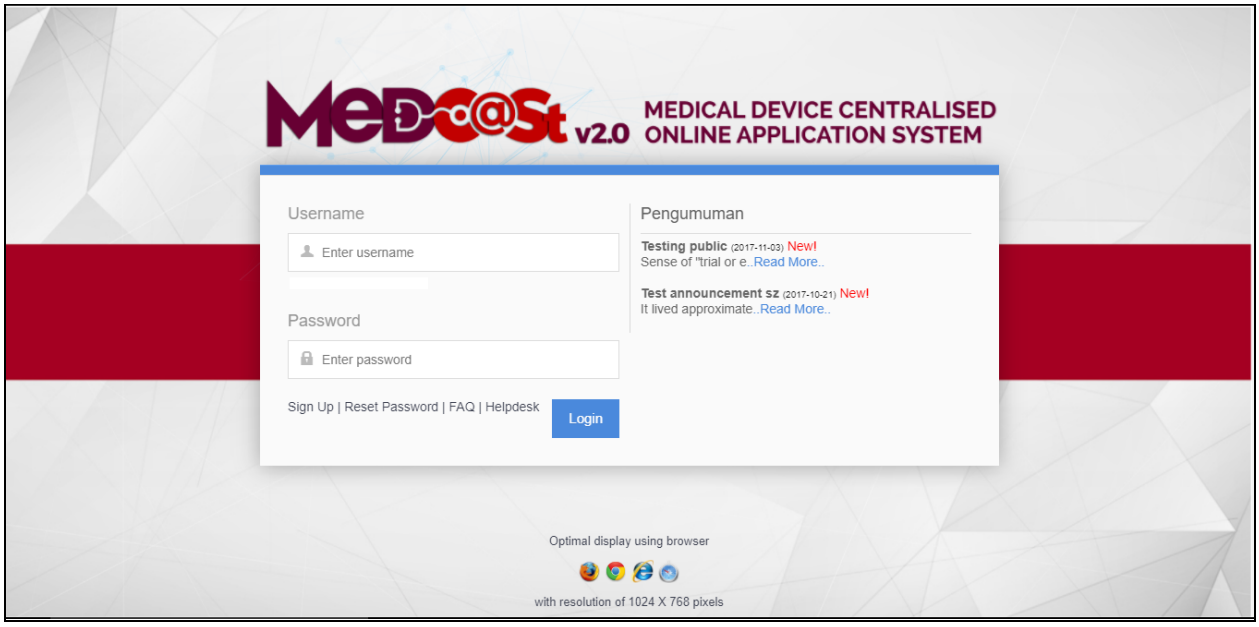
1.0 INTRODUCTION

MeDC@st (Medical Device Centralised Online Application System) is developed using web-based method in which it utilizes the internet access via internet server. In order to access Medc@st, user has to key in the URL
address onto the internet server as followed:

https://www.mda.gov.my/medcastv2/backend/web/index.php/admin/user/login

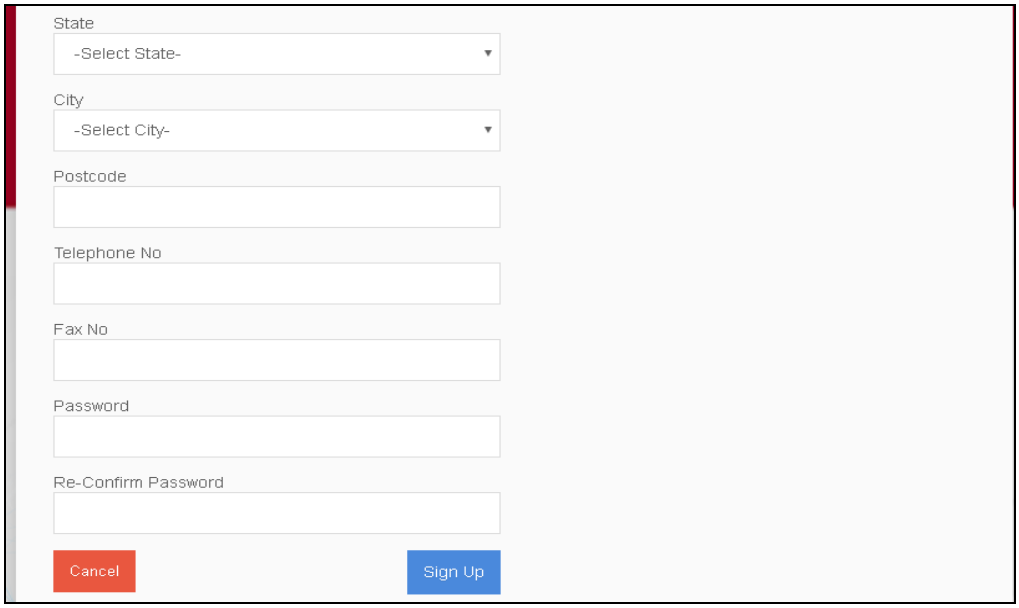
The screen below shows the expected webpage after the address has been keyed In.



User has to log into the system using registered User ID and its respective password. Click the [Login] button to proceed.

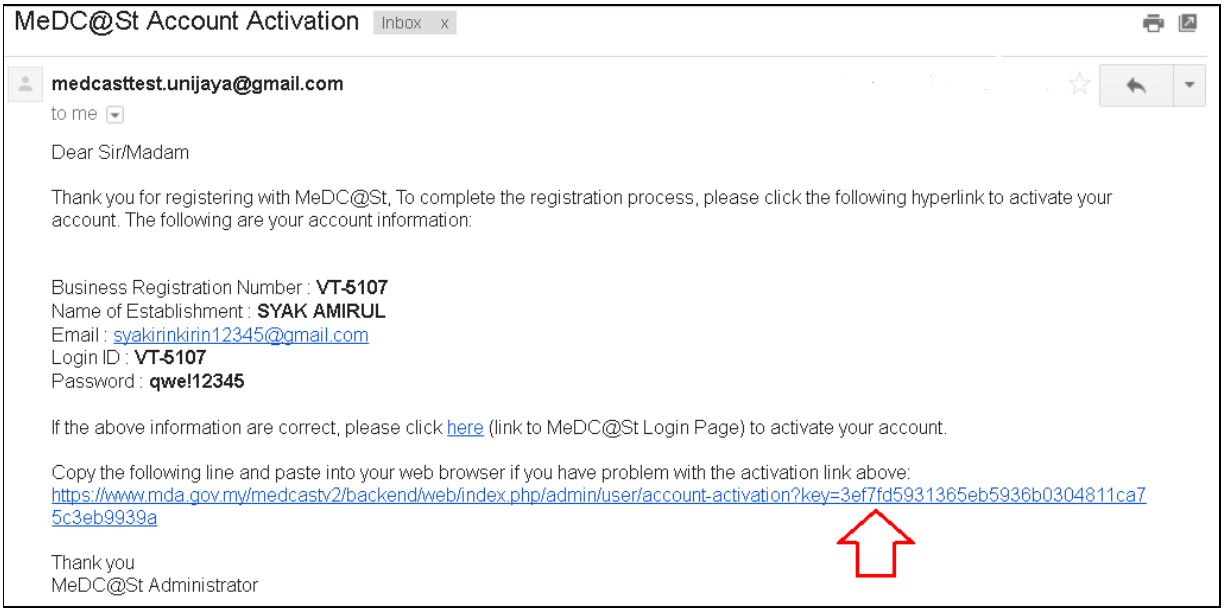
1.1 SIGN UP

Click on the Sign Up at the bottom of login form to display the following screen. Fill the following empty form and choose drop down list such as Business Registration No, Name, Username, E-mail, Address, State, City, Postcode, Telephone No, Fax No, Password, Reconfirm Password and choose the radio button that has been highlighted to create new MDR-BCD account. After complete fill registration form user must verified email.

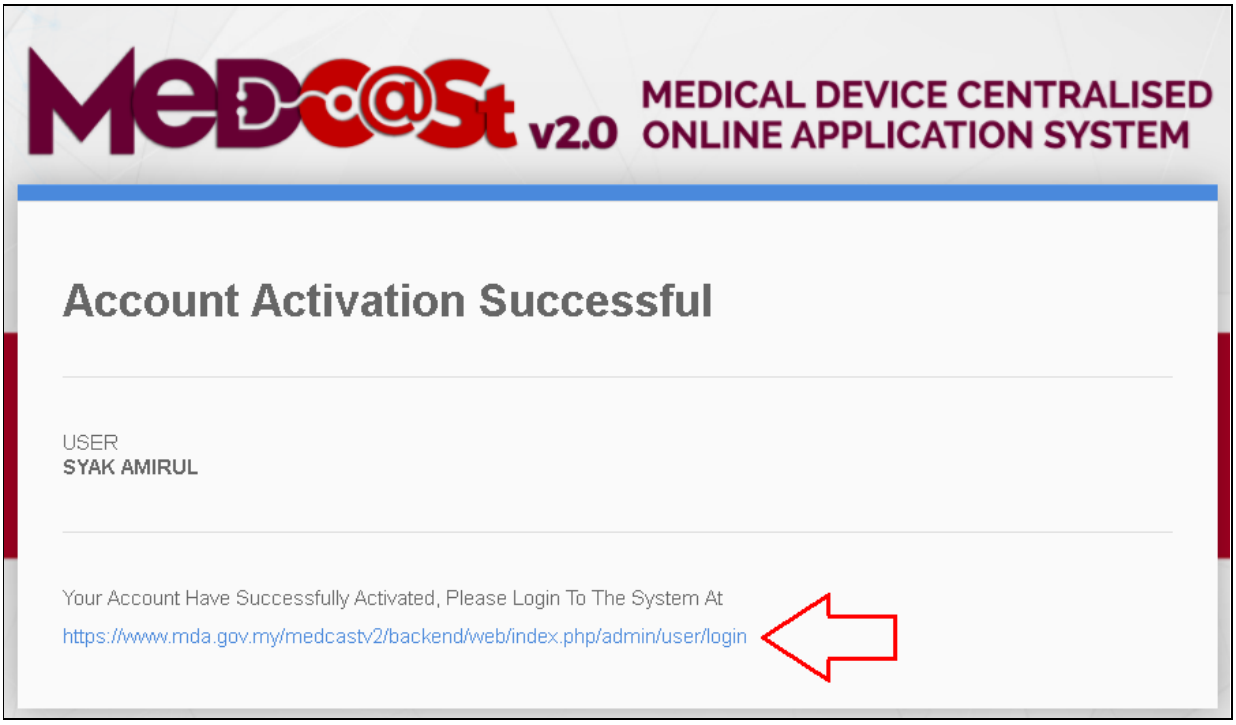


1.1.1 VERIFIED EMAIL FOR NEW ACCOUNT

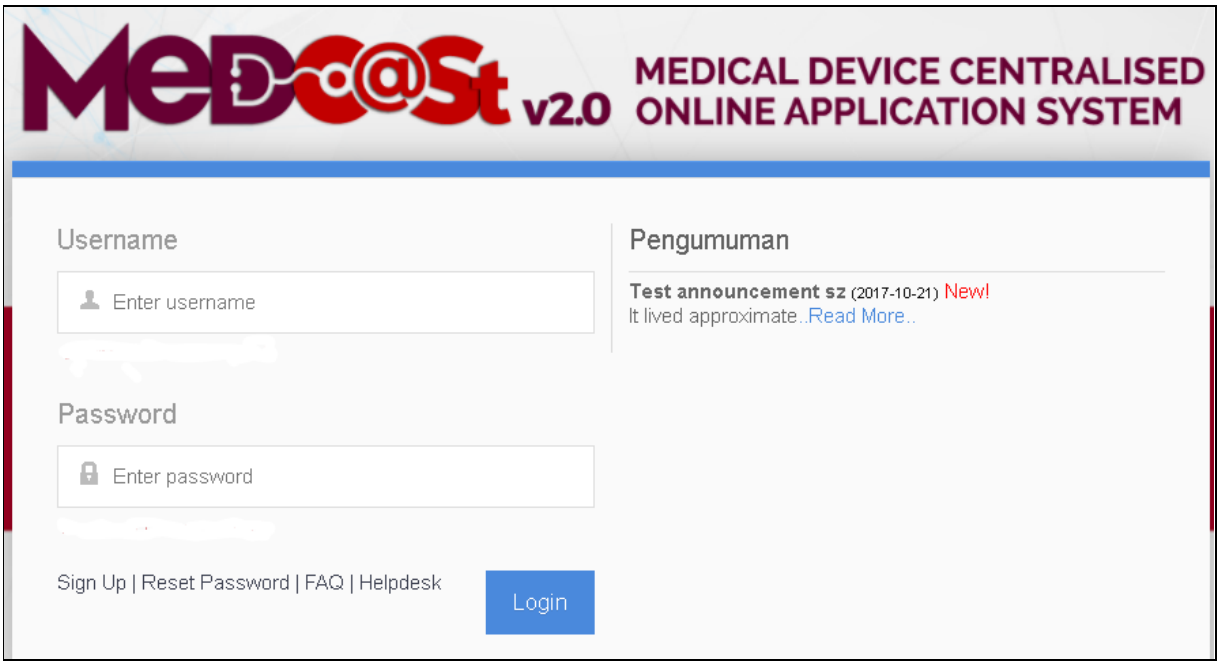
The user must verified email to completed the last step of the registration. Click at the link given to verified email in the system medcast V2.0.



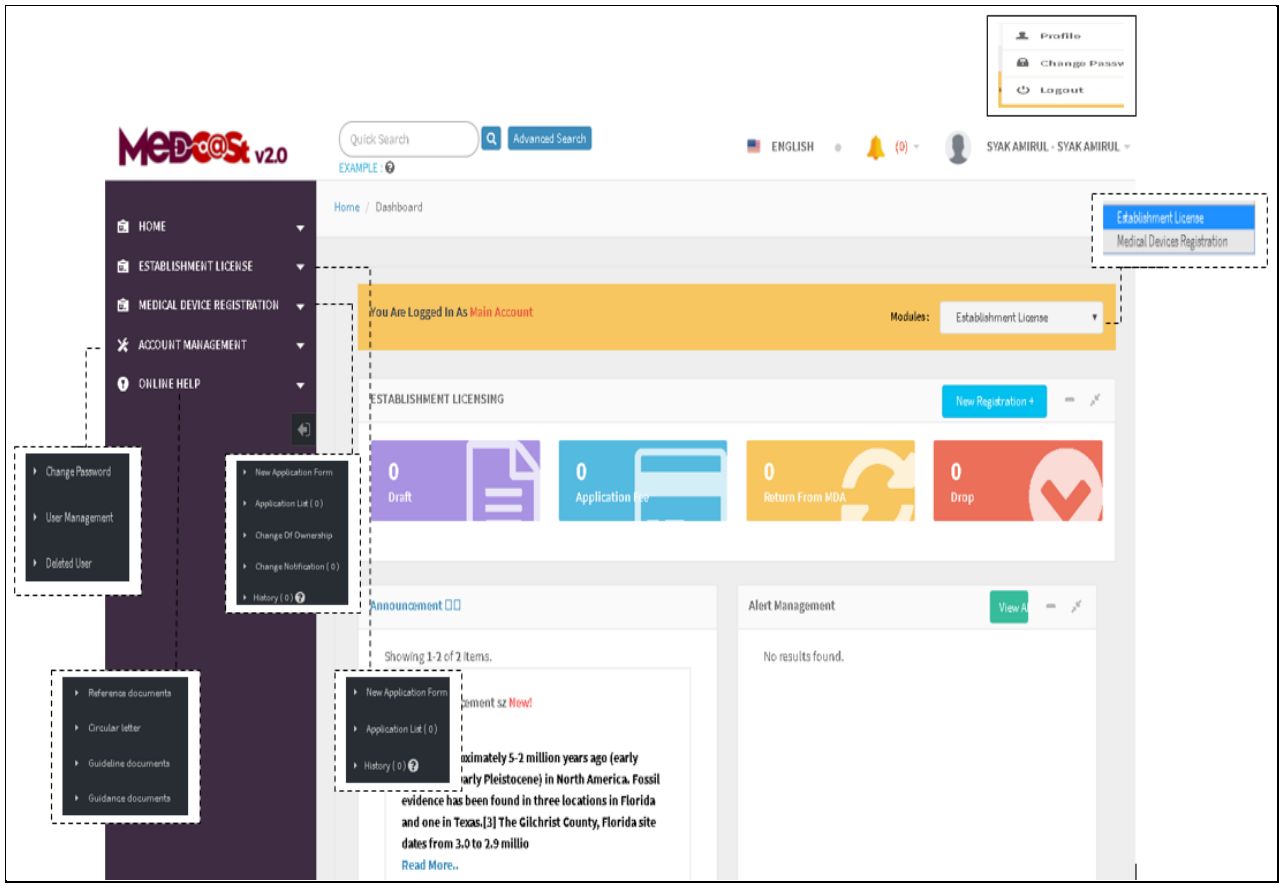
The account activation screen will display. The user must click at the link to login into the account.



The login screen will display.

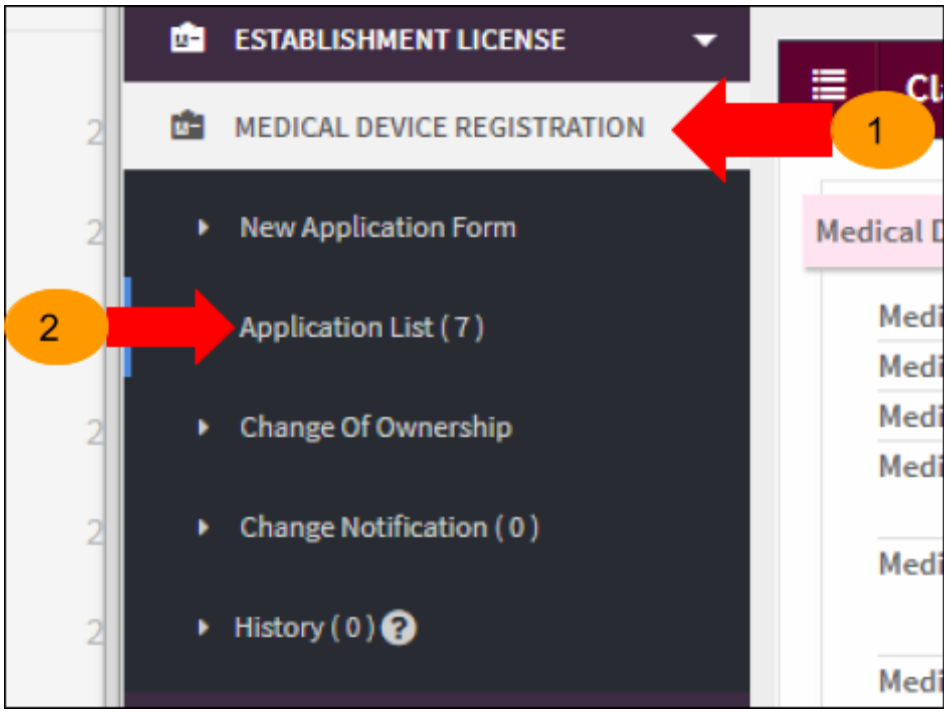


The user login successfully in the system medcast. It show the dashboard of the account.



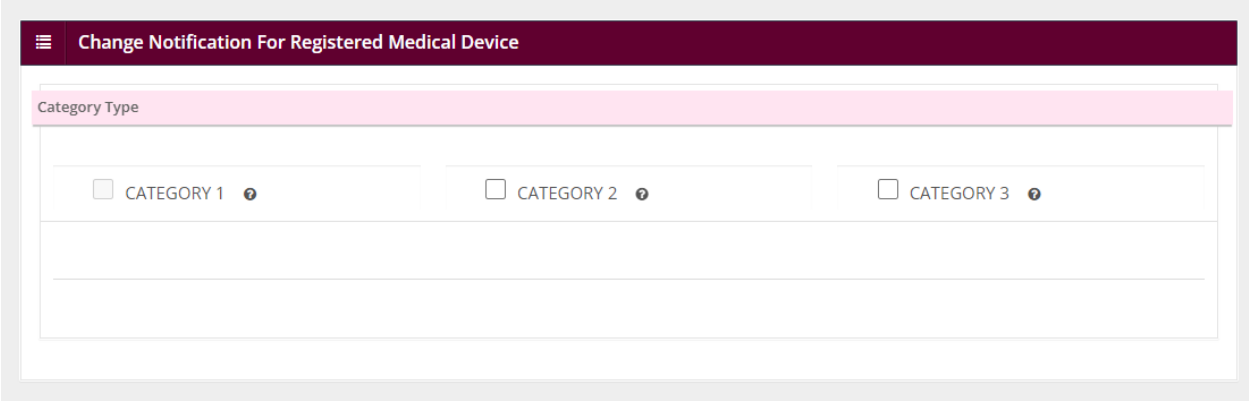
2.0 CHANGE OF NOTIFICATION - SINGLE APPLICATION

User go to *Application List* page to change of notification application.

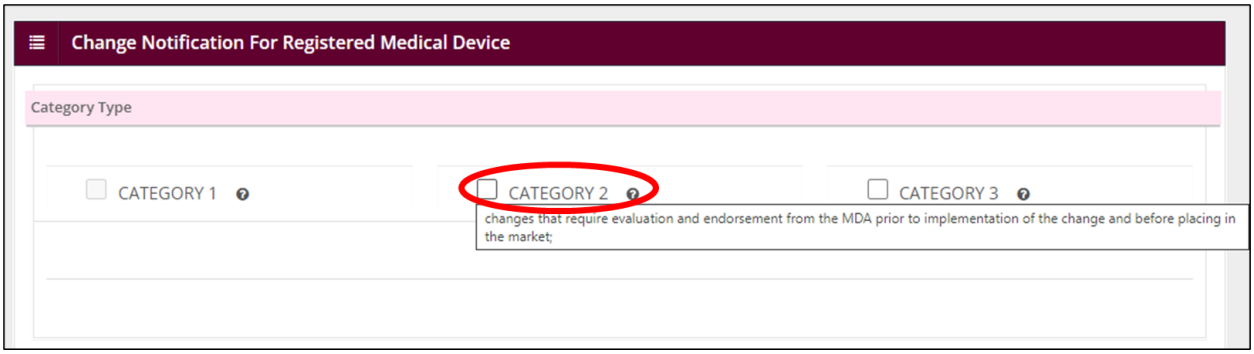


The diagram below show *Application List* page. Click Change Of Notification to change of notification application.

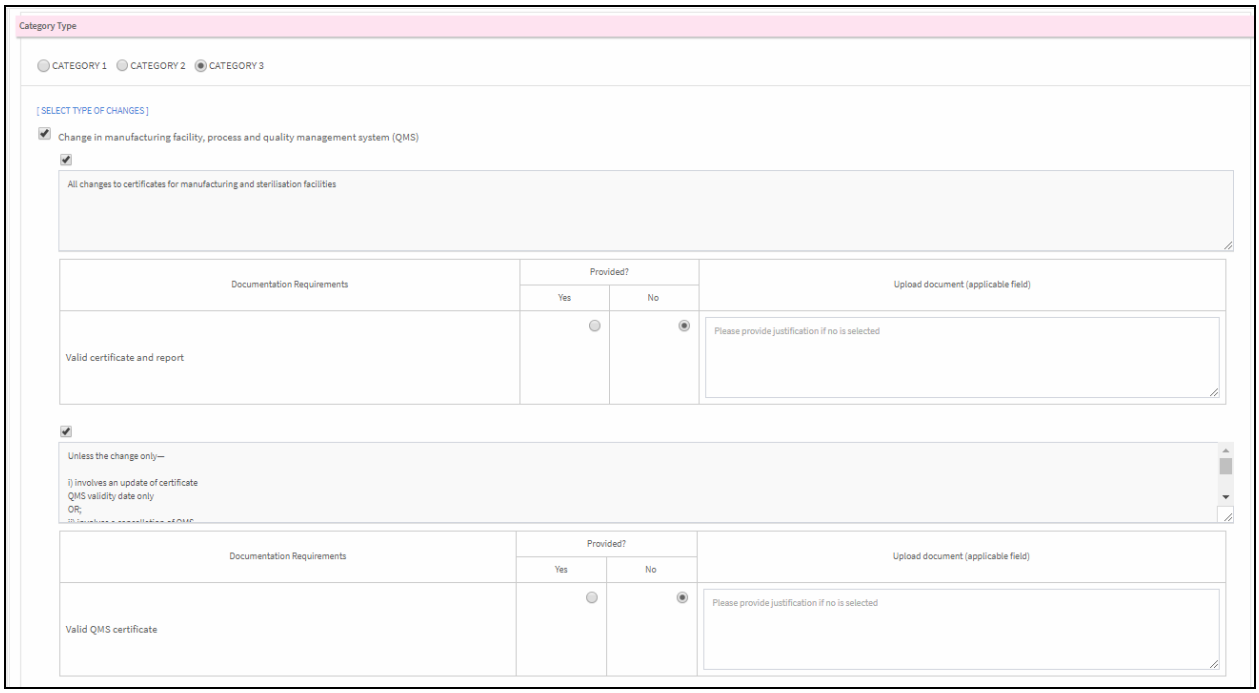
Create a Change of Notification application. Category type will be display. The user can tick one of any category or can tick both of the category.



The user can know the definition of category 1, category 2 or category 3 when the user hovers the pointer over its category type



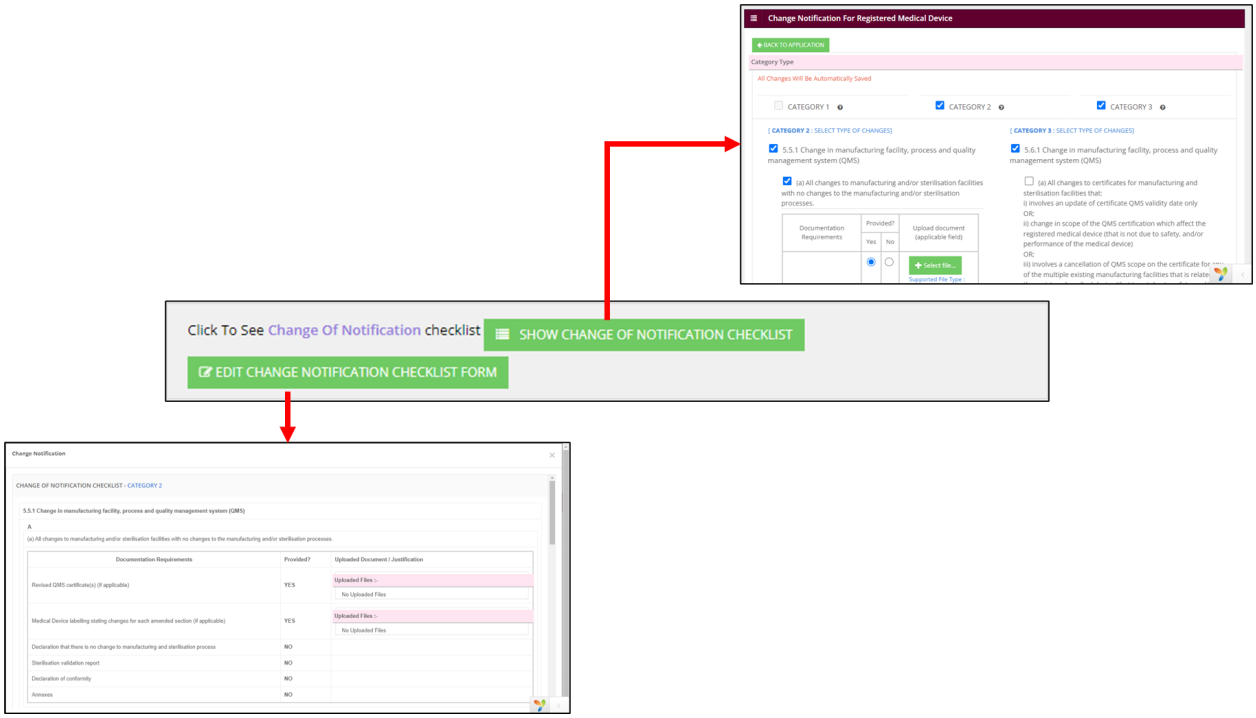
The user can select more than one type of changes.

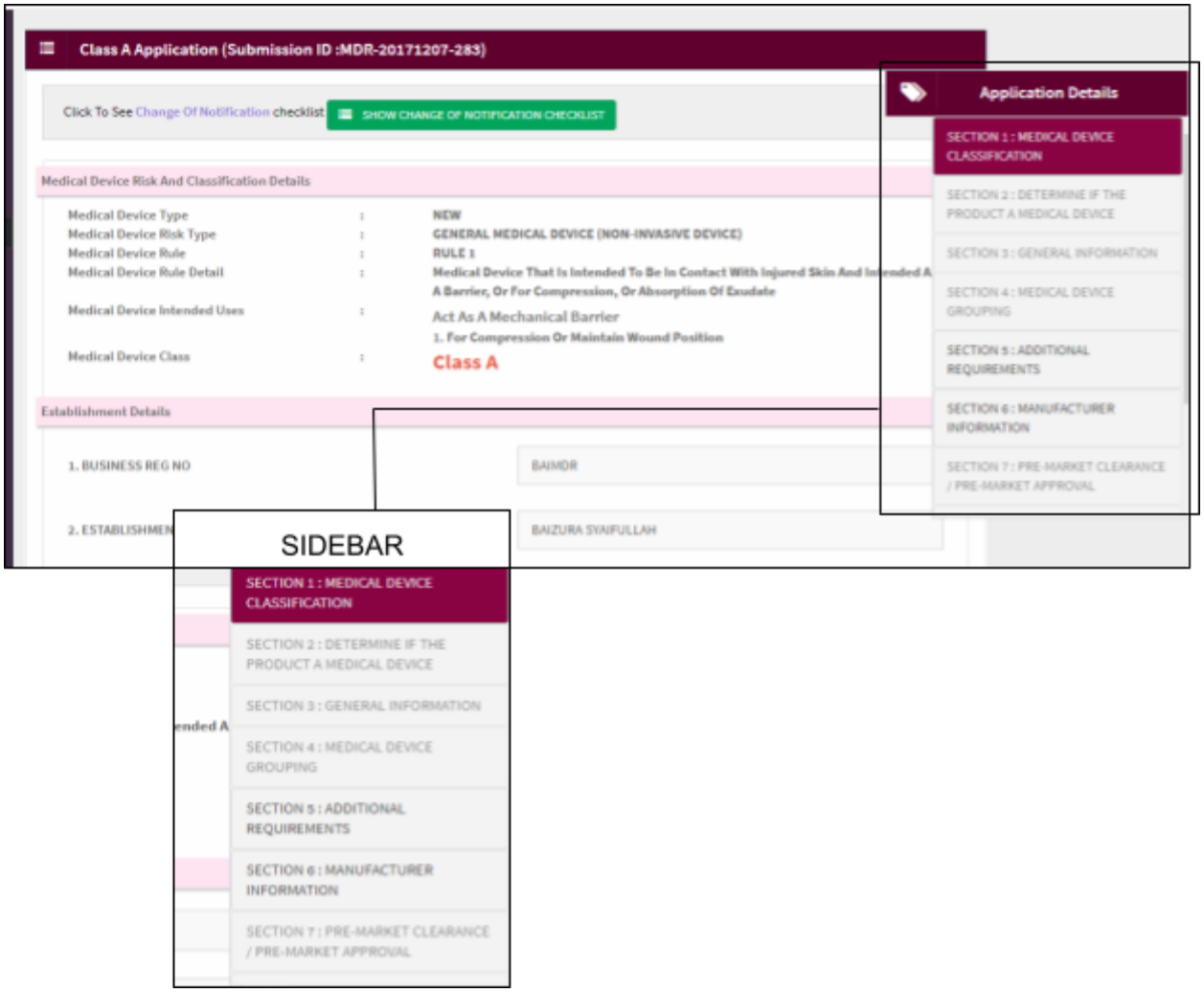


For the change of notification application. User can register new application or to edit certain section based on their change of notification category

Then, click PROCEED TO REGISTRATION APPLICATION CHANGE OF NOTIFICATION to proceed the registration of the change of notification application.

At the top of the page, user can view the checklist of the Change Notification by clicking the SHOW CHANGE OF NOTIFICATION CHECKLIST and user also can edit the checklist of Change Notification by clicking the EDIT CHANGE NOTIFICATION CHECKLIST FORM.



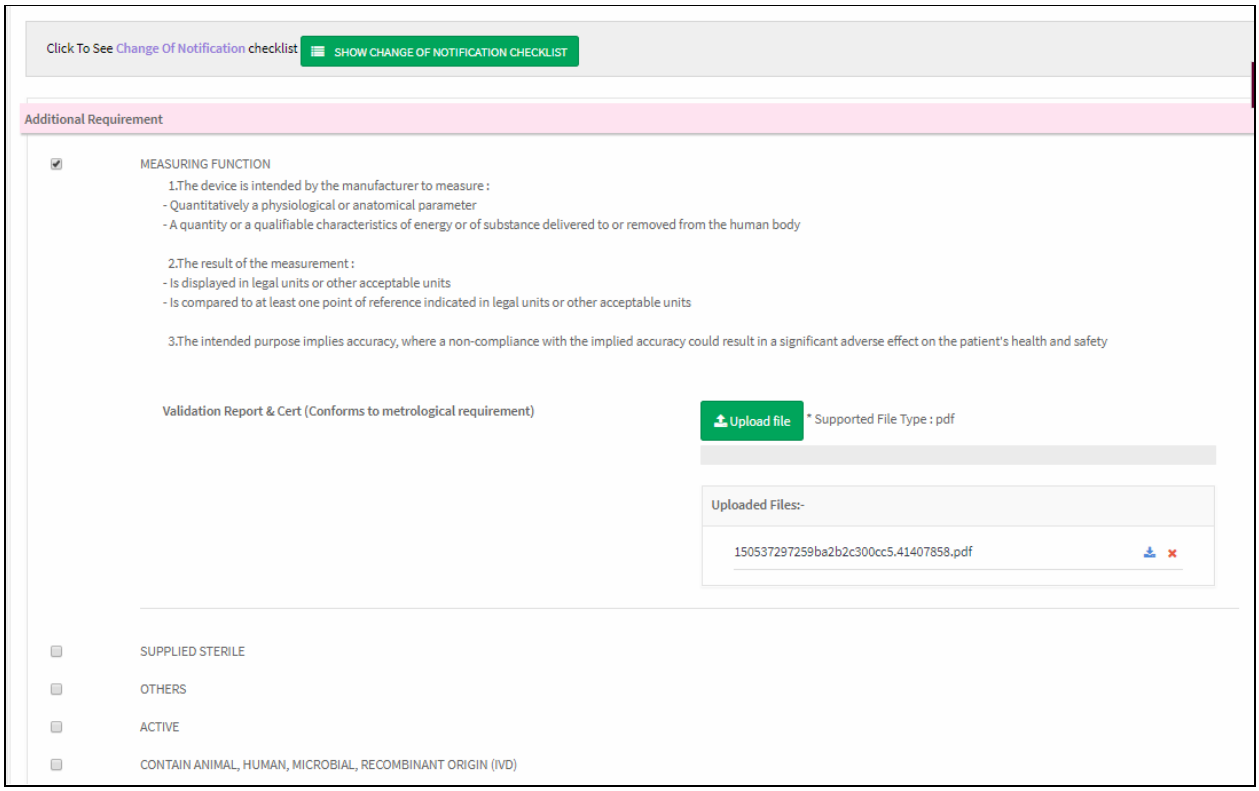


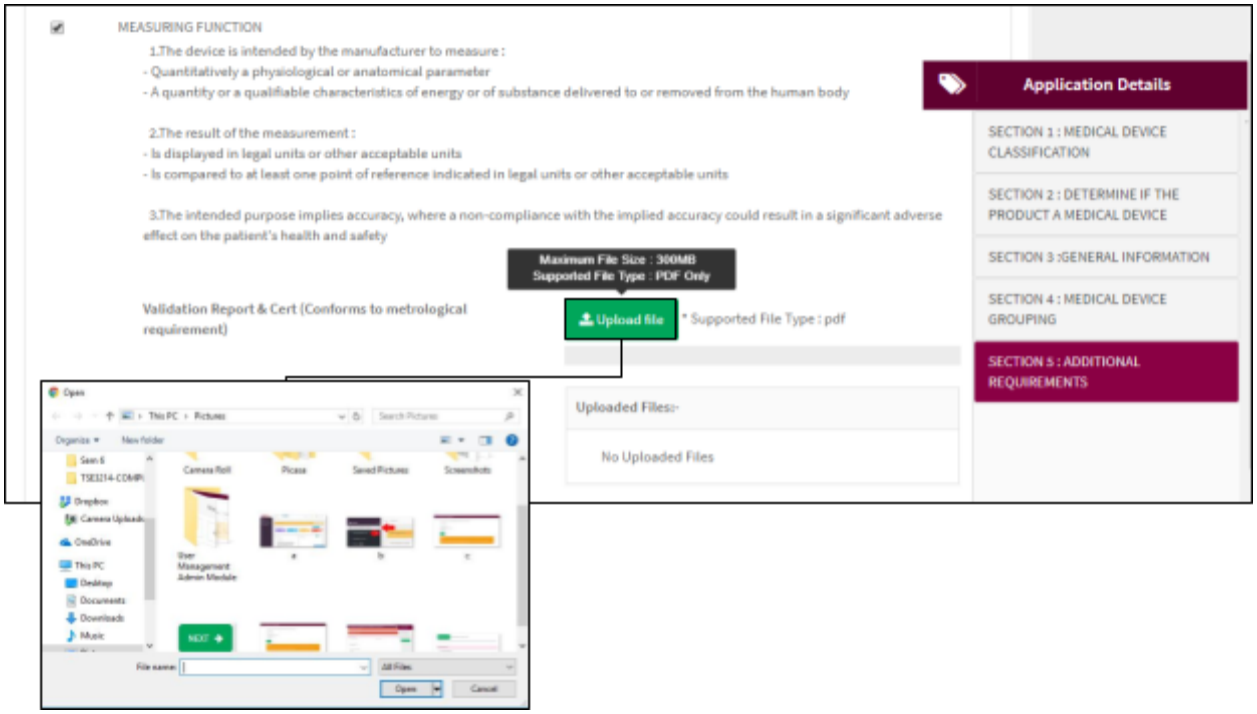
To edit a certain section, the user can click 

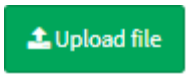
to go to the editable section or click the sidebar to go directly to the editable section.

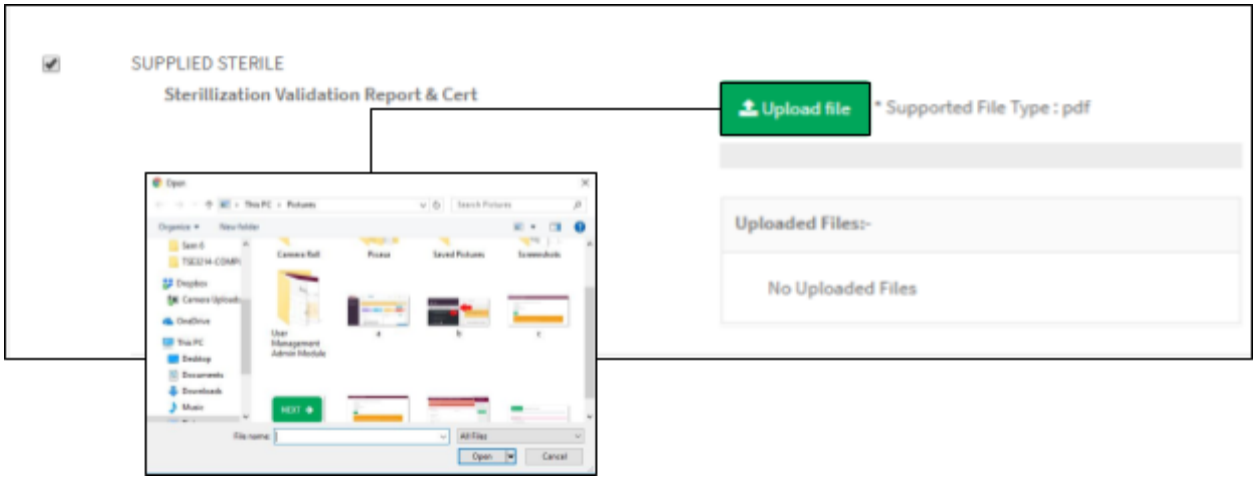
The diagram below show SECTION 4: CSDT that need to be change.

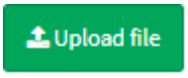
User can tick checkbox other than previous in other to make a change and user can tick more than one checkbox. If not, user click  to go to next section.

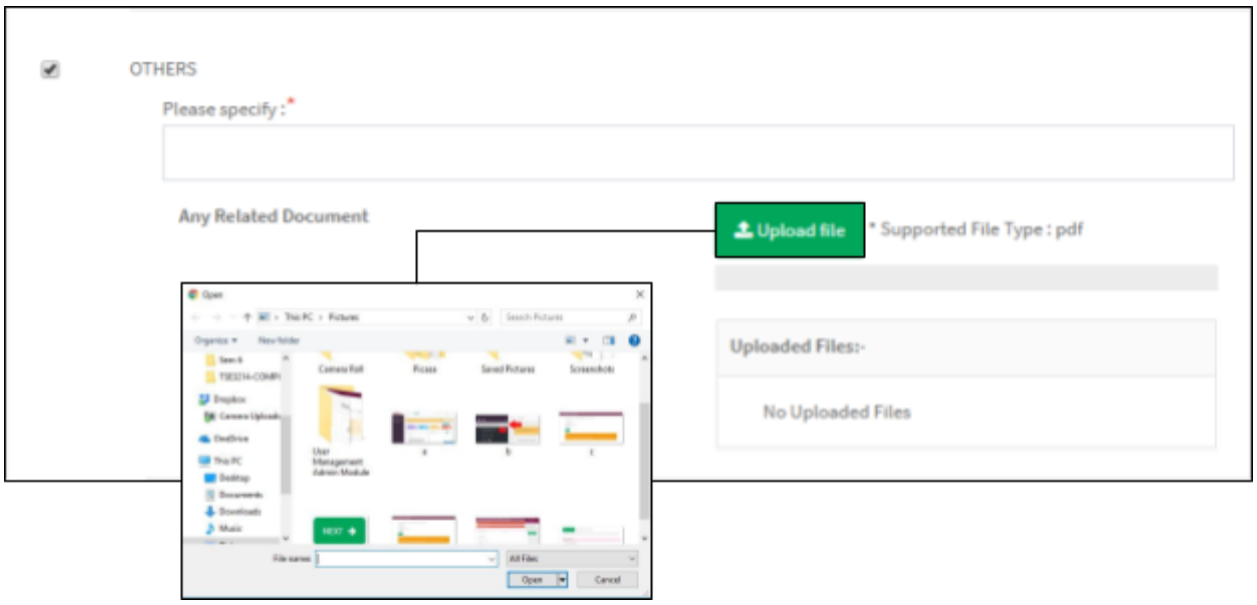


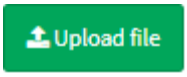


User click  to change the old upload file to the new upload file. **The file must be pdf format.**

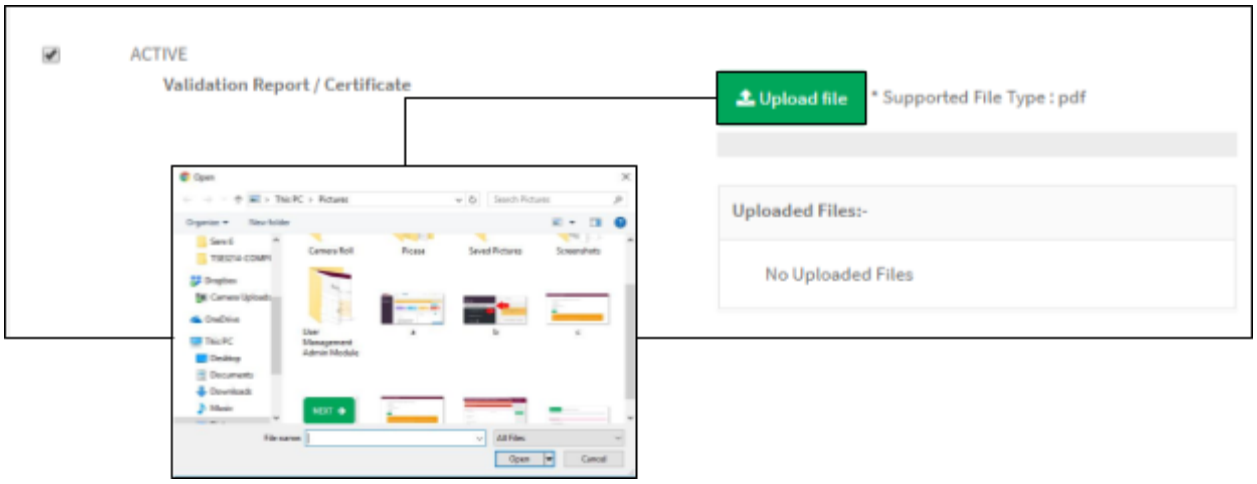


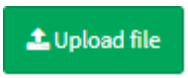
User click  to upload file. **The file must be pdf format.**



User has fill 'Please specify' text box first then click 

to upload file. **The file must be pdf format.**



User click 

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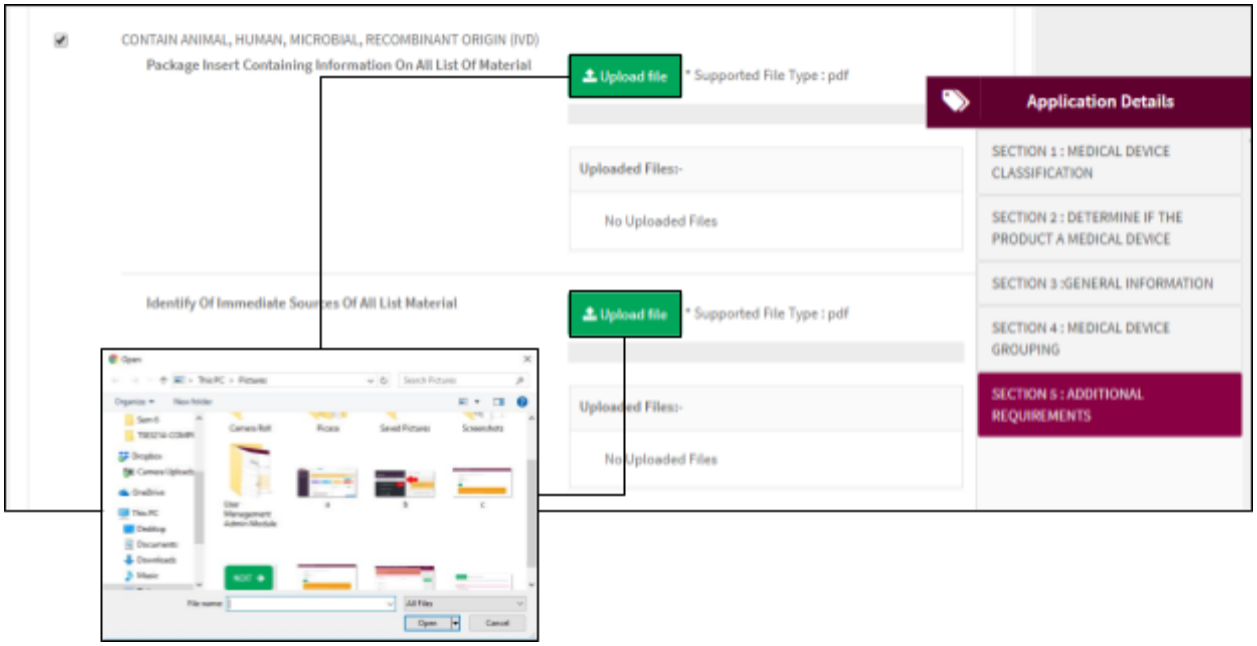


User click 

to upload file. **The file must be pdf format.**

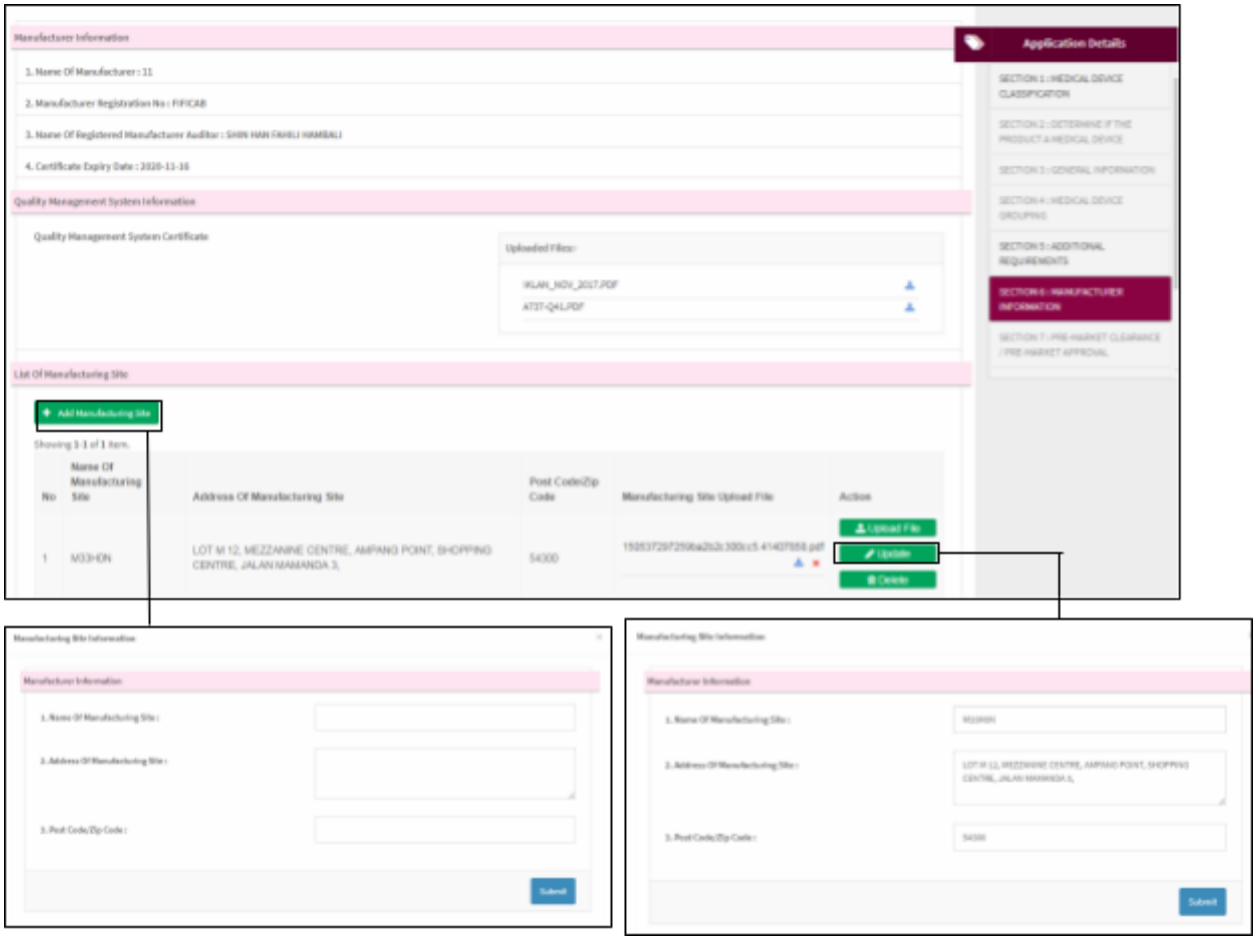
The user can click 

to go to the editable section

Click 

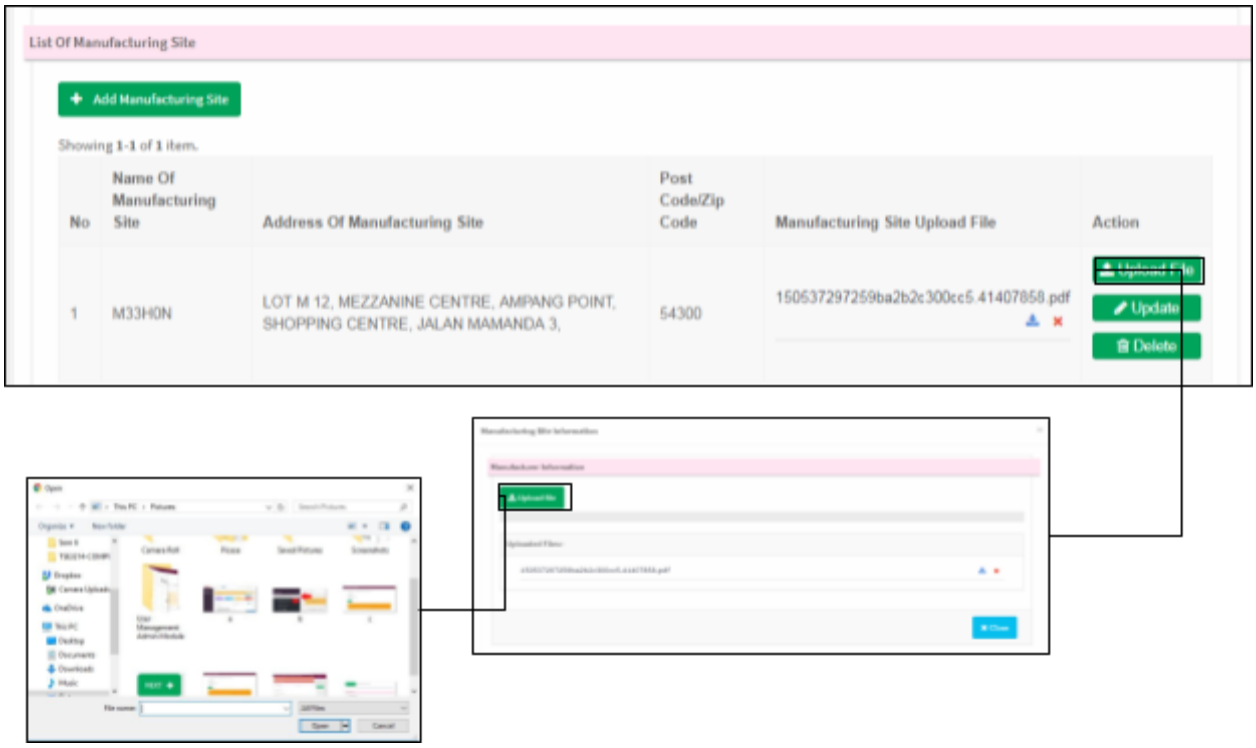
to go to the previous section to continue edit the change.

The diagram below show SECTION 6 : MANUFACTURER INFORMATION that need to be change.

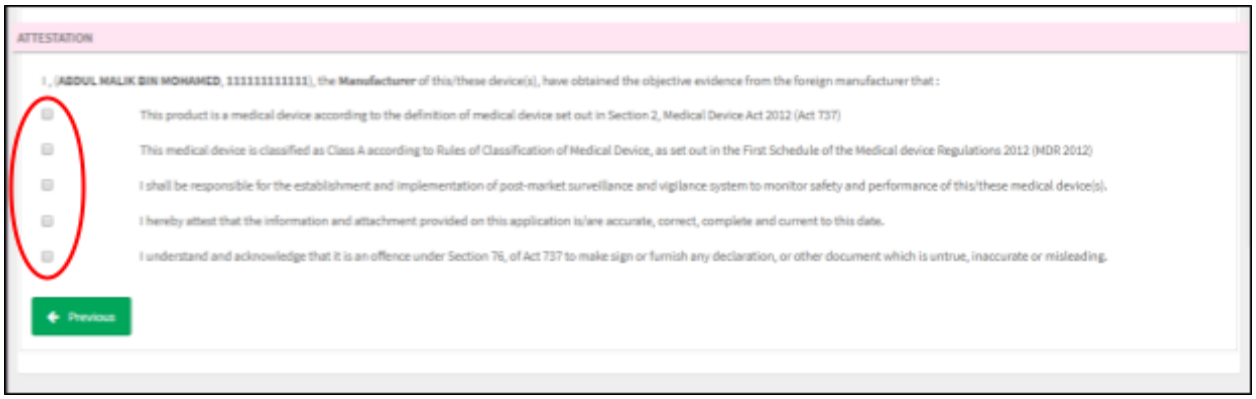


User click + Add Manufacturing Site to add new data or click Update to change the old data. User has to fill all the text box then click Submit. The new data will display in 'List Of Manufacturing Site' table.

User click  to change the old upload file or to new upload files.



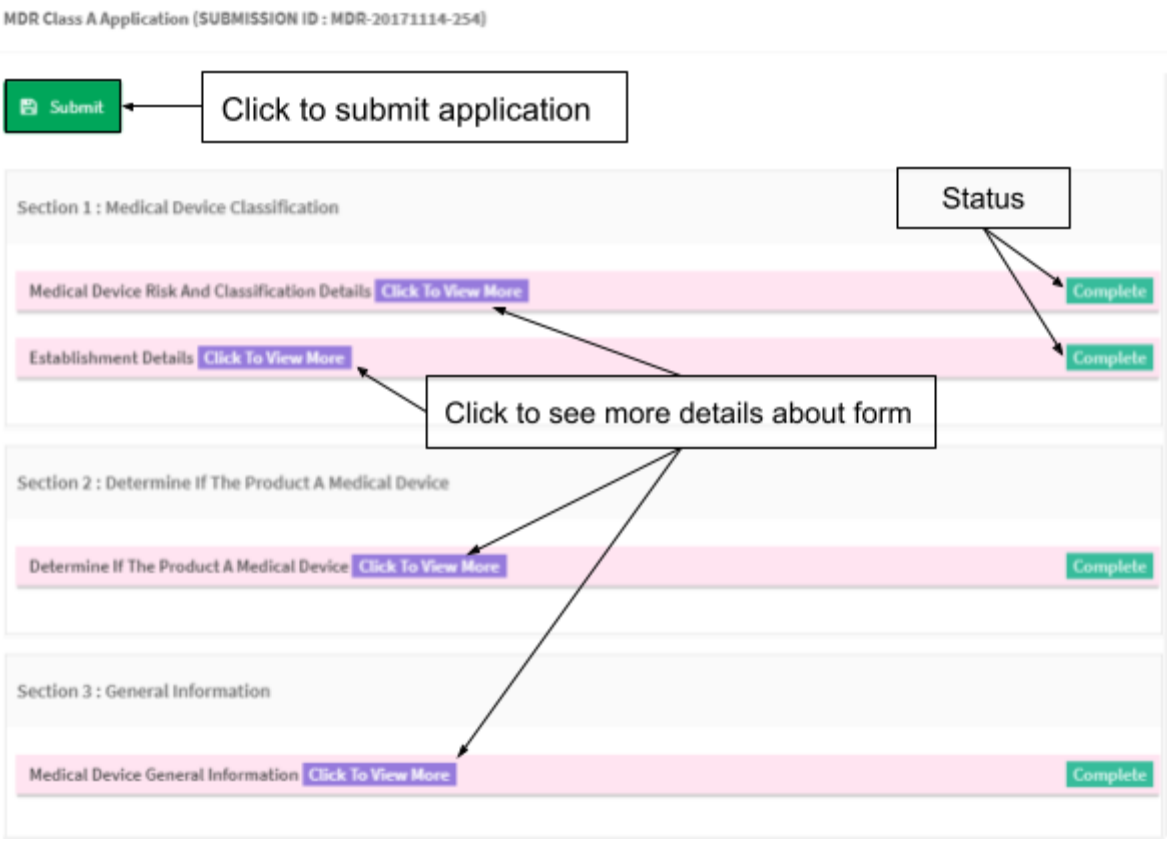
Next, user will go to SECTION 10 : DECLARATION OF CONFORMITY & ATTESTATION page to complete the change of notification application.



User has to tick all the checkbox before user can submit application.

User click 

to preview before submit application.

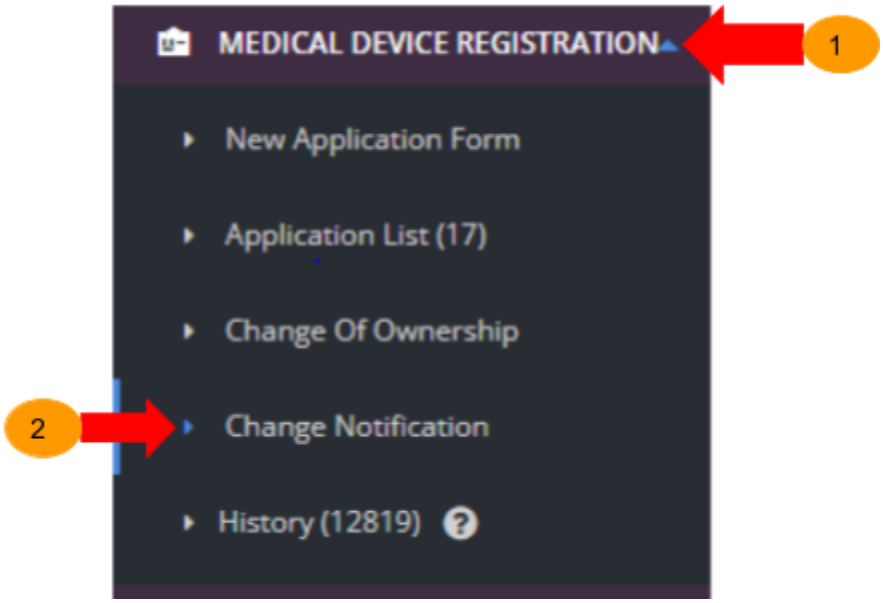


Submission only can do if all form status is Complete . If status Not Complete , user has to complete the form.

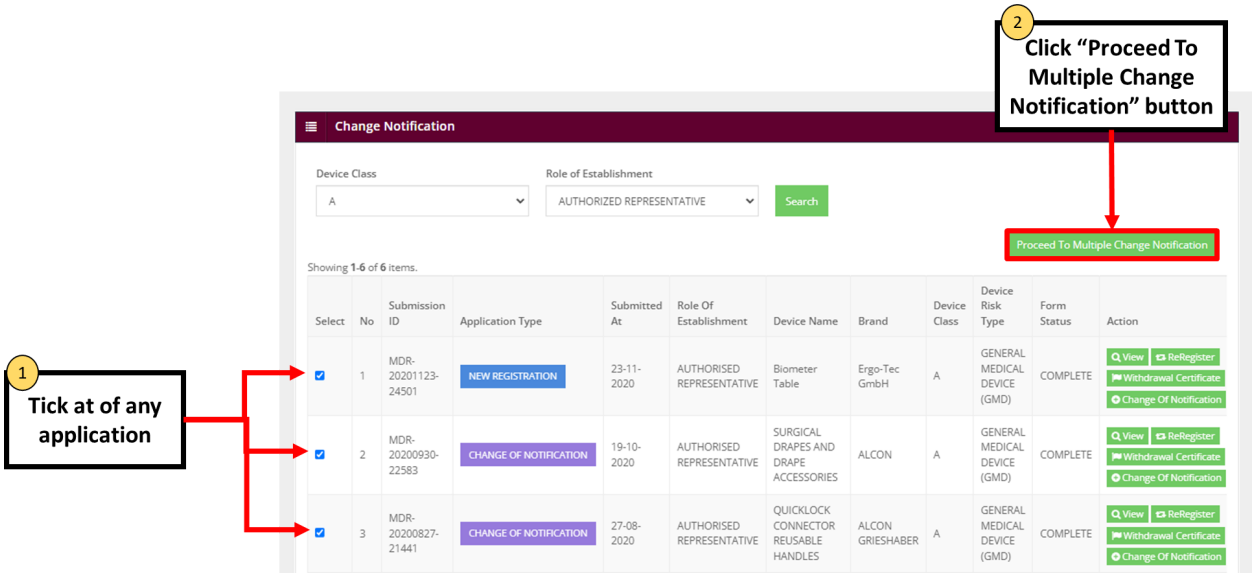
Then, click Submit to submit application.

3.0 CHANGE OF NOTIFICATION APPLICATION - MULTIPLE APPLICATION

User go to *Change Notification* page to make multiple change notification application.

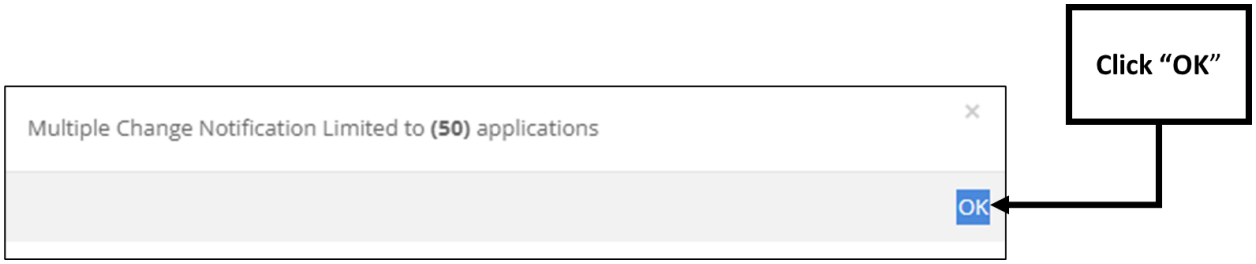


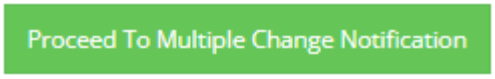
The diagram below show *Change Notification* page. User choose *Device Class = A and Role of Establishment = Authorised of Representative* and then click Search.



- After click Search, the list of application from *Class A* and *Authorised of Representative are appeared.*
- The user can select more than one application. The user tick at the checkbox at *"Select"* column to make multiple application change notification.

The multiple application can be made up until only 50 applications. If user tick more than 50 application, a pop-out message *"Multiple Change Notification Limited to **(50)** applications"* appeared. Then click "OK" to close the pop-out message.



- Click 

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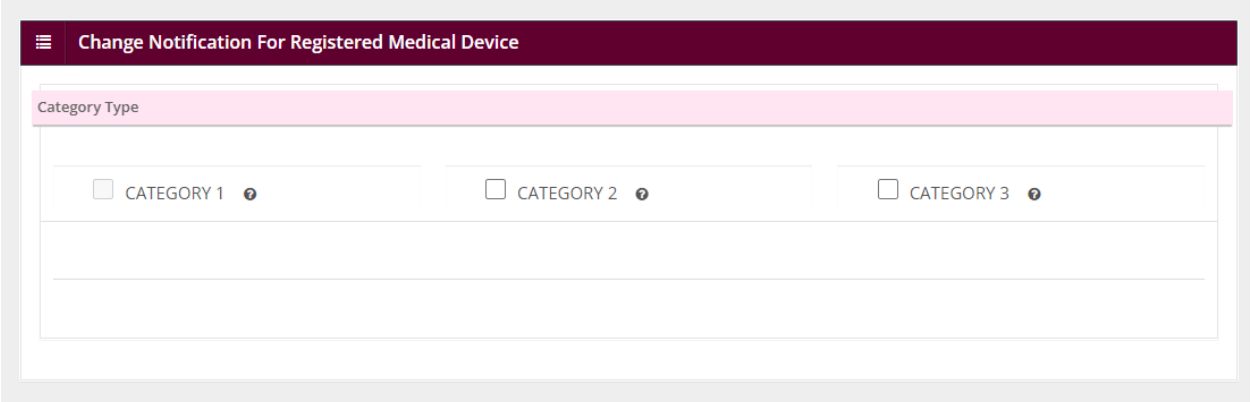

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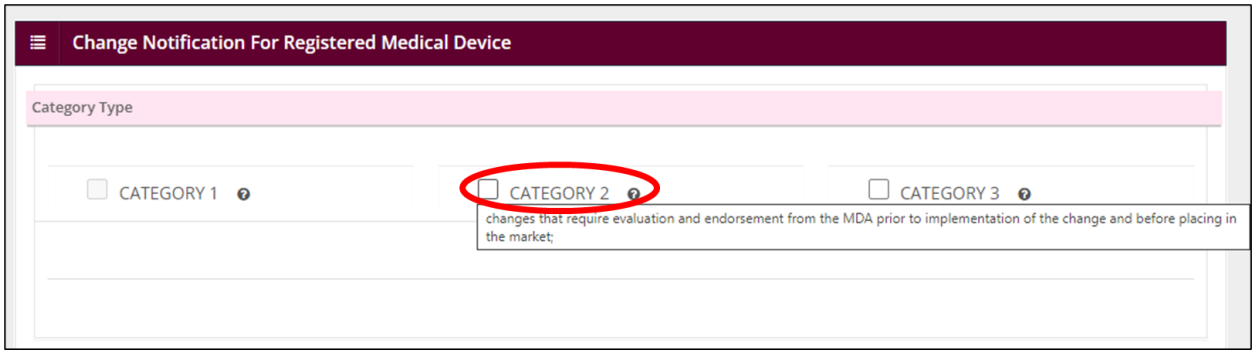

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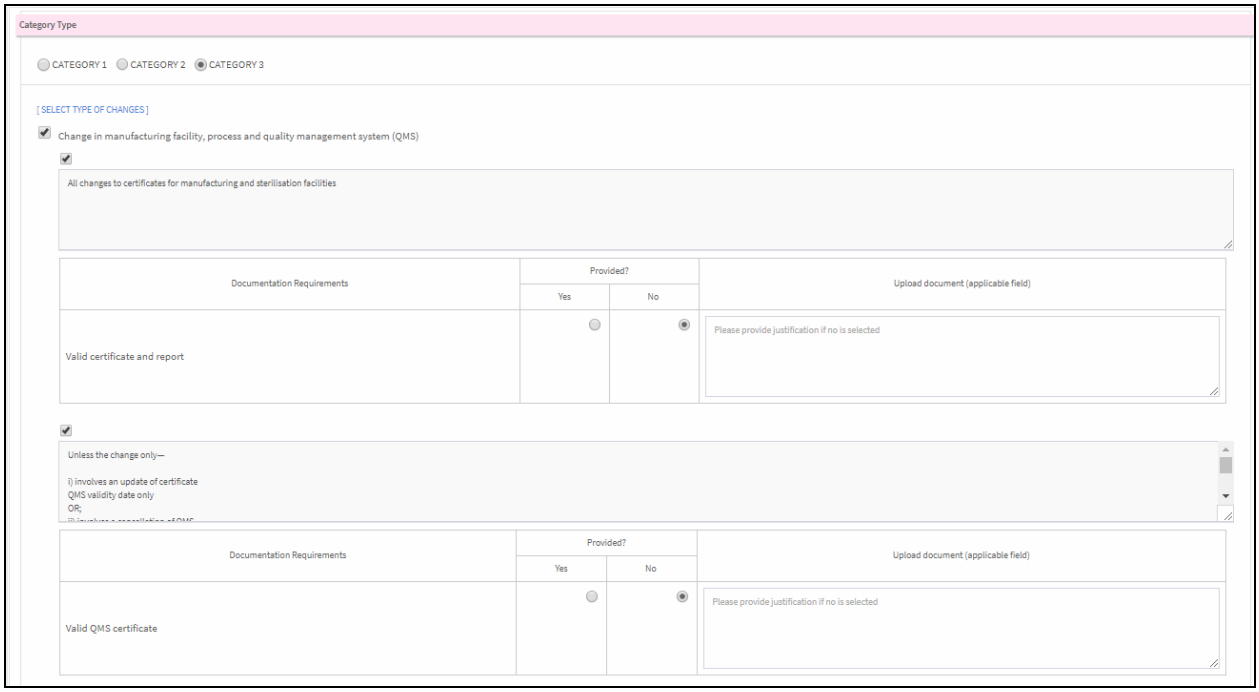

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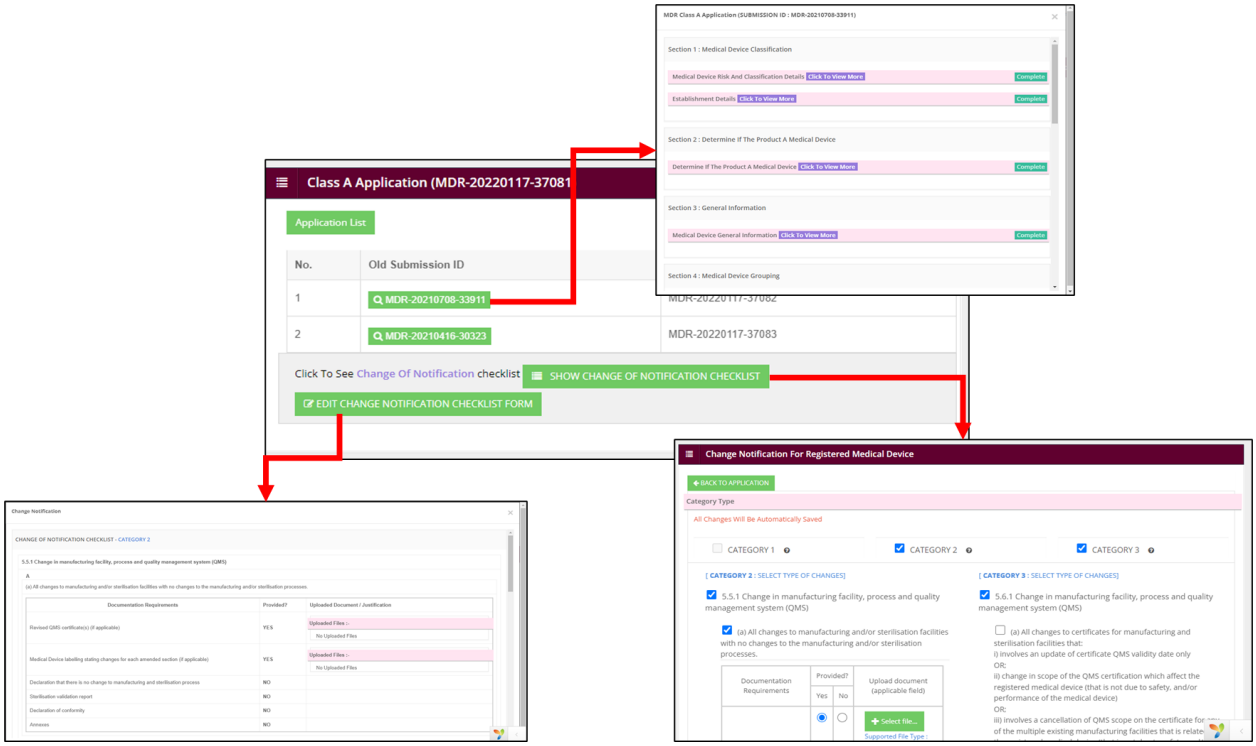
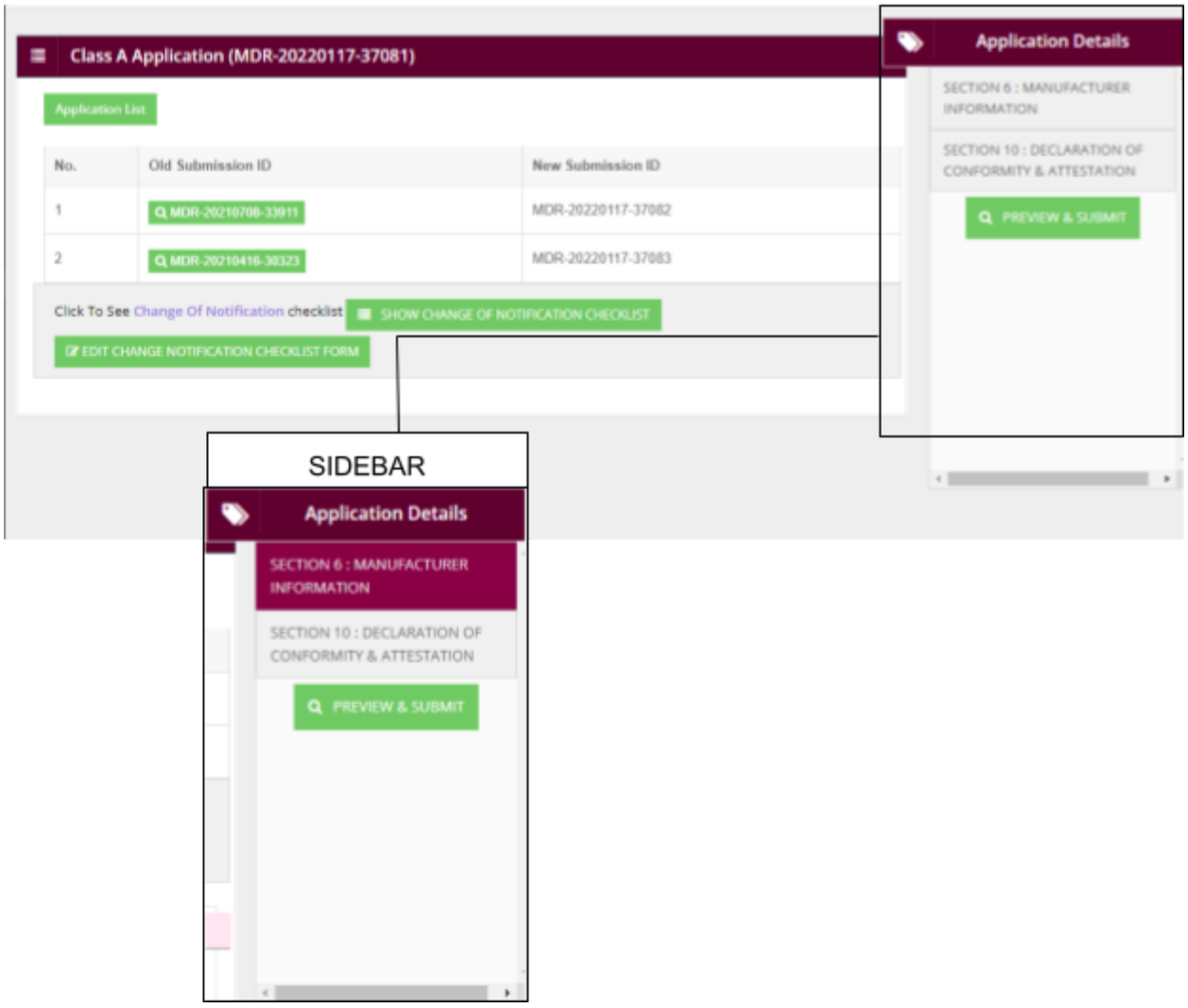
- The user also can edit the checklist of Change Notification by clicking the 

.
- The user click 

to view the old application information.





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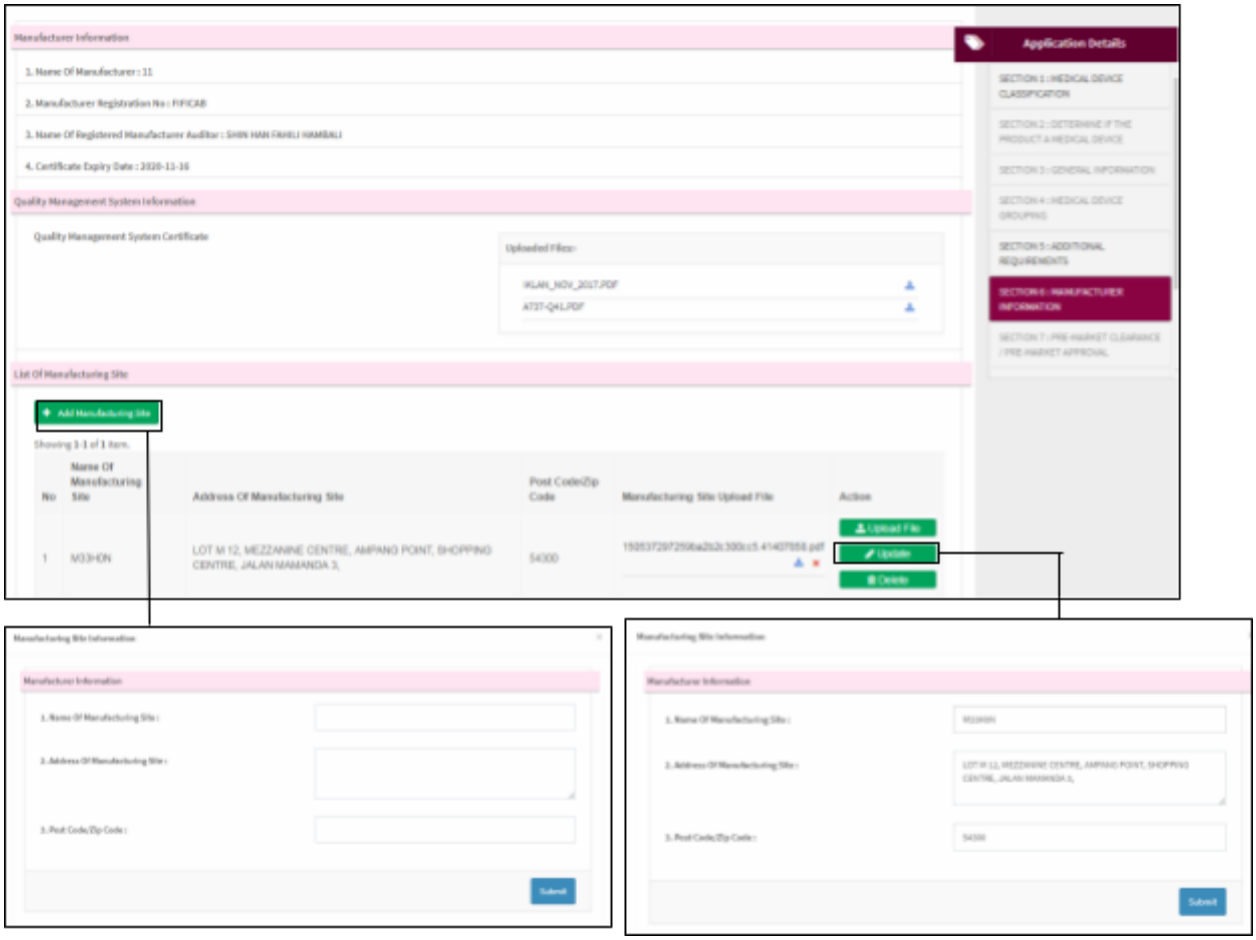

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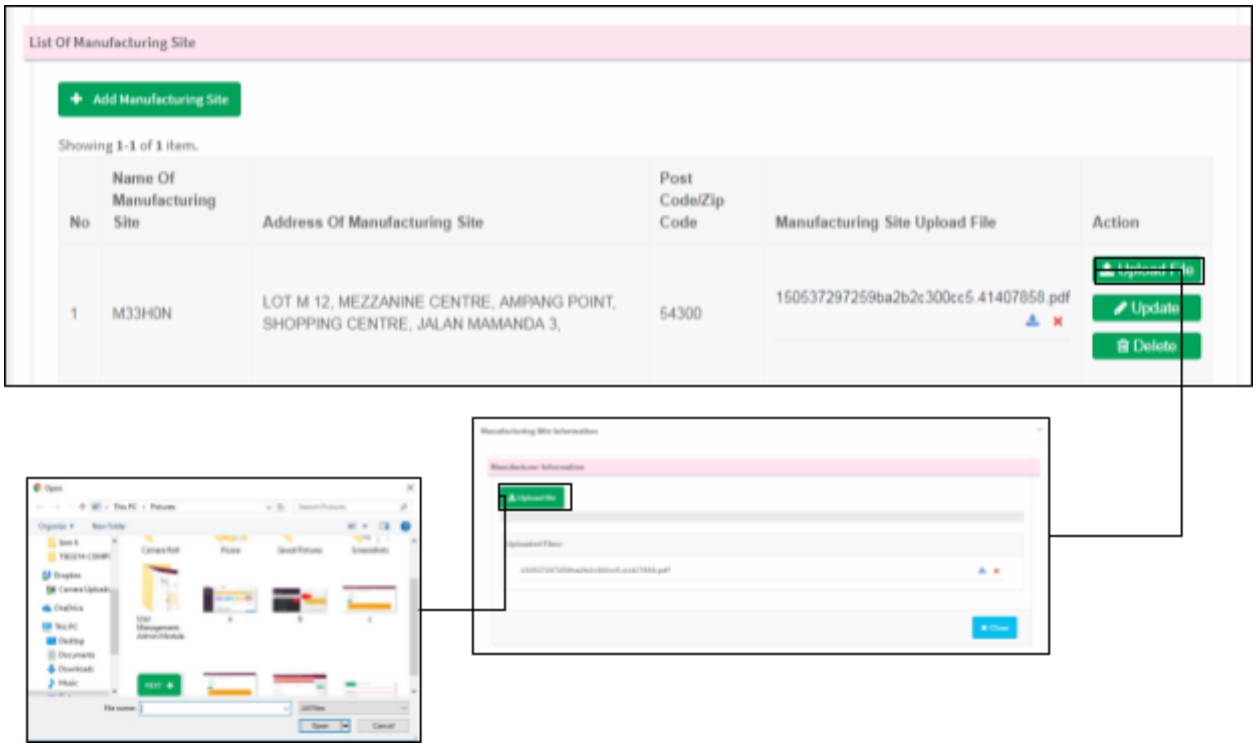

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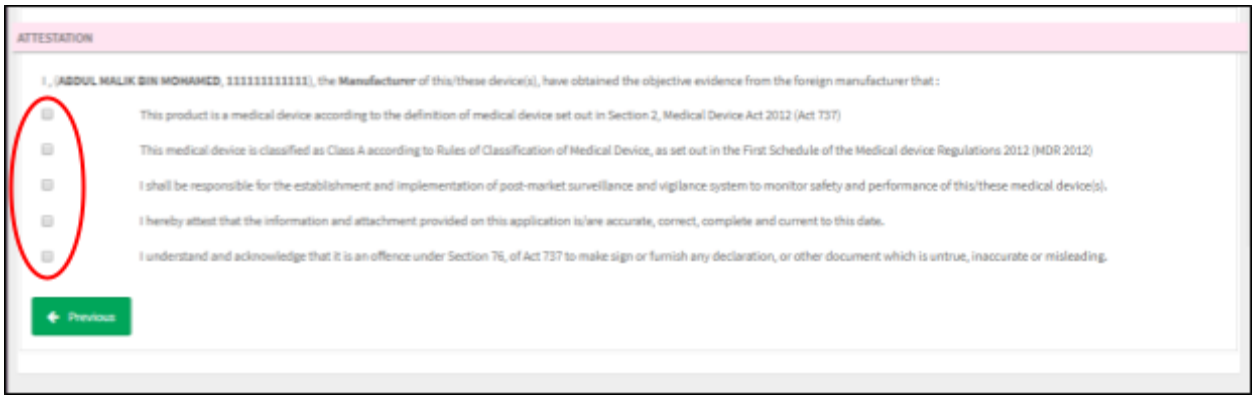

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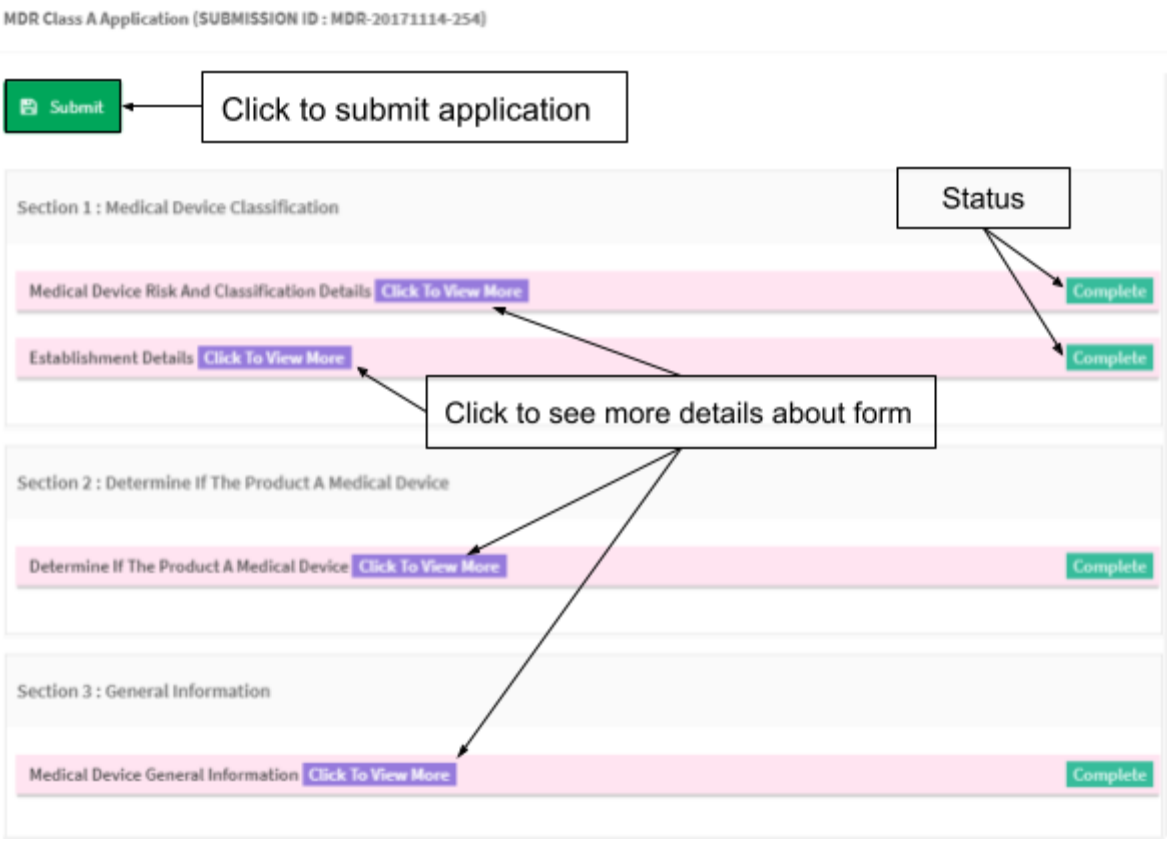

Submission only can do if all form status is Complete . If status Not Complete , user has to complete the form.

Then, click Submit to submit application.