# USER MANUAL FRONT END USER

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

## MODUL UTAMA - MDR CLASS A

**DISEDIAKAN OLEH :**

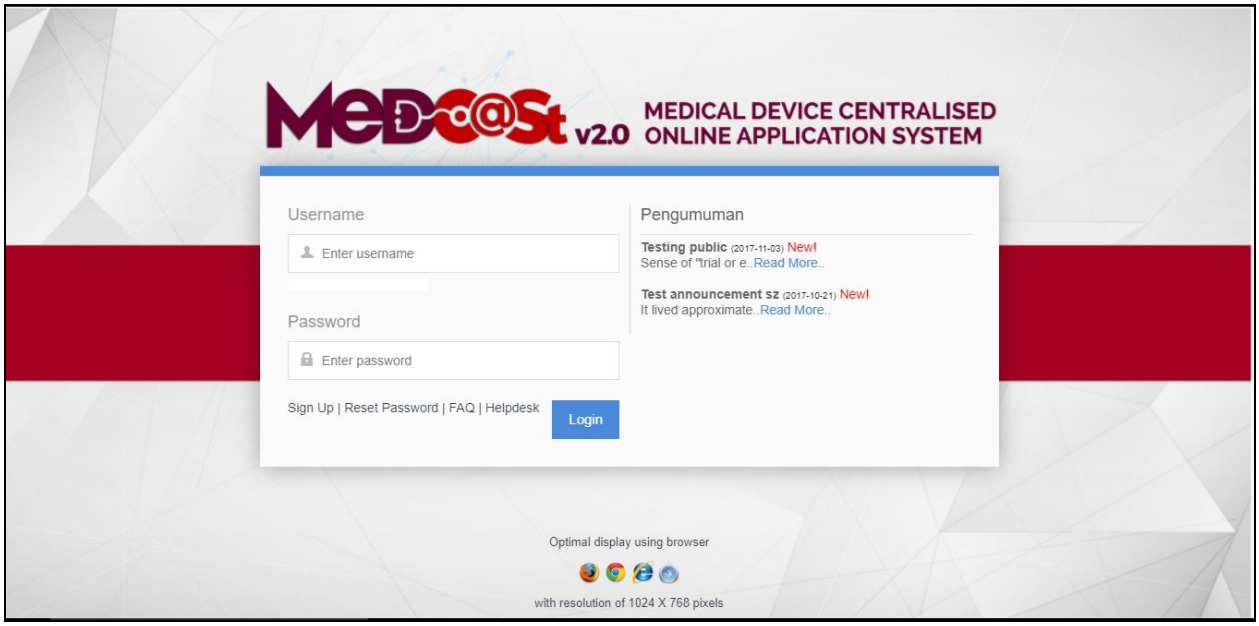
## LIST OF CONTENTS

## 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

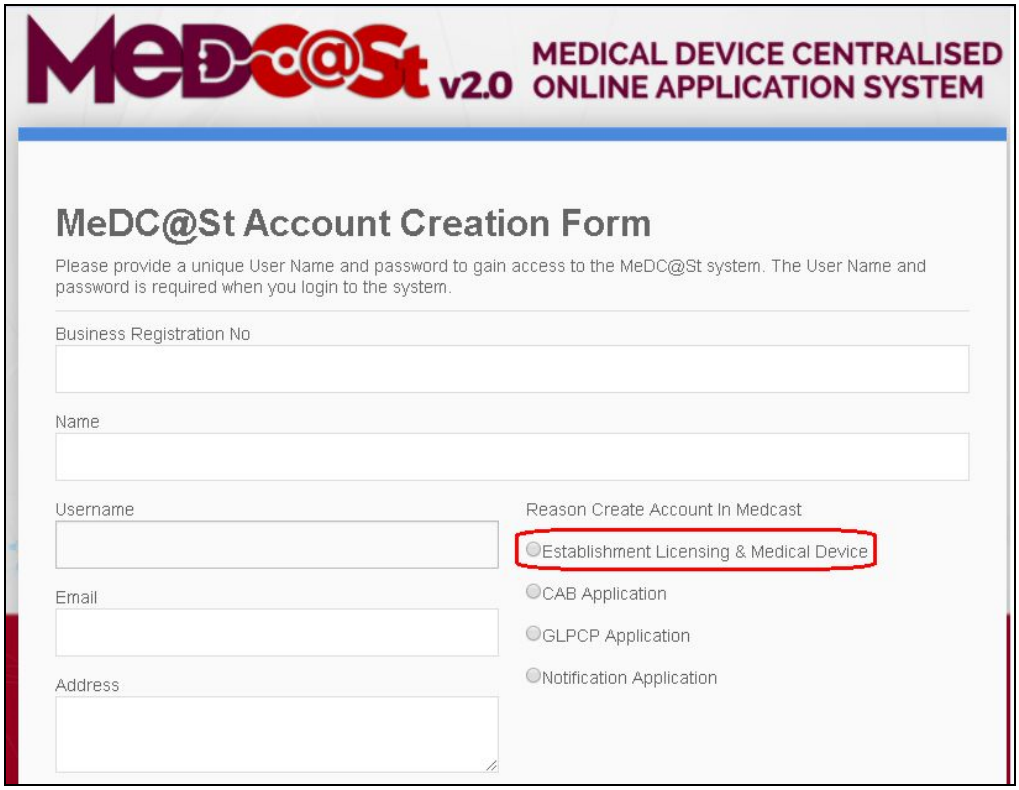
The screen below shows the expected webpage after the address has been keyed In.

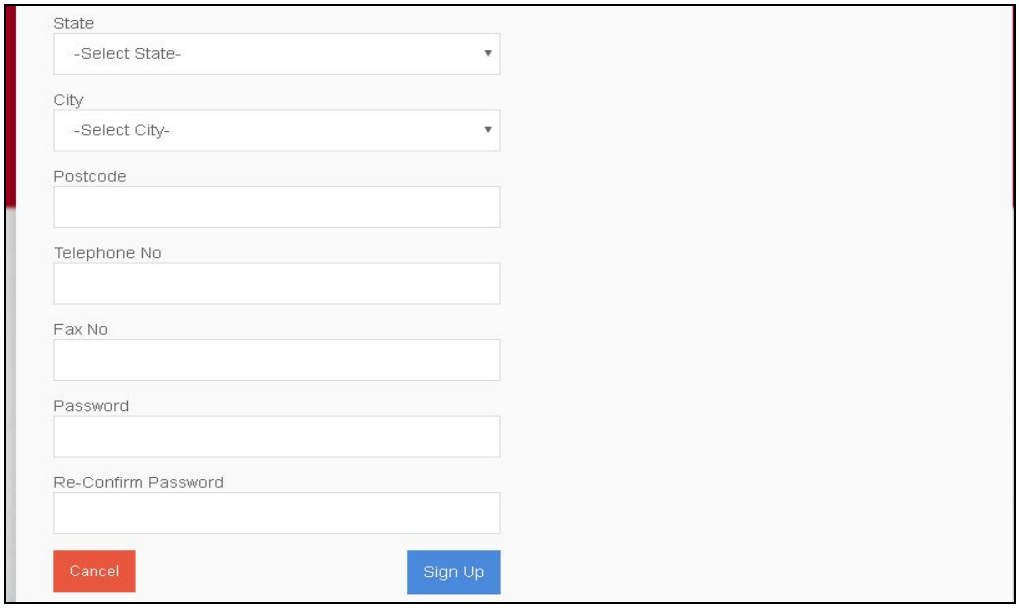



User has to log into the system using registered User ID and its respective password. Click the [Login] button to proceed.

## 1.1 SIGN UP

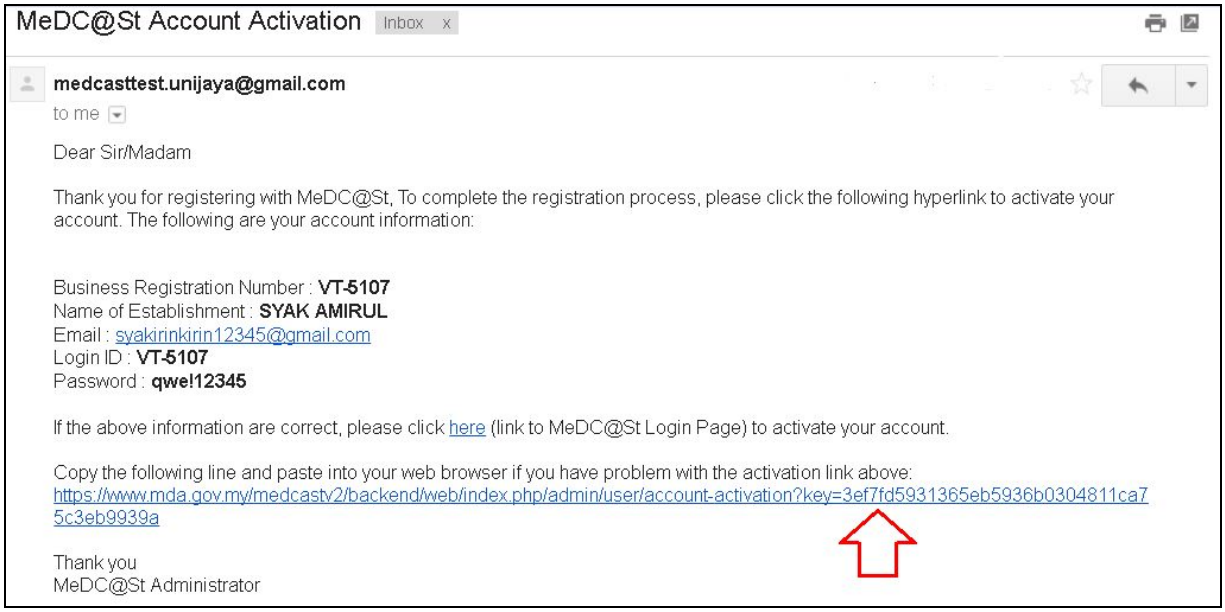
Click on the Sign Up at the bottom of login form to display the following screen. Fill the following empty form and choose drop down list such as Business Registration No, Name, Username, E-mail, Address, State, City, Postcode, Telephone No, Fax No, Password, Reconfirm Password and choose the radio button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



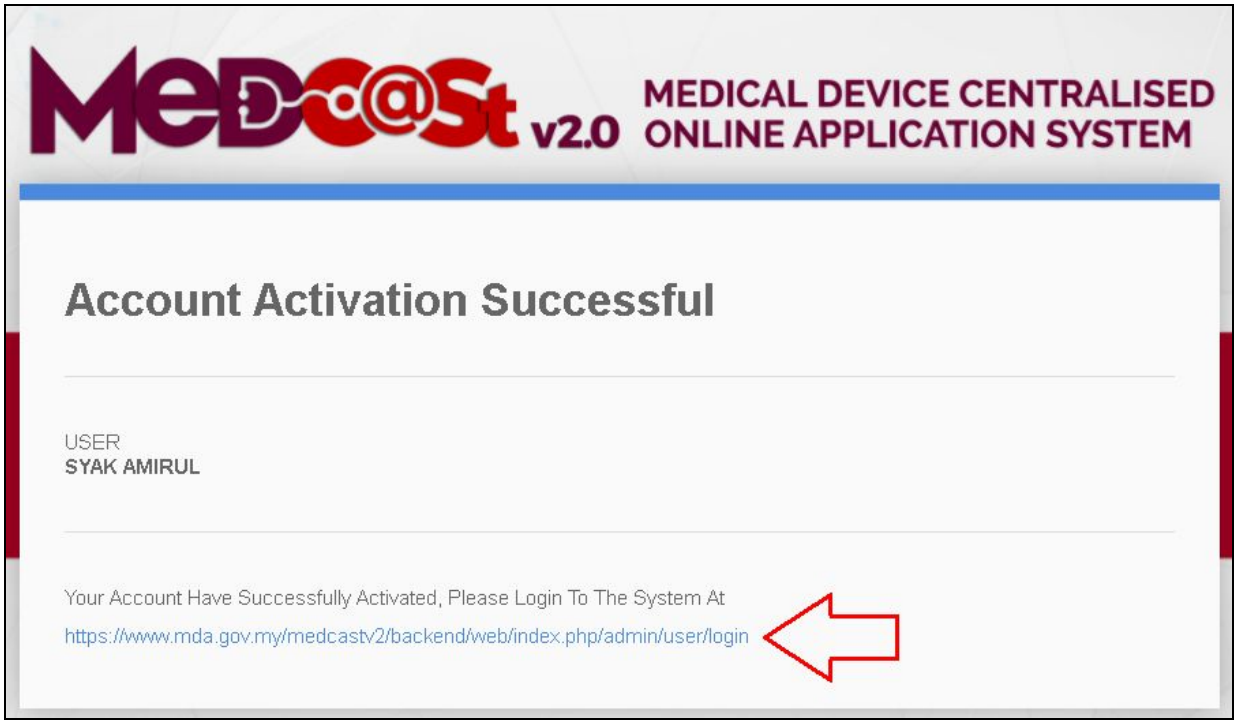



### 1.1.1 VERIFIED EMAIL FOR NEW ACCOUNT

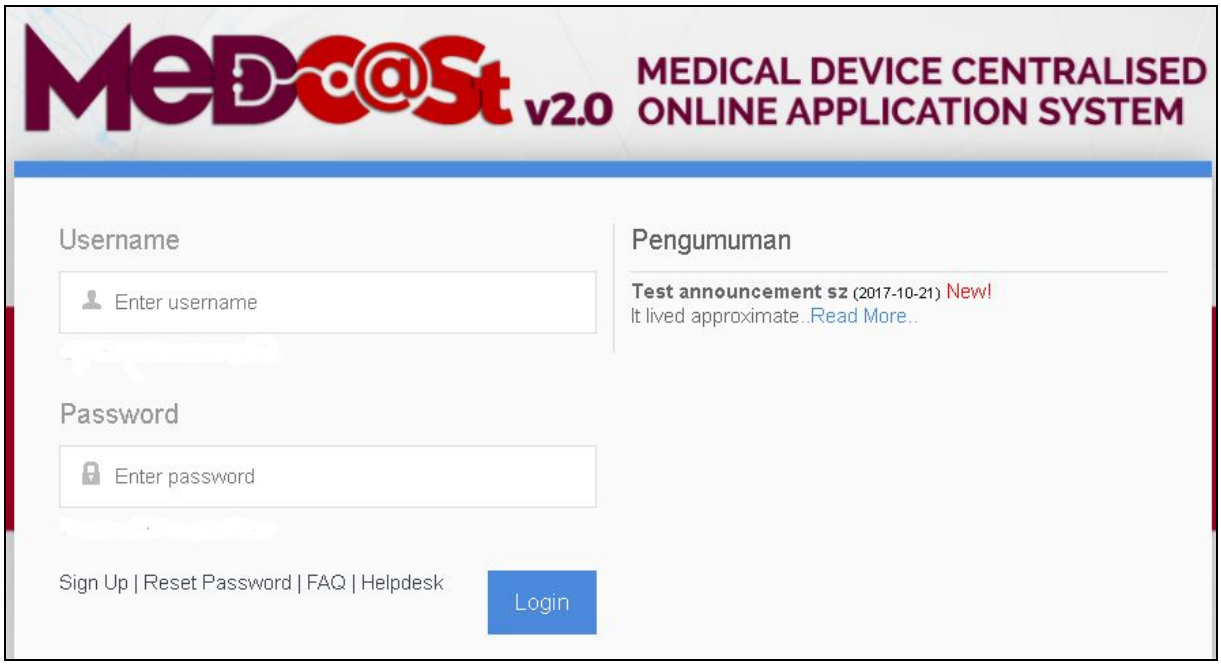
The user must verified email to completed the last step of the registration. Click at the link given to verified email in the system medcast V2.0.



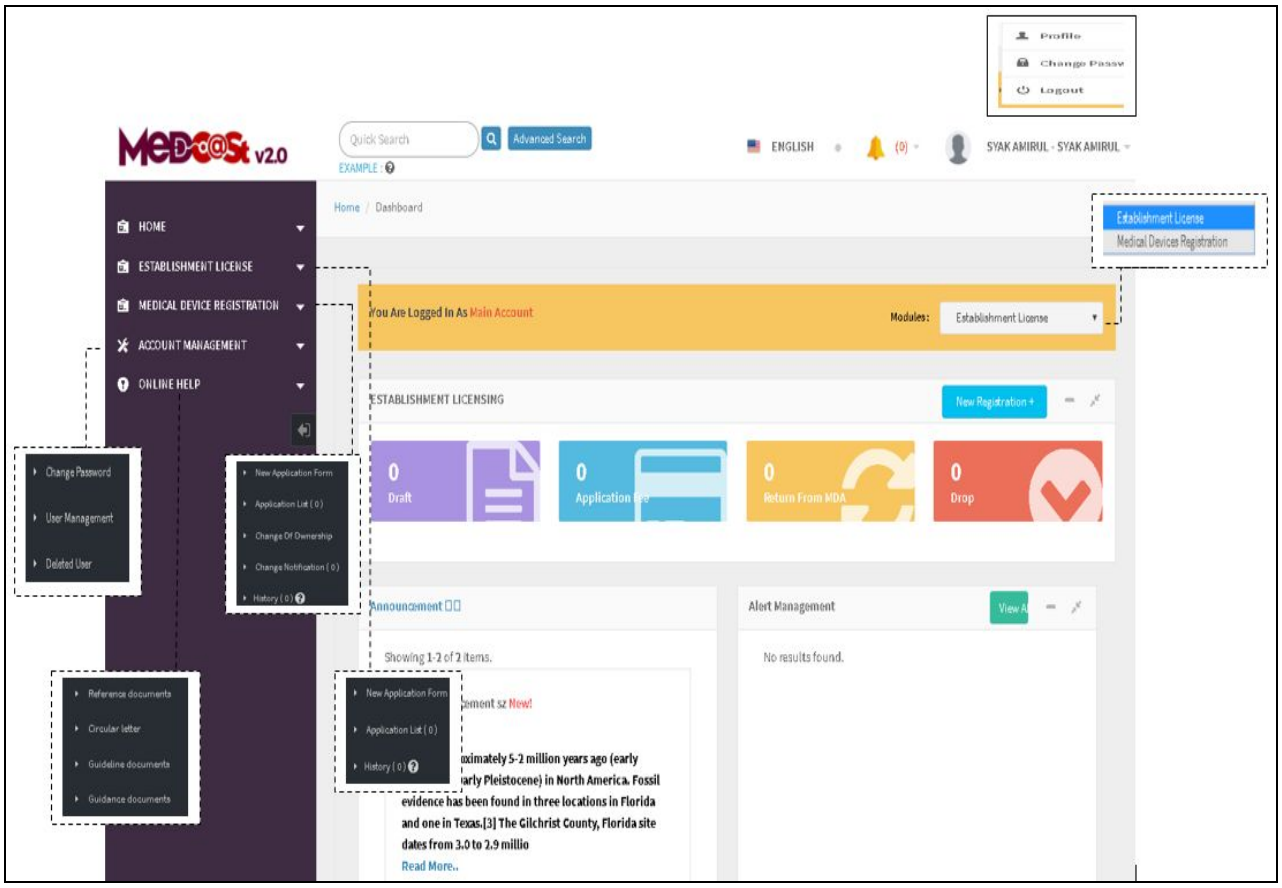
The account activation screen will display. The user must click at the link to login into the account.




The login screen will display.

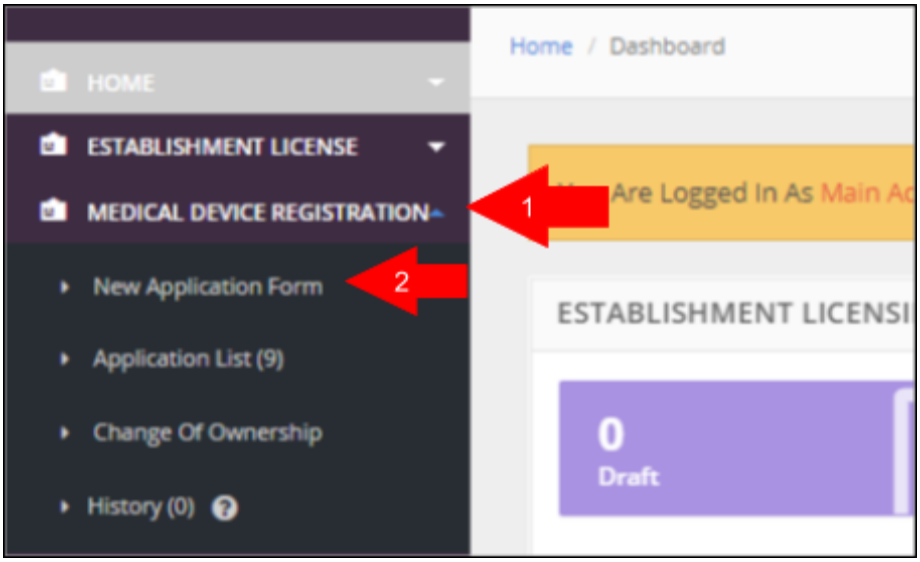


The user login successfully in the system medcast. It show the dashboard of the account.

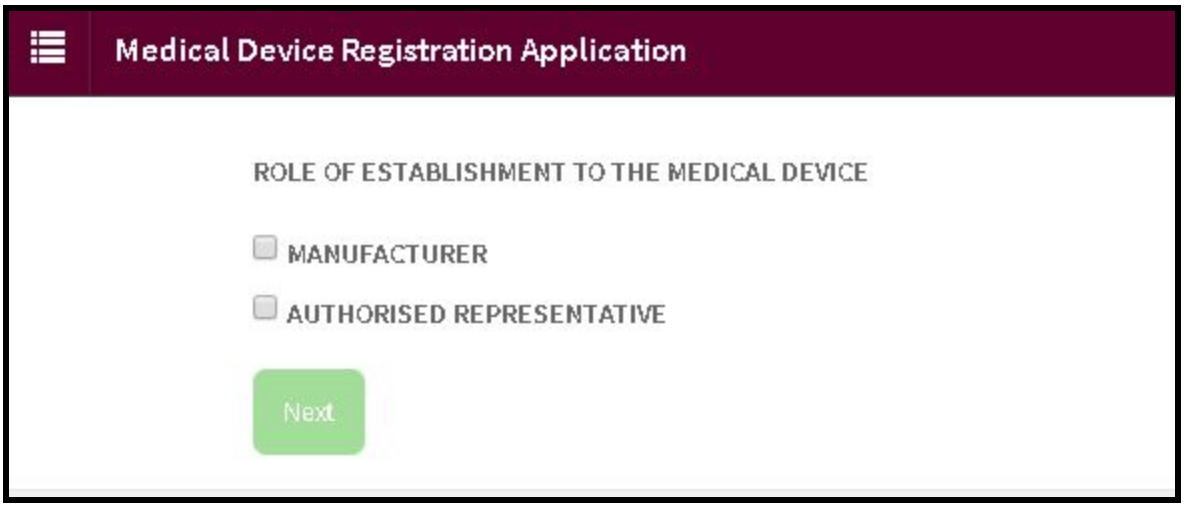



**User must create new establishment license first to create new medical device registration (Refer User Manual EL Front End User)

Click on the ‘MEDICAL DEVICE REGISTRATION’ at the left menu sidebar and click at the New Application Form’ to create new form.



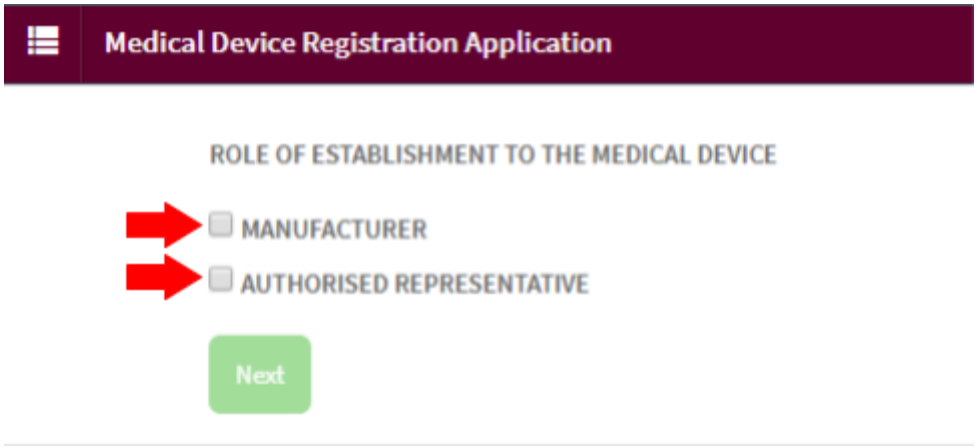

Medical Device Registration Application will display.



## 2.0 CREATE NEW MEDICAL DEVICE REGISTRATION A APPLICATION

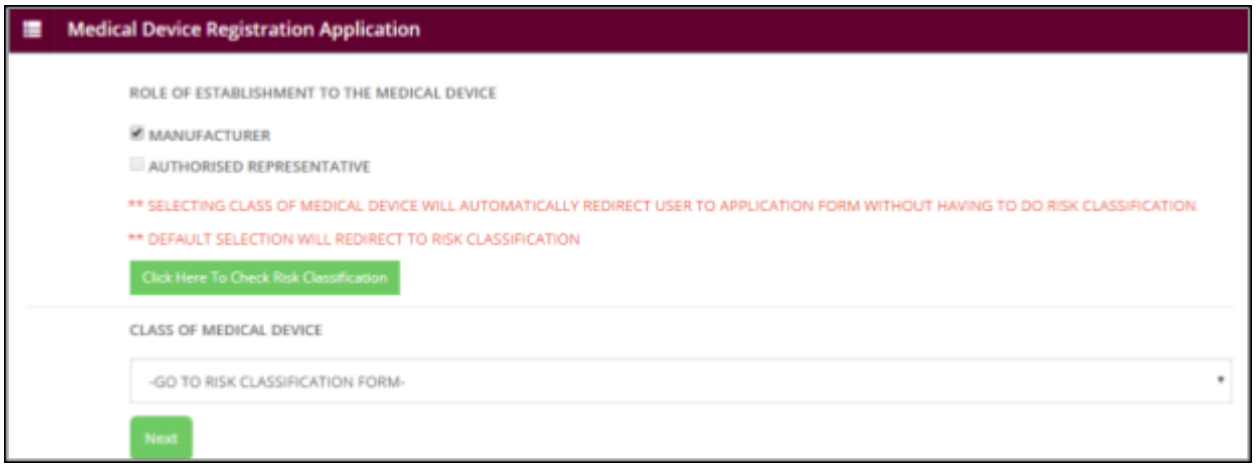
Tick on the checkbox ‘MANUFACTURER’ or ‘AUTHORISED REPRESENTATIVE’ to create new application and click on the button 

to proceed. User only can make one application at one time. ‘Next’ button will enable after user tick applications checkbox.

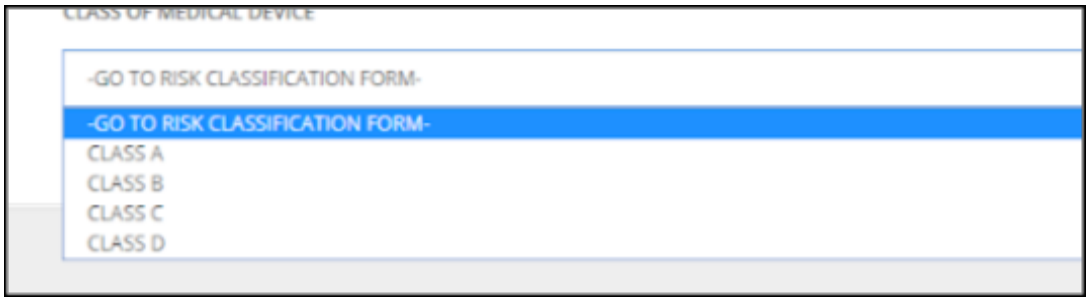



After click 

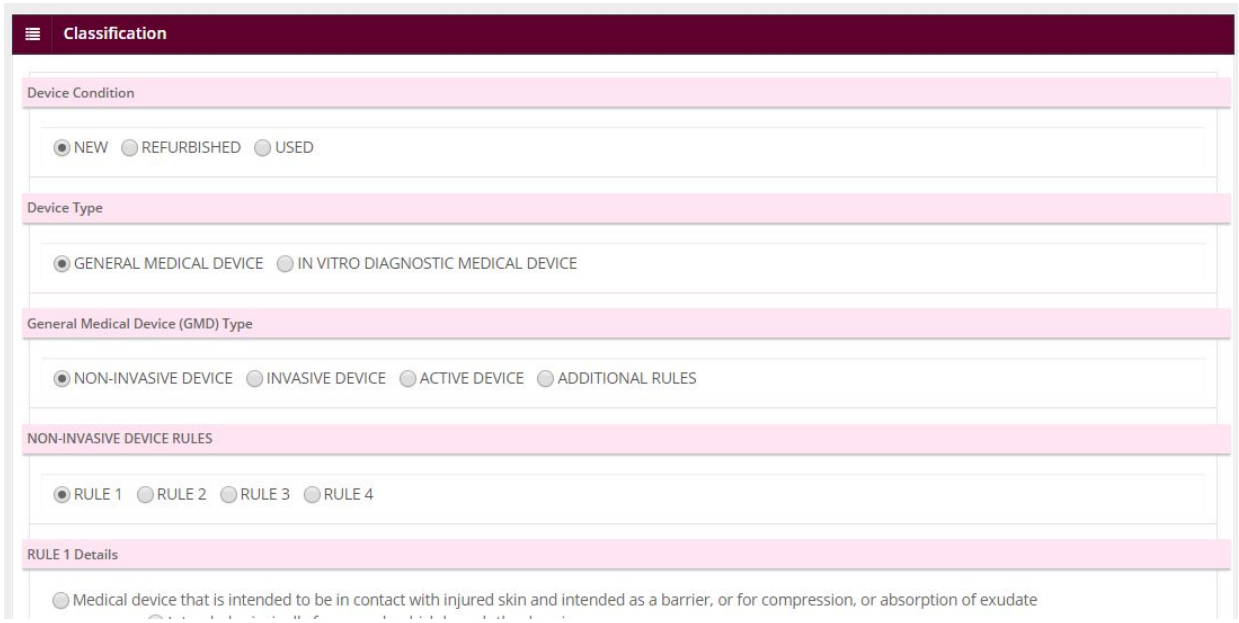
the diagram will show.



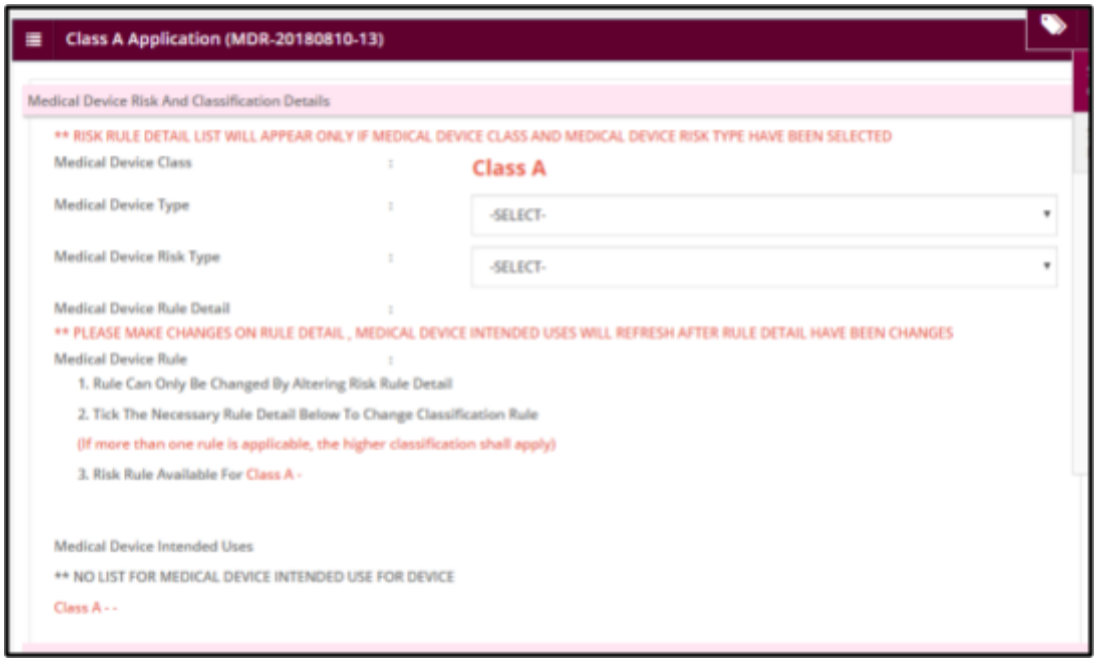
In class of medical device section you can choose CLASS A, CLASS B, CLASS C and CLASS D but also you can choose GO TO RISK CLASSIFICATION FORM.




If the user choose GO TO RISK CLASSiFICATION FORM and click Next the classification section will be display.

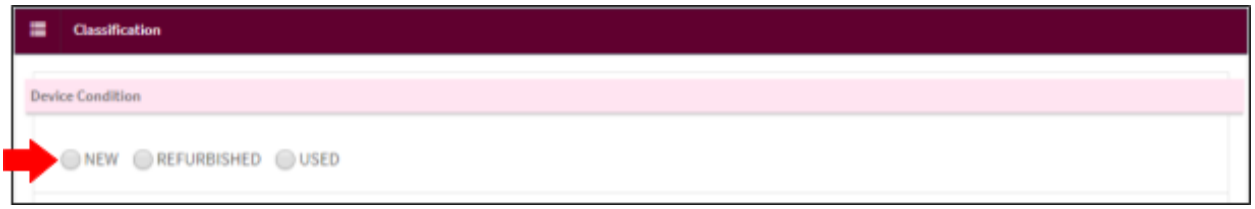



If the user choose CLASS A and click Next the Class A Application will be display.

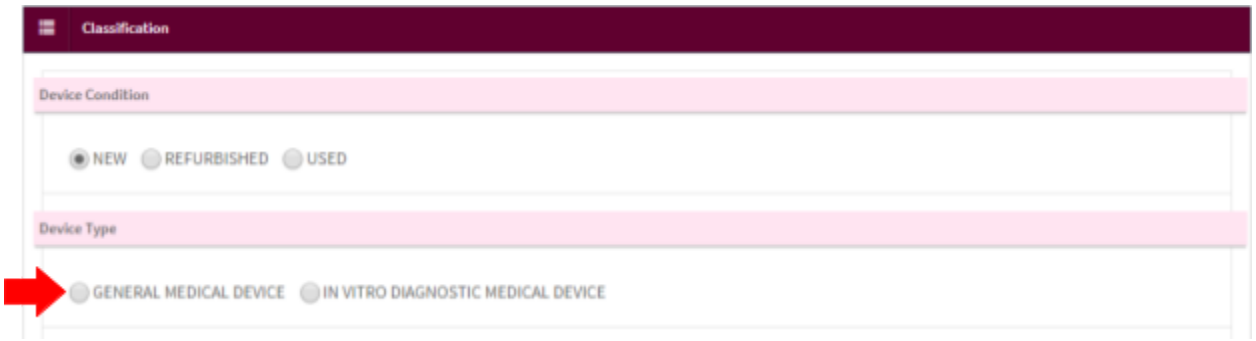

Class A Application (MDR-20180810-13)
Medical Device Risk And Classification Details
** RISK RULE DETAIL LIST WILL APPEAR ONLY IF MEDICAL DEVICE CLASS AND MEDICAL DEVICE RISK TYPE HAVE BEEN SELECTED
Medical Device Class
Class A
Medical Device Type
-SELECT-
Medical Device Risk Type
-SELECT-
Medical Device Rule Detail
** PLEASE MAKE CHANGES ON RULE DETAIL , MEDICAL DEVICE INTENDED USES WILL REFRESH AFTER RULE DETAIL HAVE BEEN CHANGES
Medical Device Rule
1. Rule Can Only Be Changed By Altering Risk Rule Detail
2. Tick The Necessary Rule Detail Below To Change Classification Rule
(If more than one rule is applicable, the higher classification shall apply)
3. Risk Rule Available For Class A -
Medical Device Intended Uses
** NO LIST FOR MEDICAL DEVICE INTENDED USE FOR DEVICE
Class A - -

## 2.1 CLASSIFICATION FORM

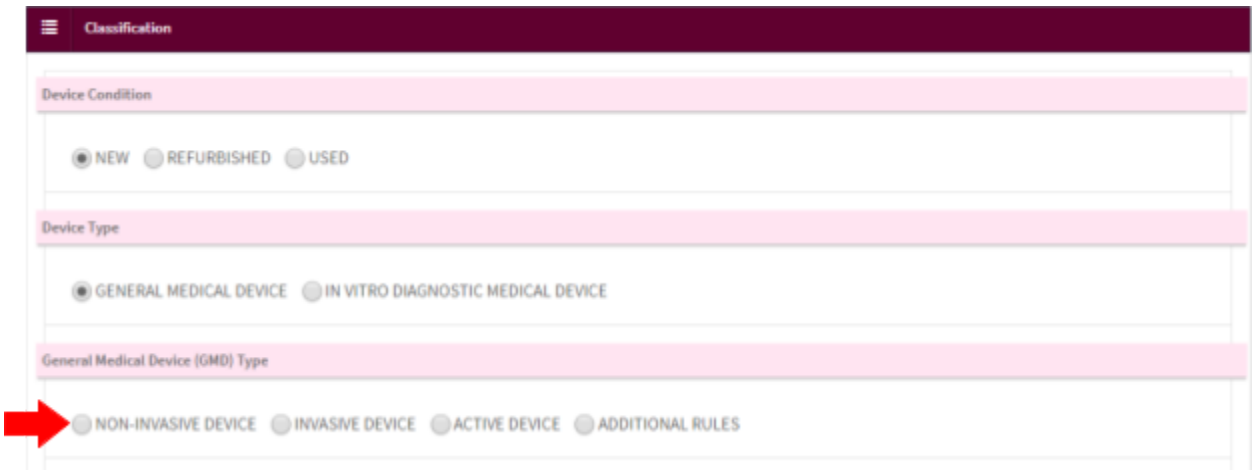
Classification form will be display. Tick at 'NEW' radio button in 'Device Conditions' field.



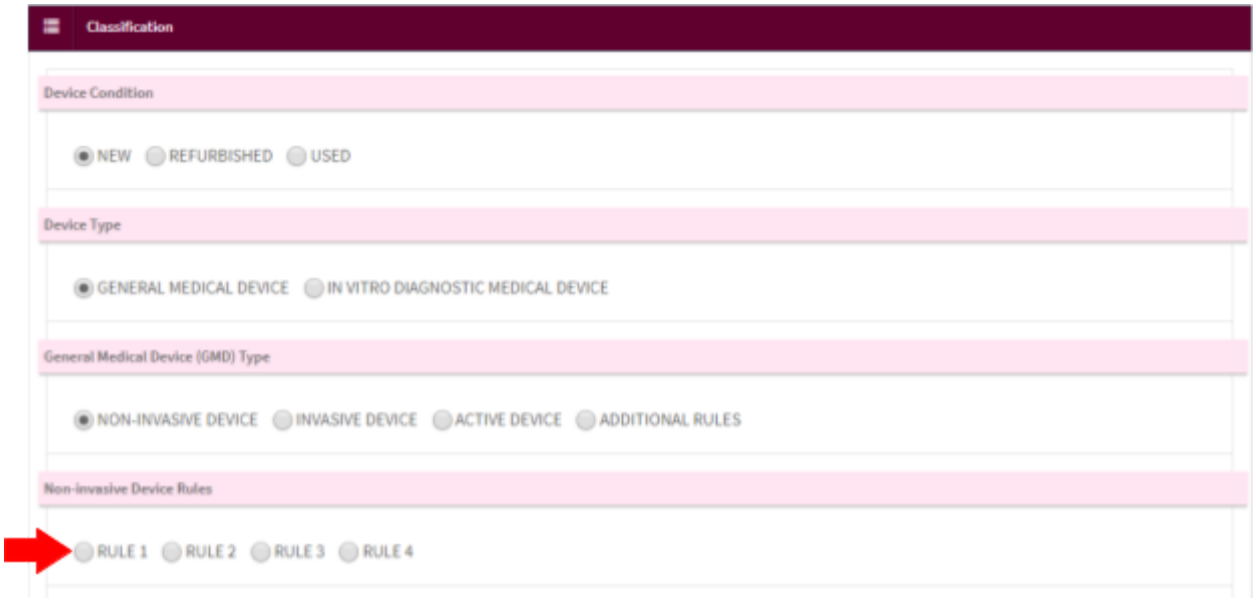

Then, tick at 'GENERAL MEDICAL DEVICE' radio button in 'Device Type' field.




Next, tick 'NON-INVASIVE DEVICE' radio button in general 'Medical Device (GMD) Type' field.

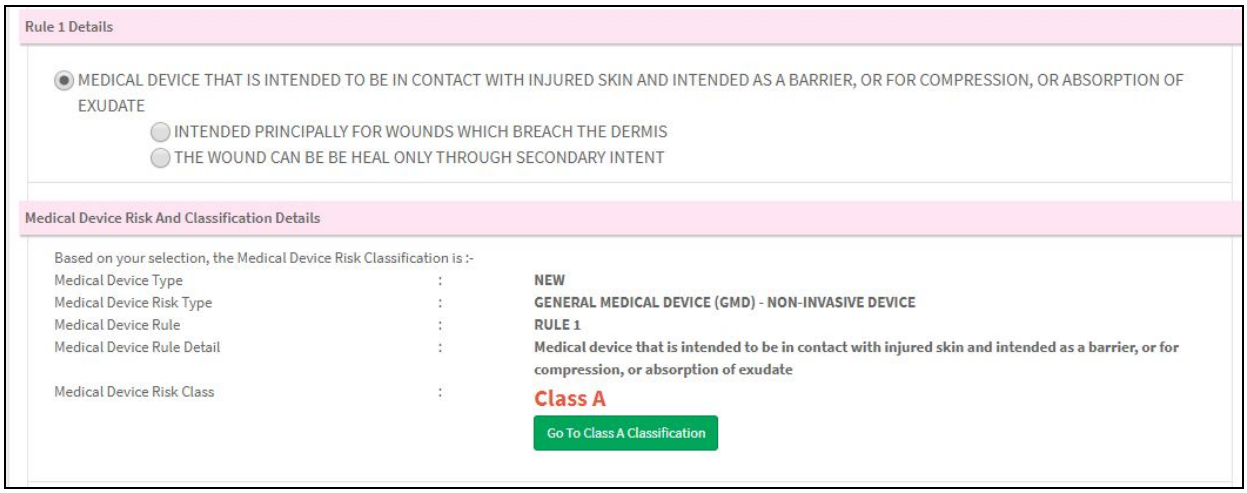


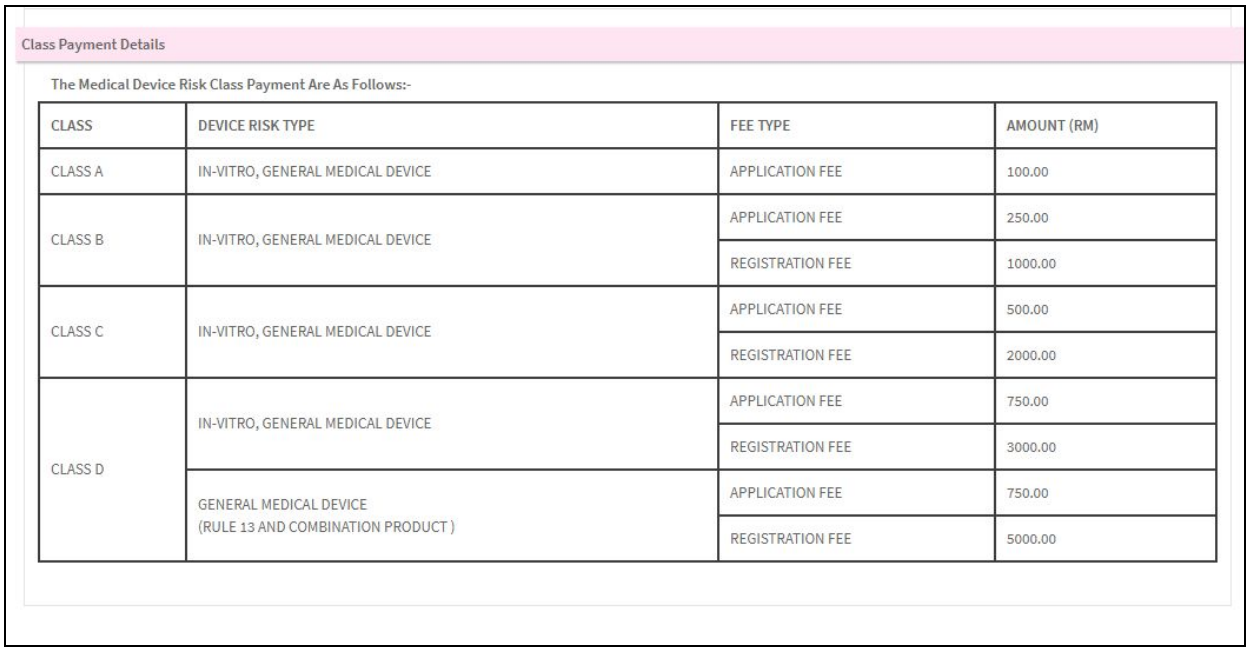
After that, tick ‘RULE 1’ radio button in ‘Non-invasive Device Rules’ field.




Next step, tick ‘MEDICAL DEVICE THAT IS INTENDED TO BE IN WITH INJURED SKIN AND INTENDED AS A BARRIER, OR FOR COMPRESSION, OR ABSORPTION OF EXUDATE’ radio button at ‘Rules 1 Details’ field.

Then, 'Medical Device Risk And Classification Details' and 'Class Payment Details' will display on screen.

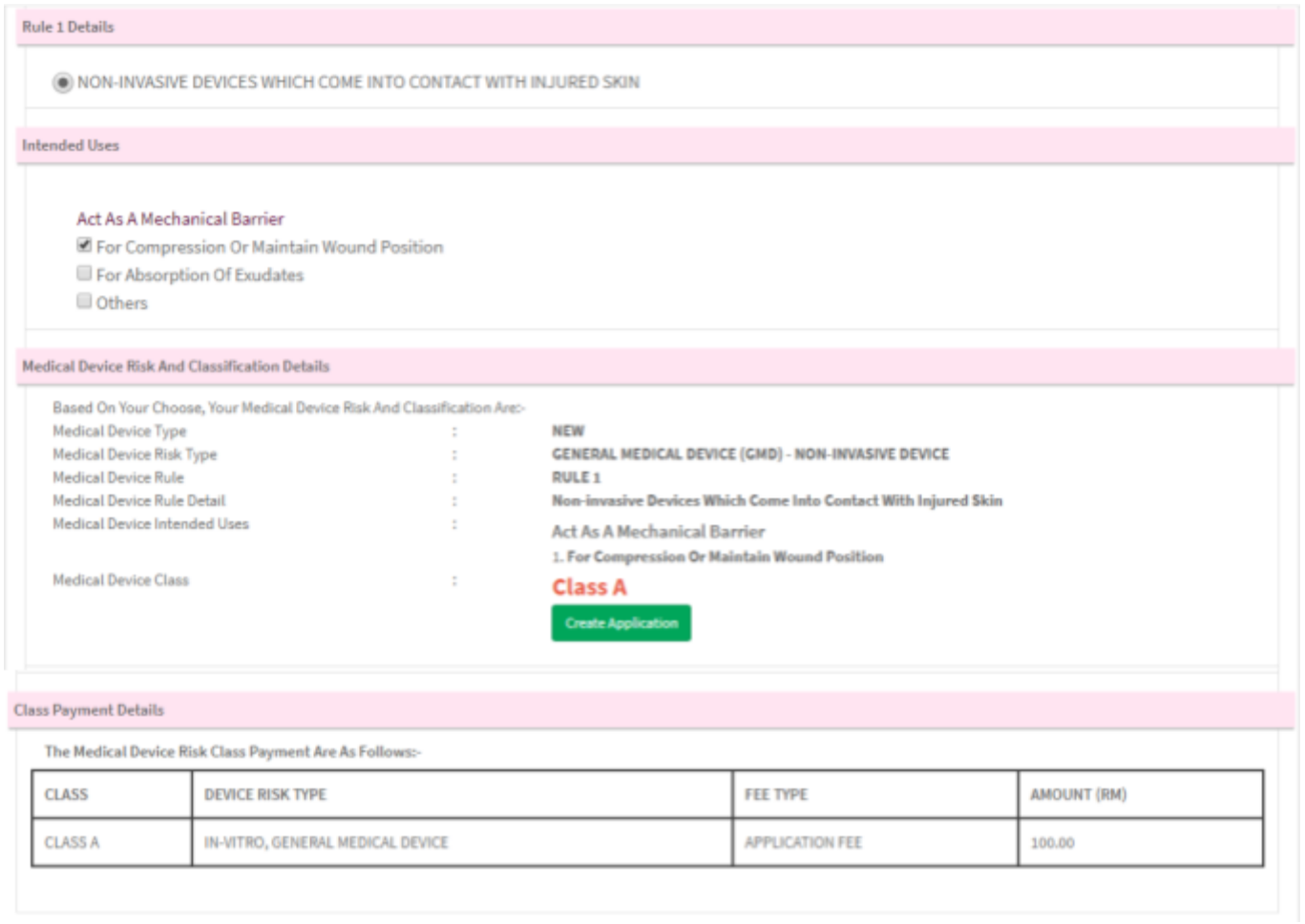


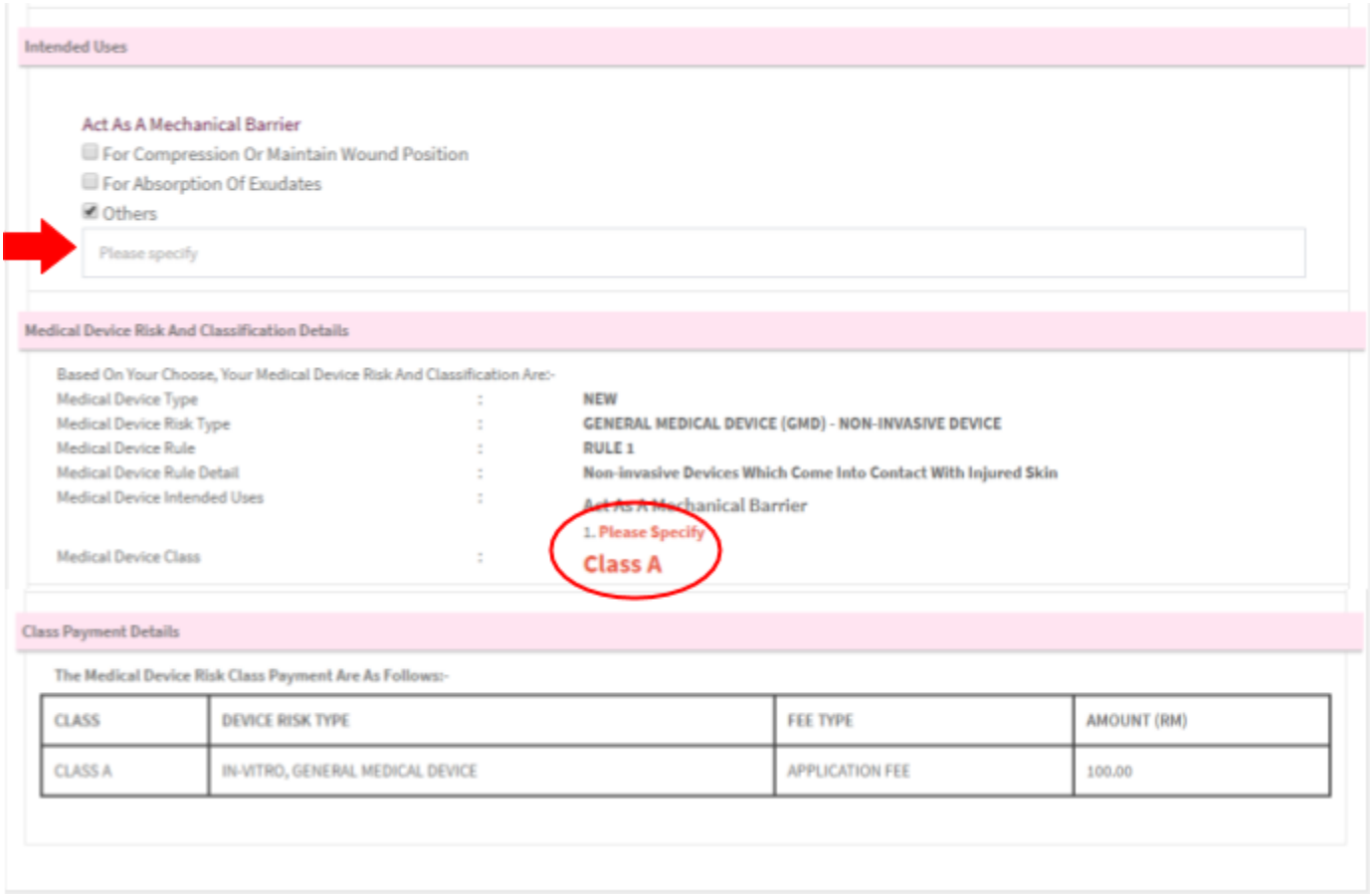

Click  to go to next step step.

User tick checkbox at ‘Intended Uses’ field.

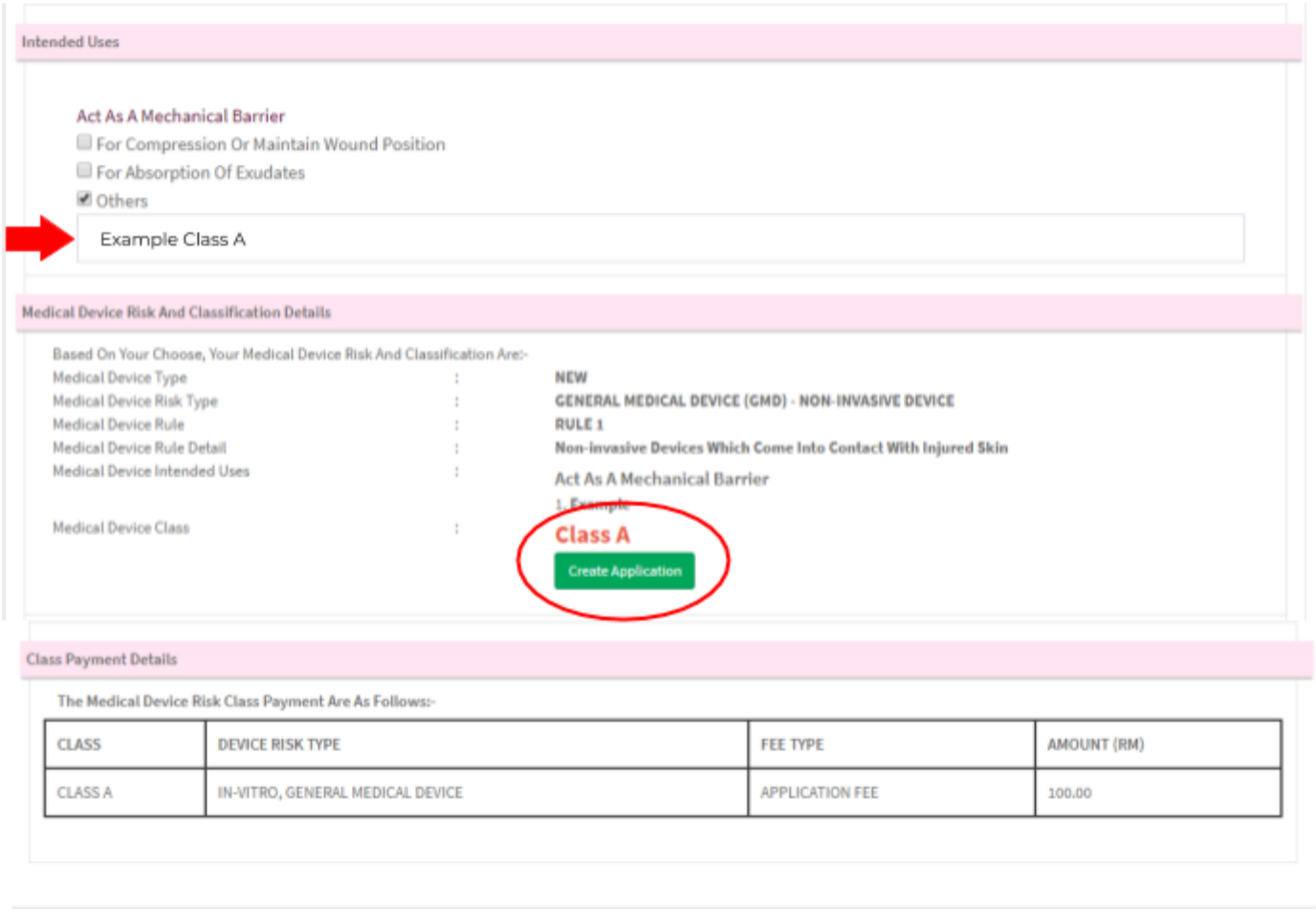

Then, ‘Medical Device Risk And Classification Details’ and ‘Class Payment Details’ will display.

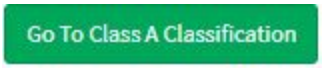


If user tick ‘Others’ checkbox. User has to fill ‘Please specify’ text box. User will not allowed to go to the next step until user fill that text box.



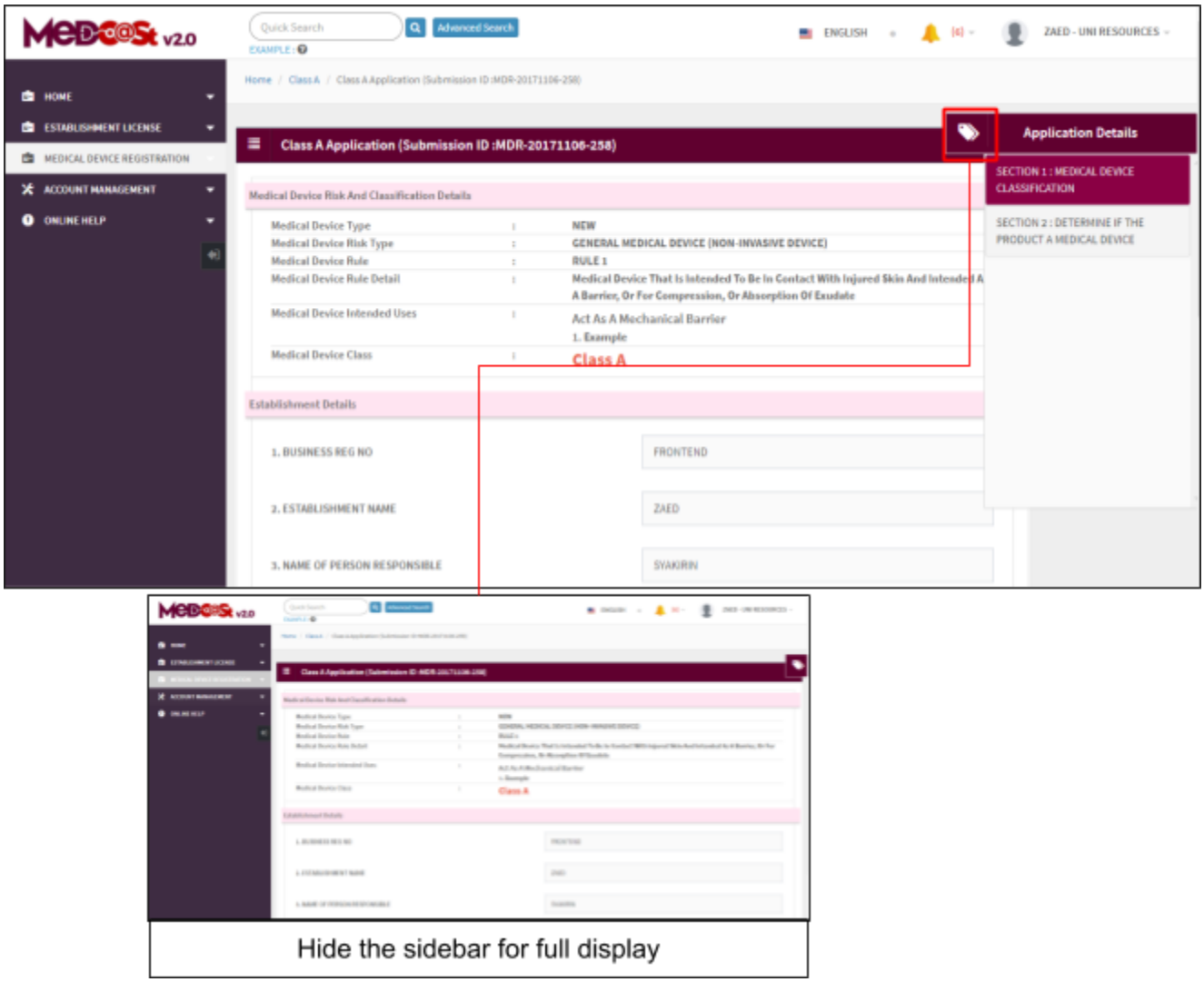
Display after user fill ‘Please specify’ text box.




Click  to go to next step step.

## 2.2 FILL IN THE APPLICATION FORMS

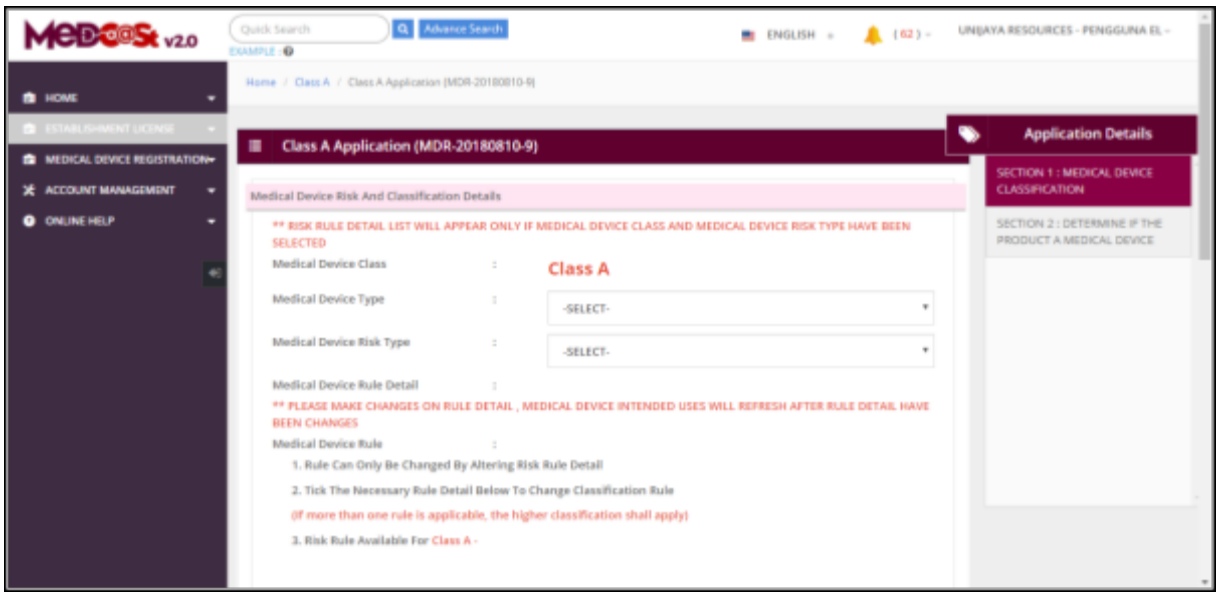
### 2.2.1 SECTION 1 : MEDICAL CLASS CLASSIFICATION





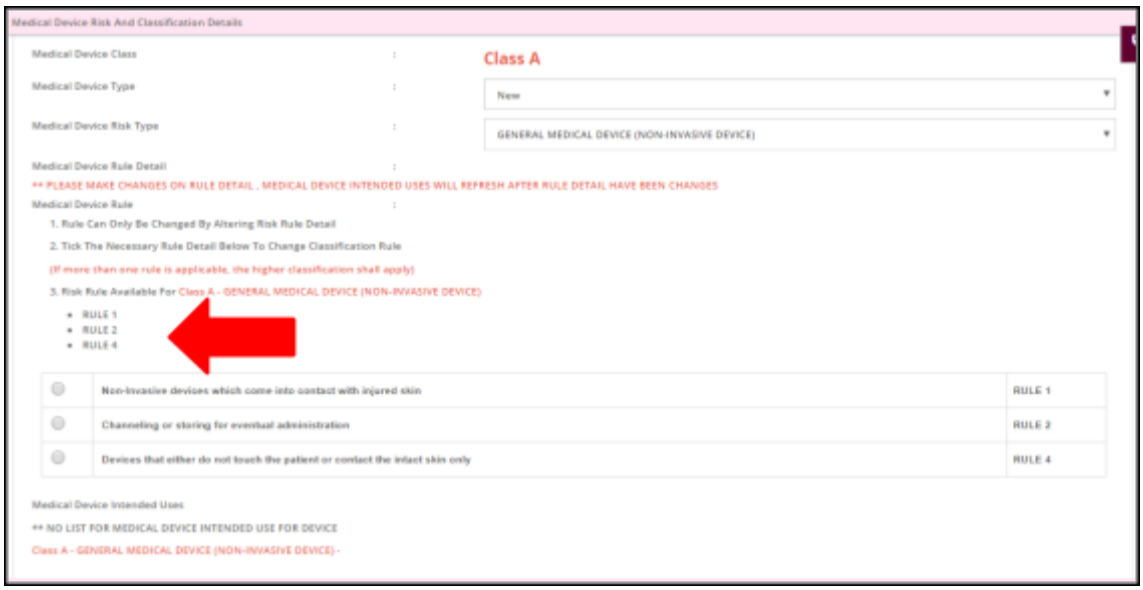

Hide the sidebar for full display

Rules detail will be display




User can choose the Medical Risk Type.

The system will display a Risk Rule that selected by user on Risk type.



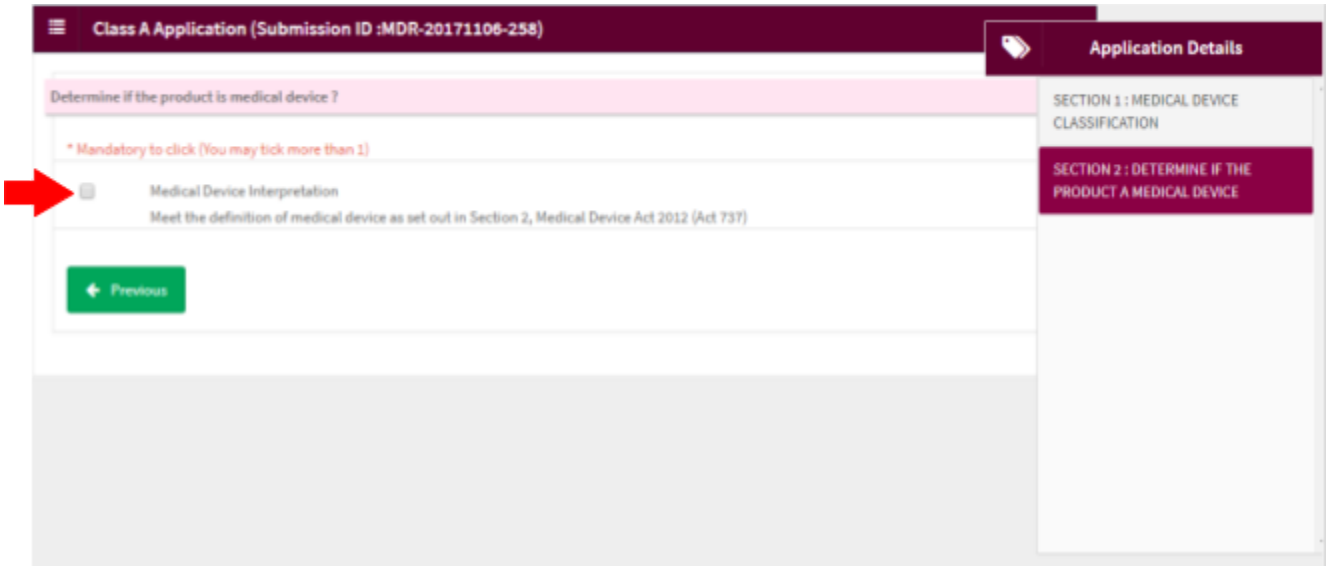

Choose Rules that appropriate with Risk Rules Available.


After that, choose intended uses that appropriate with user.

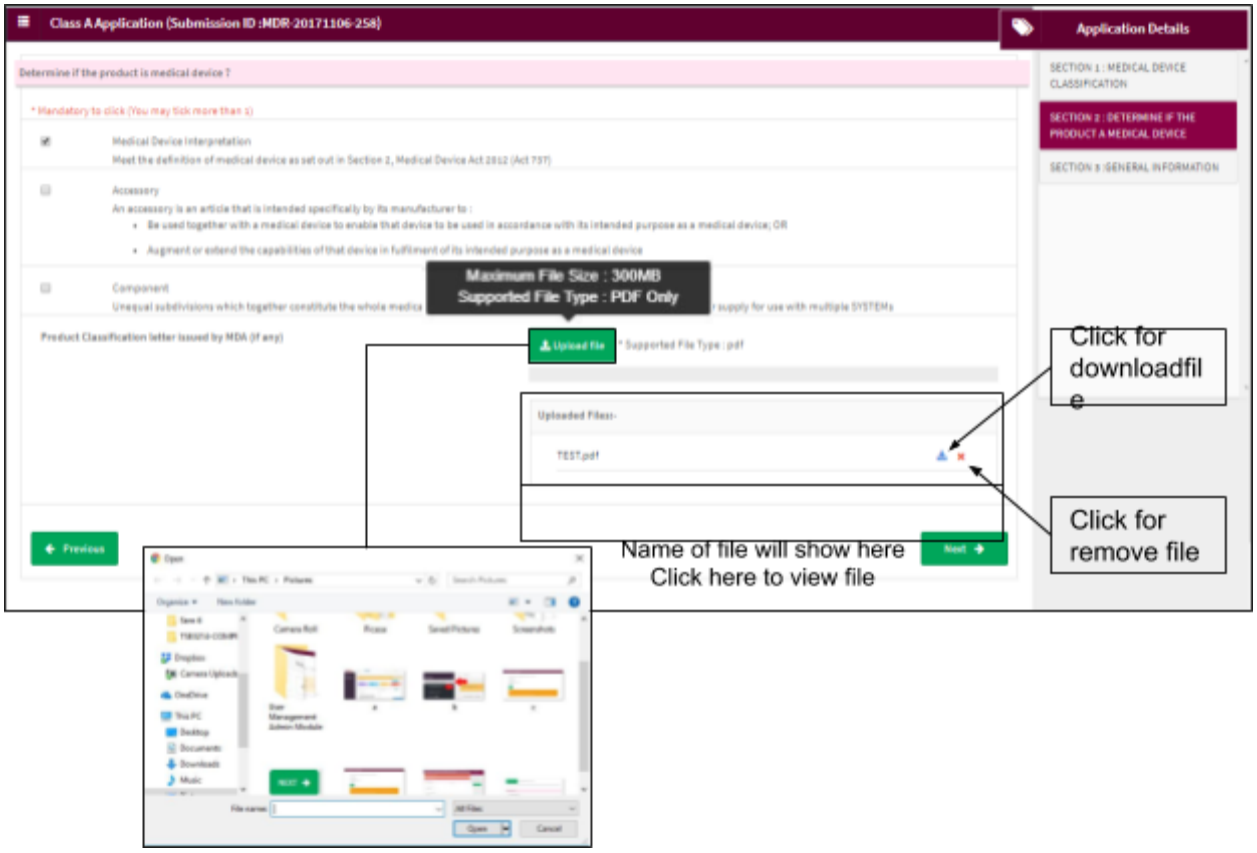

Click 

to proceed next step.

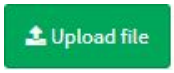
### 2.2.2 SECTION 2 : DETERMINE IF THE PRODUCT A MEDICAL DEVICE




User click a checkbox and automatically other checkboxes will display.




User tick ‘Accessory’ or ‘Component’ checkbox.**(If necessary)**

User click 

to upload file ‘Product Classification letter issued by MDA (if any)’. **The file must be pdf format and size not more than 300 MB**. **(If necessary)**

Click 

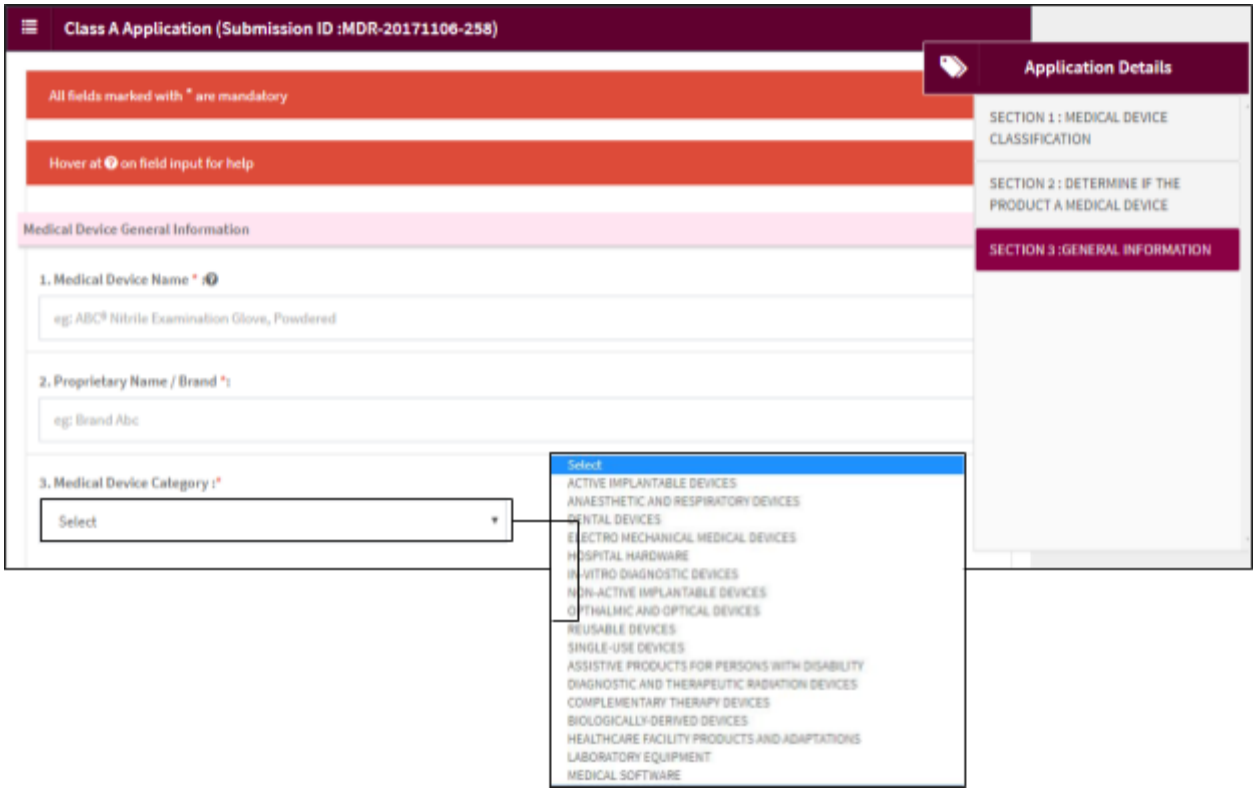
to go to the next section.

Click 

to go to the previous section.

### 2.2.3 SECTION 3 : GENERAL INFORMATION

**'Next' button is invisible until user complete this section.**




User fill 'Medical Device Name' and 'Proprietary Name / Brand'. For Medical Device Category' user select from drop down checkbox.

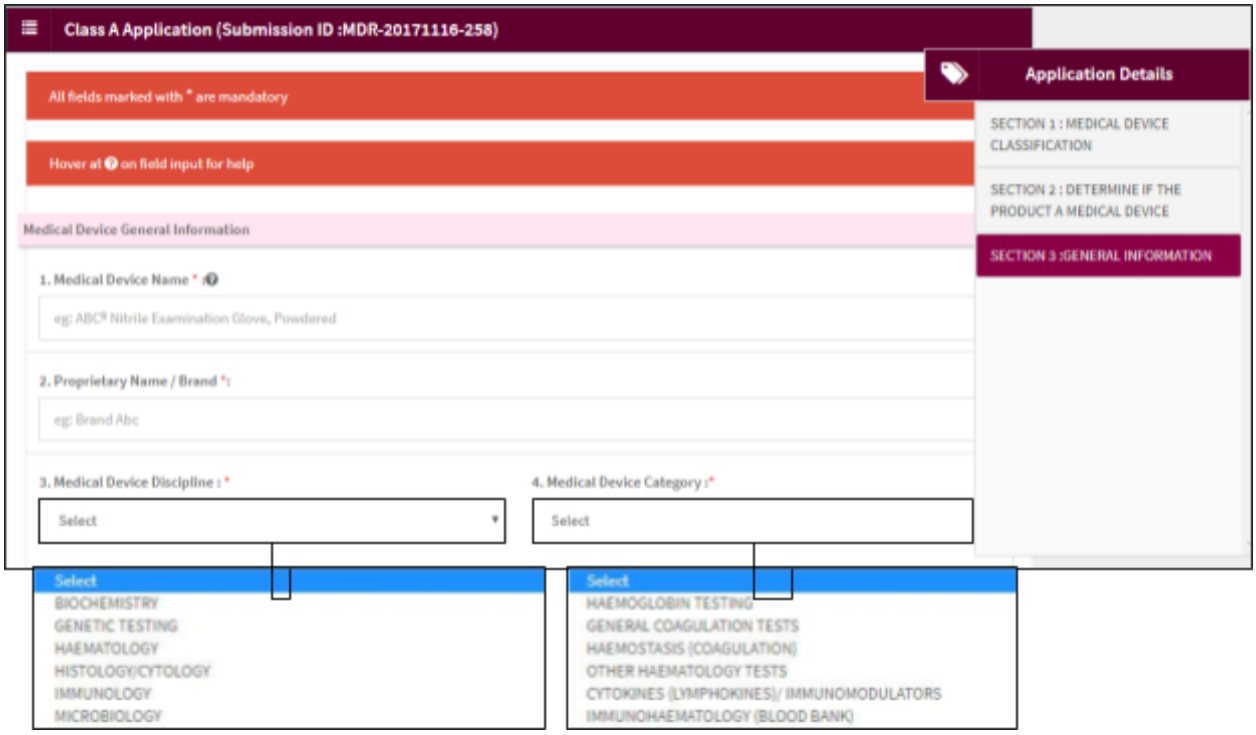
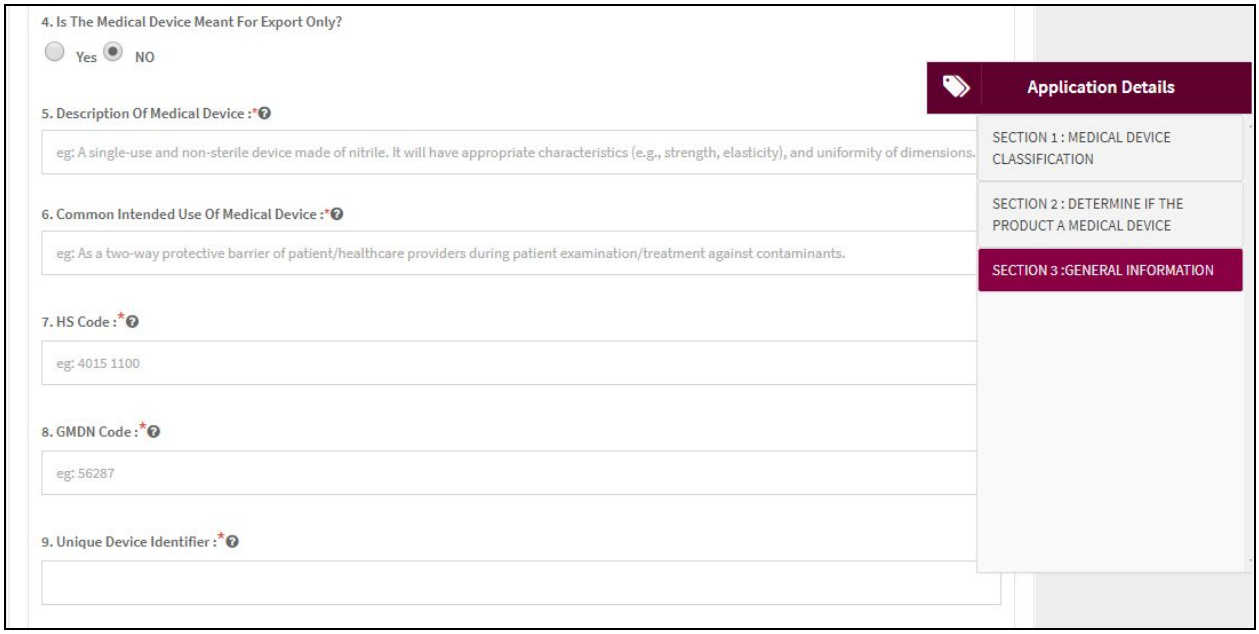
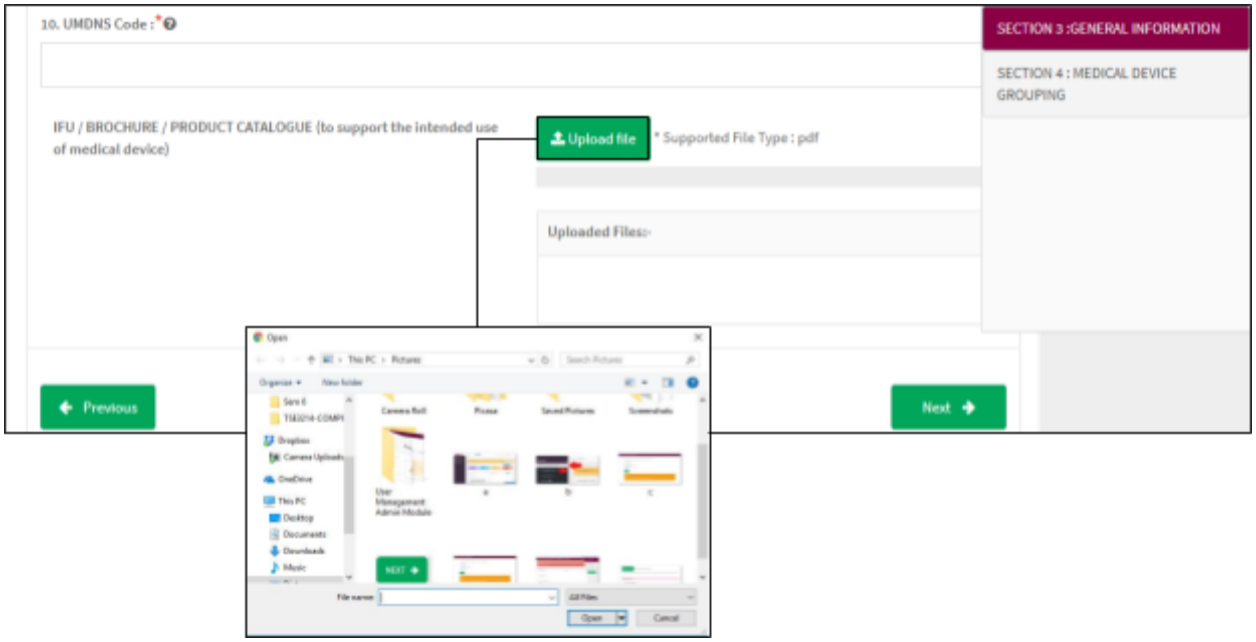
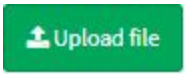



Diagram below show additional question form if user choose 'IN-VITRO DIAGNOSTIC MEDICAL DEVICE (IVD)' medical device risk type, user has to fill ' Medical Device Discipline' first and then 'Medical Device Category'. Drop down text box will show different data at 'Medical Device Category' according to selected data by user in ' Medical Device Discipline'.




All of text boxes above is mandatory, user has to fill all the text boxes.




User enter the UMDNS Code and then click 

to upload file. **The file must be pdf format and size not more than 300 MB**.

Click 

to go to the next section.

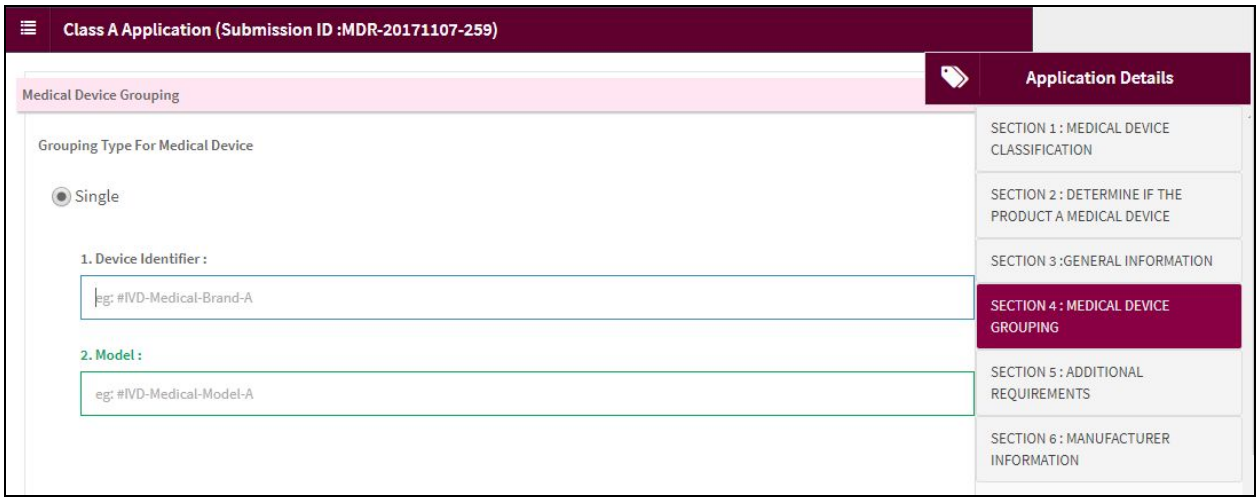
Click 

to go to the previous section.

### 2.2.4 SECTION 4 : MEDICAL DEVICE GROUPING

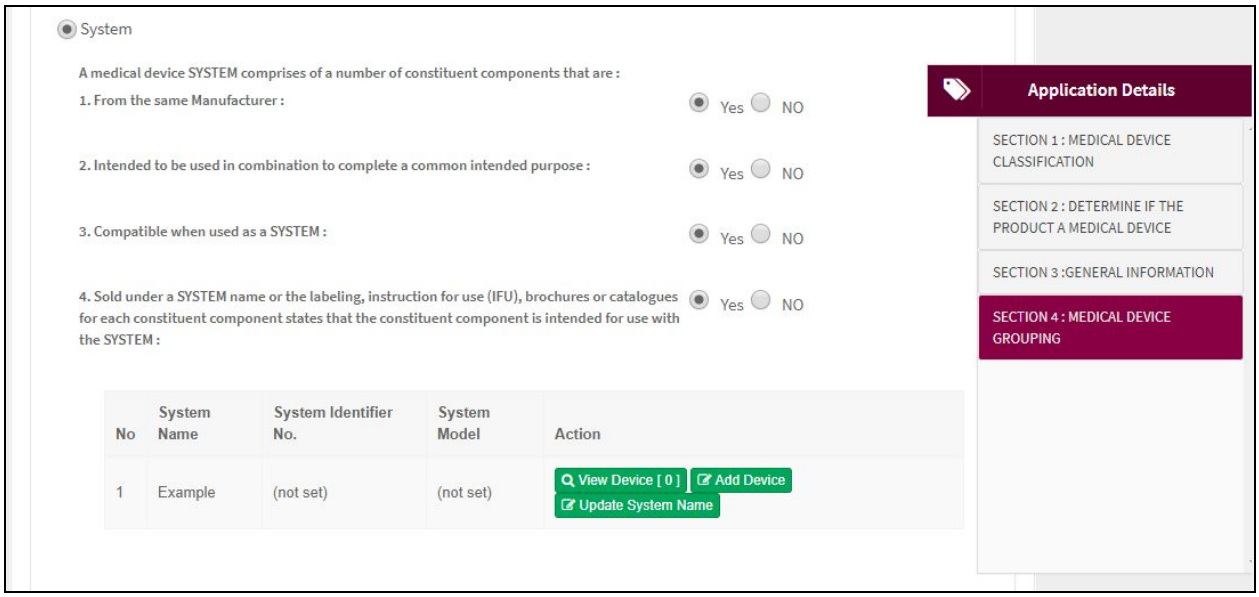

User only can tick one radio button in Medical Device Grouping field before user can go to next step. **'Next' button is invisible until user complete this section.**

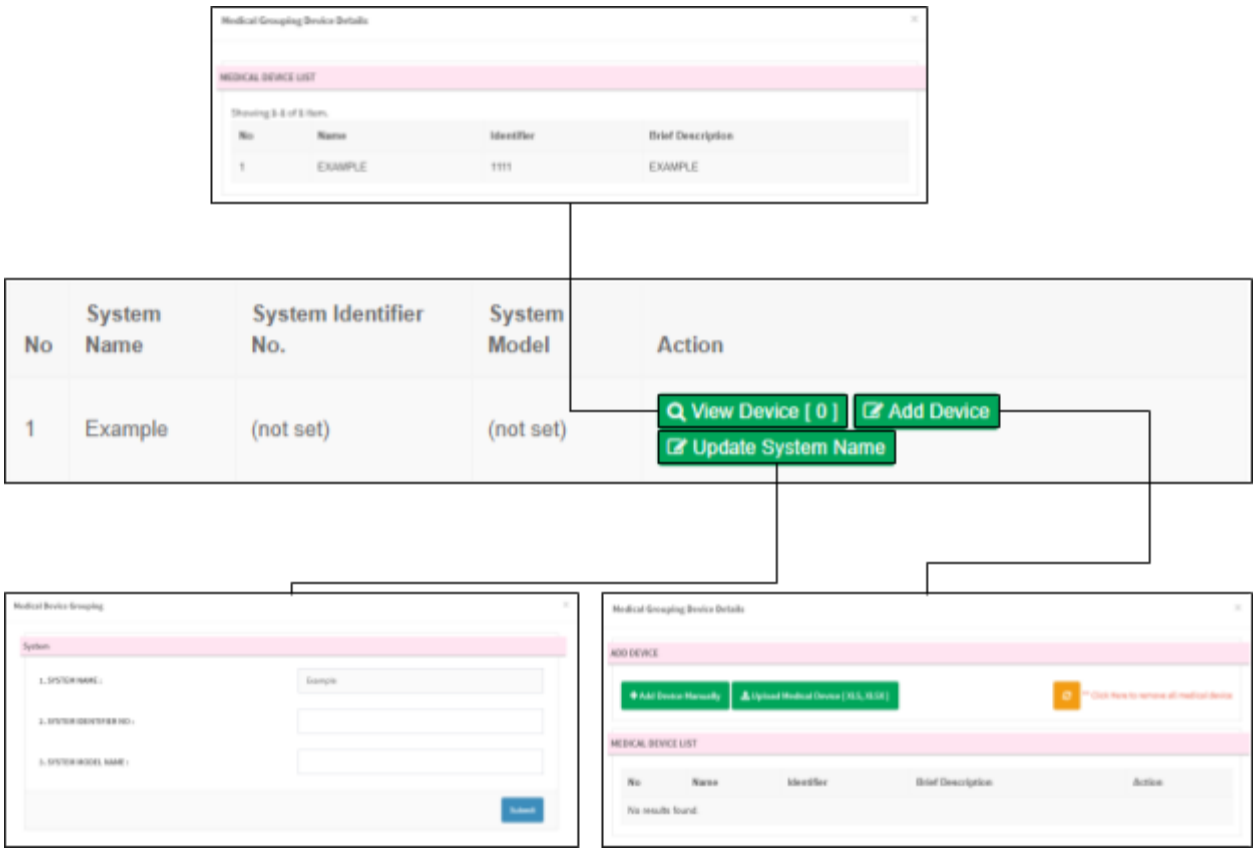
i) 'Single' radio button.




User has to fill '1. Device Identifier' and '2. Model' text boxes. Warning texts will display if user do not fill the text boxes.

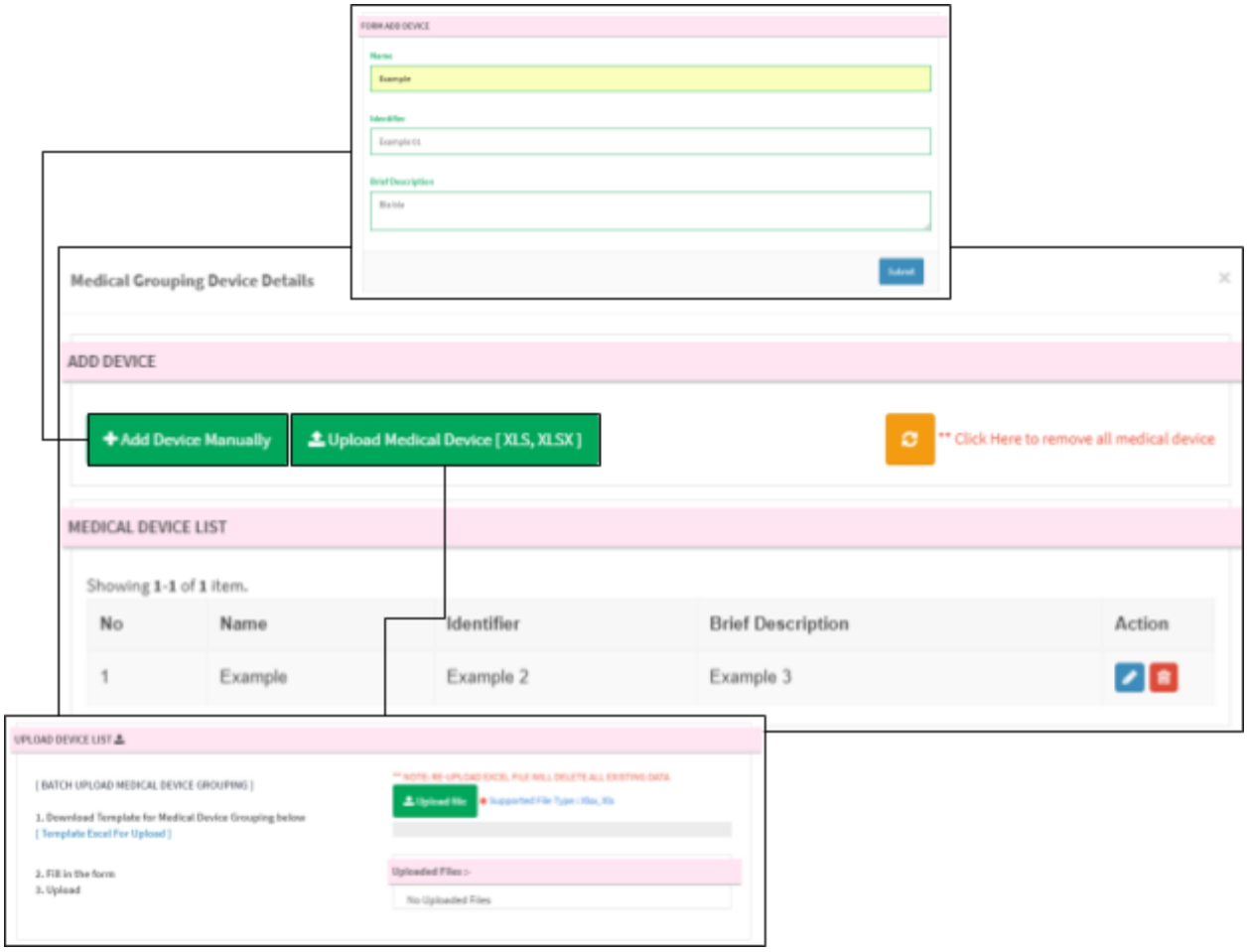
ii) 'System' radio button.






Click View Device [ 0 ] to view device list.

Click Update System Name to update [System Identifier No.] and [System Model] then click Submit to confirm update.

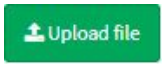



User click 

, then user has to fill the form and click 

to add device.

User click 

, then user click [Template Excel For Upload] to download excel template. Next, user click 

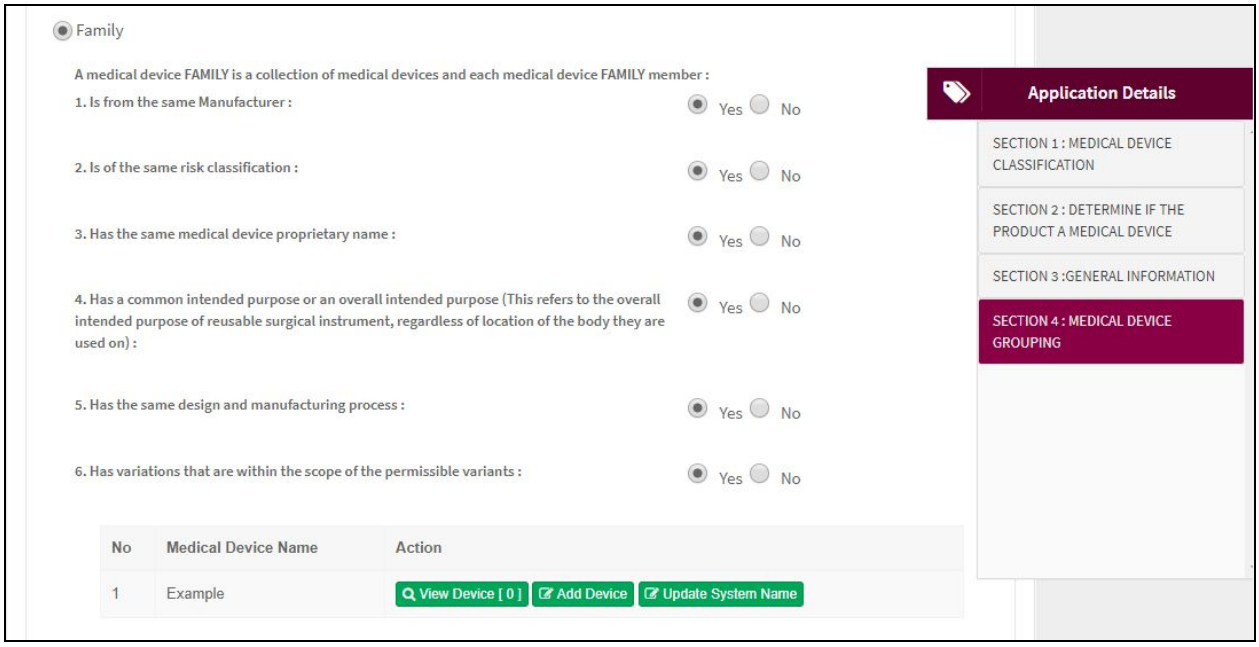
to upload excel file. **The file must be xlsx or xls format.**

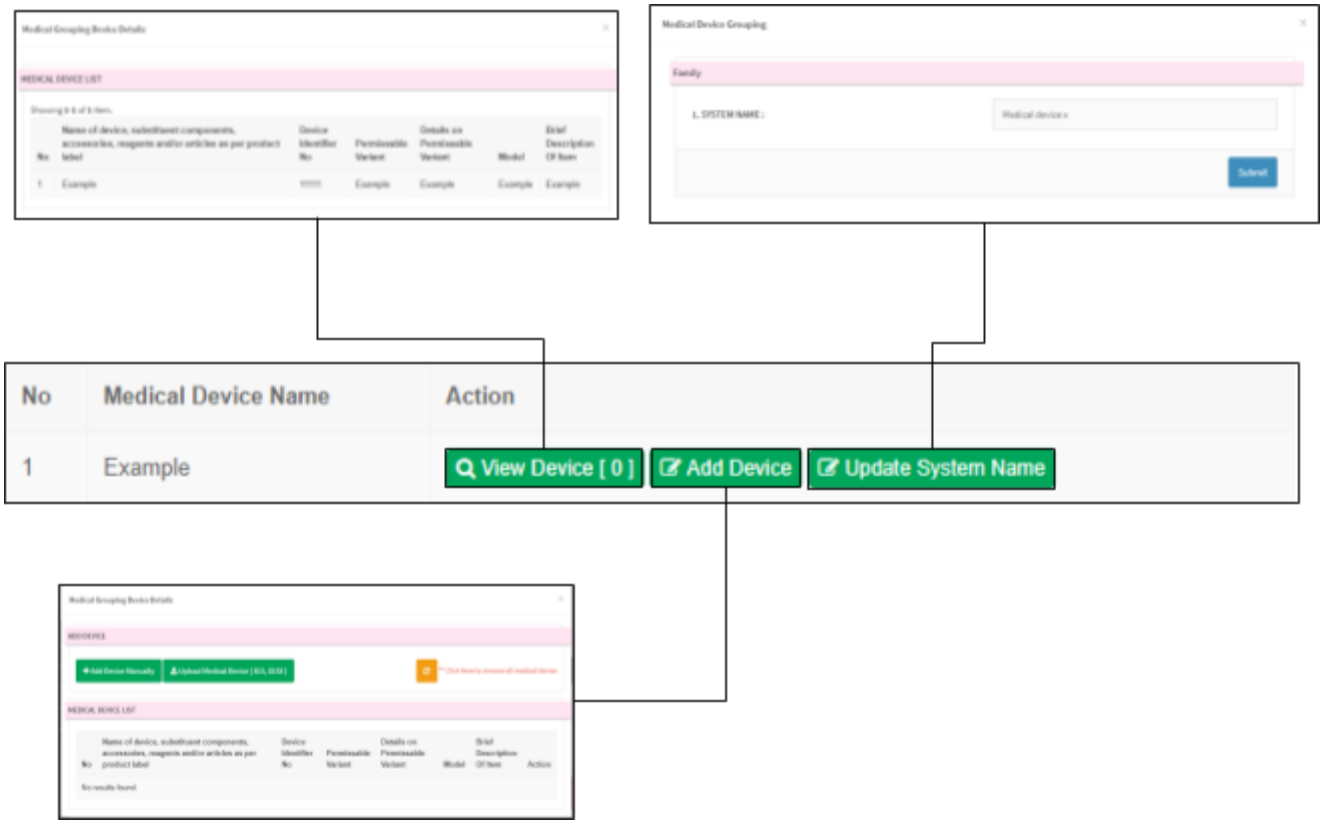
 button for user edit device details.

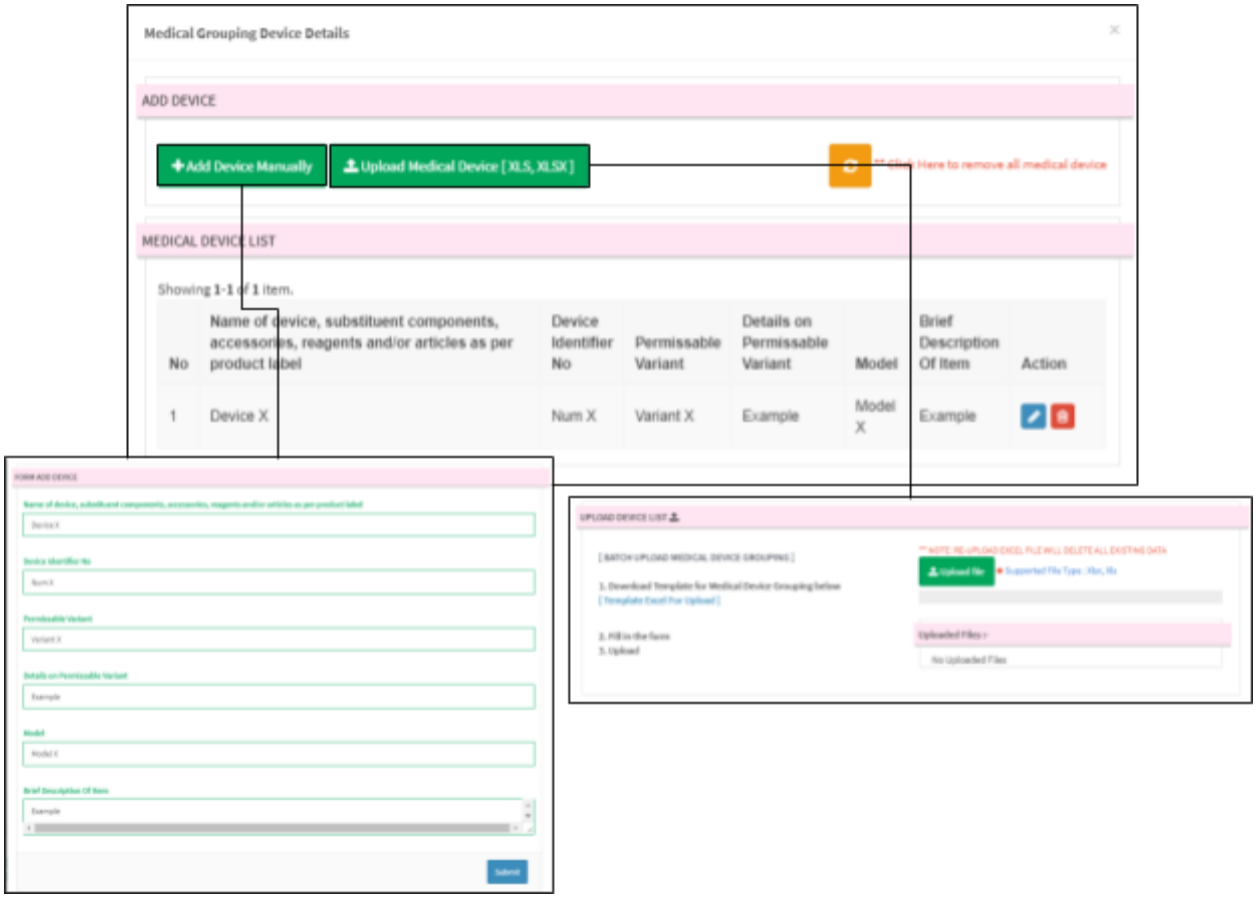
 button for user delete device.

 button for user delete all medical devices.

iii) ‘Family’ radio button.




No
Medical Device Name
Action
1
Example
View Device [ 0 ]
Add Device
Update System Name




Click View Device [ 0 ] to view device list.

User click Add Device Manually, then user has to fill the form and click Submit to add device.

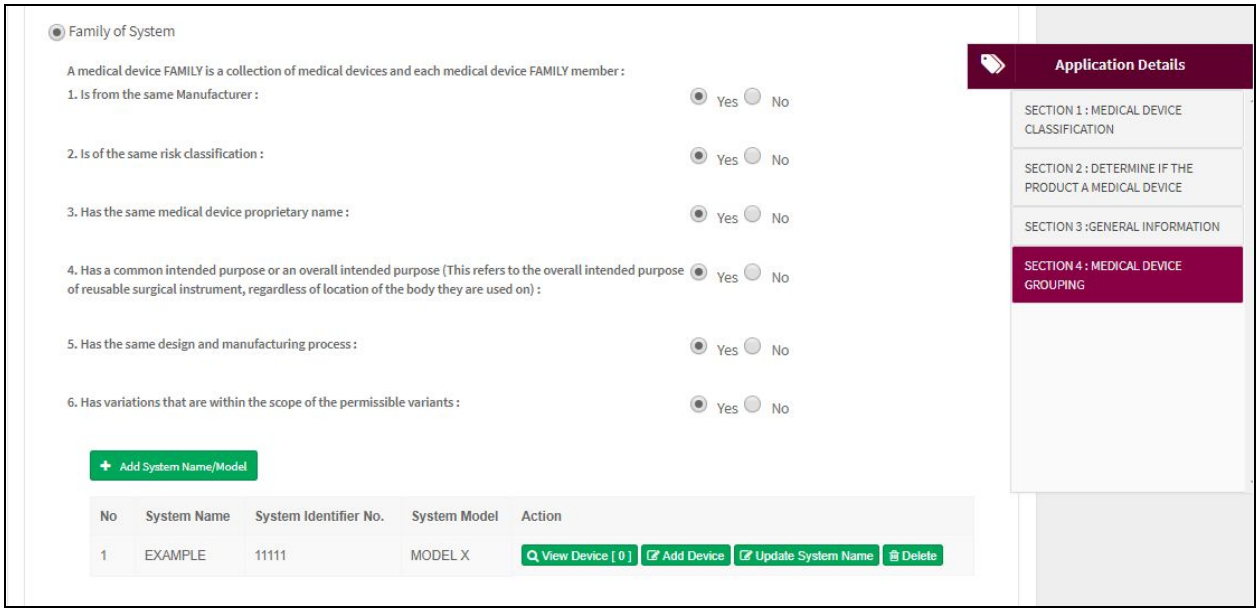
User click Upload Medical Device [ XLS, XLSX ], then user click [Template Excel For Upload] to download excel template. Next, user click Upload file to upload excel file. **The file must be xlsx or xls format.**

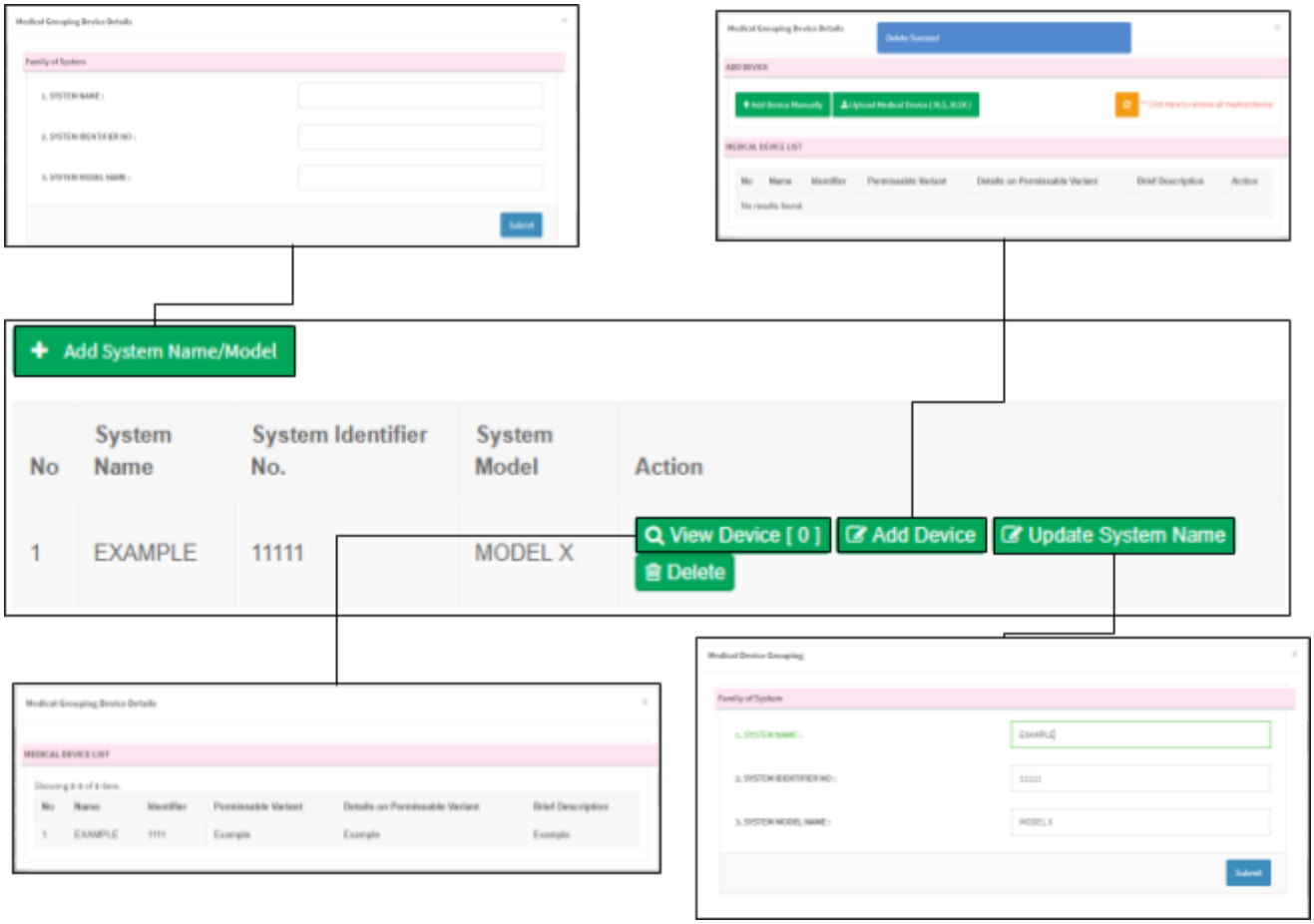
button for user edit device details.

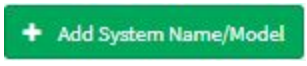
button for user delete device.

button for user delete all medical devices.

iv) ‘Family Of System’ radio button.





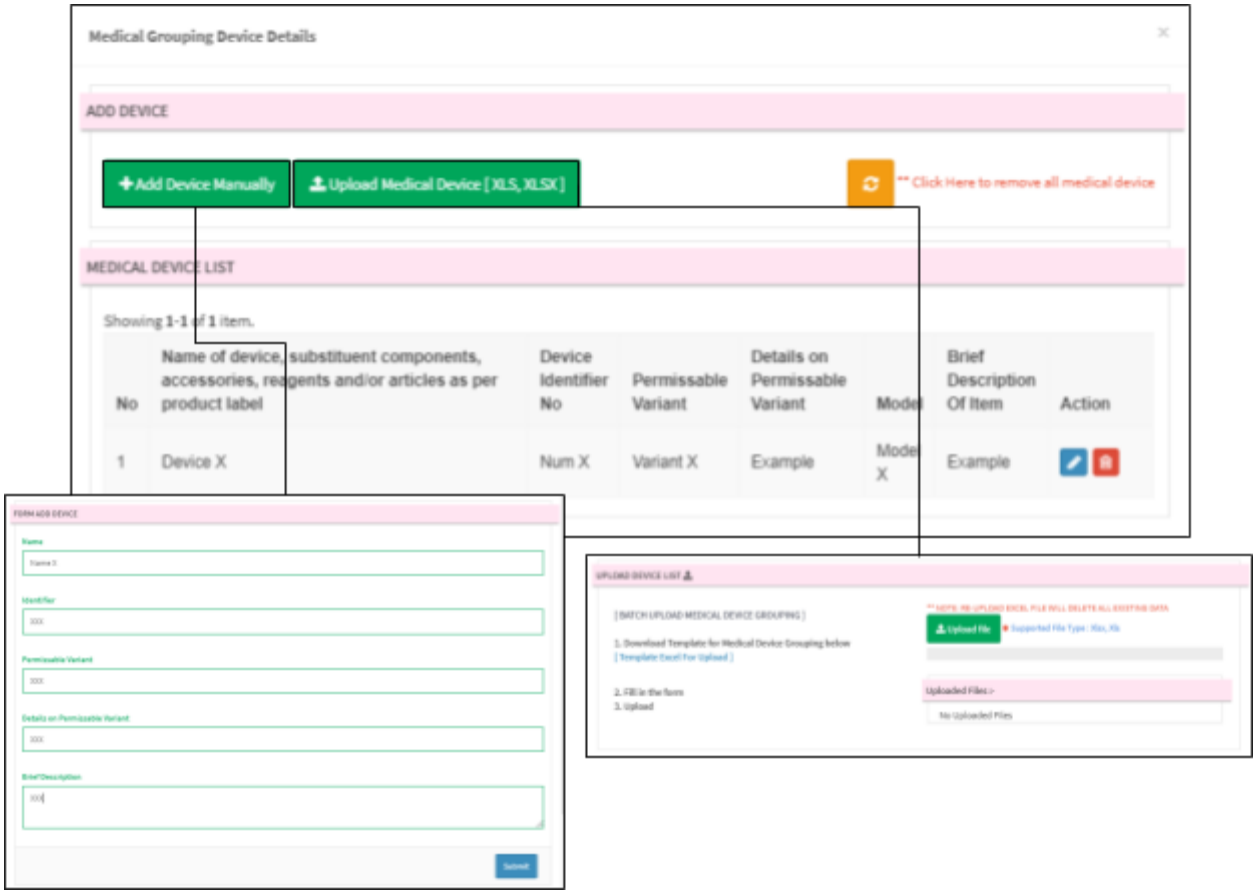

Click  to add system name or model.

Click  to view device list.

Click  to update [System Identifier No.] and [System Model Name] then

Click  to confirm update.

Click  to delete device.

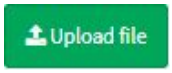



User click 

, then user has to fill the form and click 

to add device.

User click 

, then user click [Template Excel For Upload] to download excel template. Next, user click 

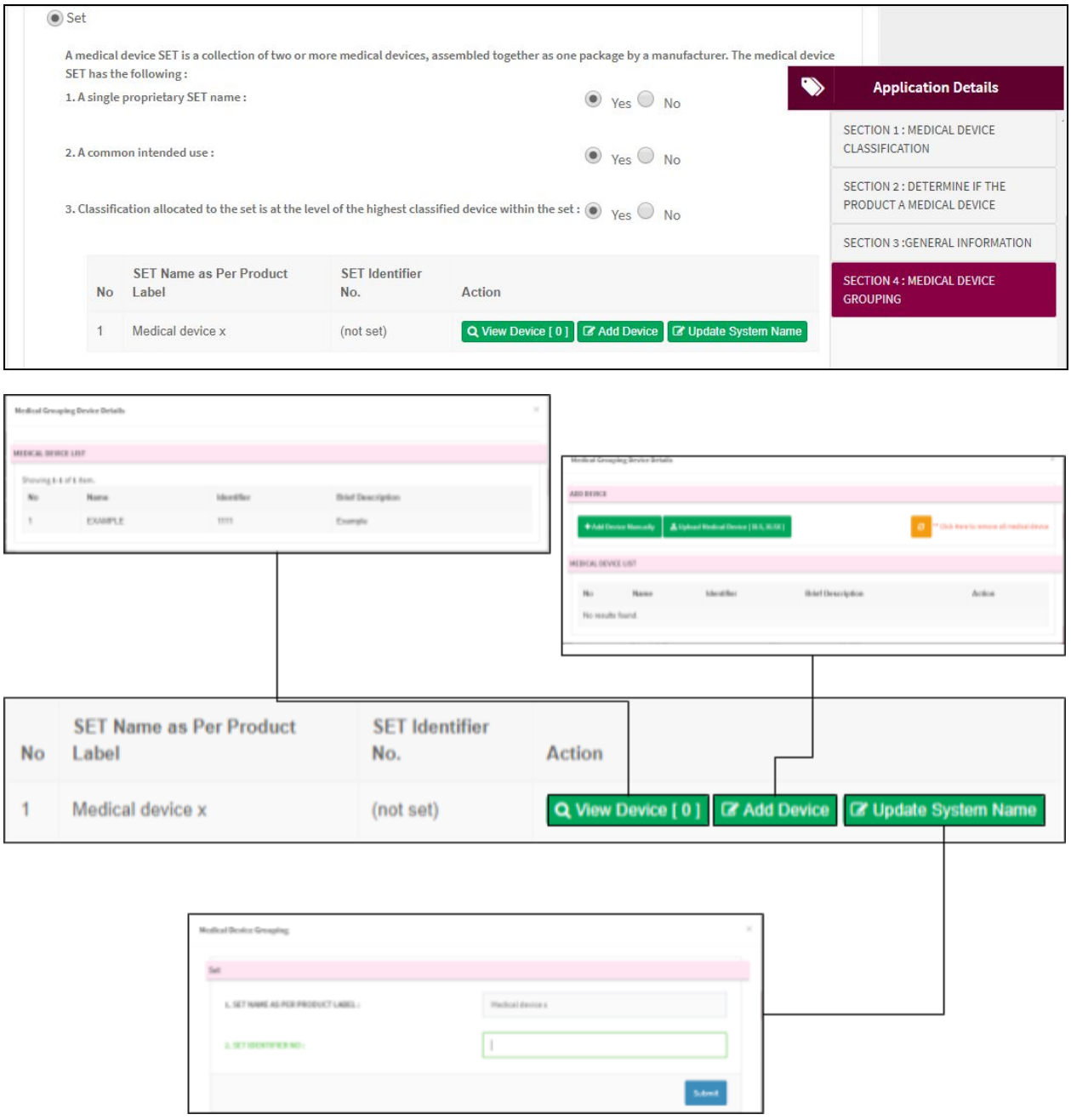
to upload excel file. **The file must be xlsx or xls format.**

 button for user edit device details.

 button for user delete device.

 button for user delete all medical devices.

v) ‘Set’ radio button.

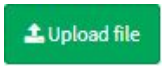



Click  to view device list.

Click  to update [System Identifier No.] then click  to confirm update.



User click  , then user has to fill the form and click  to add device.

User click  , then user click [Template Excel For Upload] to download excel template. Next, user click  to upload excel file. **The file must be xlsx or xls format.**

 button for user edit device details.

 button for user delete device.

 button for user delete all medical devices.

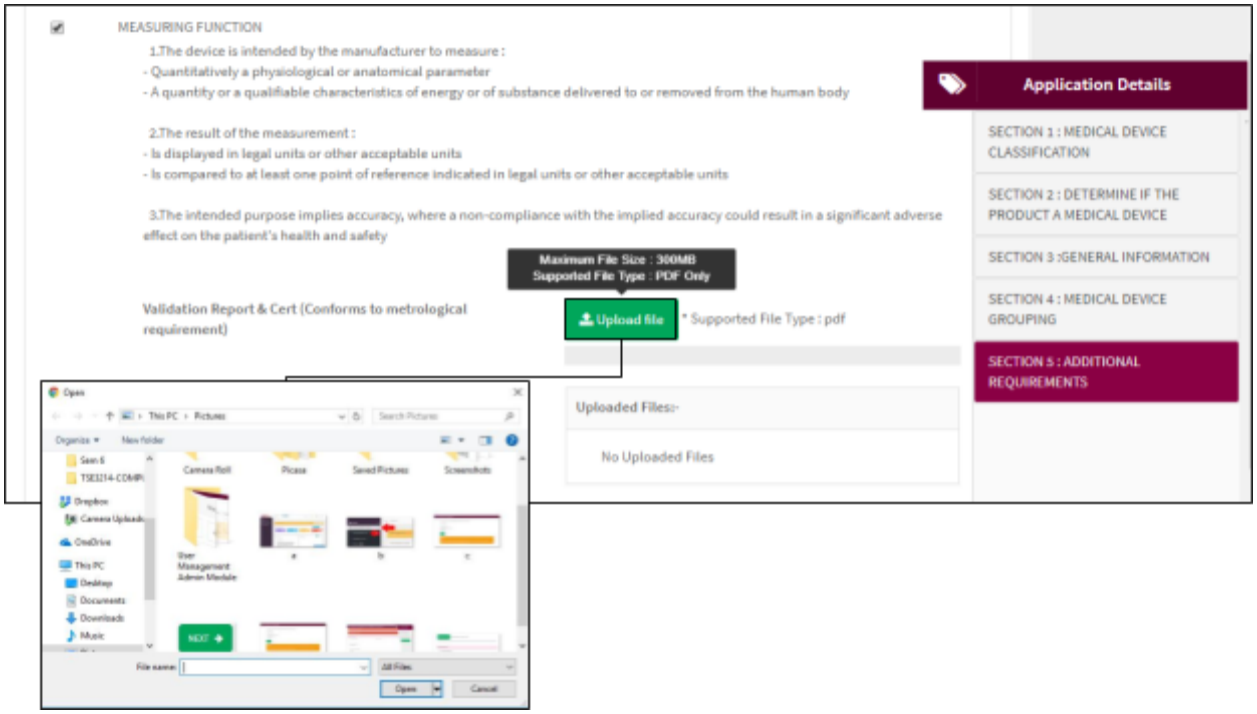
Click Next → to go to the next section.

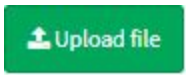
Click ← Previous to go to the previous section.

### 2.2.5 SECTION 5 : ADDITIONAL REQUIREMENTS

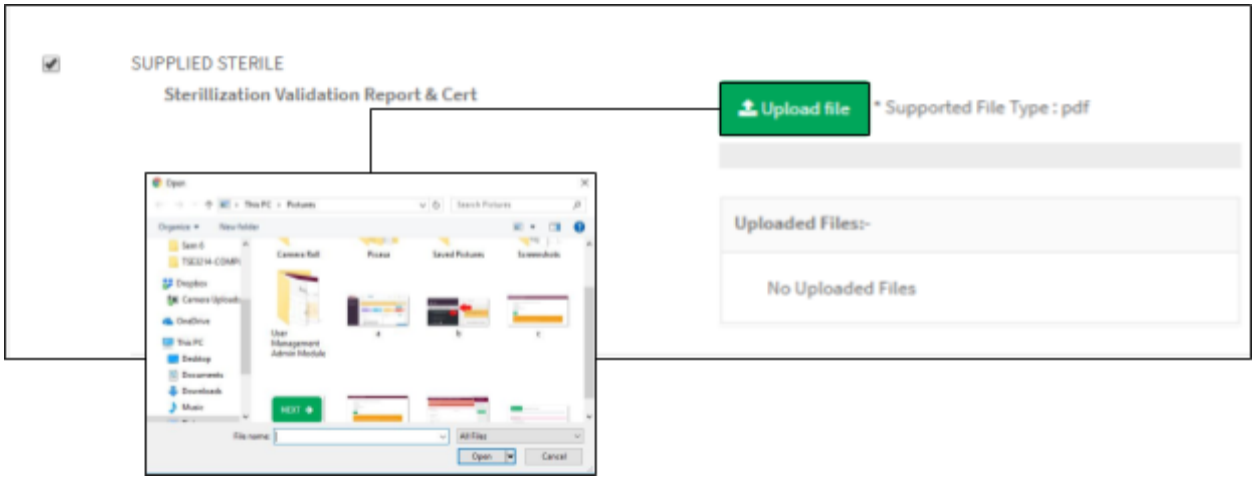

User tick checkbox in red circle **(if necessary)** and user can tick more than one checkbox. If not, user click Next → to go to next section.

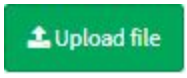
If user tick any checkboxes above, user has to complete that field before user go to the next section.

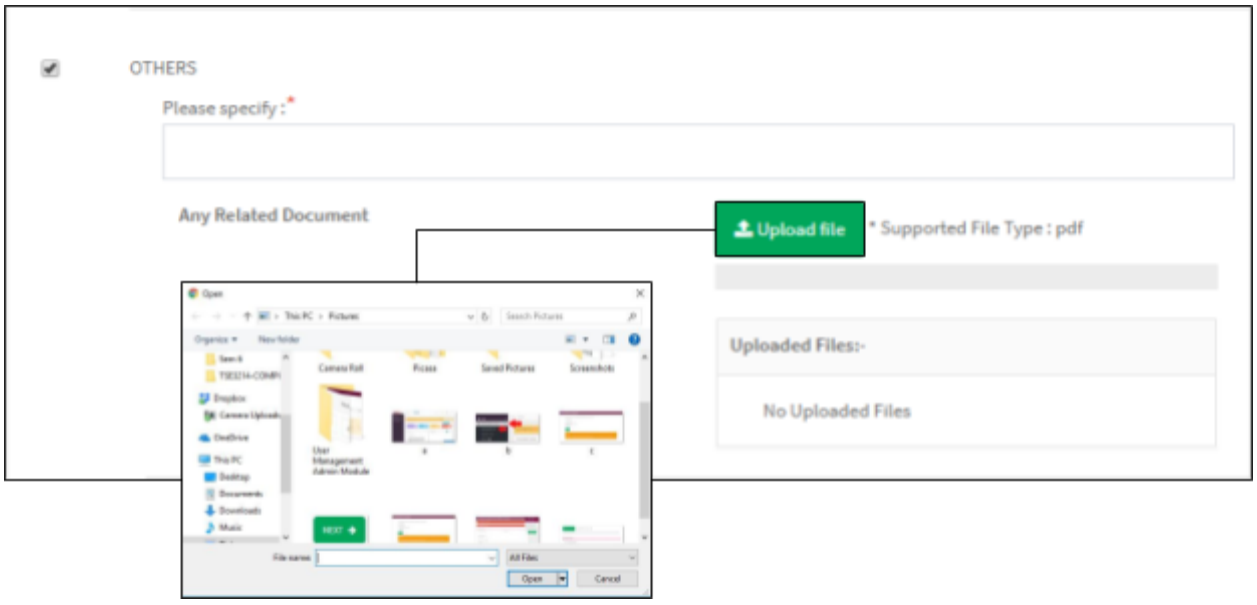



User click  to upload file. **The file must be pdf format and size not more than 300 MB**.

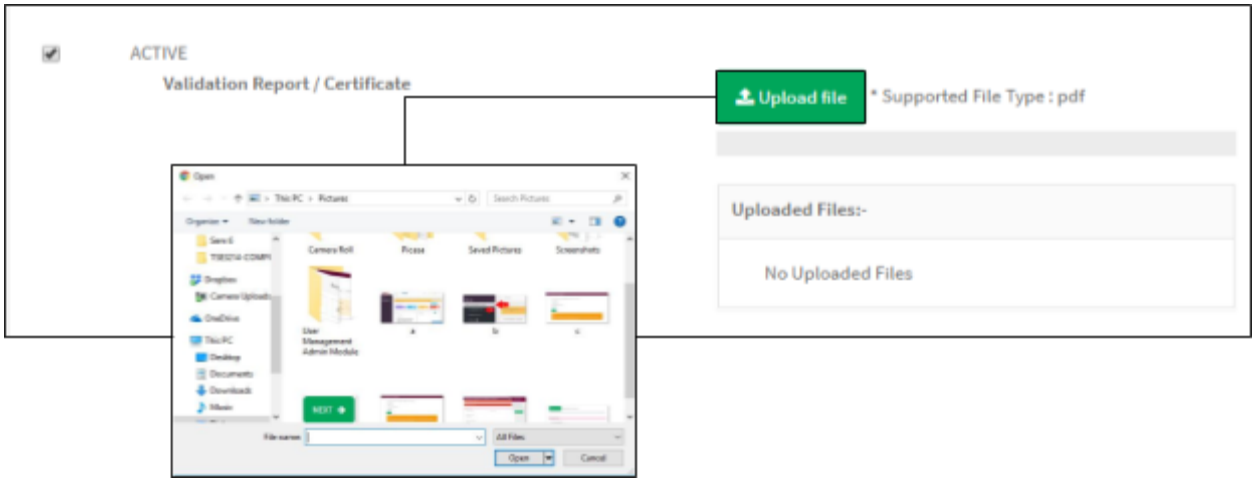




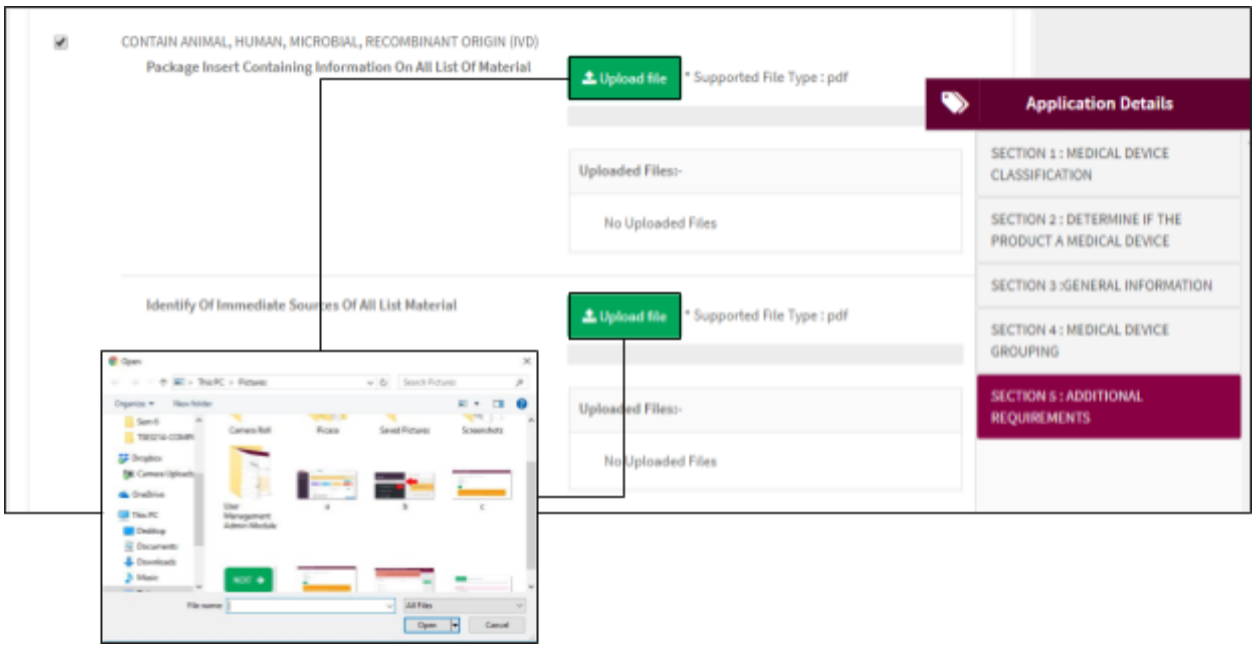

User click  to upload file. **The file must be pdf format and size not more than 300 MB**.

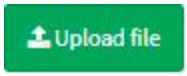



User has fill 'Please specify' text box first then click Upload file to upload file. **The file must be pdf format and size not more than 300 MB**.




User click Upload file to upload file. **The file must be pdf format and size not more than 300 MB**.

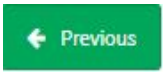



User click 

to upload file. **The file must be pdf format and size not more than 300 MB**.

Click 

to go to the next section.

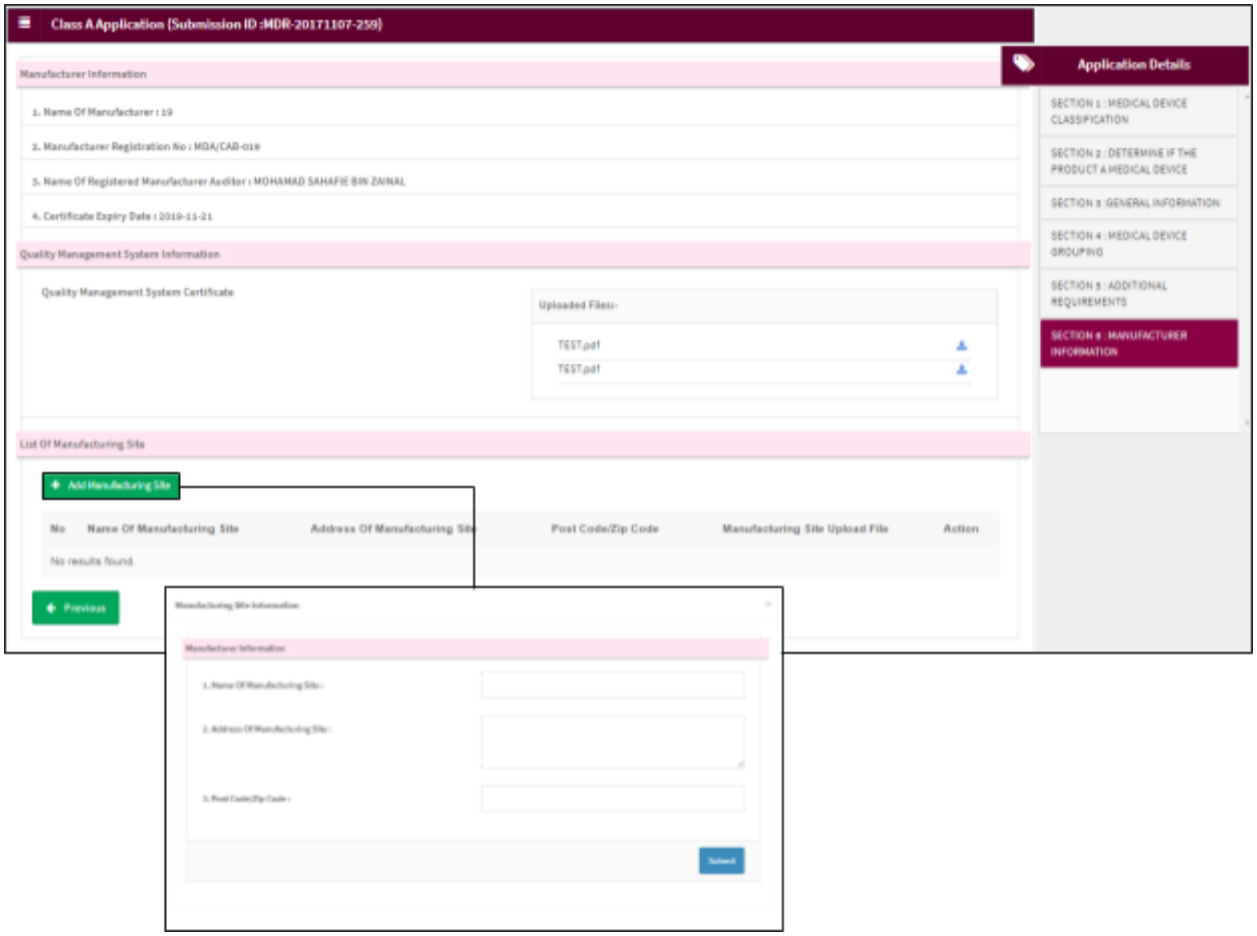
Click 

to go to the previous section.

### 2.2.6 SECTION 6 : MANUFACTURER INFORMATION

Diagram below show section 6 for Manufacturer.

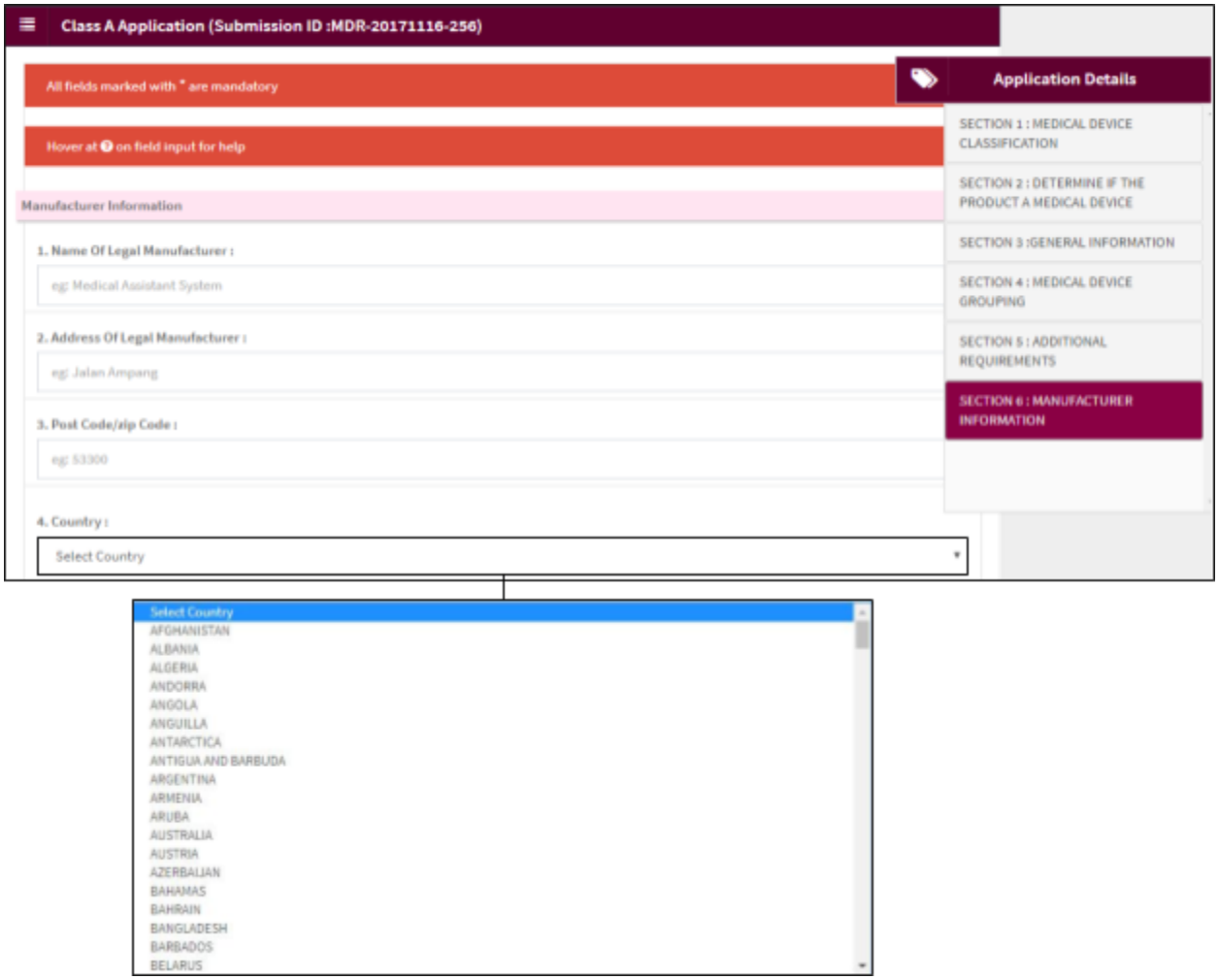
**'Next' button is invisible until user complete this section.**



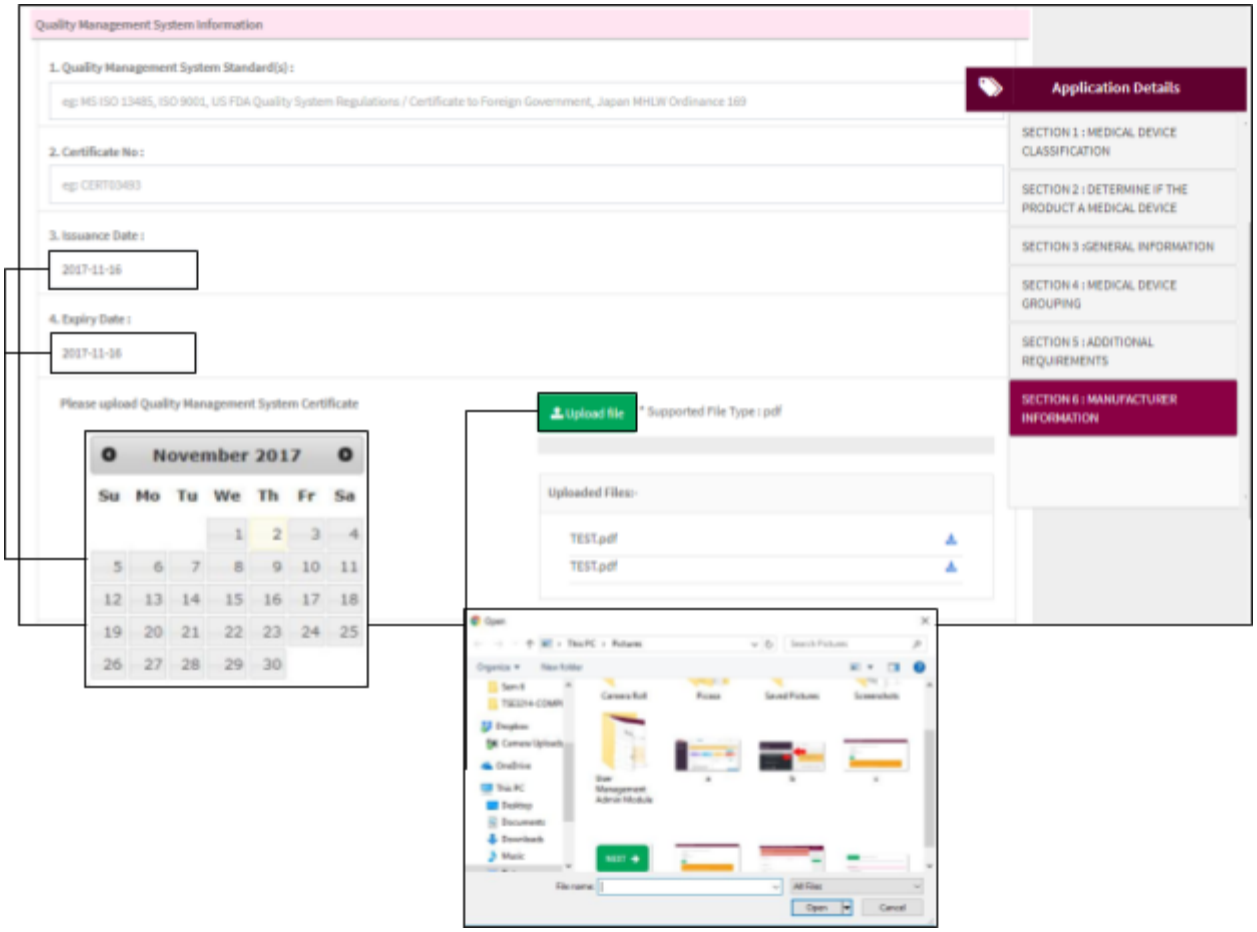

User click  to add new data. User has to fill all the text box then click  . New data will display in 'List Of Manufacturing Site' table.

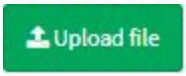
Diagram below show section 6 for Authorised Representative.

**'Next' button is invisible until user complete this section.**

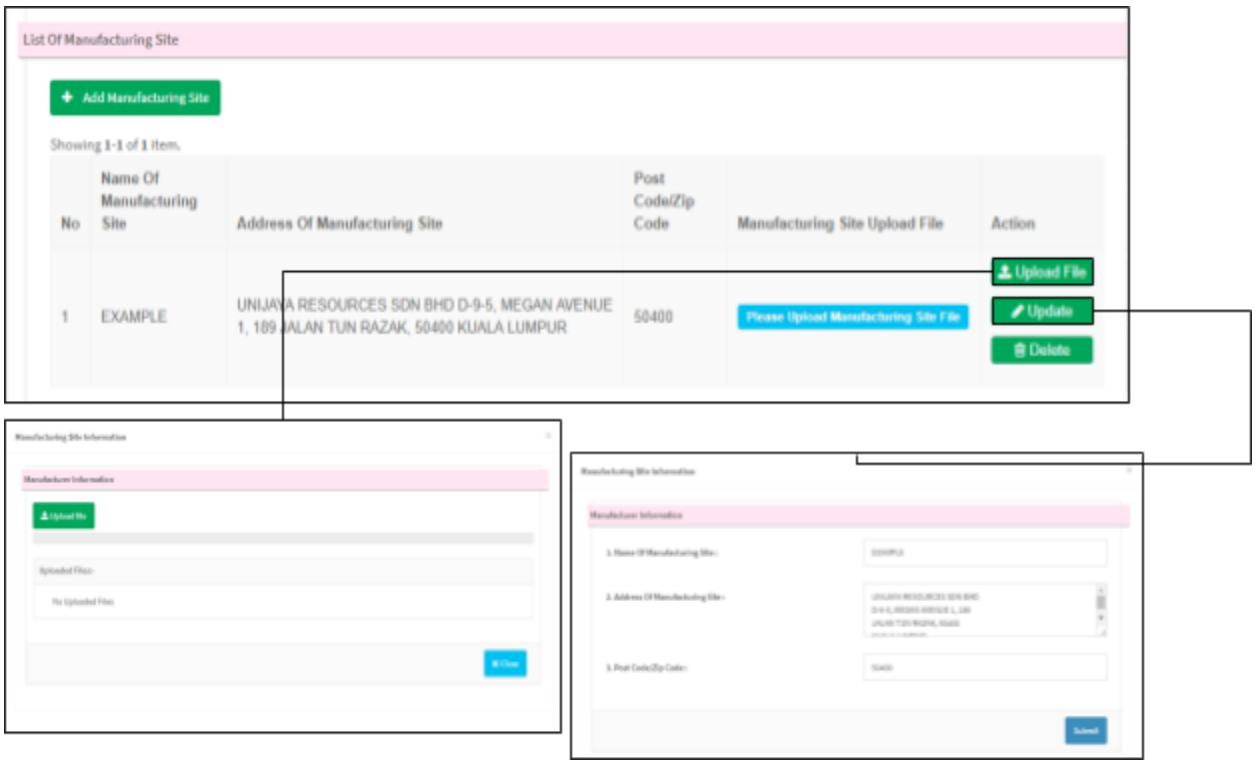


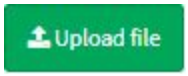

User fill all text boxes **(if necessary)**. User select country at 'Country' drop down text box.

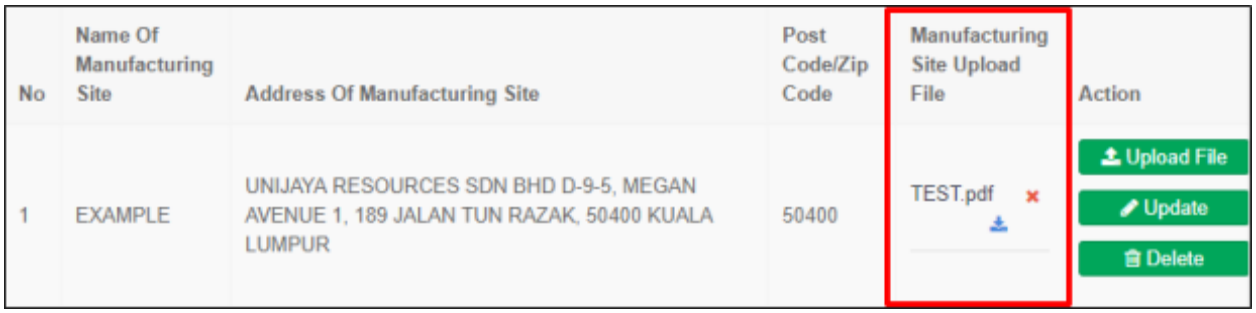



.User fill all text boxes and then user select date in 'Issuance Date' and 'Expiry Date' calendar text box or user can write the date using **YYYY-MM-DD** format. Click at 

to upload file. **The file must be pdf format and size not more than 300 MB.(If necessary)**




Click  then 'Manufacturing Site Information' will display on screen. Click at  to upload file. **The file must be pdf format and size not more than 300 MB**. 'Manufacturing Site Upload File' column will appear in the table.



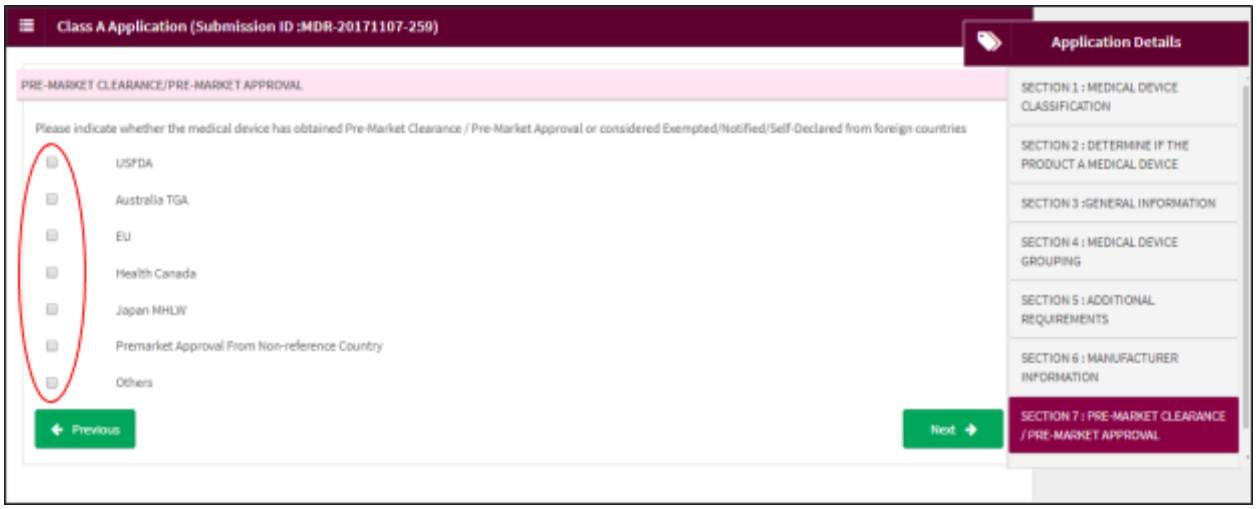

Click  to update the data.

Click  to delete the data.

Click Next → to go to the next section.

Click ← Previous to go to the previous section.

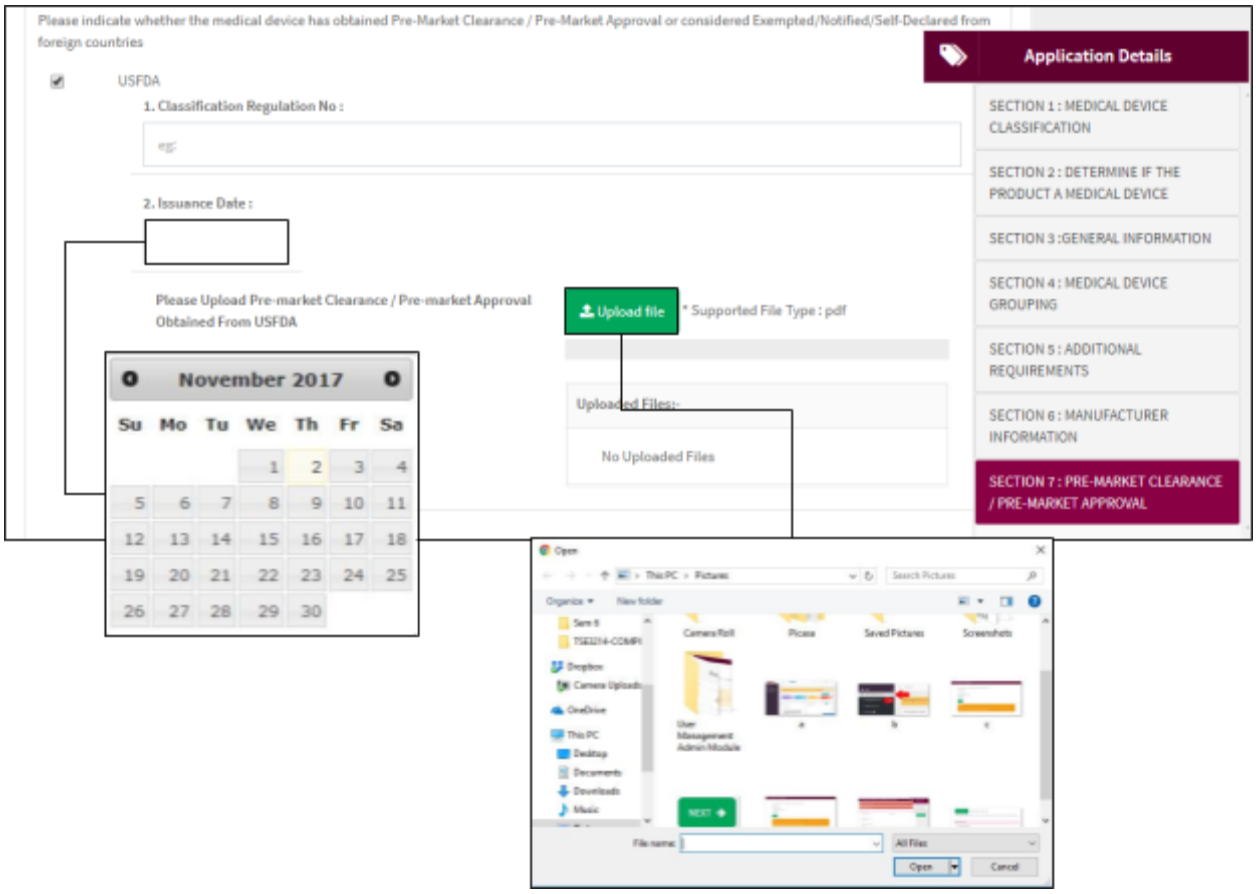
### 2.2.7 SECTION 7 : PRE-MARKET CLEARANCE / PRE-MARKET APPROVAL




User tick checkbox in red circle **(if necessary)** and user can tick more than one checkbox. If not, user click Next → to skip this section.

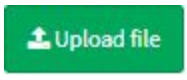
If user tick any checkboxes above, user has to complete that field before user go to the next section

i) 'USFDA' checkbox.



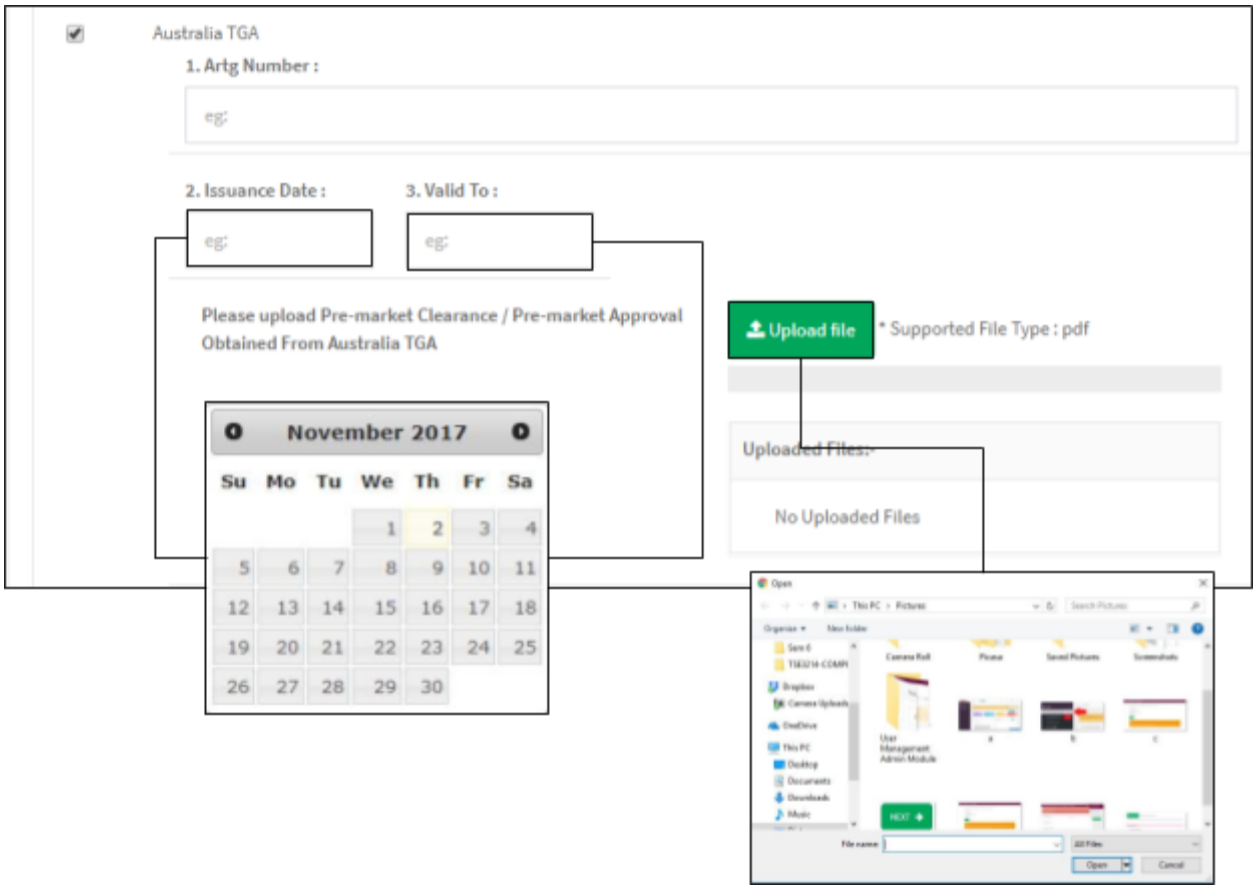

User fill 'Classification Regulation No' text box.

User select date in 'Issuance Date' calendar text box or user can write the date using **YYYY-MM-DD** format.

User click 

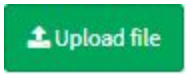
to upload file. **The file must be pdf format and size not more than 300 MB**.

ii) 'Australia TGA' checkbox.



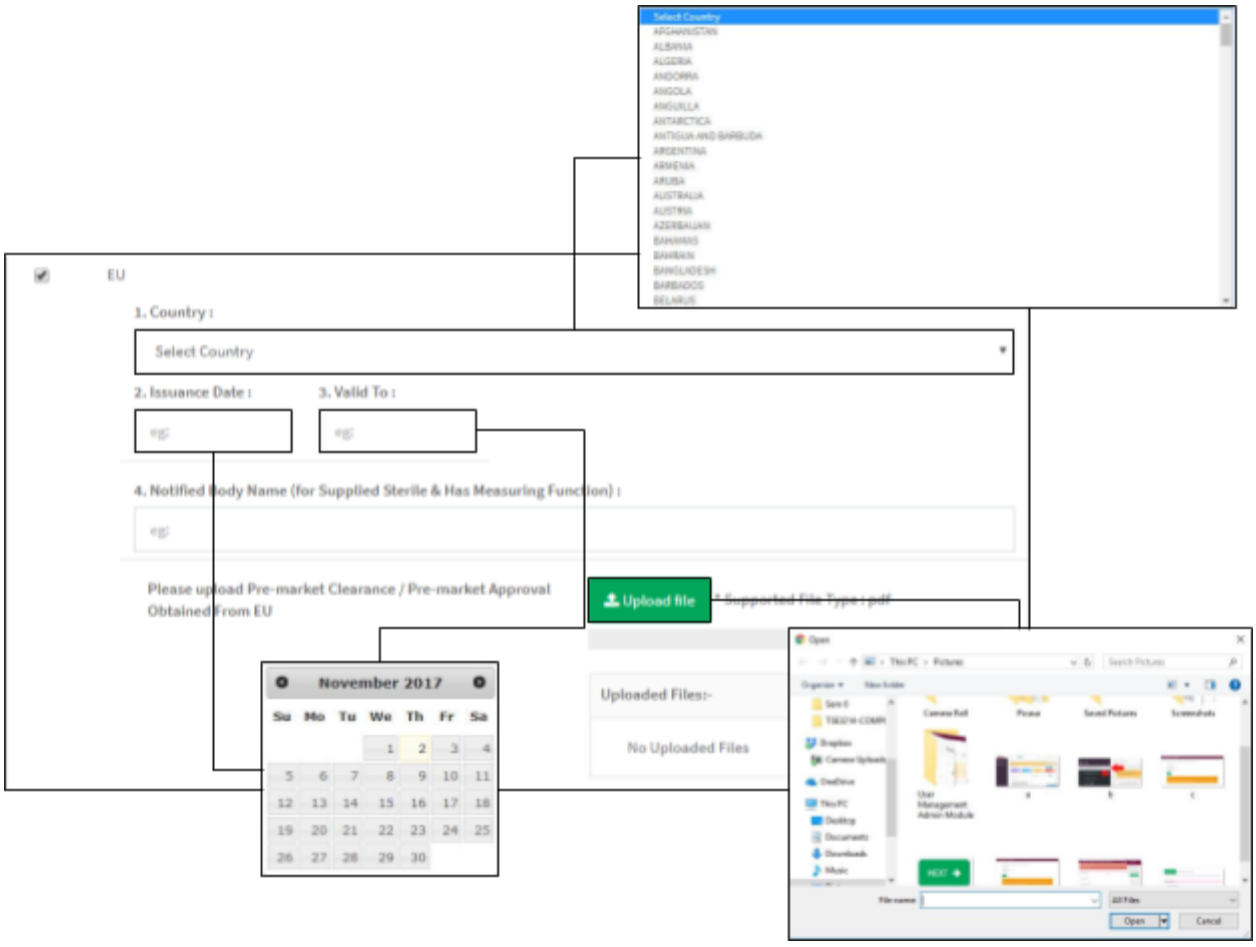

User fill ' Artg Number' textbox.

User select date in 'Issuance Date' and 'Valid To' calendar text box or user can write the date using **YYYY-MM-DD** format .

User click 

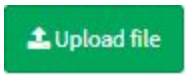
to upload file. **The file must be pdf format and size not more than 300 MB**.

iii) 'EU' checkbox.




User select from 'Country' dropdown text box.

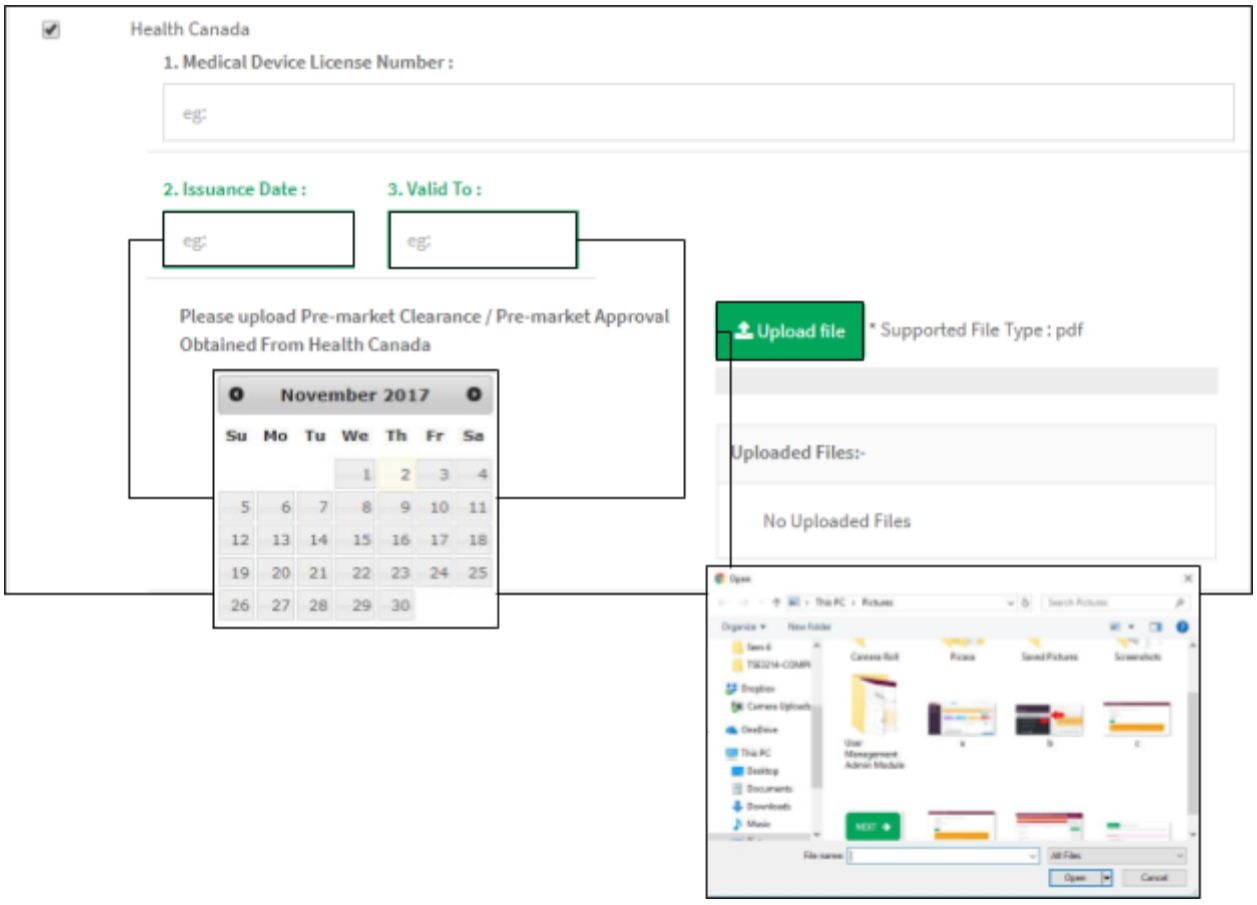
User select date in 'Issuance Date' and 'Valid To' calendar text box or user can write the date using **YYYY-MM-DD** format .

User click 

to upload file. **The file must be pdf format and size not more than 300 MB**.

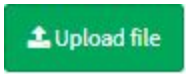
User fill 'Notified Body Name (for Supplied Sterile & Has Measuring Function)' text box.

iv) 'Health Canada' checkbox.



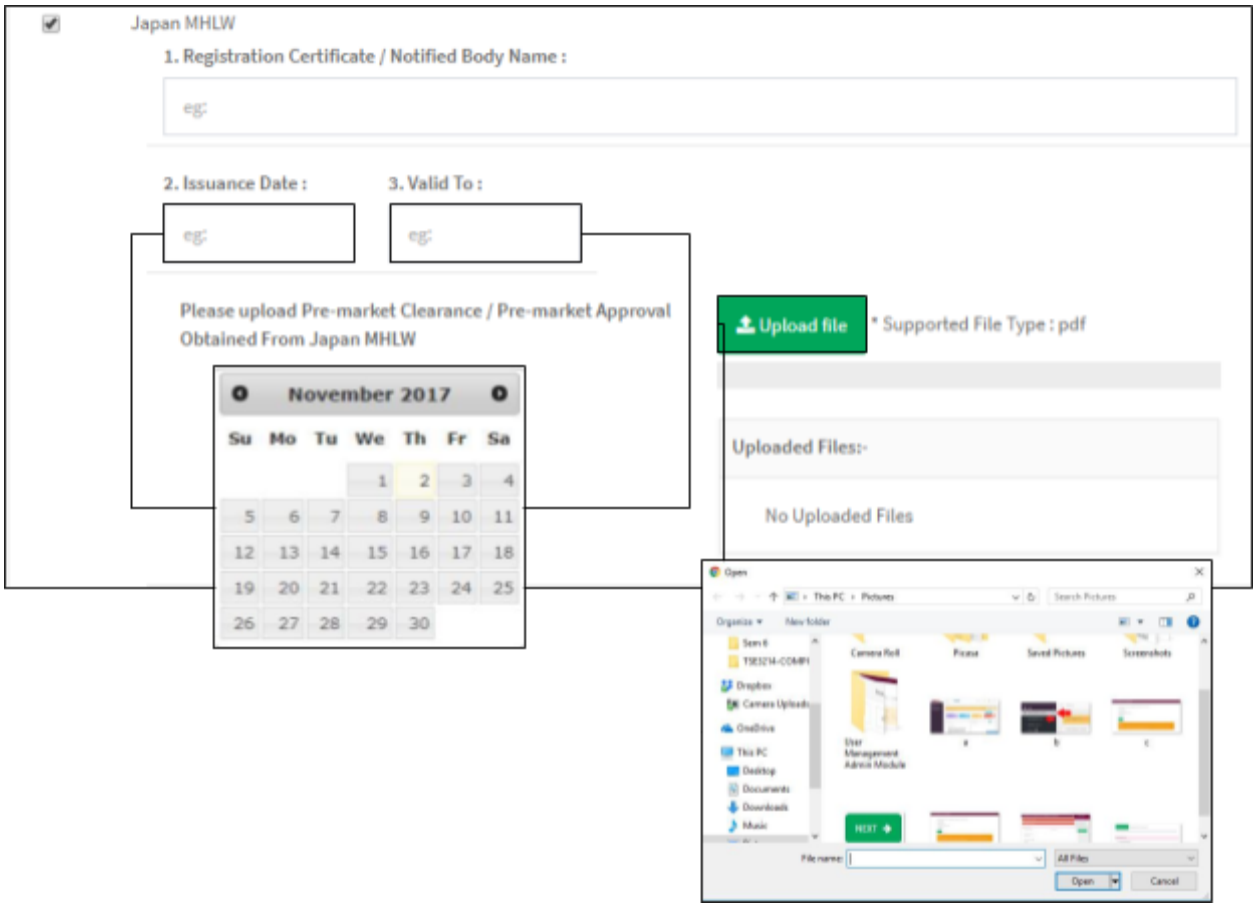

User fill 'Medical Device License Number' text box.

User select date in 'Issuance Date' and 'Valid To' calendar text box or user can write the date using **YYYY-MM-DD** format .

User click 

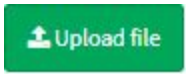
to upload file. **The file must be pdf format and size not more than 300 MB**.

v) 'Japan MHLW' checkbox.



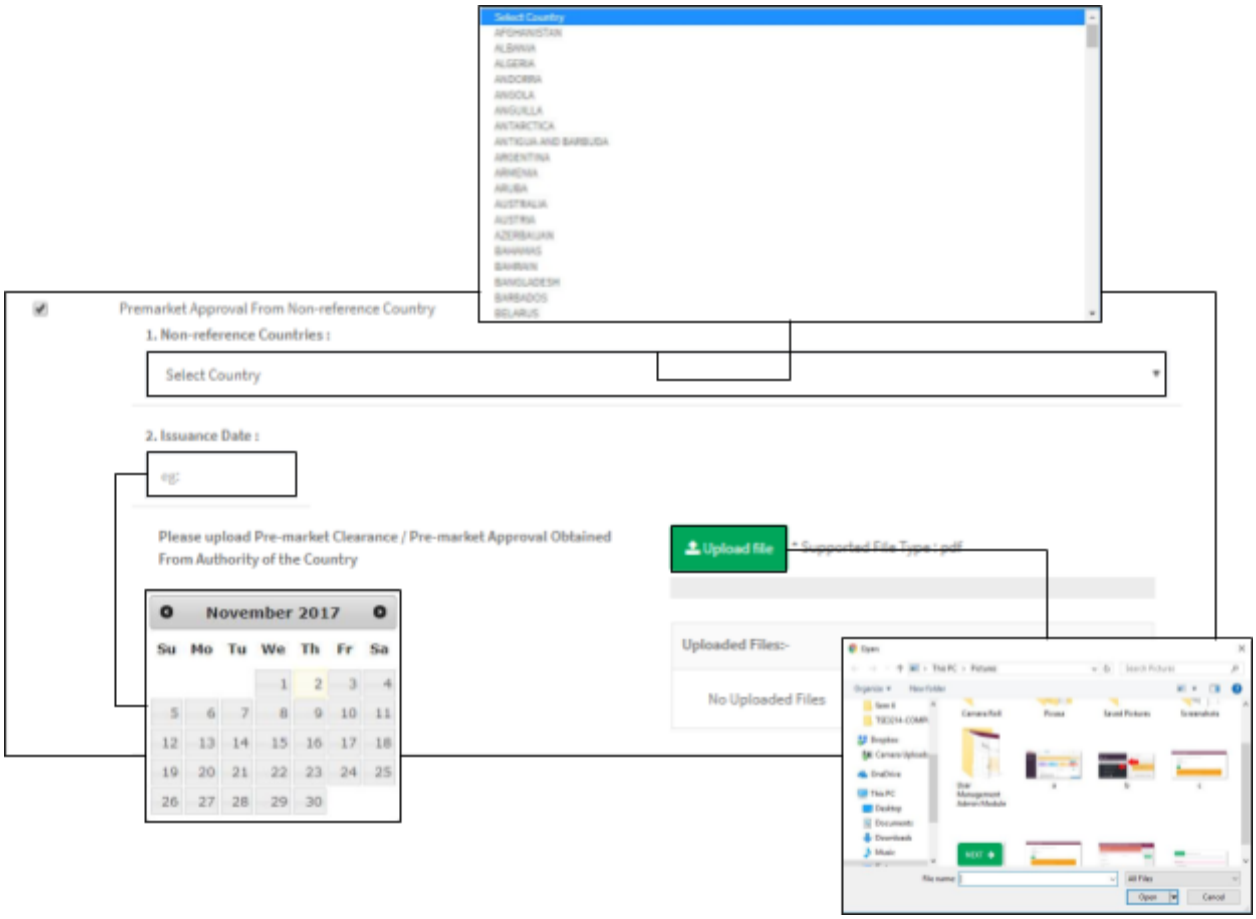

User fill 'Registration Certificate / Notified Body Name' text box.

User select date in 'Issuance Date' and 'Valid To' calendar text box or user can write the date using **YYYY-MM-DD** format .

User click 

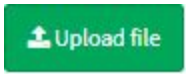
to upload file. **The file must be pdf format and size not more than 300 MB**.

vi) 'Premarket Approval From Non-reference Country' checkbox.




User select from 'Non-reference Countries' dropdown text box.

User select date in 'Issuance Date' calendar text box or user can write the date using **YYYY-MM-DD** format .

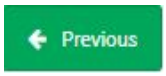
User click 

to upload file. **The file must be pdf format and size not more than 300 MB**.

vii) 'Others' checkbox.


User has to fill 'Please Specify' text box.

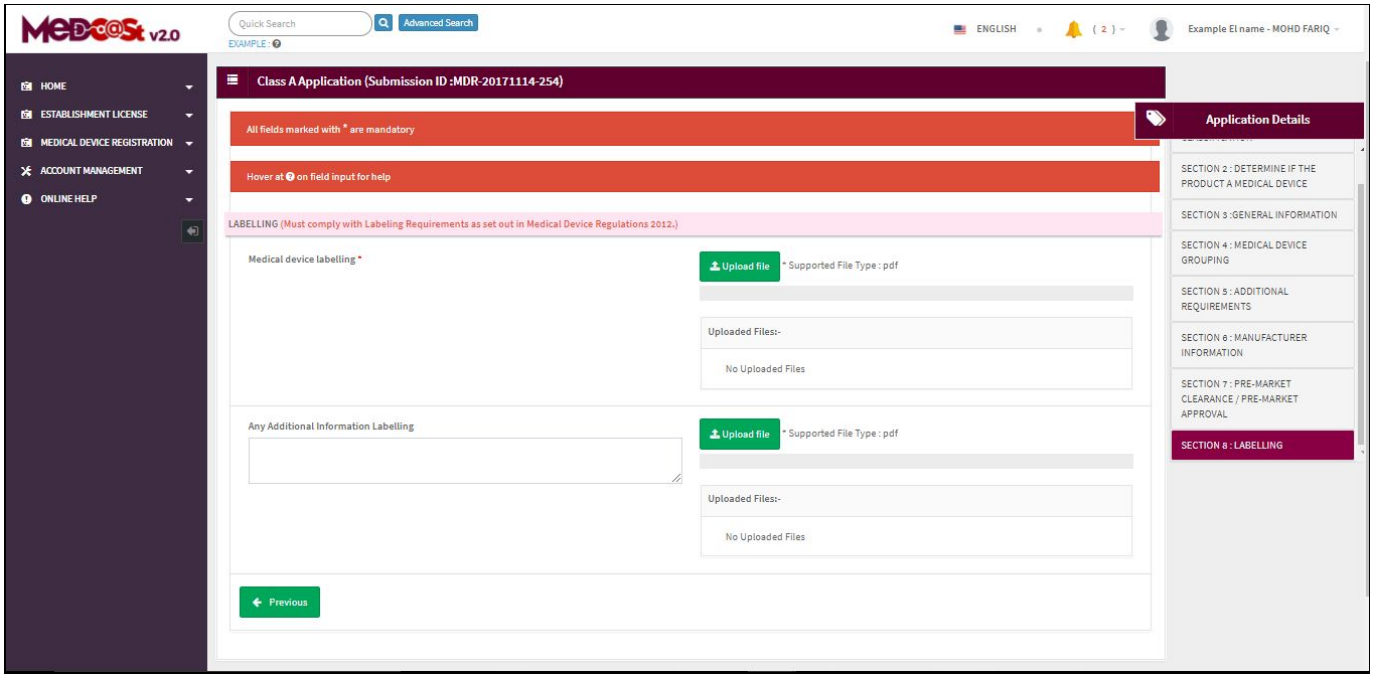
Click  to go to the next section.

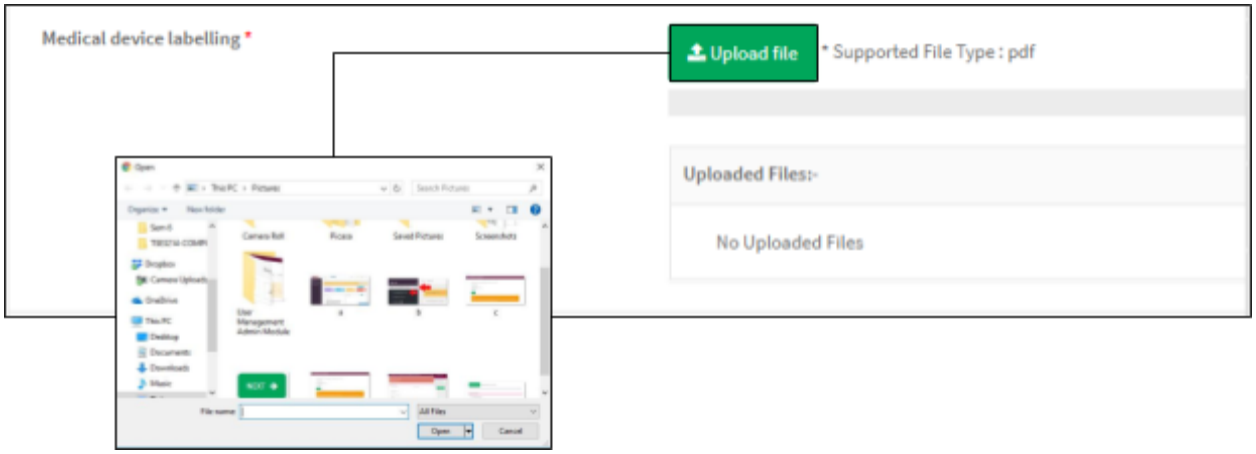

Click  to go to the previous section.

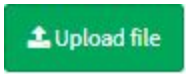
### 2.2.8 SECTION 8 : LABELLING

Diagram below show section 8 page.

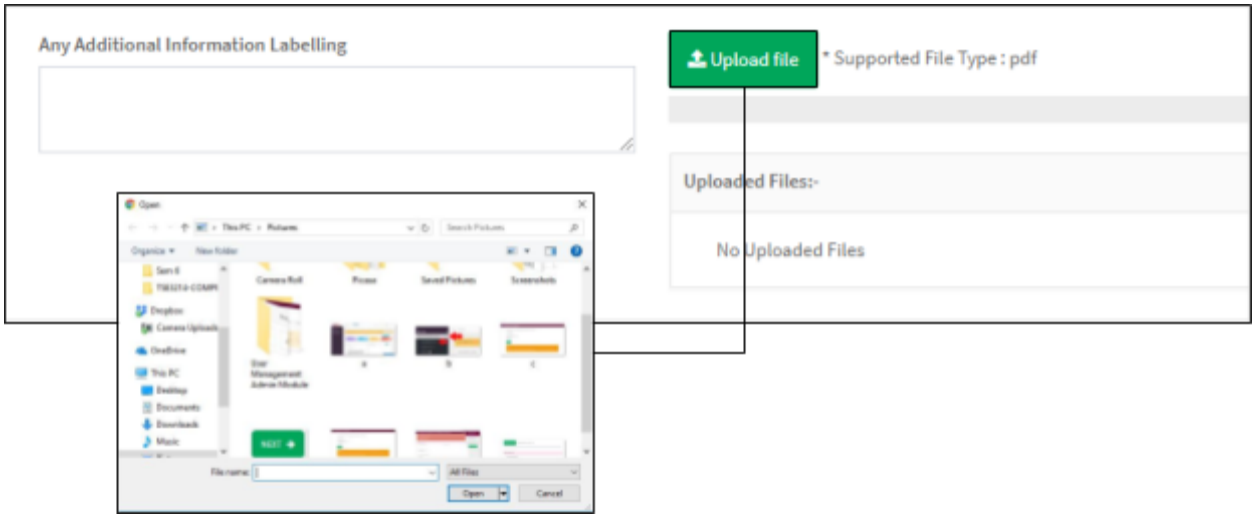
**'Next' button is invisible until user complete this section.**



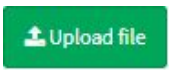



User click 

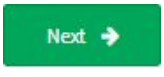
to upload file. **The file must be pdf format and size not more than 300 MB**.



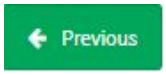

User fill 'Any Additional Information Labelling' text box.**(If necessary)**

User click 

to upload file. **The file must be pdf format and size not more than 300 MB**.

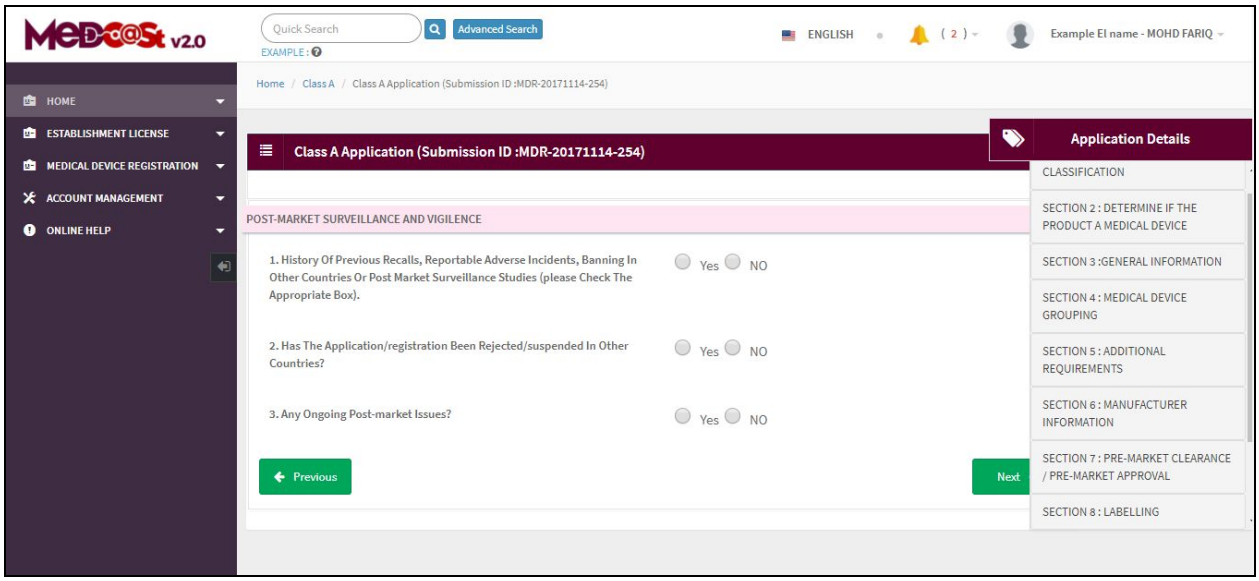
Click 

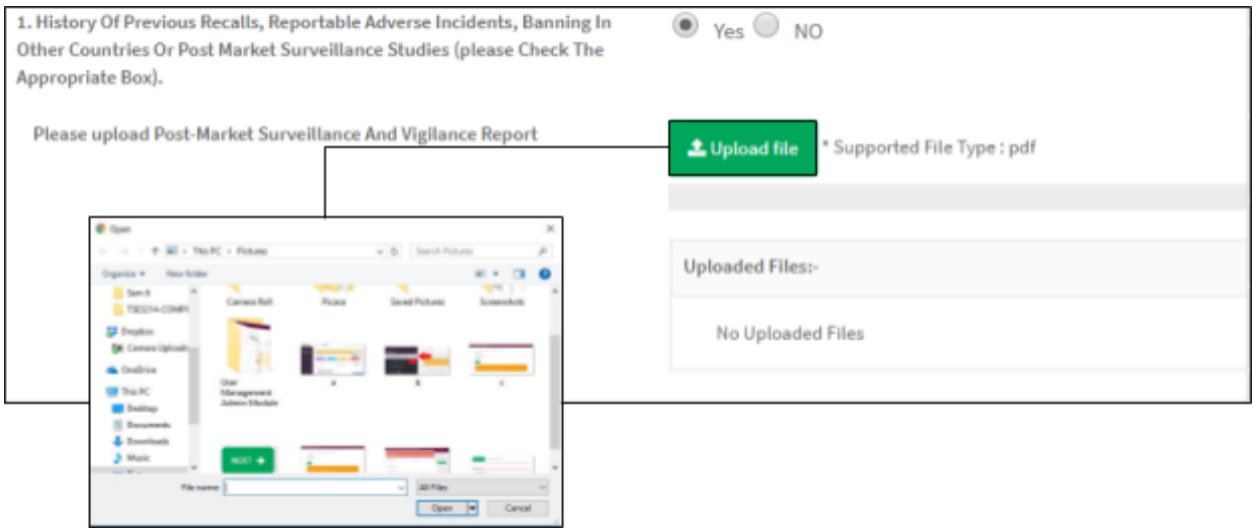
to go to the next section.

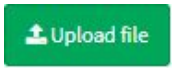
Click  to go to the previous section.



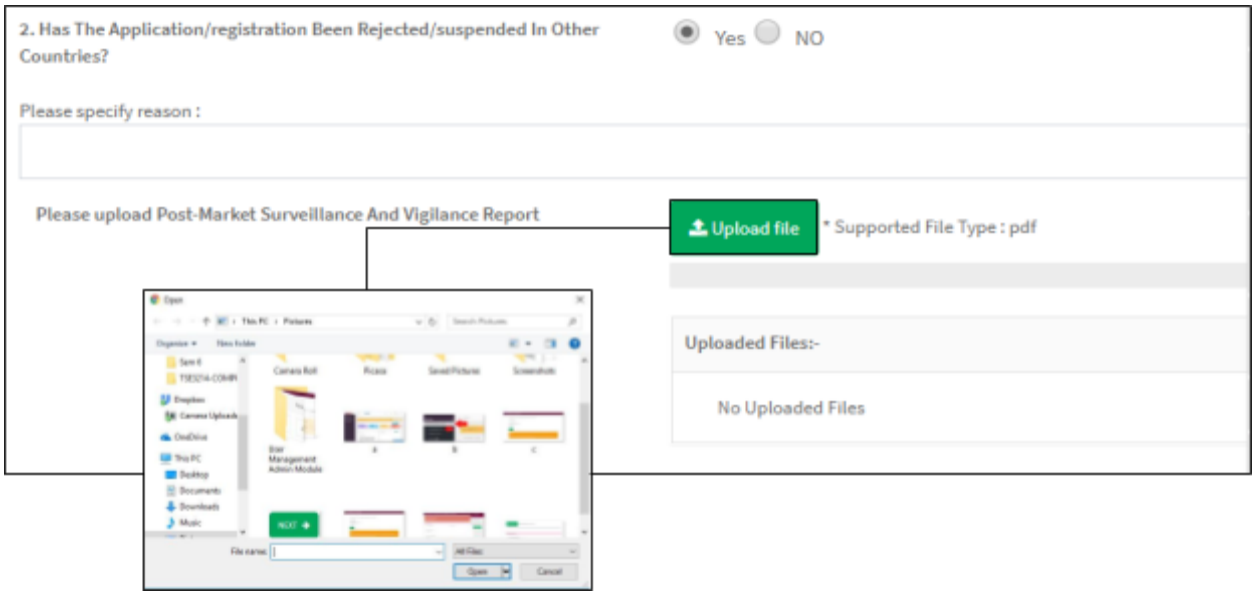
### 2.2.9 SECTION 9 : POST-MARKET SURVEILLANCE AND VIGILANCE

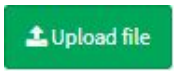


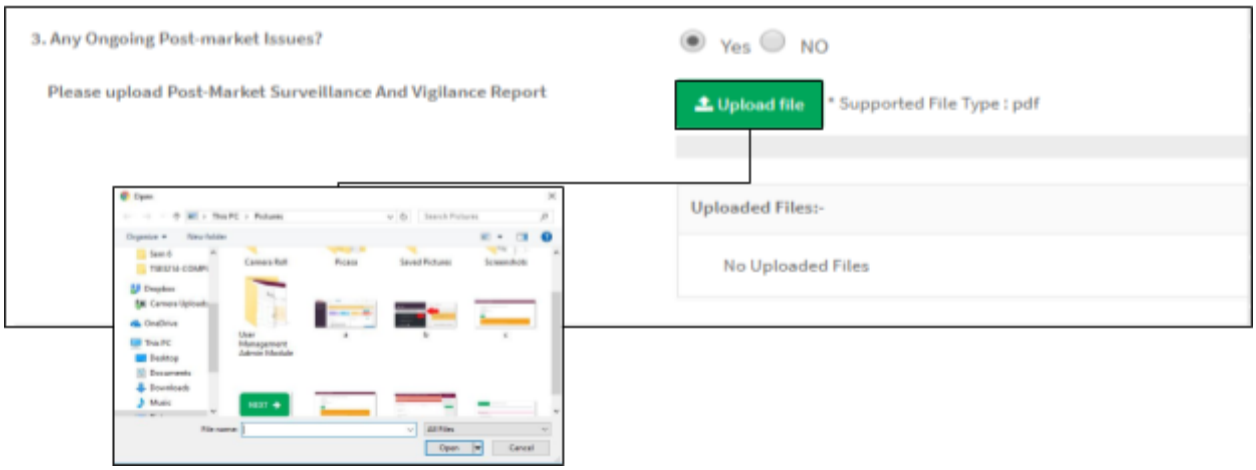
If user tick 'Yes', user has to upload file. Click 

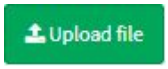
to upload file. **The file must be pdf format and size not more than 300 MB**.




If user tick 'Yes', user has to upload file. Click 

to upload file. **The file must be pdf format and size not more than 300 MB**.

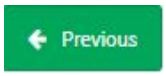


If user tick 'Yes', user has to upload file. Click 

to upload file. **The file must be pdf format and size not more than 300 MB**.

Click 

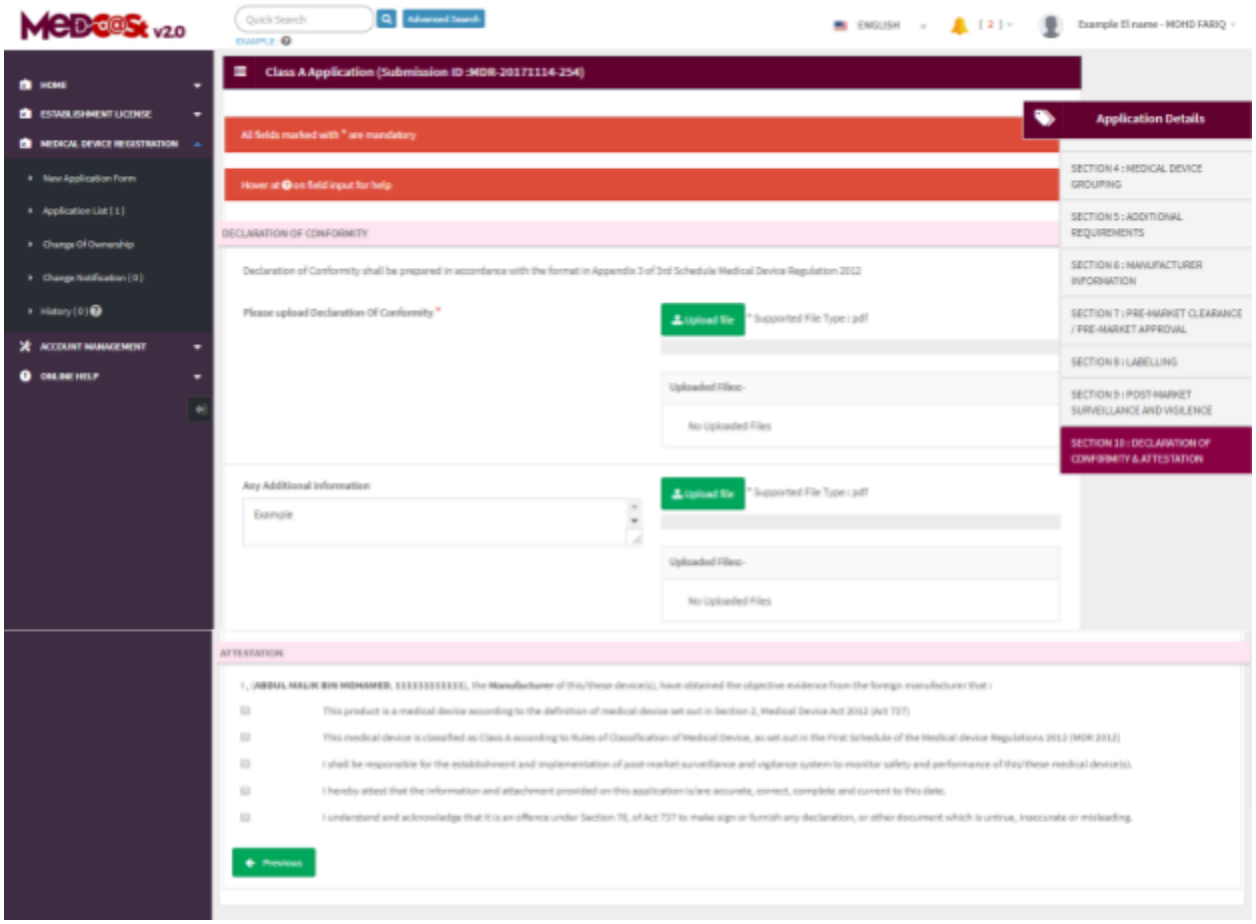
to go to the next section.

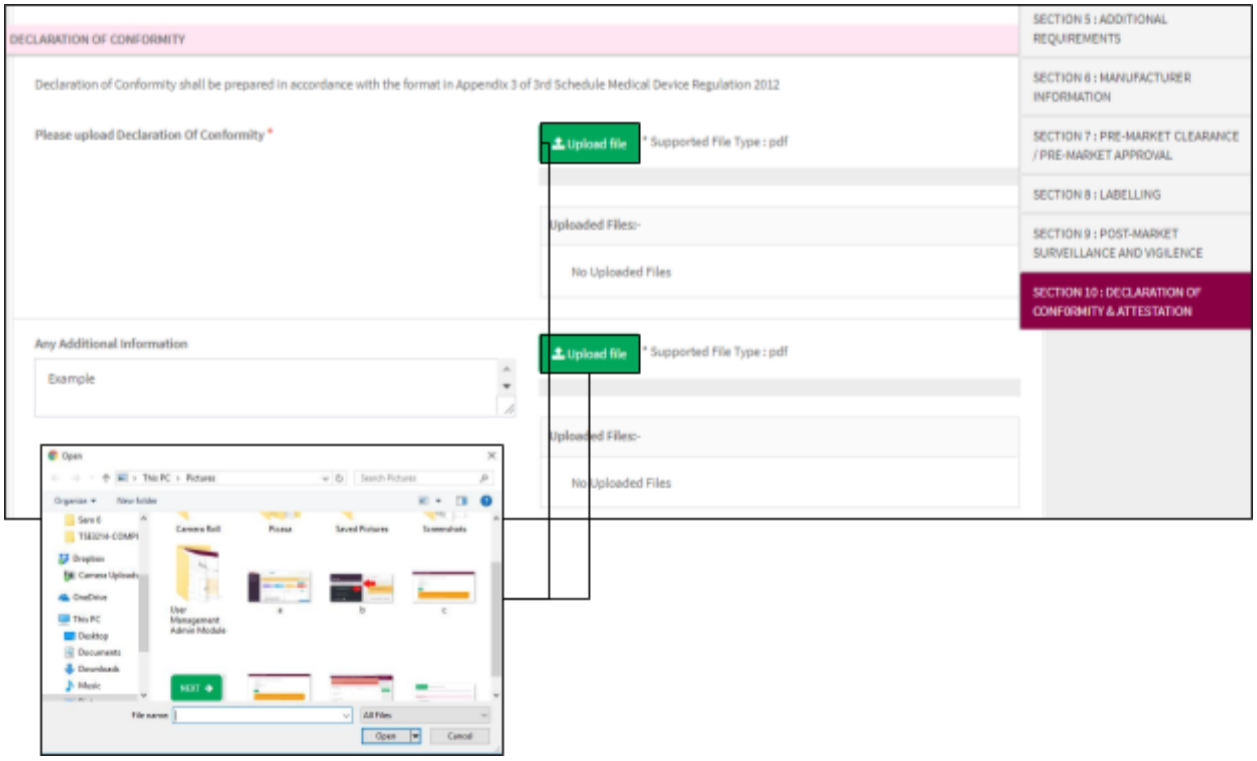
Click 

to go to the previous section.

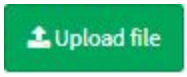
### 2.2.10 SECTION 10 : DECLARATION OF CONFORMITY & ATTESTATION

**'Preview & Submit' button is invisible until user complete this section.**

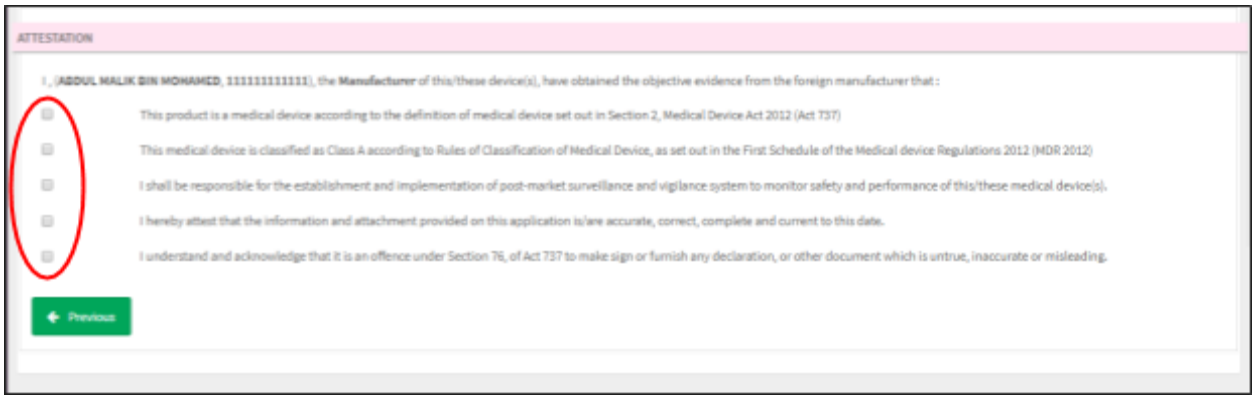




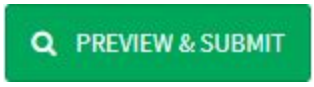

User fill 'Any Additional Information Labelling' text box.**(If necessary)**

User click 

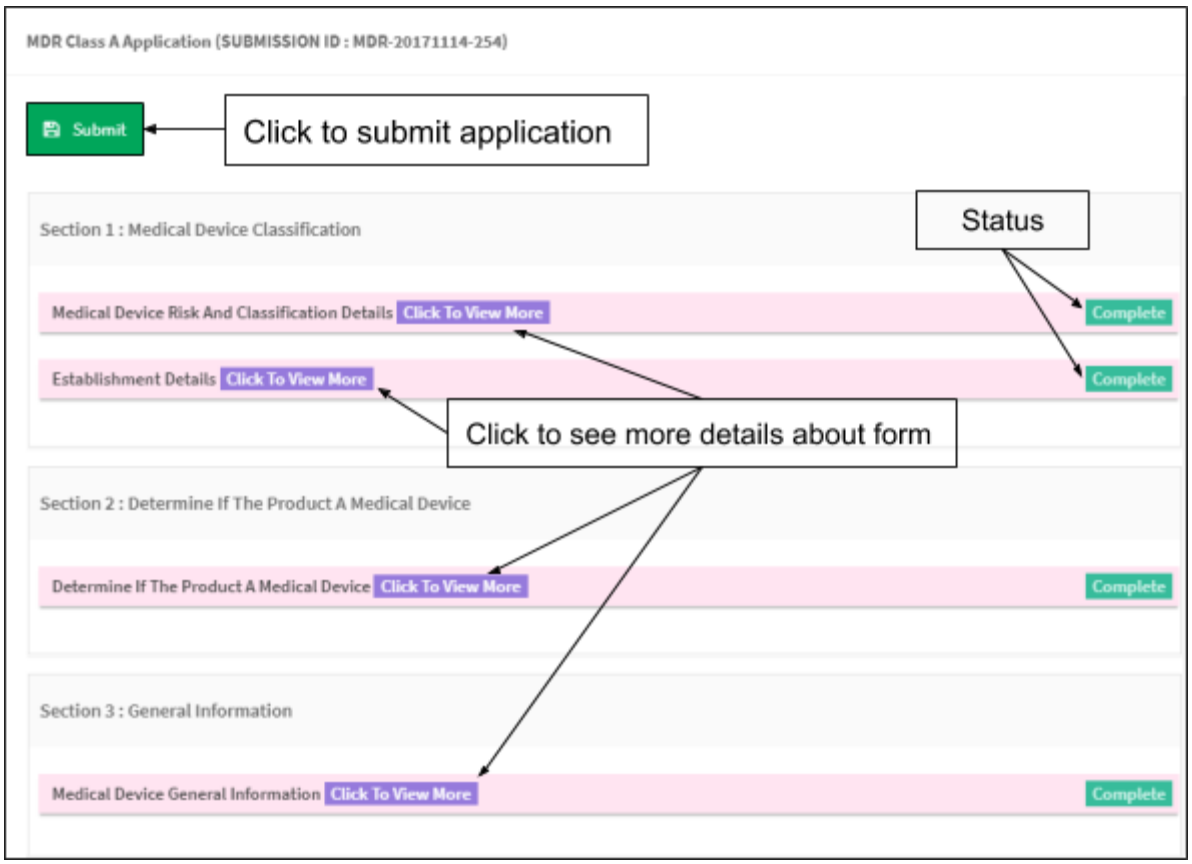
to upload file. **The file must be pdf format and size not more than 300 MB**.

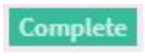



User has to tick all the checkbox before user can submit application.

User click 

to preview before submit application.




Submission only can do if all form status is 

. If status 

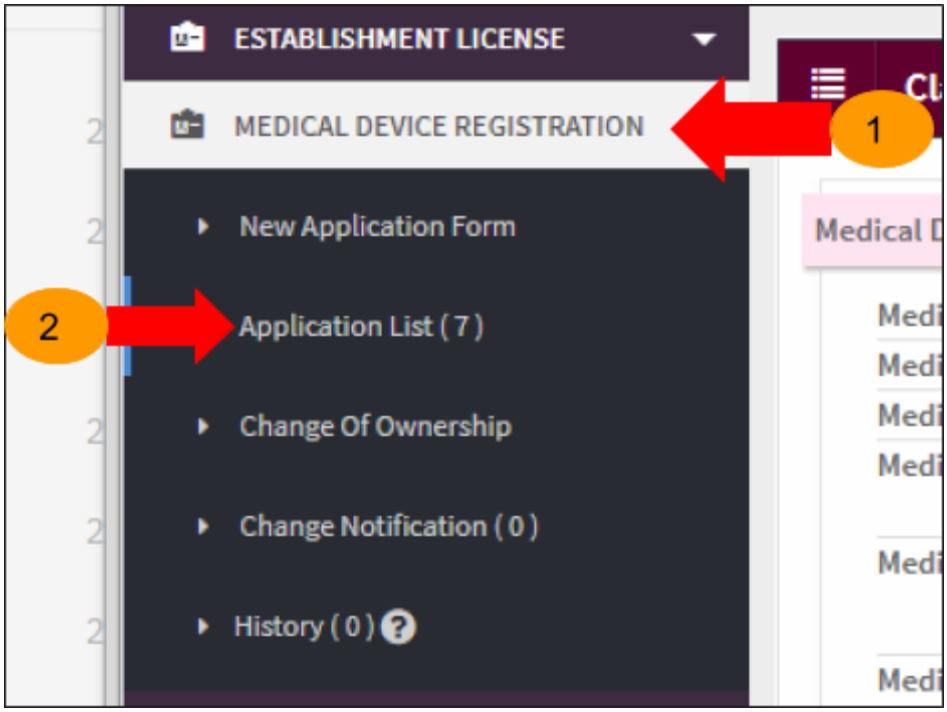
, user has to complete the form.

Then, click 

to submit application.

## 3.0 RE-REGISTRATION APPLICATION

User go to *Application List* page to re-registration application.



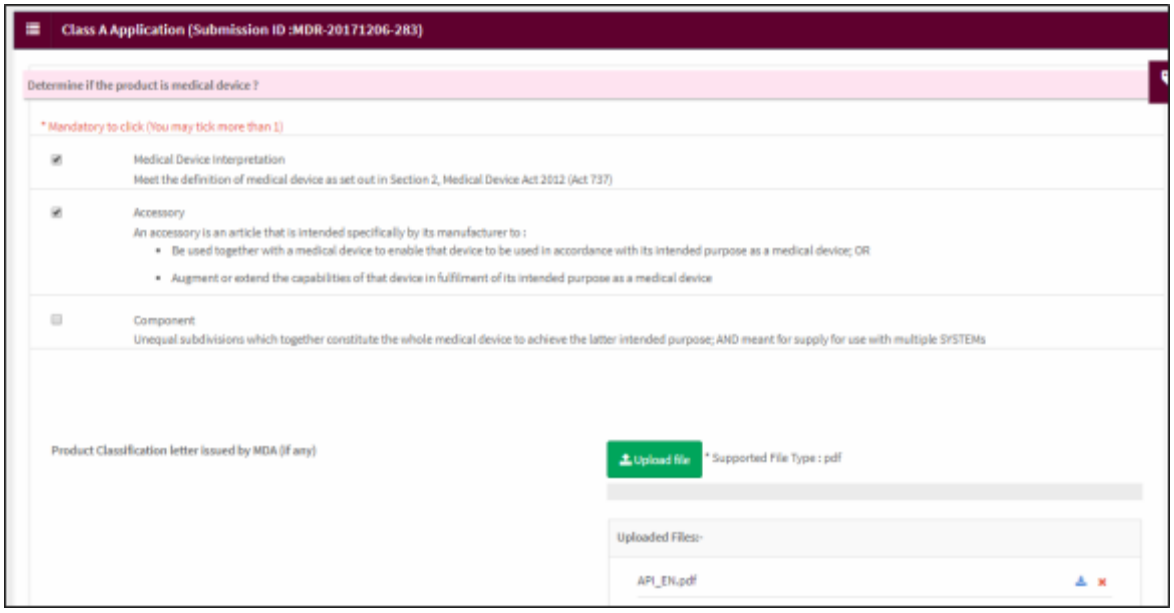

The diagram below show *Application List* page. Click 

to re-register application.


User unable to edit this section, this section only display for user. User click 

to go to the next step.

Next, user will go to SECTION 2 : DETERMINE IF THE PRODUCT A MEDICAL DEVICE page. User have to choose and fill all required information.

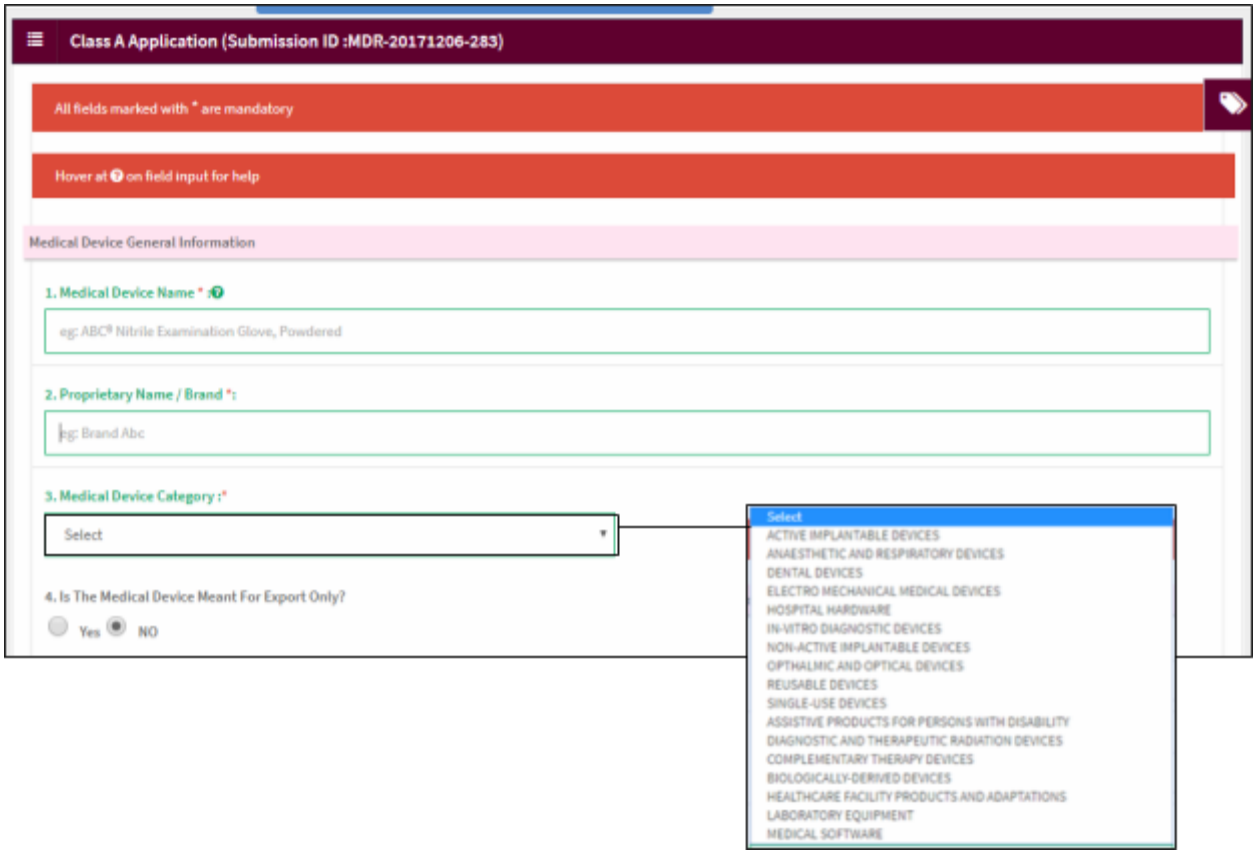


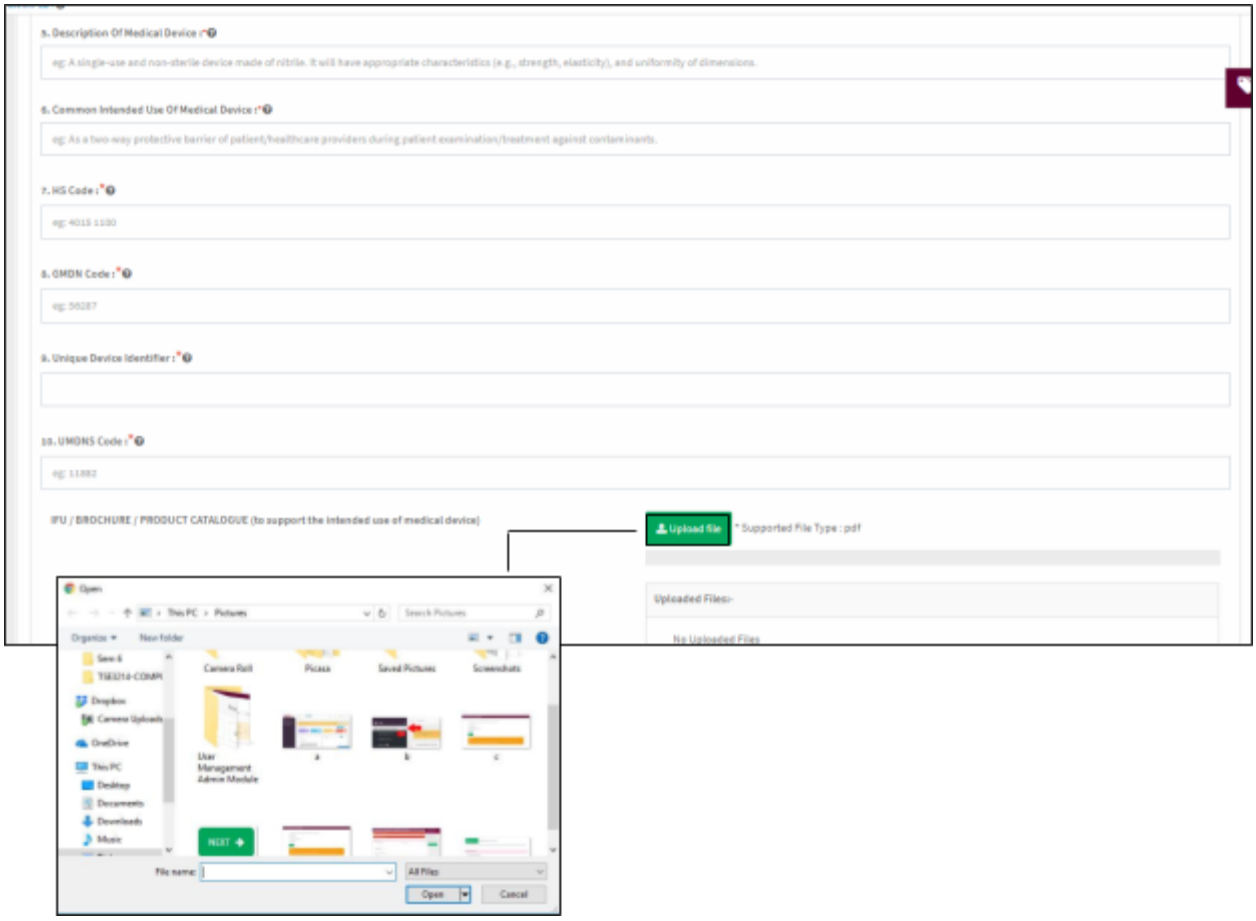

User click  to go to the next step.


User click  to go to the previous form.

The diagram below show SECTION 3 : GENERAL INFORMATION page, user need to fill :

I. Medical Device Name
II. Proprietary Name / Brand
III. Medical Device Category
IV. Is the Medical Device Meant for Export Only?
V. Description of Medical Device
VI. Common Intended Use of Medical Device
VII. HS Code
VIII. GMDN Code
IX. Unique Device Identifier
X. UMDNS Code
XI. IFU/BROCHURE/PRODUCT CATALOGUE


Class A Application (Submission ID :MDR-20171206-283)
All fields marked with * are mandatory
Hover at on field input for help
Medical Device General Information
1. Medical Device Name * :
eg: ABC® Nitrile Examination Glove, Powdered
2. Proprietary Name / Brand *:
eg: Brand Abc
3. Medical Device Category :*
Select
4. Is The Medical Device Meant For Export Only?
Yes
NO
Select
ACTIVE IMPLANTABLE DEVICES
ANAESTHETIC AND RESPIRATORY DEVICES
DENTAL DEVICES
ELECTRO MECHANICAL MEDICAL DEVICES
HOSPITAL HARDWARE
IN-VITRO DIAGNOSTIC DEVICES
NON-ACTIVE IMPLANTABLE DEVICES
OPTHALMIC AND OPTICAL DEVICES
REUSABLE DEVICES
SINGLE-USE DEVICES
ASSISTIVE PRODUCTS FOR PERSONS WITH DISABILITY
DIAGNOSTIC AND THERAPEUTIC RADIATION DEVICES
COMPLEMENTARY THERAPY DEVICES
BIOLOGICALLY-DERIVED DEVICES
HEALTHCARE FACILITY PRODUCTS AND ADAPTATIONS
LABORATORY EQUIPMENT
MEDICAL SOFTWARE




Click Upload file to upload file. **The file must be pdf format and size not more than 300 MB**.

User click Next to go to the next step.

User click Previous to go to the previous form.

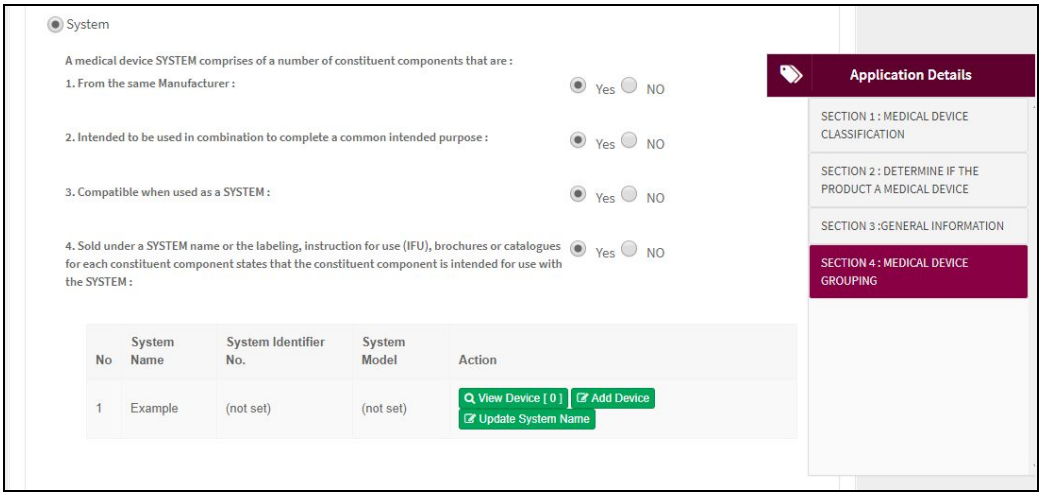
Next, user will go to SECTION 4 : MEDICAL DEVICE GROUPING page. User have to choose and fill all required information.

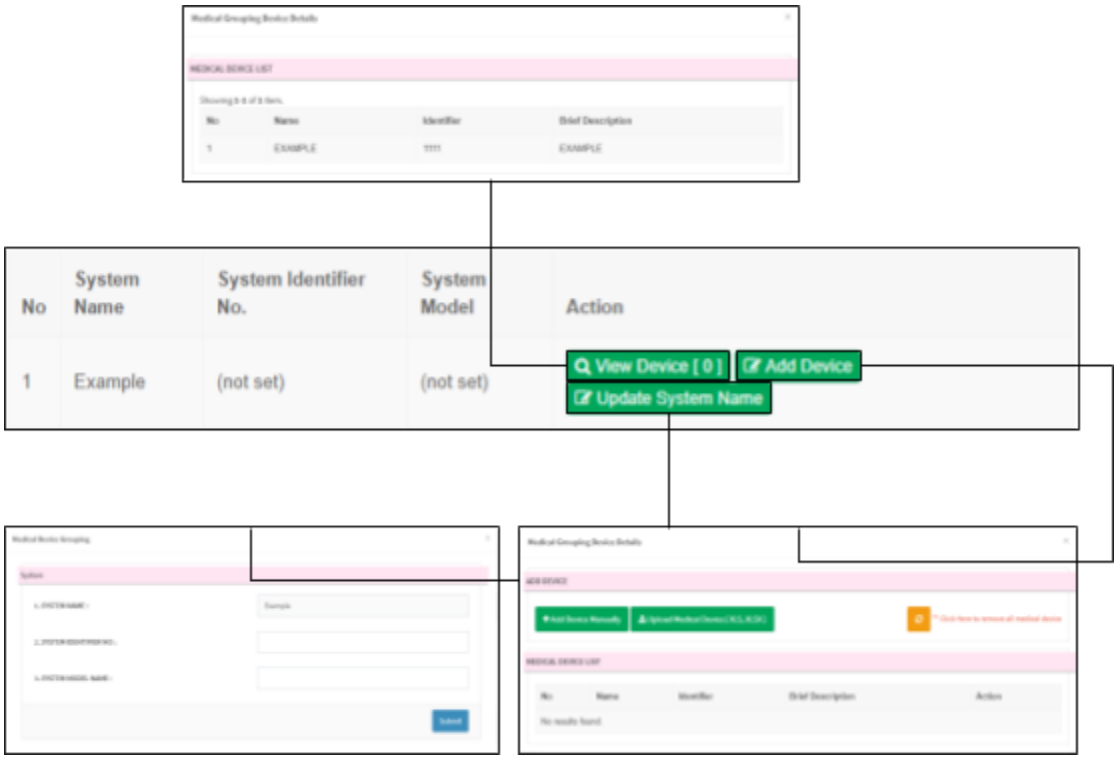
User only can tick one radio button in Medical Device Grouping field before user can go to next step.

i) ‘Single’ radio button.


User has to fill ‘1. Device Identifier’ and ‘2. Model’ text boxes. Warning texts will display if user do not fill the text boxes.

ii) ‘System’ radio button.



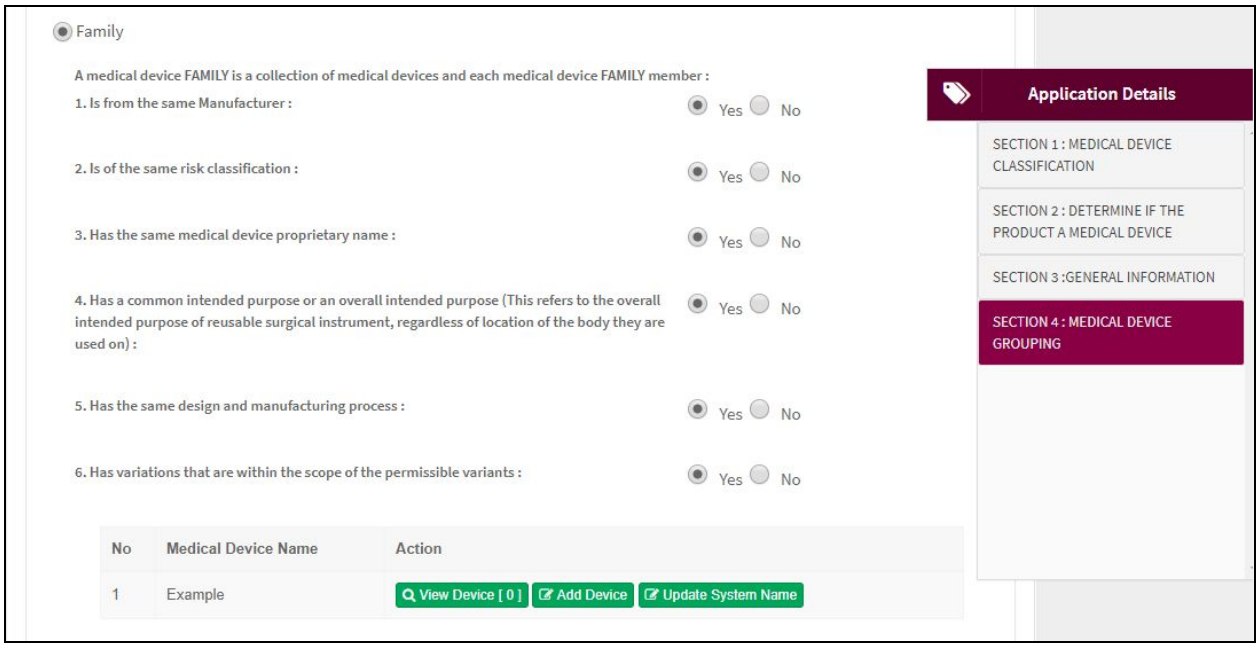

Click  to view device list.

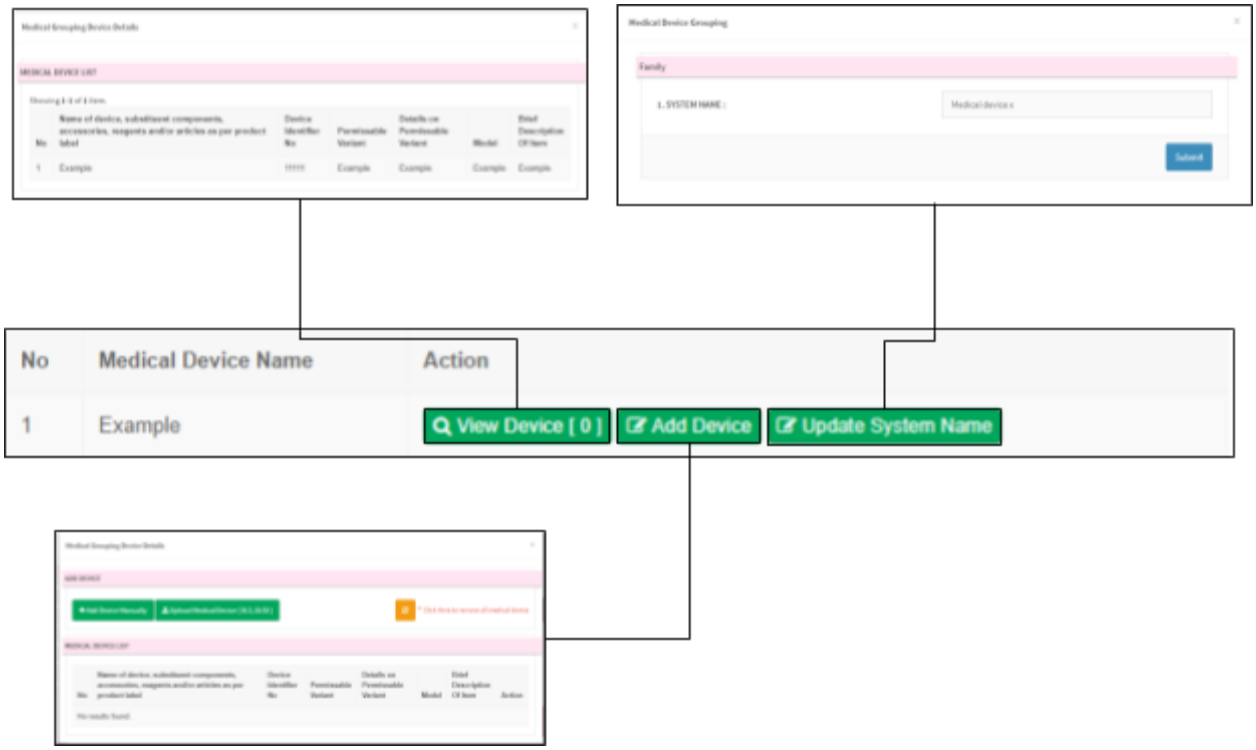
Click  to update [System Identifier No.] and [System Model] then click  to confirm update.

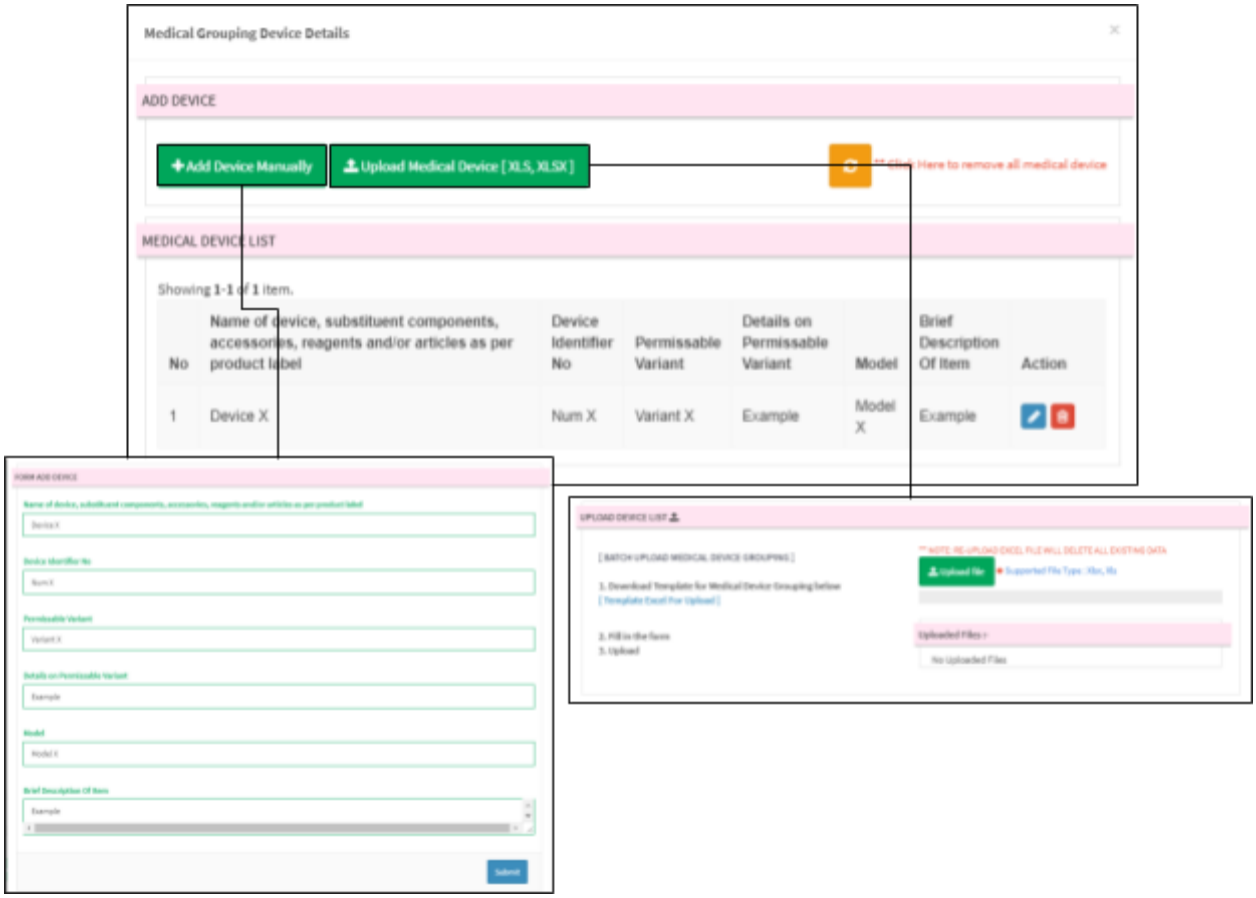




iii) 'Family' radio button




No
Medical Device Name
Action
1
Example
View Device [ 0 ]
Add Device
Update System Name



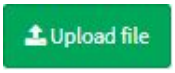

Click  to view device list.



User click  , then user has to fill the form and click  to add device.





User click  , then user click [Template Excel For Upload] to download excel template. Next, user click  to upload excel file. **The file must be xlsx or xls format.**



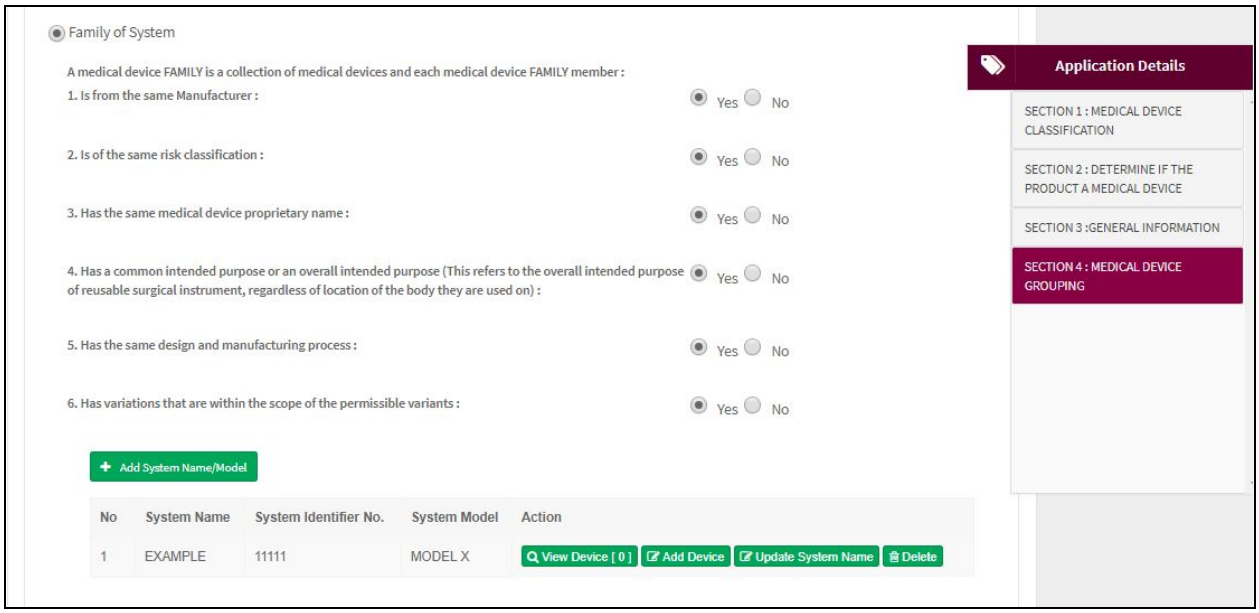


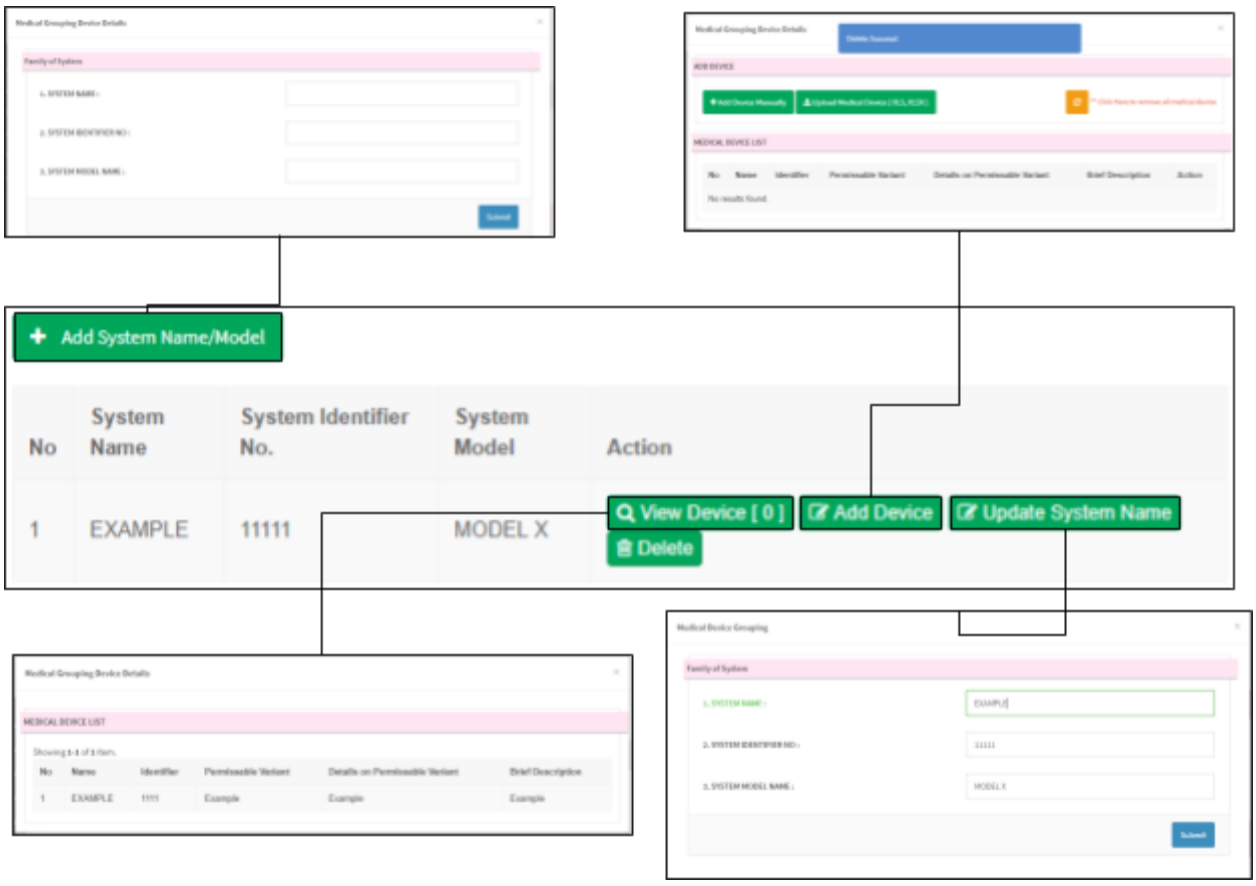
 button for user edit device details.

button for user delete device.

button for user delete all medical devices.

iv) ‘Family Of System’ radio button.






Click  to add system name or model.

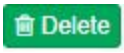


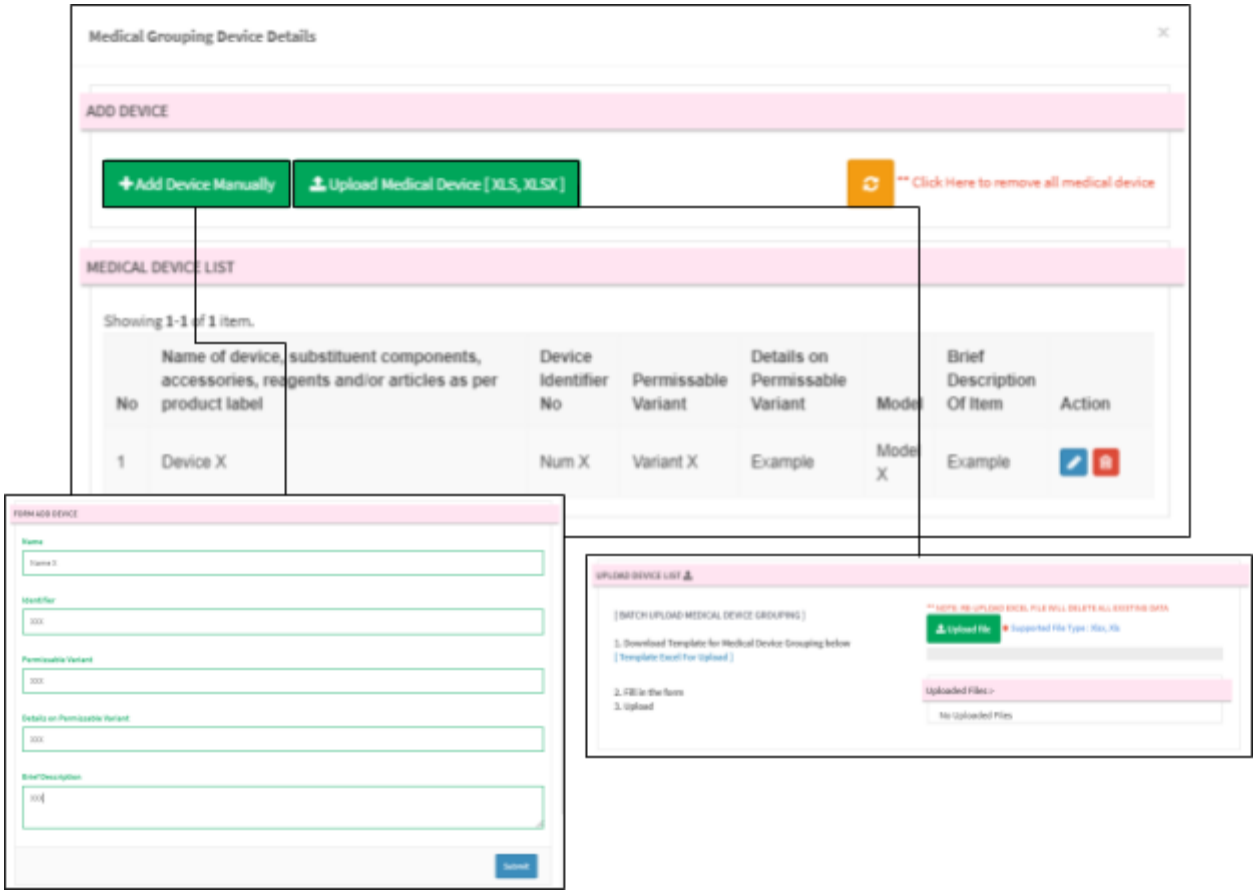
Click  to view device list.



Click  to update [System Identifier No.] and [System Model Name] then Click  to confirm update.



Click  to delete device.

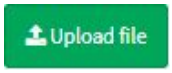



User click 

, then user has to fill the form and click 

to add device.

User click 

, then user click [Template Excel For Upload] to download excel template. Next, user click 

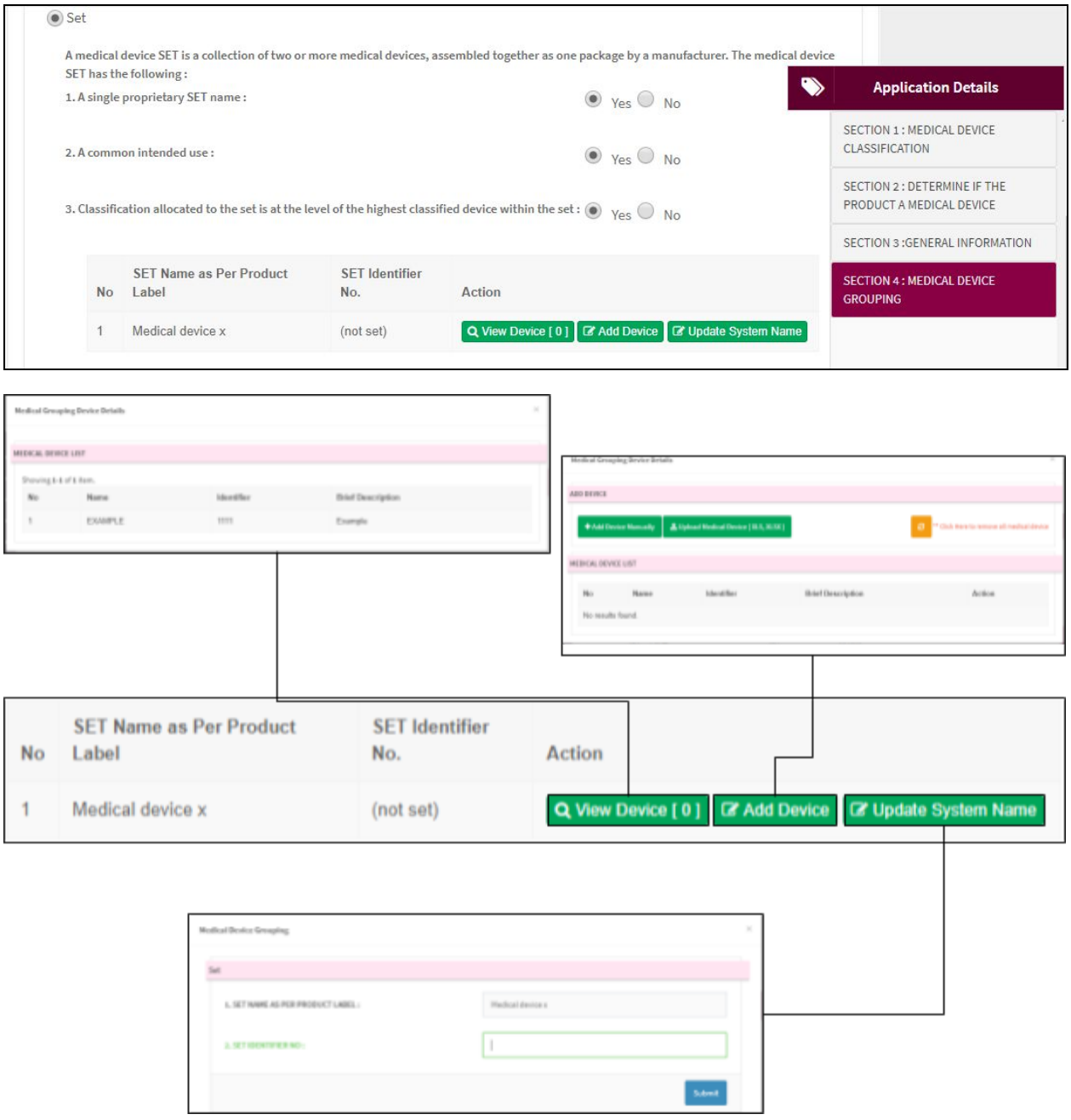
to upload excel file. **The file must be xlsx or xls format.**

 button for user edit device details.

 button for user delete device.

 button for user delete all medical devices.

v) ‘Set’ radio button.

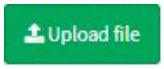



Click  to view device list.

Click  to update [System Identifier No.] then click  to confirm update.



User click  , then user has to fill the form and click  to add device.

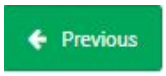
User click  , then user click [Template Excel For Upload] to download excel template. Next, user click  to upload excel file. **The file must be xlsx or xls format.**

 button for user edit device details.

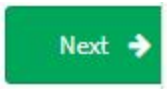
 button for user delete device.

 button for user delete all medical devices.

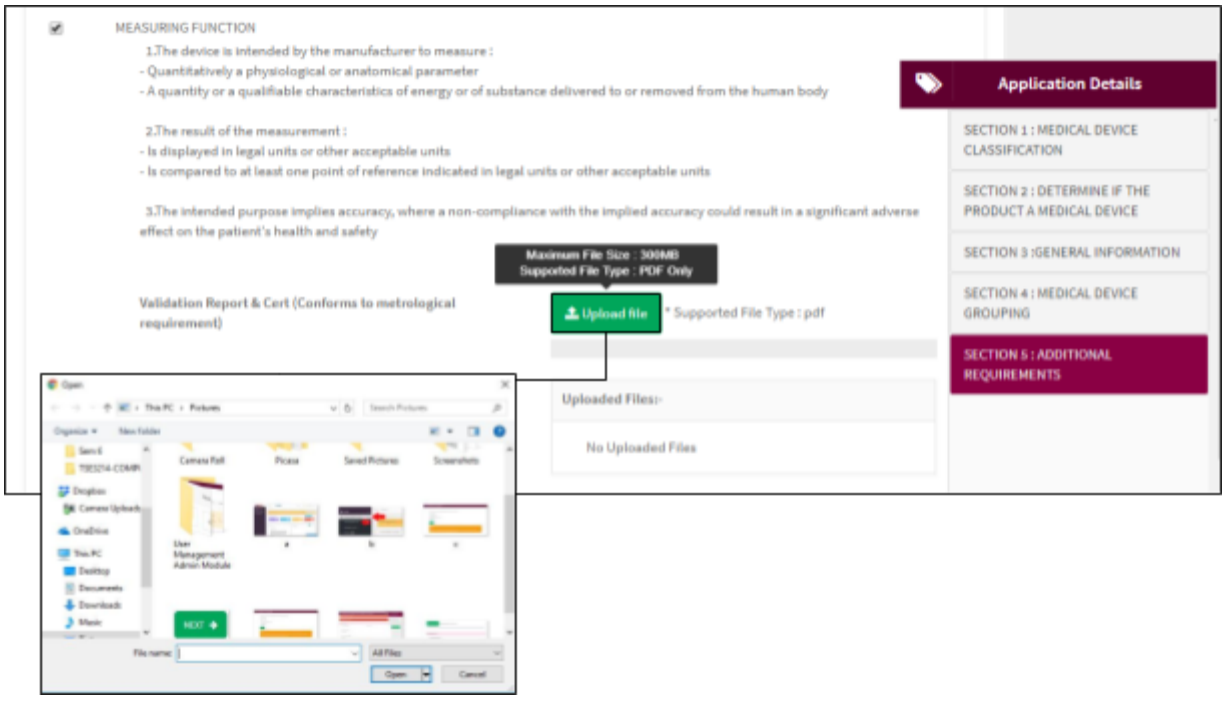
Click  to go to the next section.

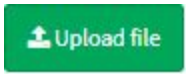
Click  to go to the previous section.

The diagram below show SECTION 5 : ADDITIONAL REQUIREMENT

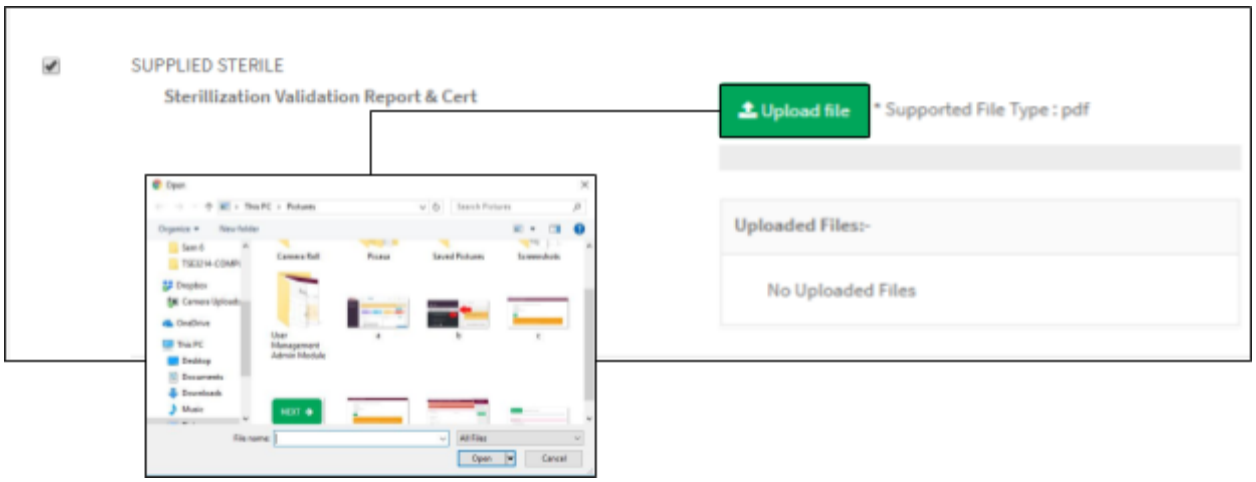

User tick checkbox in red circle **(if necessary)** and user can tick more than one checkbox. If not, user click  to go to next section.

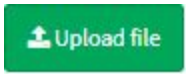
If user tick any checkboxes above, user has to complete that field before user go to the next section.



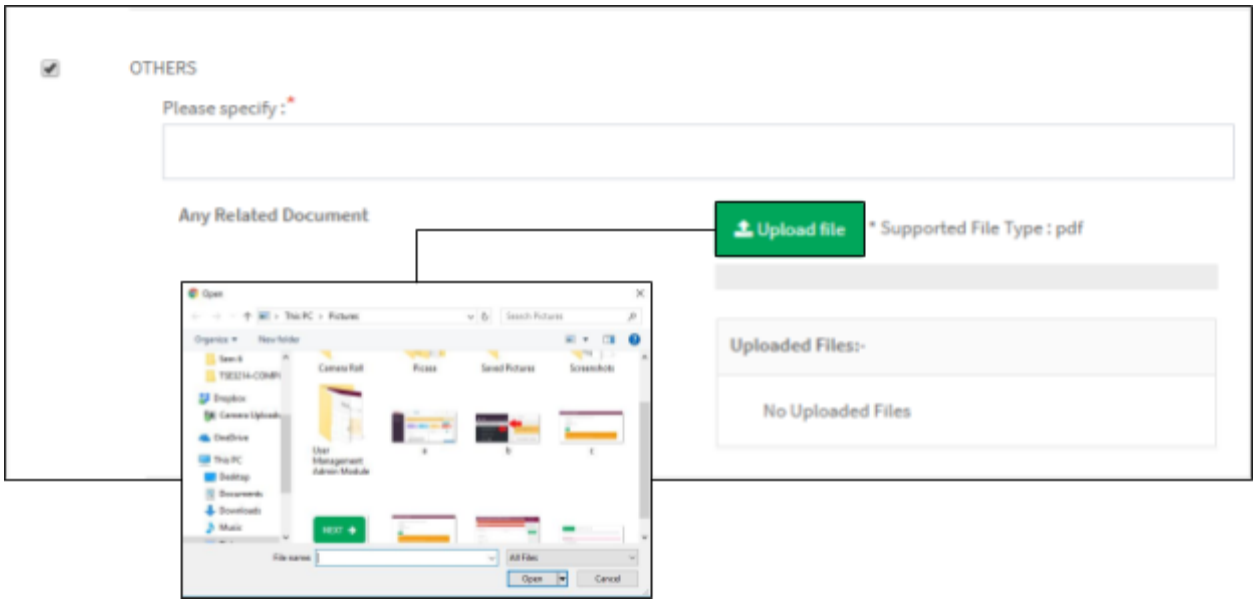

User click  to upload file. **The file must be pdf format and size not more than 300 MB**.

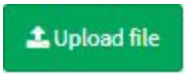


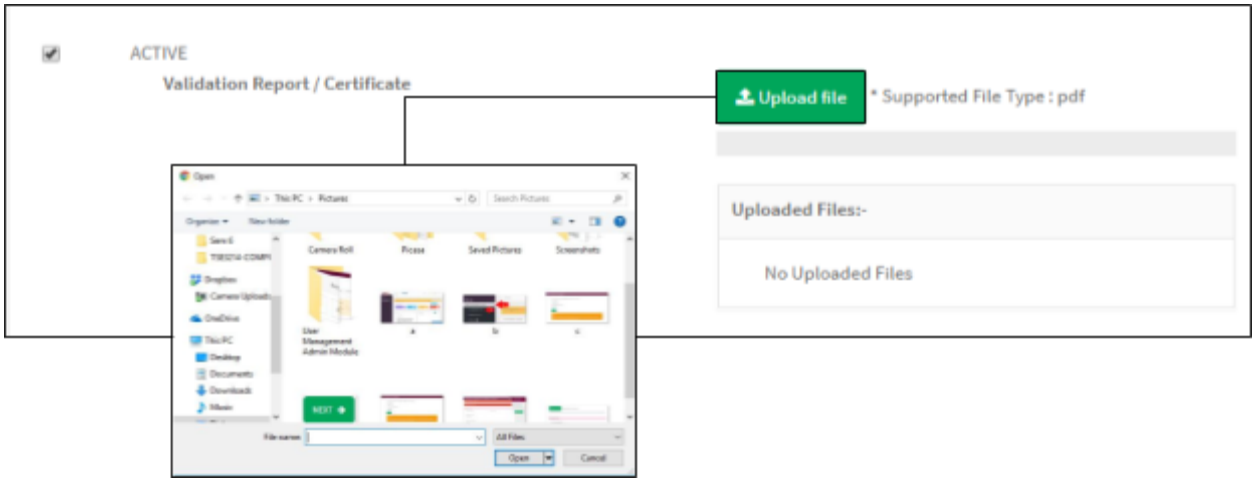


User click  to upload file. **The file must be pdf format and size not more than 300 MB**.

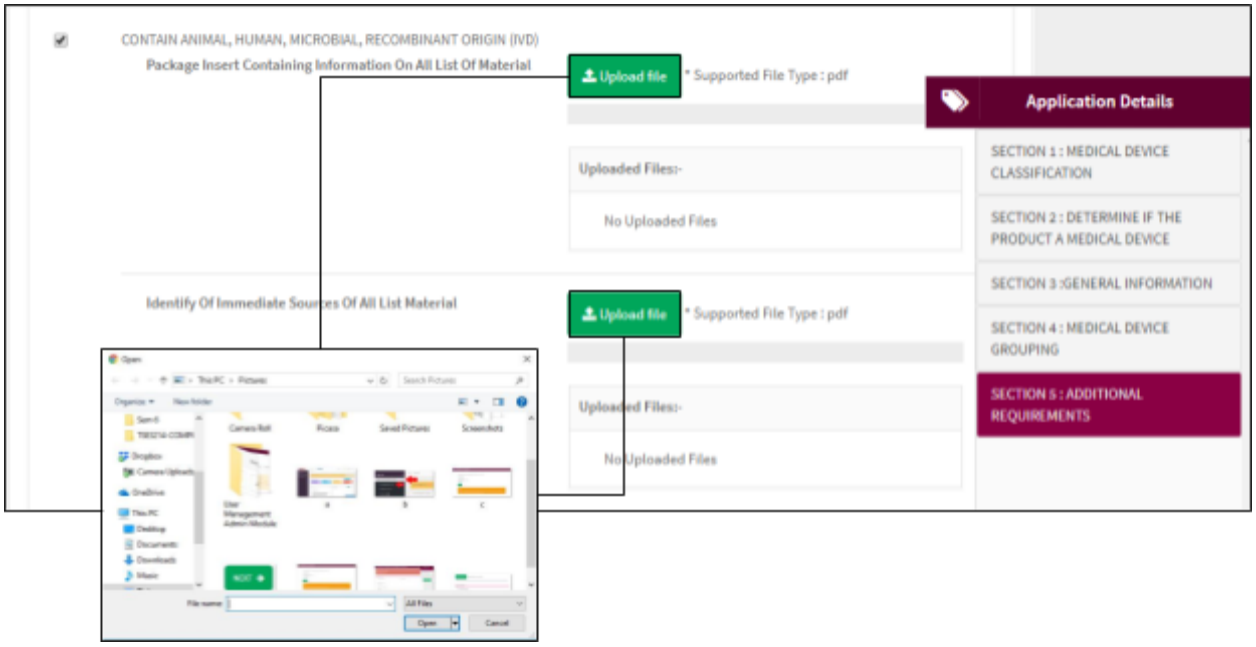





User has fill 'Please specify' text box first then click  to upload file. **The file must be pdf format and size not more than 300 MB**.



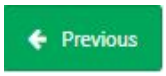

User click Upload file to upload file. **The file must be pdf format and size not more than 300 MB**.




User click Upload file to upload file. **The file must be pdf format and size not more than 300 MB**.

Click 

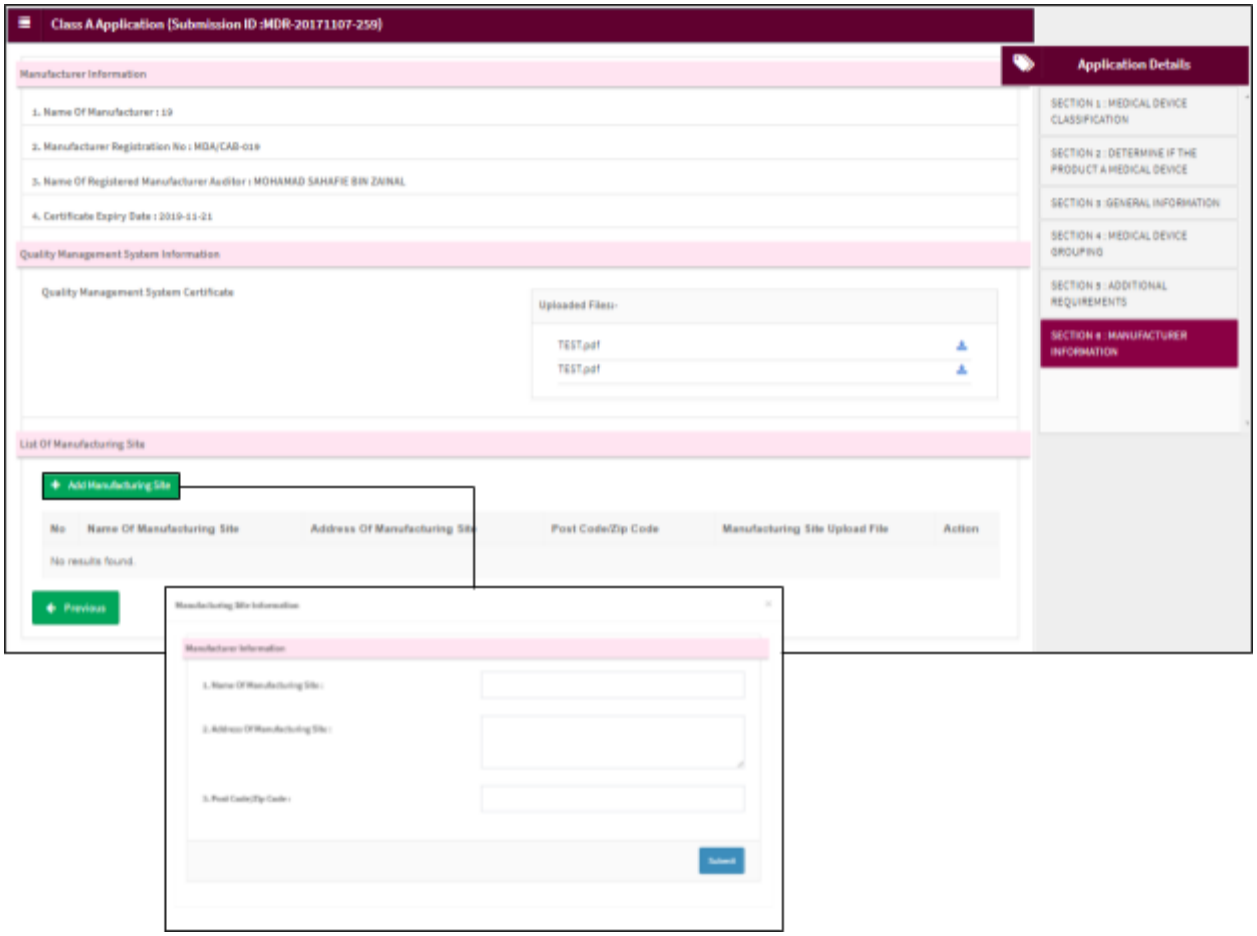
to go to the next section.

Click 

to go to the previous section.

Next, user will go to SECTION 6 : MANUFACTURER INFORMATION page.

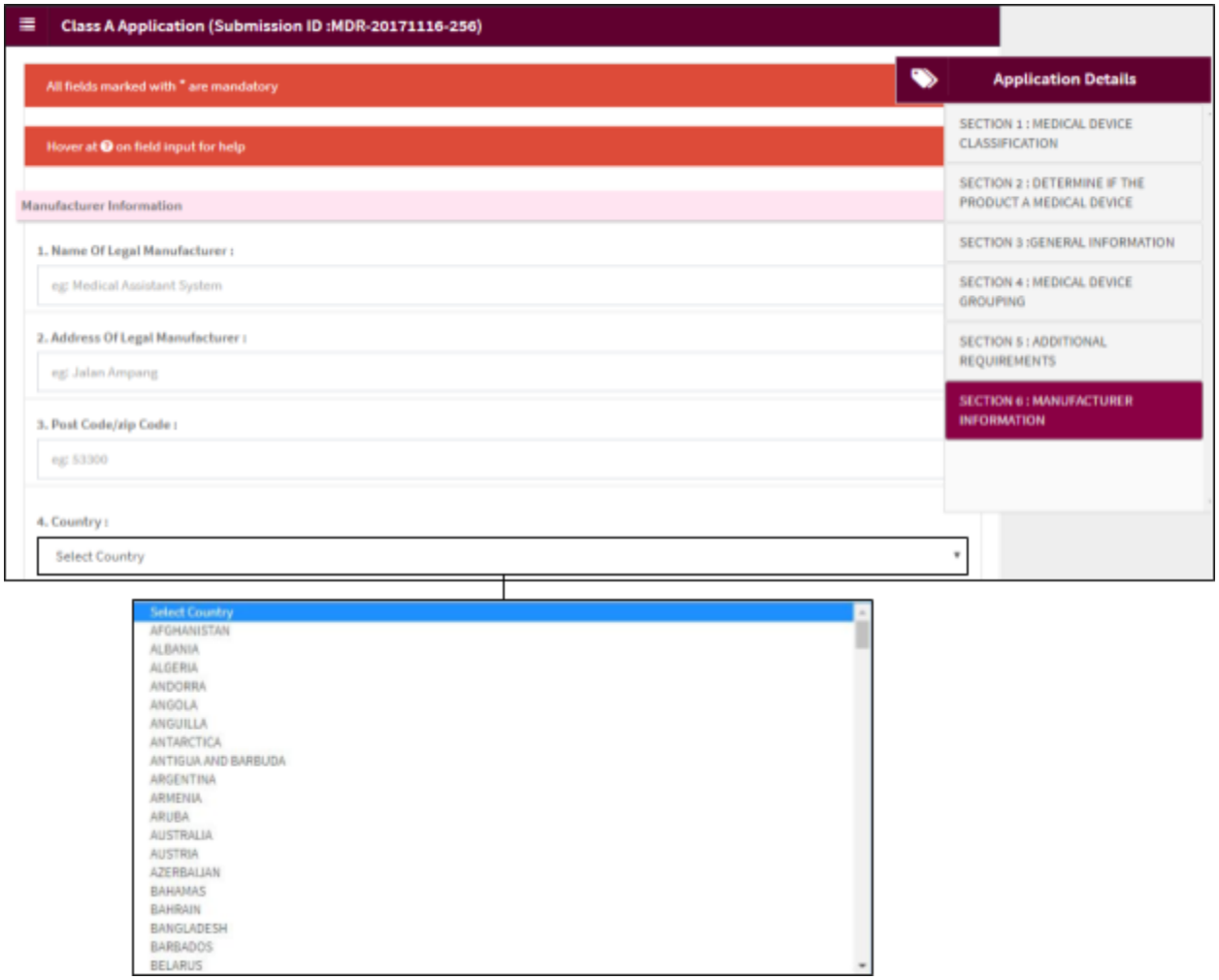
Diagram below show section 6 for Manufacturer.



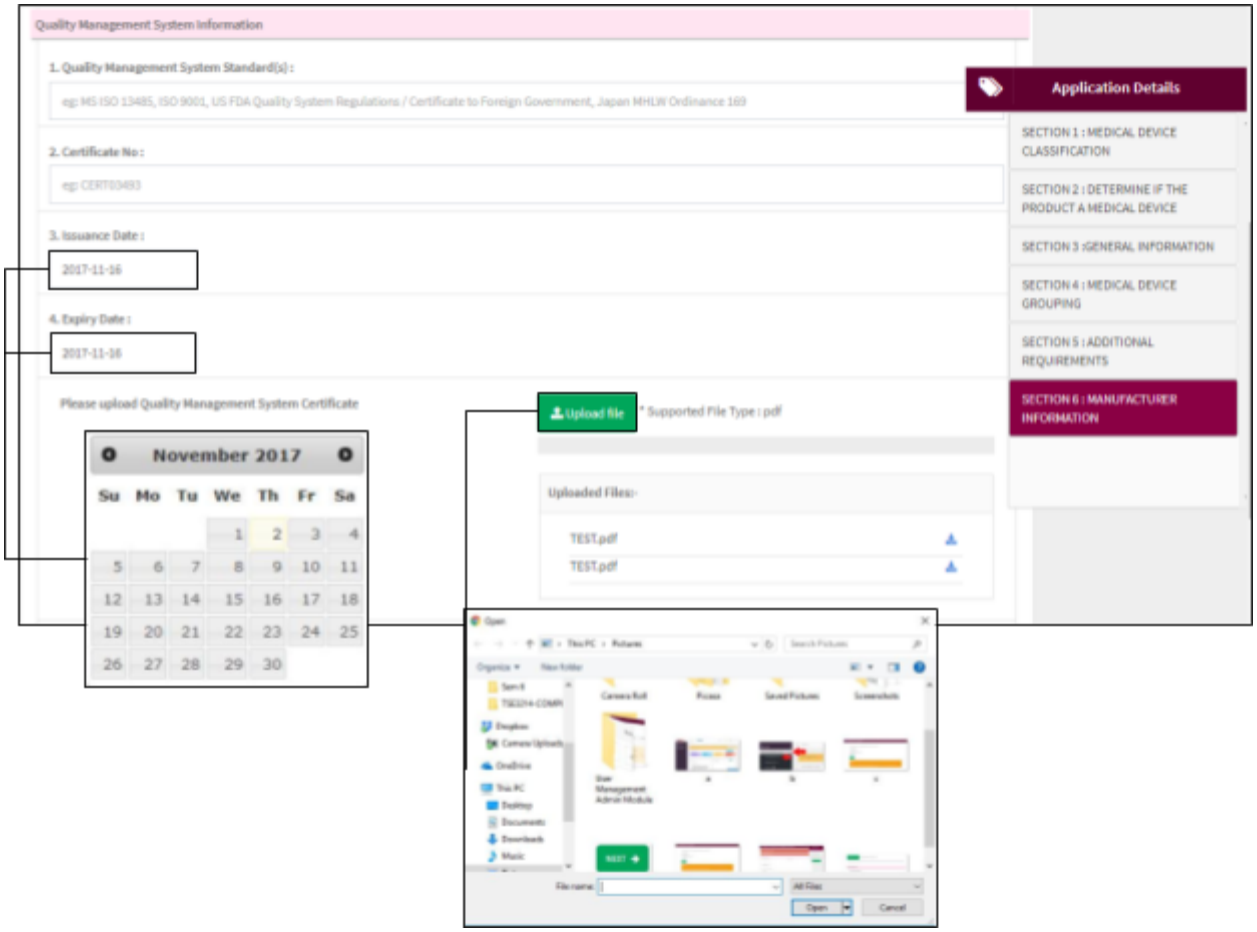

User click  to add new data. User has to fill all the text box then click  . New data will display in 'List Of Manufacturing Site' table.

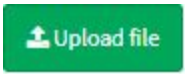
Diagram below show section 6 for Authorised Representative.

**'Next' button is invisible until user complete this section.**

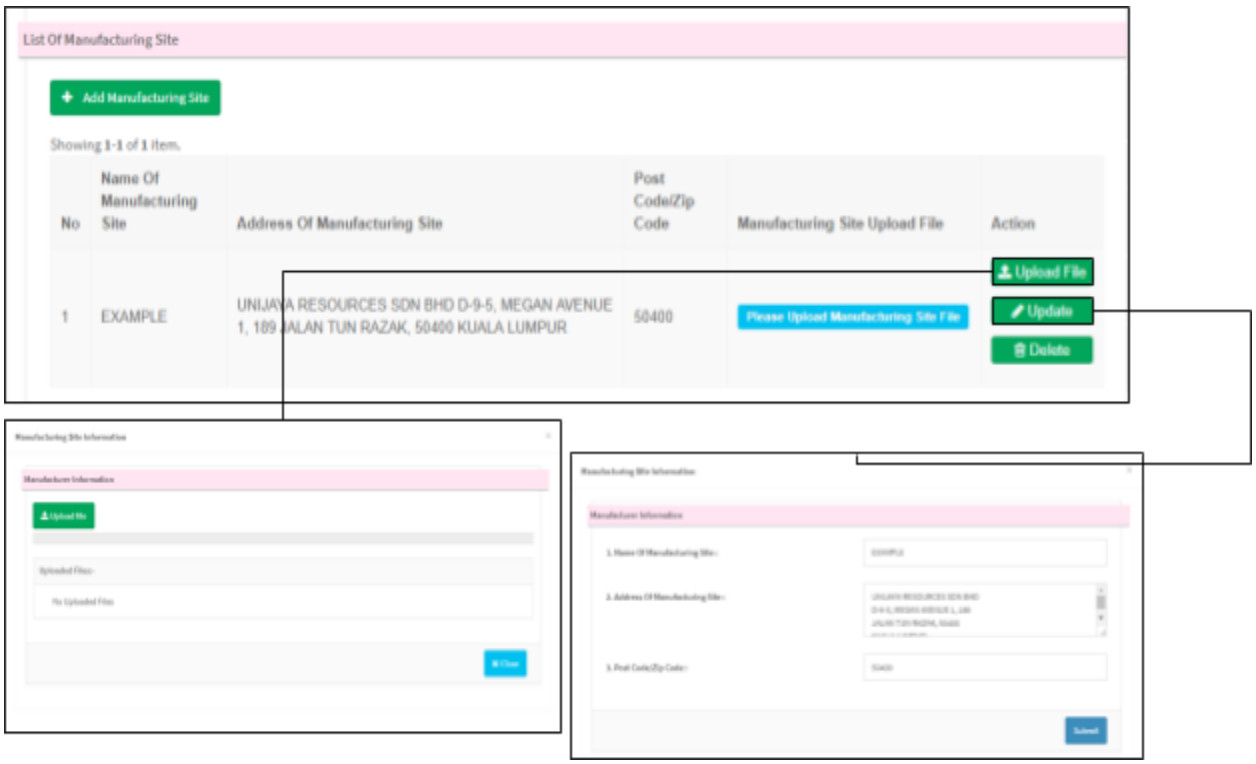



User fill all text boxes **(if necessary)**. User select country at ‘Country’ drop down text box.




.User fill all text boxes and then user select date in 'Issuance Date' and 'Expiry Date' calendar text box or user can write the date using **YYYY-MM-DD** format. Click at 

to upload file. **The file must be pdf format and size not more than 300 MB.(If necessary)**




Click Upload File then 'Manufacturing Site Information' will display on screen. Click at Upload file to upload file. **The file must be pdf format and size not more than 300 MB**. 'Manufacturing Site Upload File' column will appear in the table.

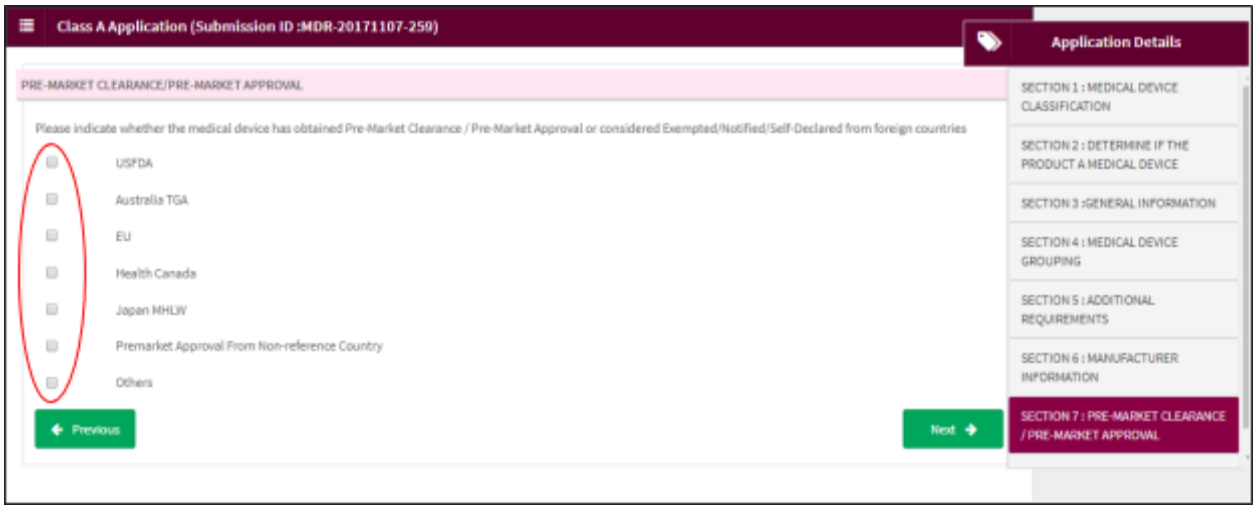

Click Update to update the data.

Click Delete to delete the data.

Click Next to go to the next section.

Click Previous to go to the previous section.

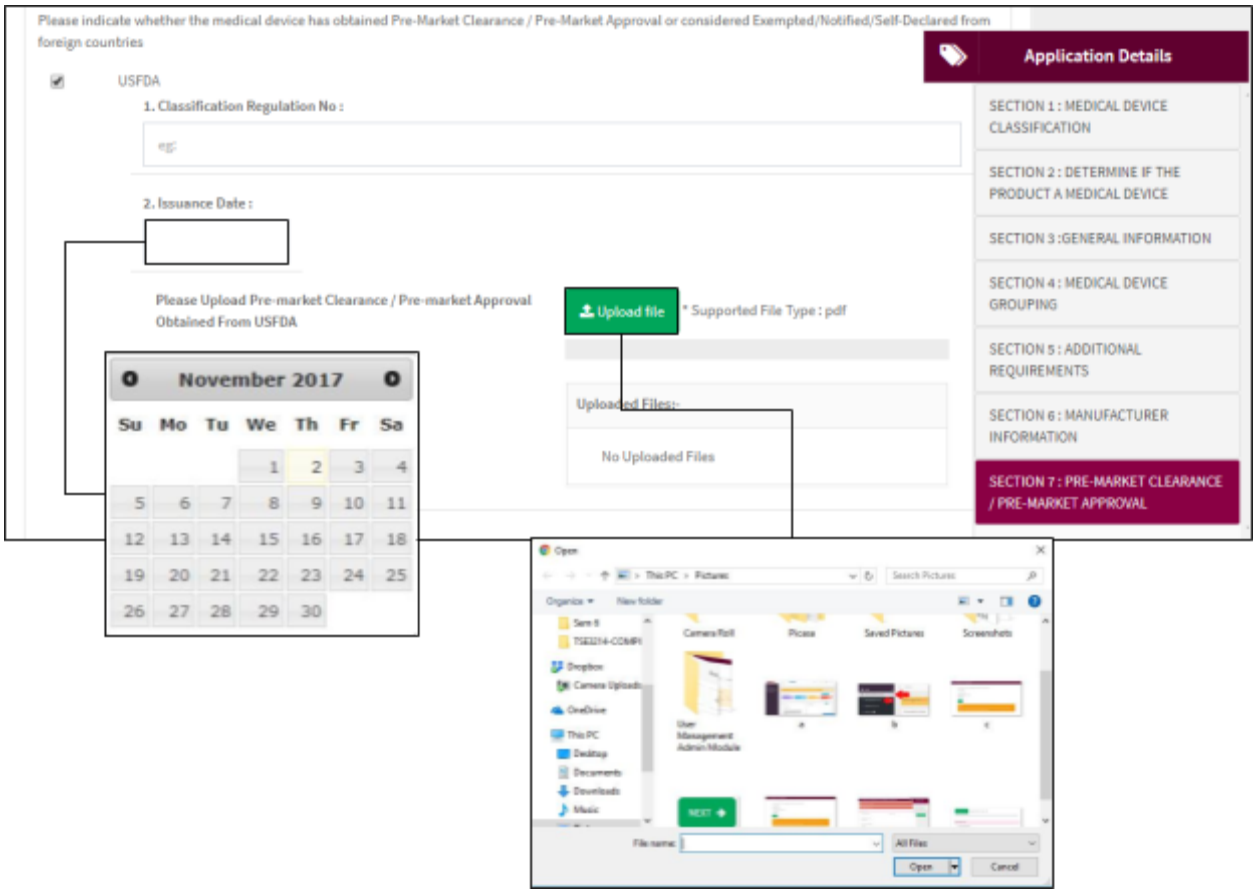
The diagram below show SECTION 7 : PRE-MARKET CLEARANCE / PRE-MARKET APPROVAL




User tick checkbox in red circle **(if necessary)** and user can tick more than one checkbox. If not, user click Next to skip this section.

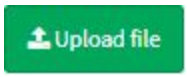
If user tick any checkboxes above, user has to complete that field before user go to the next section

i) 'USFDA' checkbox.



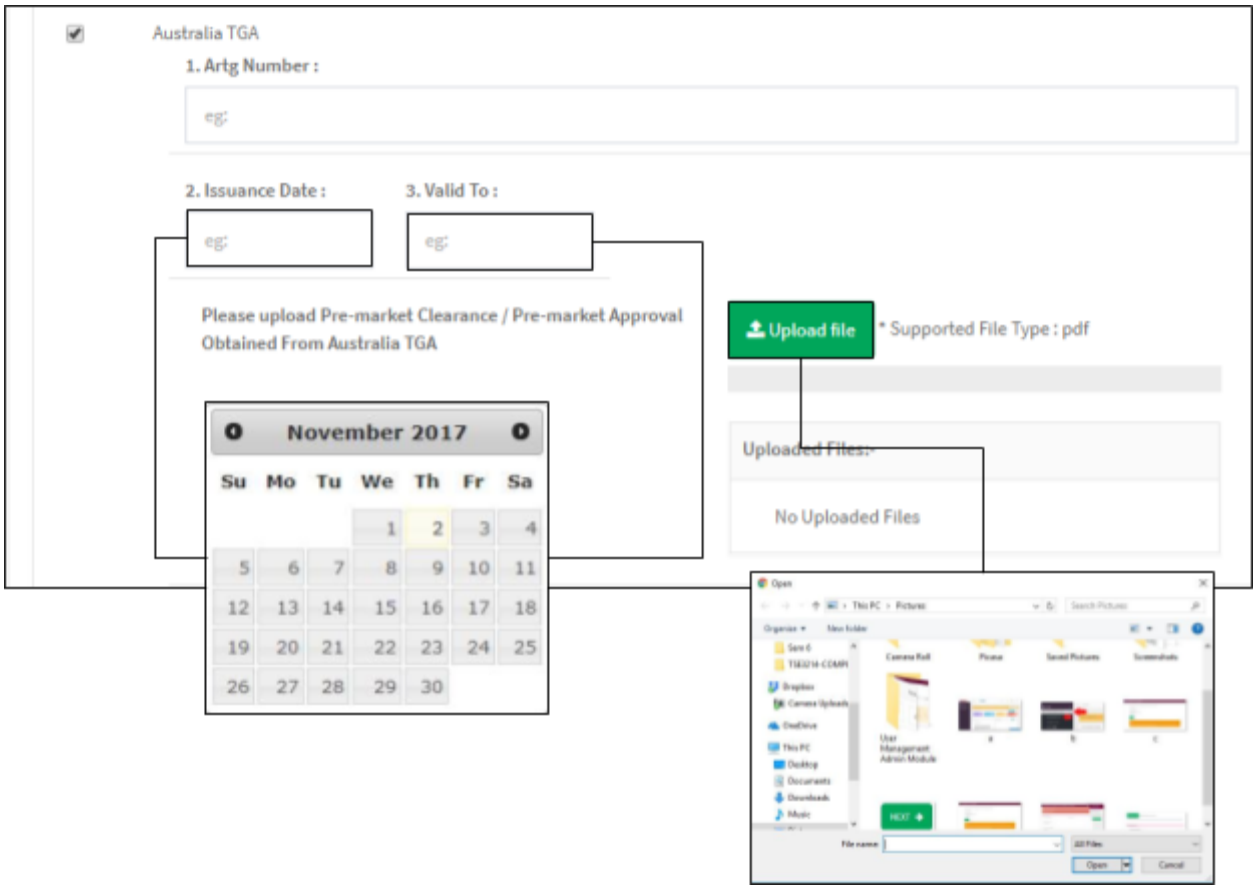

User fill 'Classification Regulation No' text box.

User select date in 'Issuance Date' calendar text box or user can write the date using **YYYY-MM-DD** format.

User click 

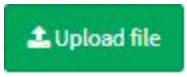
to upload file. **The file must be pdf format and size not more than 300 MB**.

ii) 'Australia TGA' checkbox.



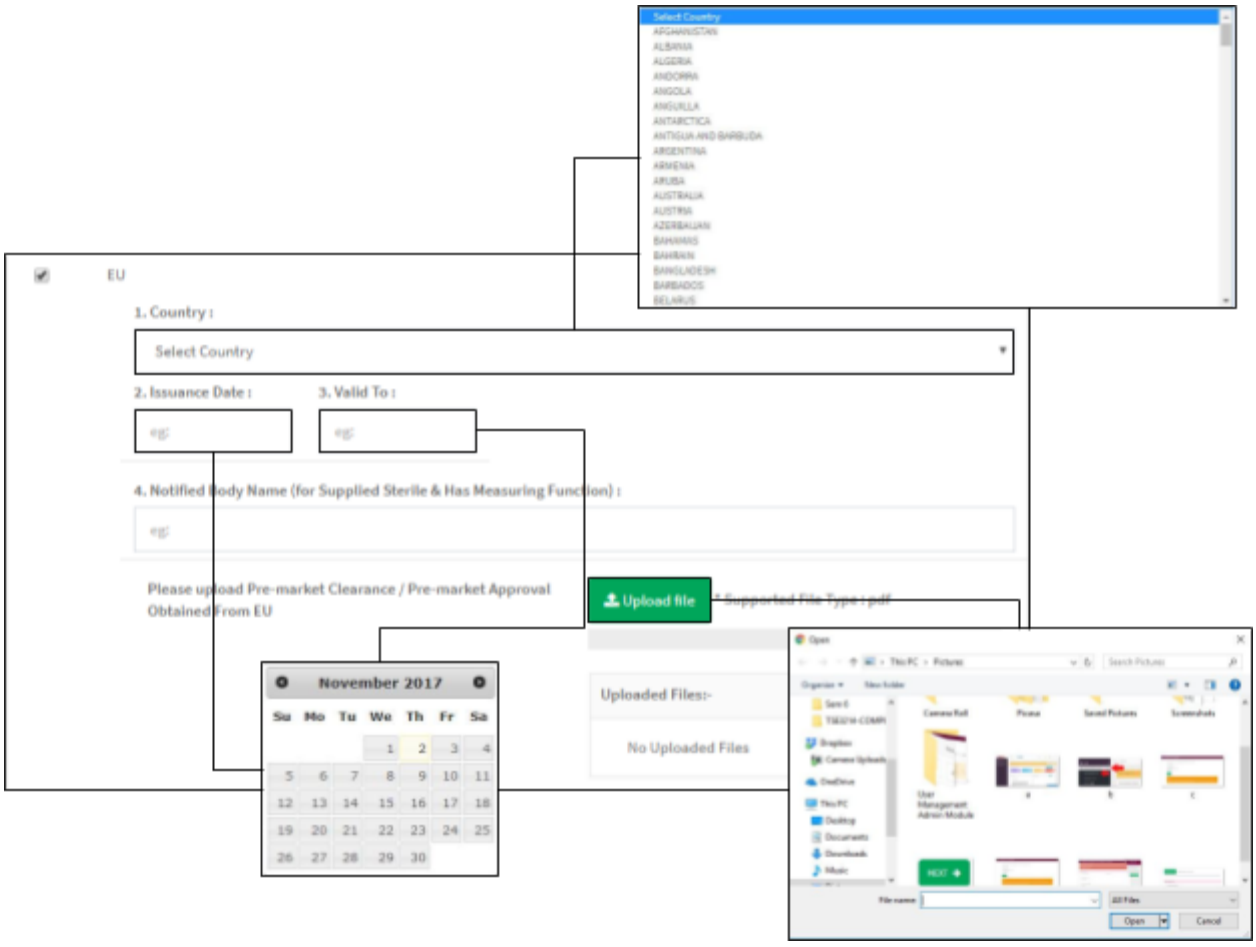

User fill ' Artg Number' textbox.

User select date in 'Issuance Date' and 'Valid To' calendar text box or user can write the date using **YYYY-MM-DD** format .

User click 

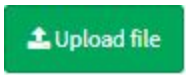
to upload file. **The file must be pdf format and size not more than 300 MB**.

iii) 'EU' checkbox.




User select from 'Country' dropdown text box.

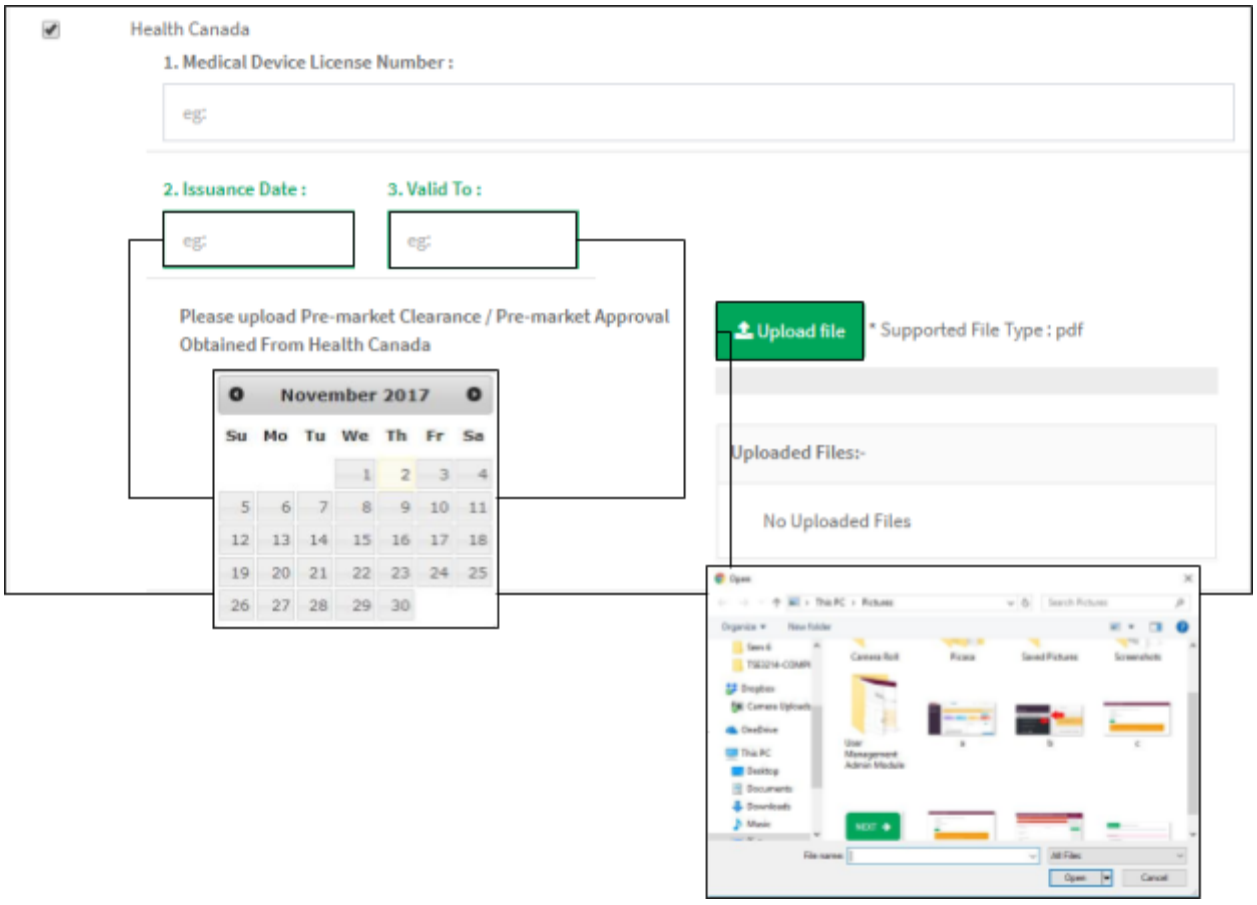
User select date in 'Issuance Date' and 'Valid To' calendar text box or user can write the date using **YYYY-MM-DD** format .

User click 

to upload file. **The file must be pdf format and size not more than 300 MB**.

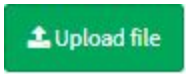
User fill 'Notified Body Name (for Supplied Sterile & Has Measuring Function)' text box.

iv) 'Health Canada' checkbox.



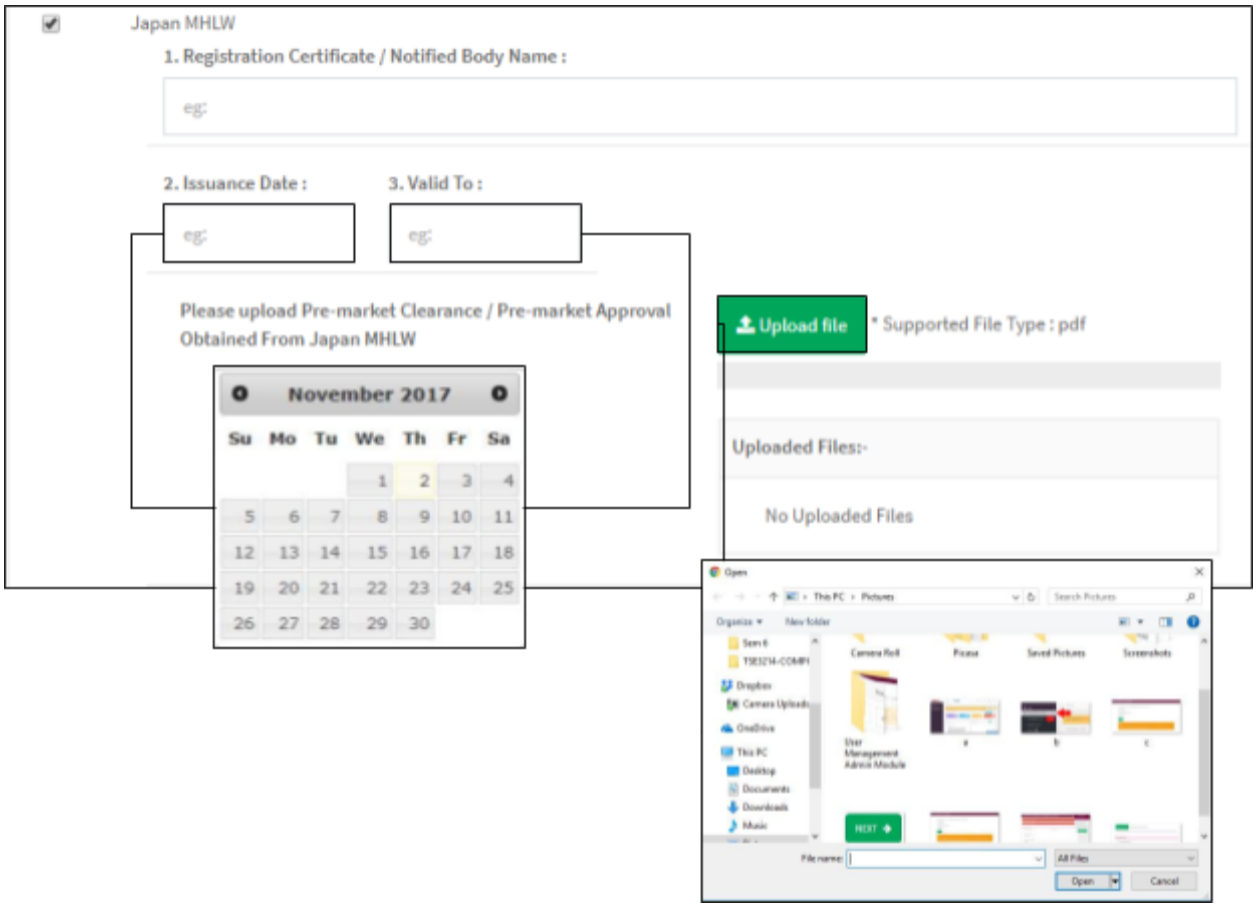

User fill 'Medical Device License Number' text box.

User select date in 'Issuance Date' and 'Valid To' calendar text box or user can write the date using **YYYY-MM-DD** format .

User click 

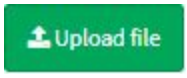
to upload file. **The file must be pdf format and size not more than 300 MB**.

v) ‘Japan MHLW’ checkbox.



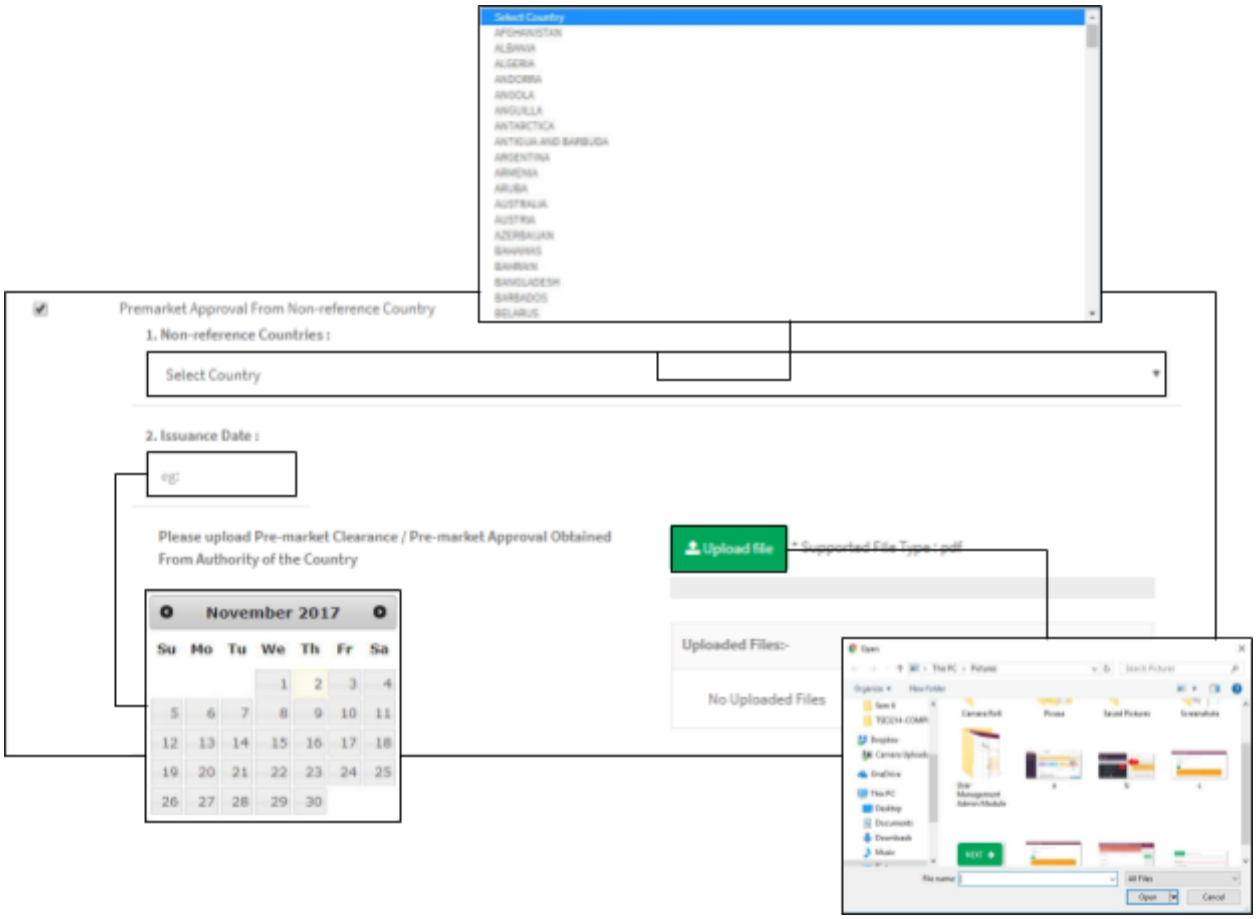

User fill ‘Registration Certificate / Notified Body Name’ text box.

User select date in ‘Issuance Date’ and ‘Valid To’ calendar text box or user can write the date using **YYYY-MM-DD** format .

User click 

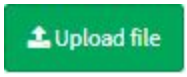
to upload file. **The file must be pdf format and size not more than 300 MB**.

vi) 'Premarket Approval From Non-reference Country' checkbox.




User select from 'Non-reference Countries' dropdown text box.

User select date in 'Issuance Date' calendar text box or user can write the date using **YYYY-MM-DD** format .

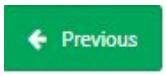
User click 

to upload file. **The file must be pdf format and size not more than 300 MB**.

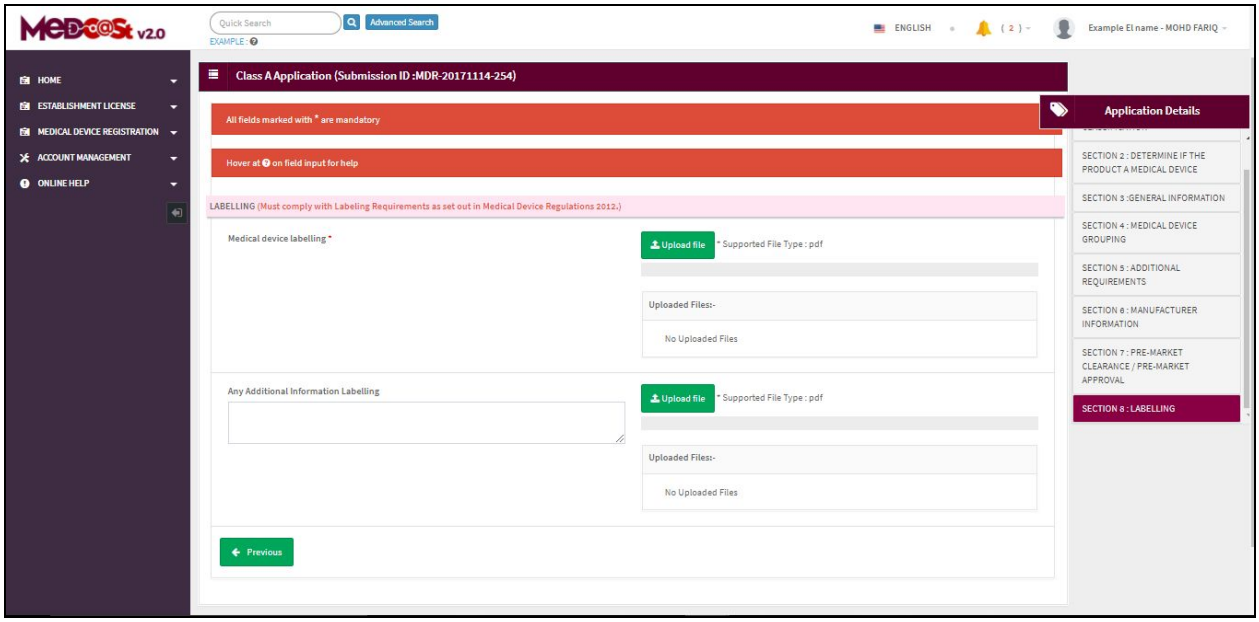
vii) 'Others' checkbox.

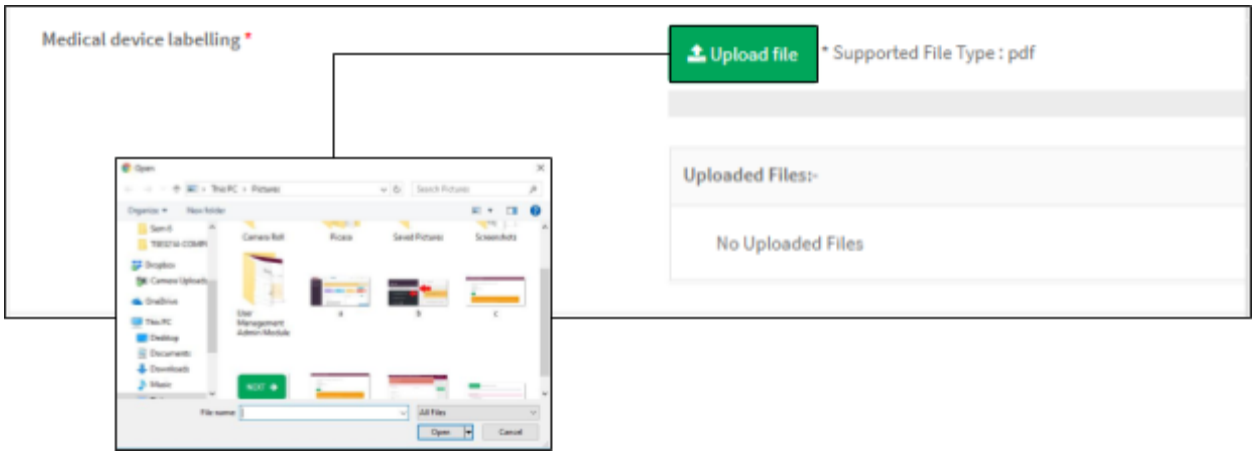

User has to fill 'Please Specify' text box.

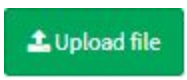
Click  to go to the next section.


Click  to go to the previous section.

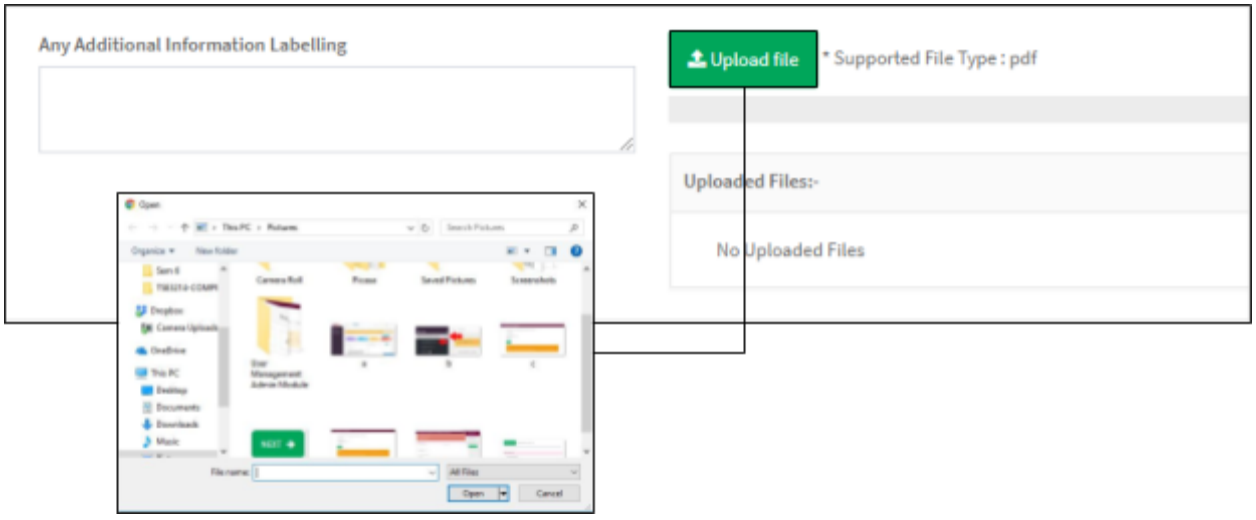
Next, user will go to SECTION 8 : LABELLING page




User click 

to upload file. **The file must be pdf format and size not more than 300 MB**.



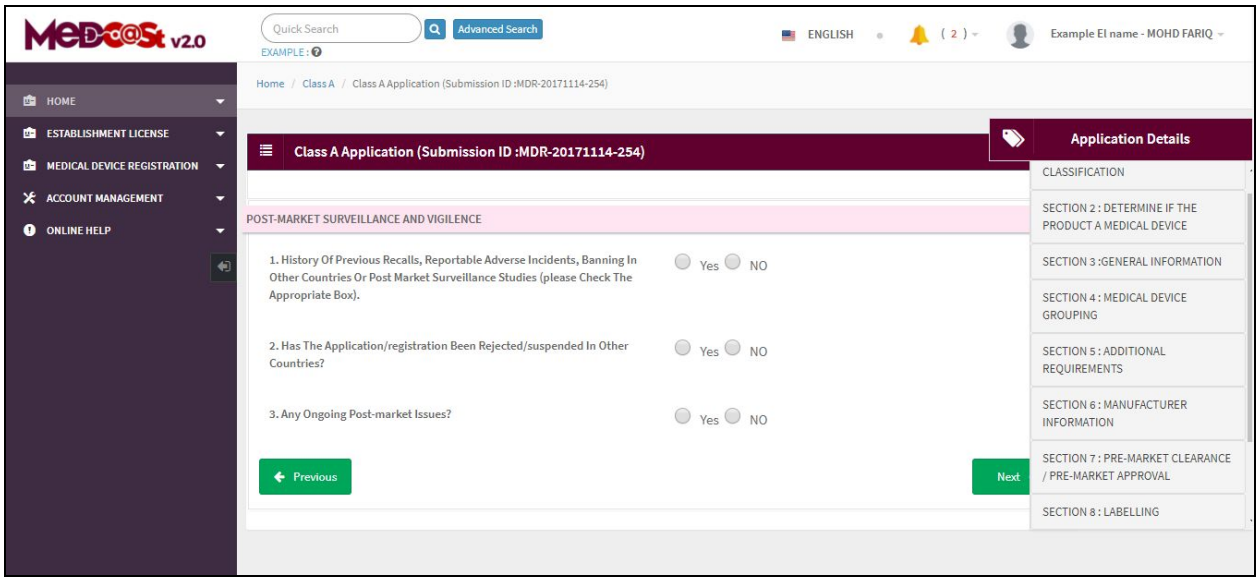

User fill 'Any Additional Information Labelling' text box.**(If necessary)**

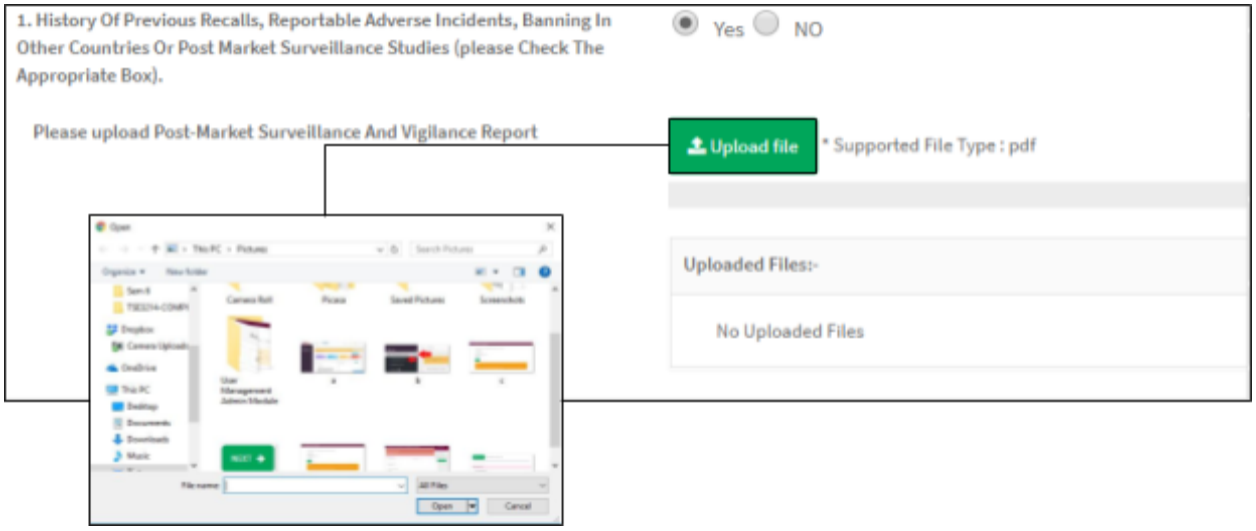
User click Upload file to upload file. **The file must be pdf format and size not more than 300 MB**.

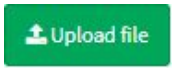
Click Next to go to the next section.

Click Previous to go to the previous section.

The diagram below show SECTION 9 : POST -MARKET SURVEILLANCE AND VIGILENCE

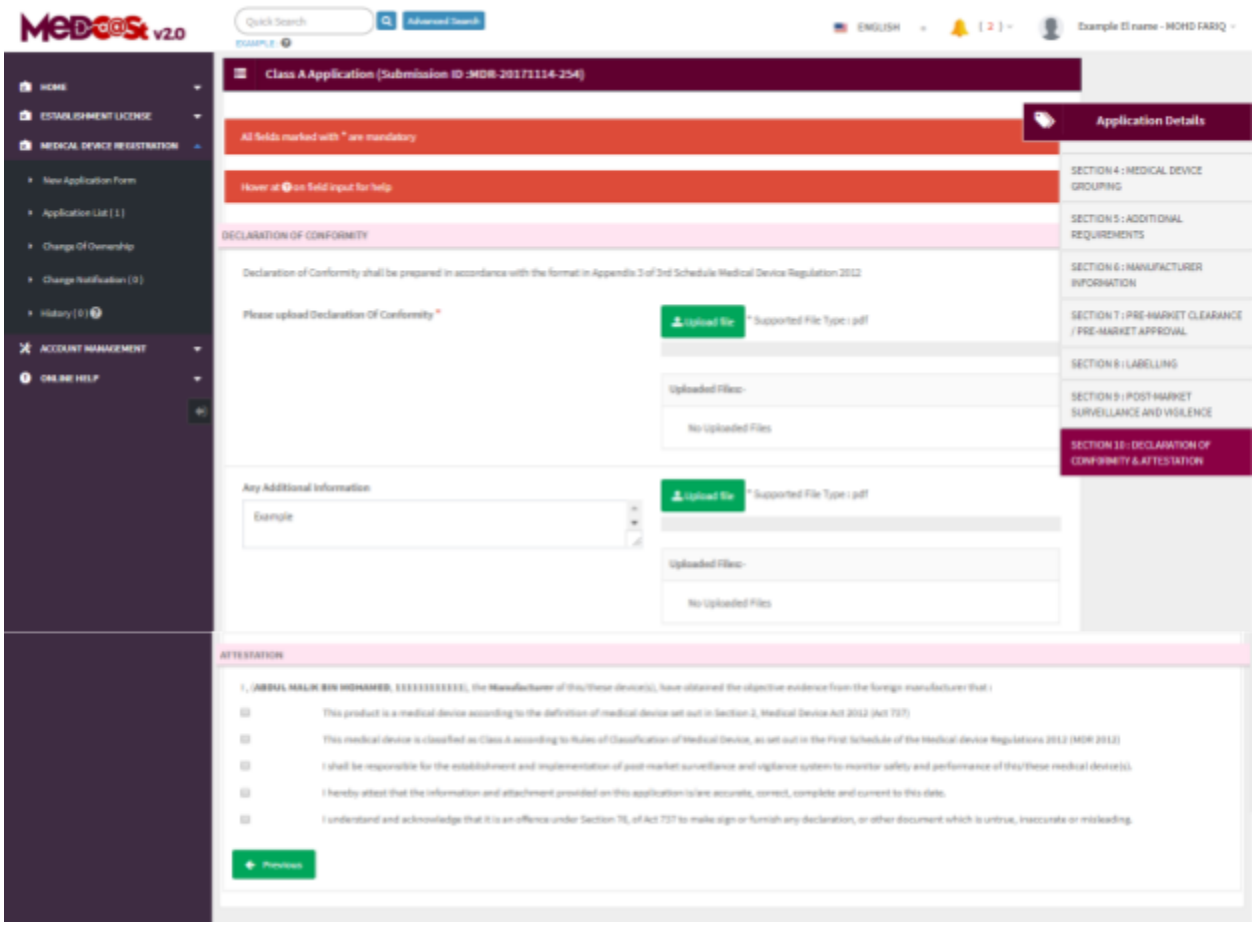


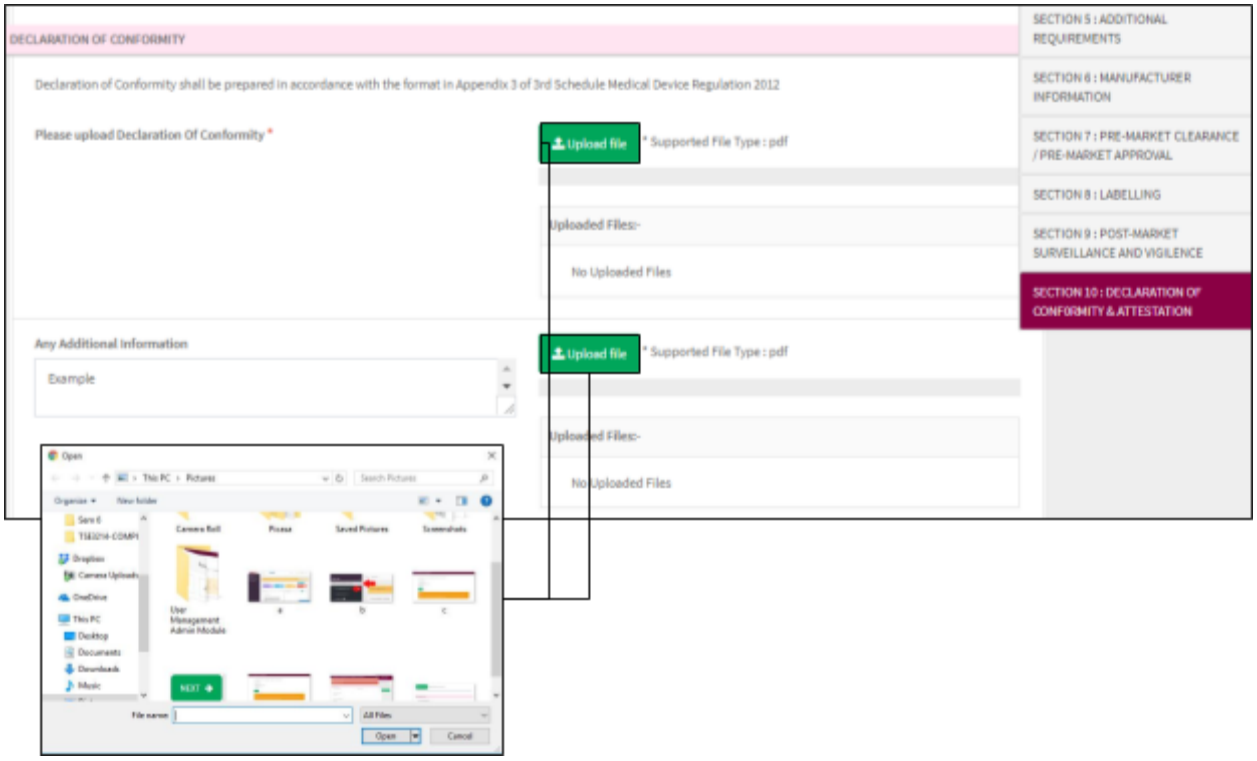




If user tick 'Yes', user has to upload file. Click 

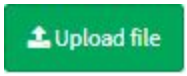
to upload file. **The file must be pdf format and size not more than 300 MB**.

Next, user will go to SECTION 10 : DECLARATION OF CONFORMITY & ATTESTATION page.

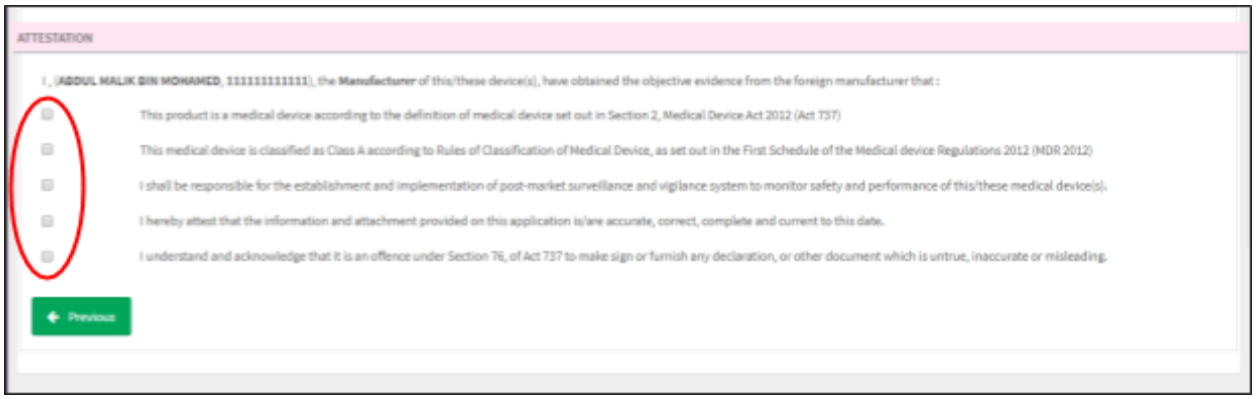




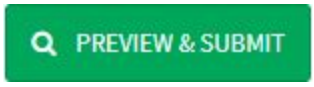

User fill 'Any Additional Information Labelling' text box.**(If necessary)**

User click  to upload file. **The file must be pdf format and size not more than 300 MB**.

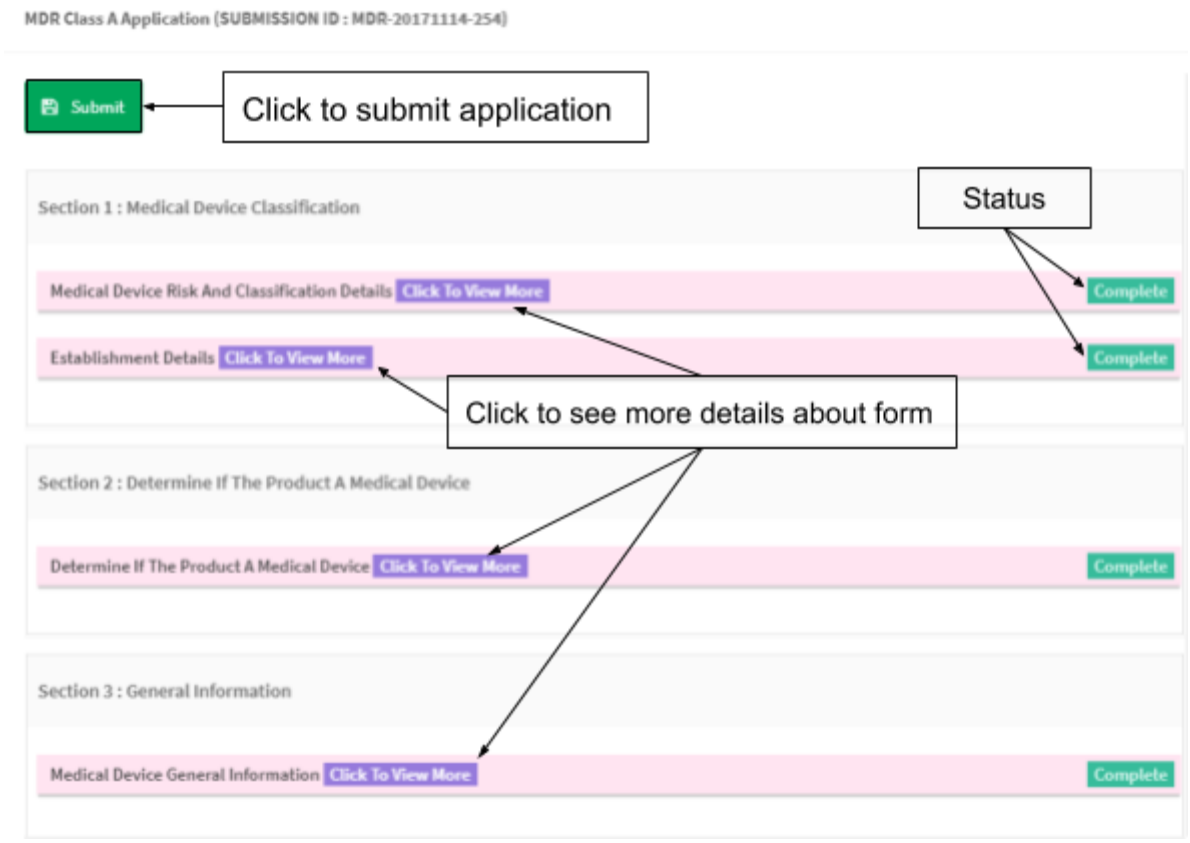




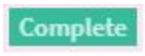

User has to tick all the checkbox before user can submit application.

User click 

to preview before submit application.



has

Submission only can do if all form status is 

. If status 

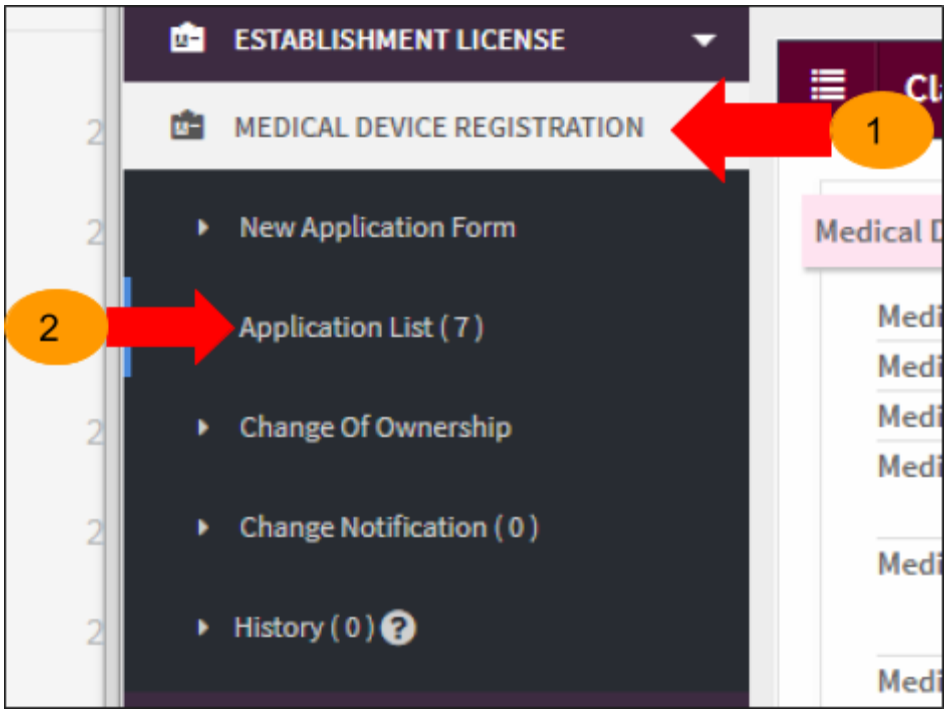
, user has to complete the form.

Then, click 

to submit application.

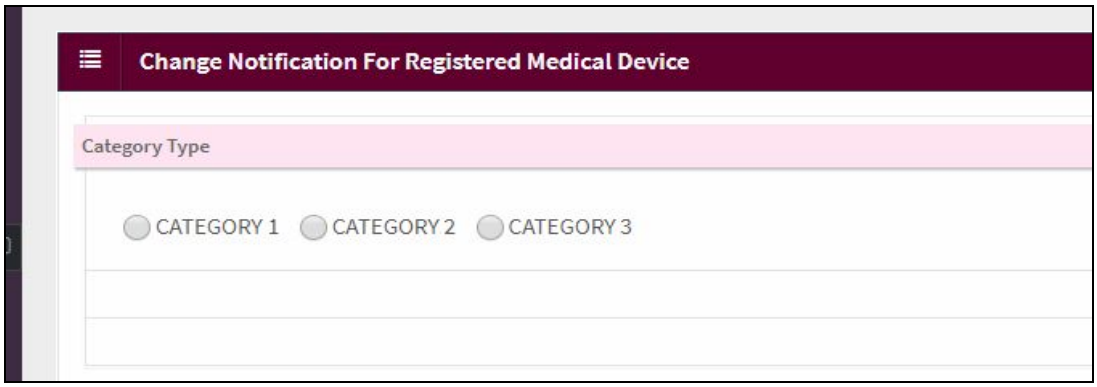
## 4.0 CHANGE OF NOTIFICATION APPLICATION

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

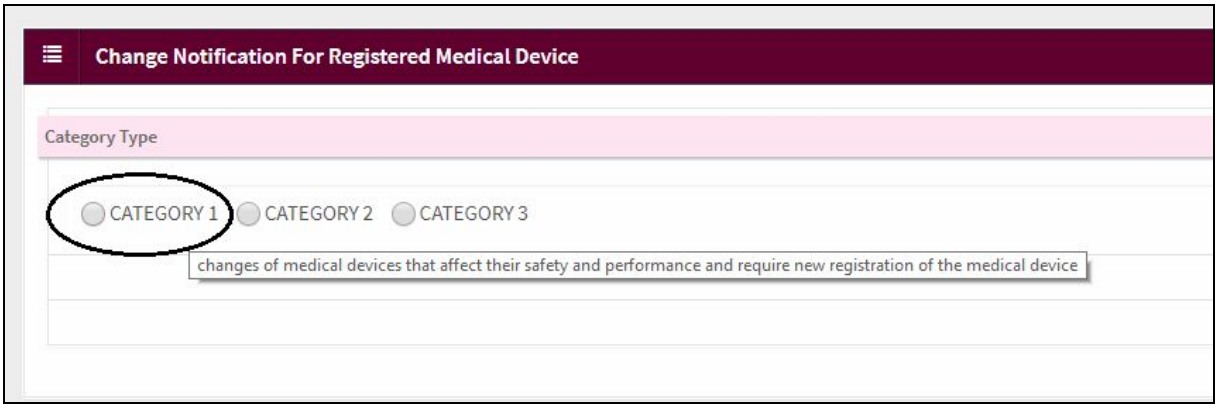



The diagram below show *Application List* page. Click Change Of Notification to change of notification application.

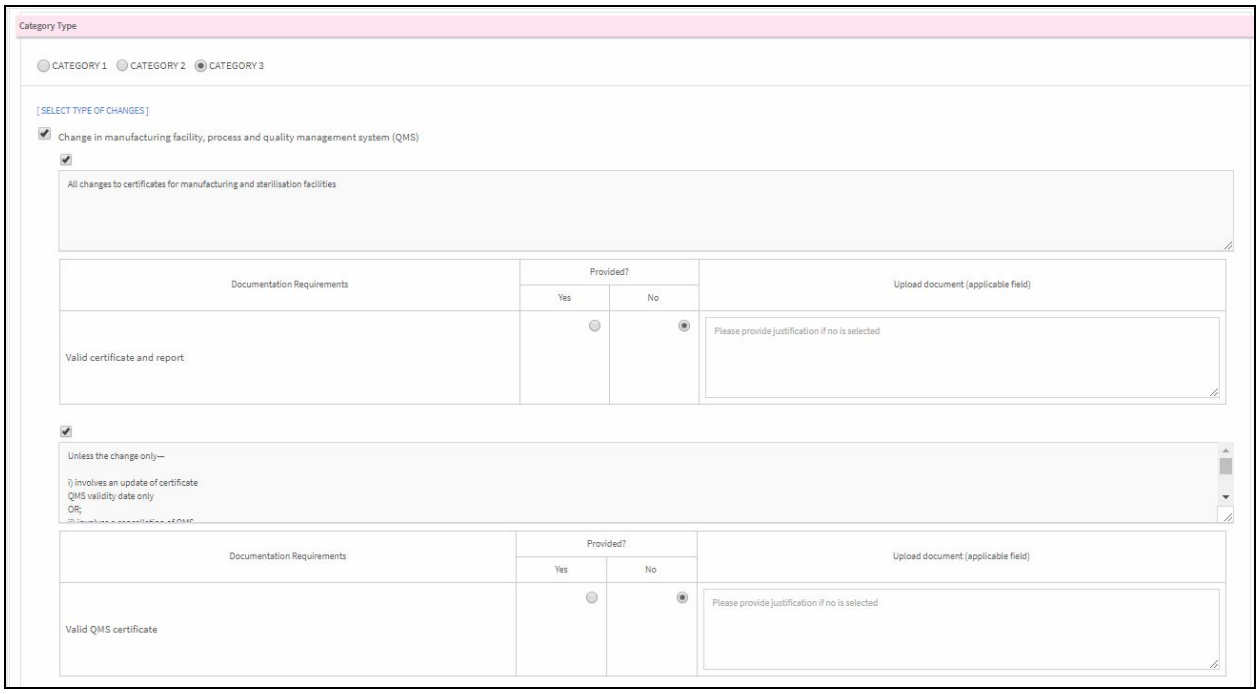
Create a Change of Notification application. Category type will be display. The user can tick one of any category.




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



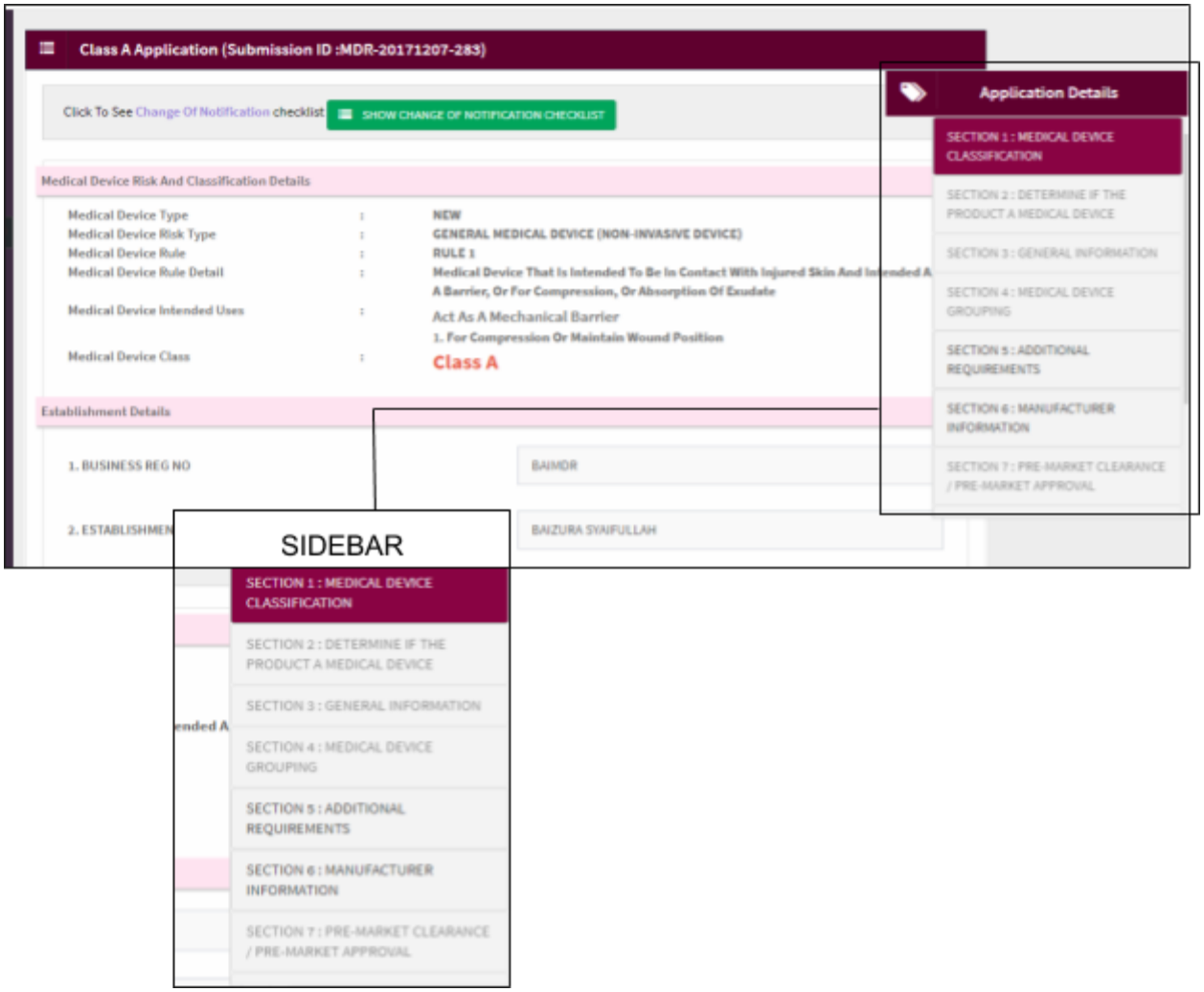
The user can select more than one type of changes.




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

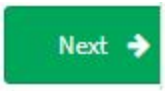
Then, click 

to proceed the registration of the change of notification application.

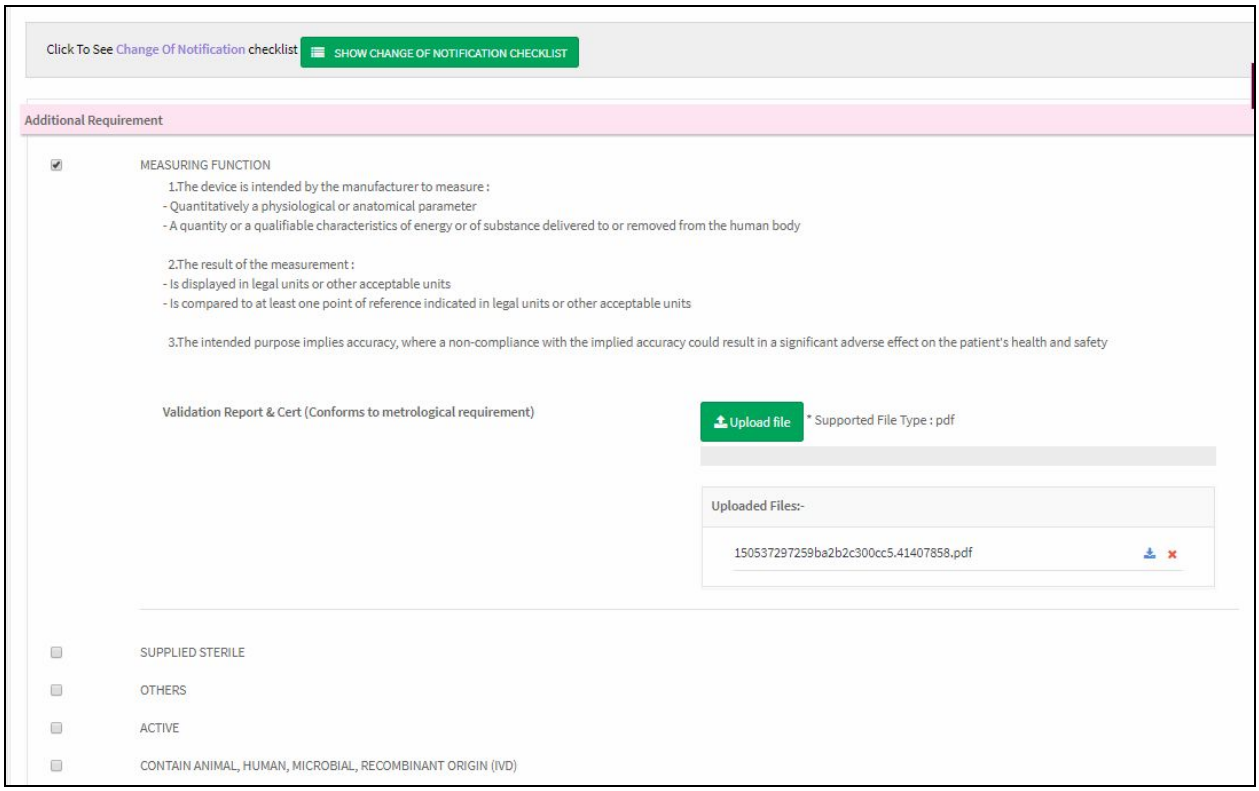


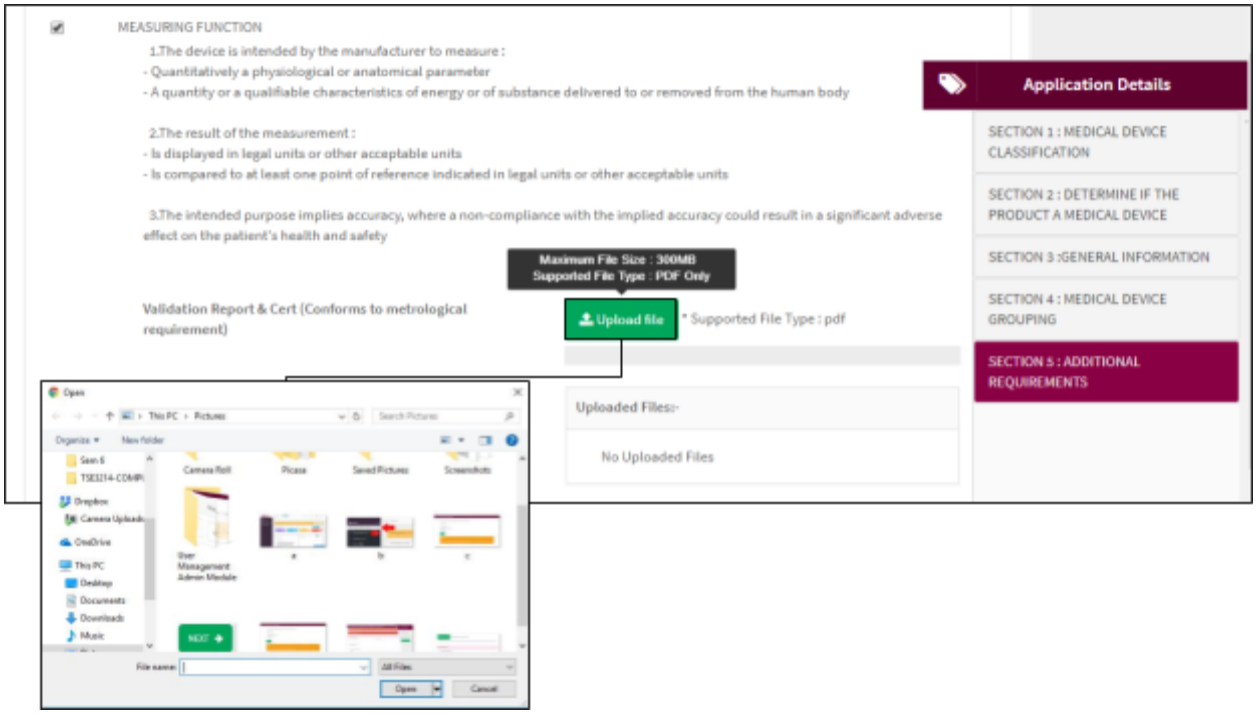

To edit a certain section, the user can click 

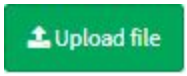
to go to the editable section or click the sidebar to go directly to the editable section.

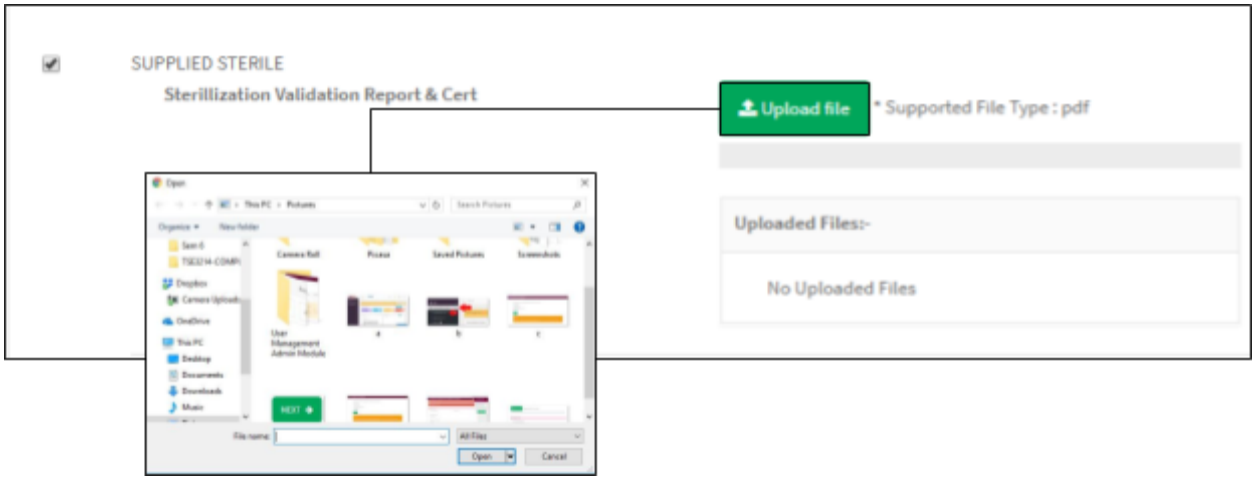
The diagram below show SECTION 5 : ADDITIONAL REQUIREMENT that need to be change. User can tick checkbox other than previous in other to make a change and user can tick more than one checkbox. If not, user click  to go to next section.



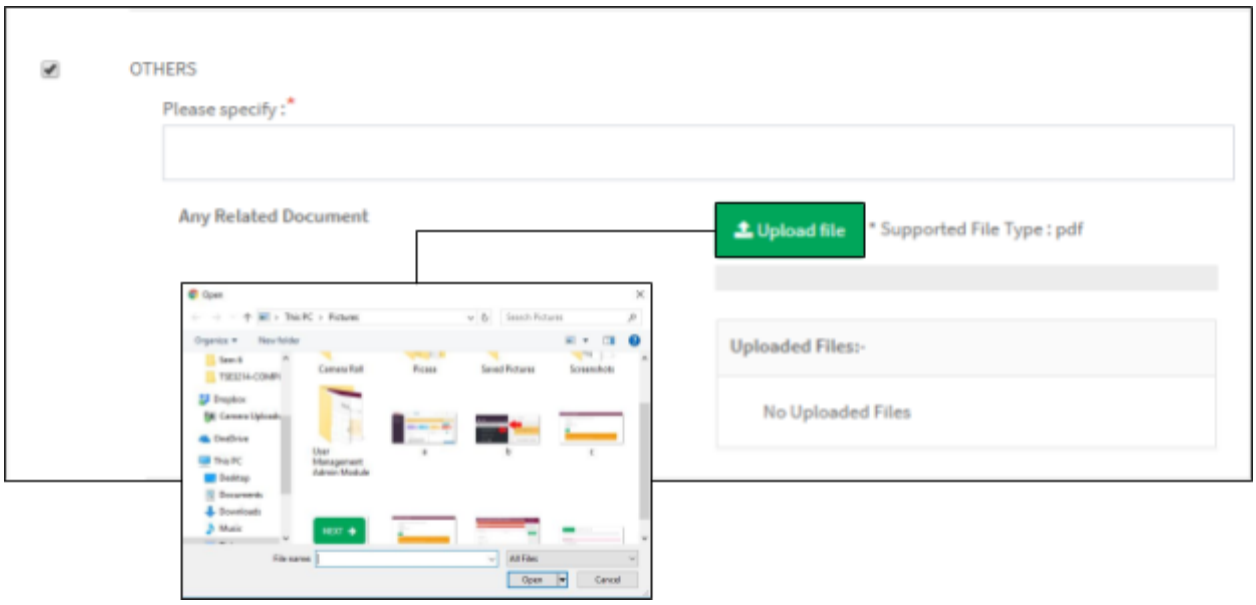




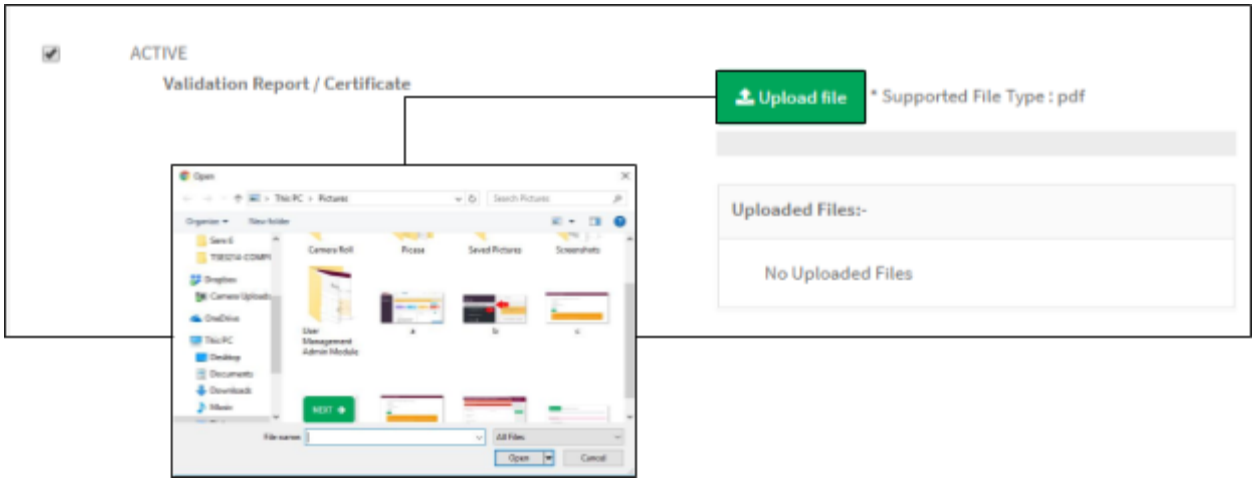

User click  to change the old upload file to the new upload file. **The file must be pdf format and size not more than 300 MB**.



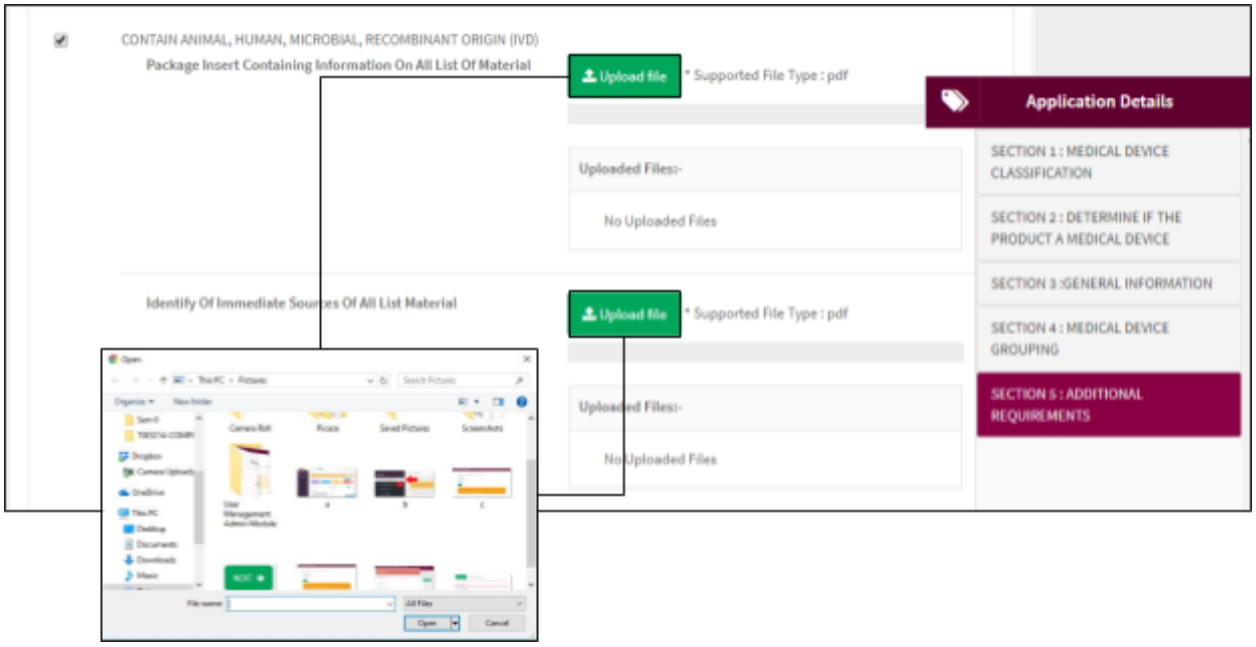

User click Upload file to upload file. **The file must be pdf format and size not more than 300 MB**.




User has fill 'Please specify' text box first then click Upload file to upload file. **The file must be pdf format and size not more than 300 MB**.



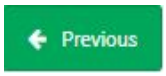

User click Upload file to upload file. **The file must be pdf format and size not more than 300 MB**.




User click Upload file to upload file. **The file must be pdf format and size not more than 300 MB**.

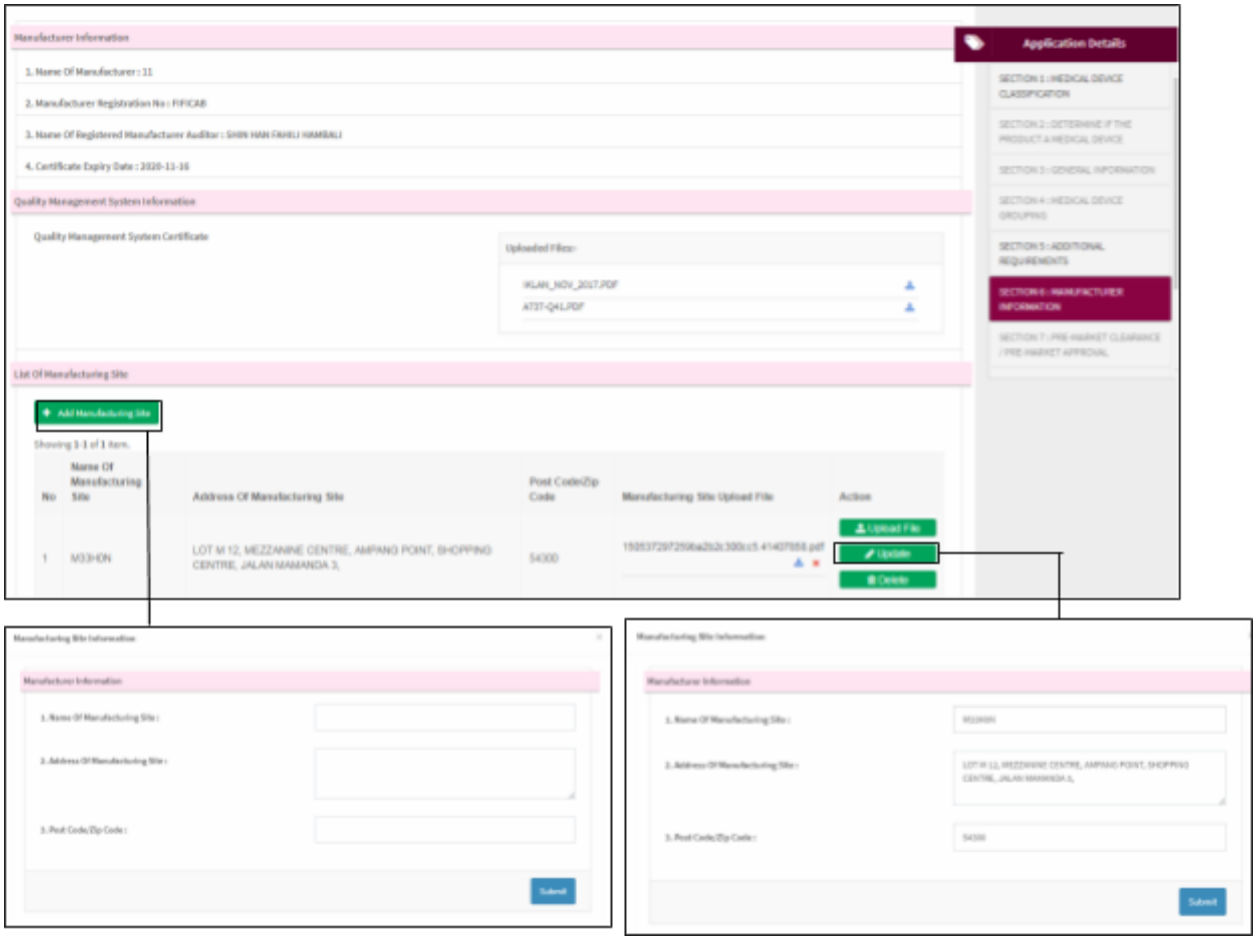
The user can click 

to go to the editable section

Click 

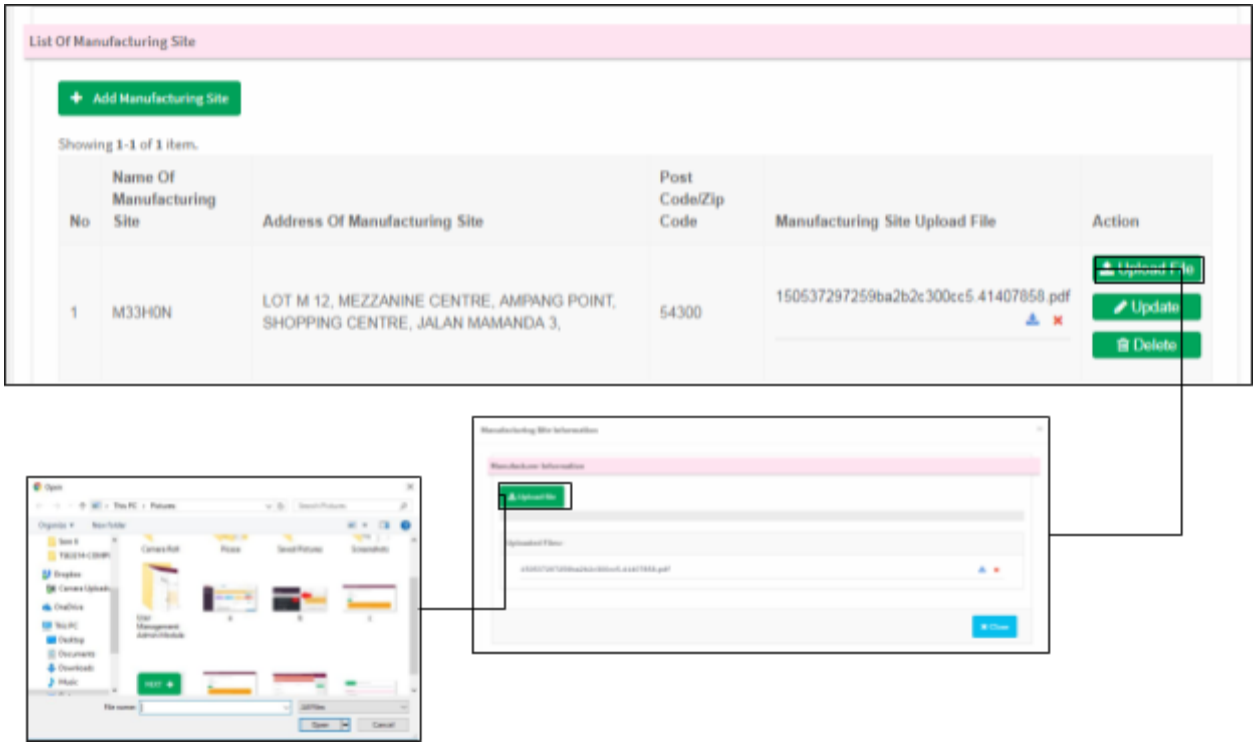
to go to the previous section to continue edit the change.

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

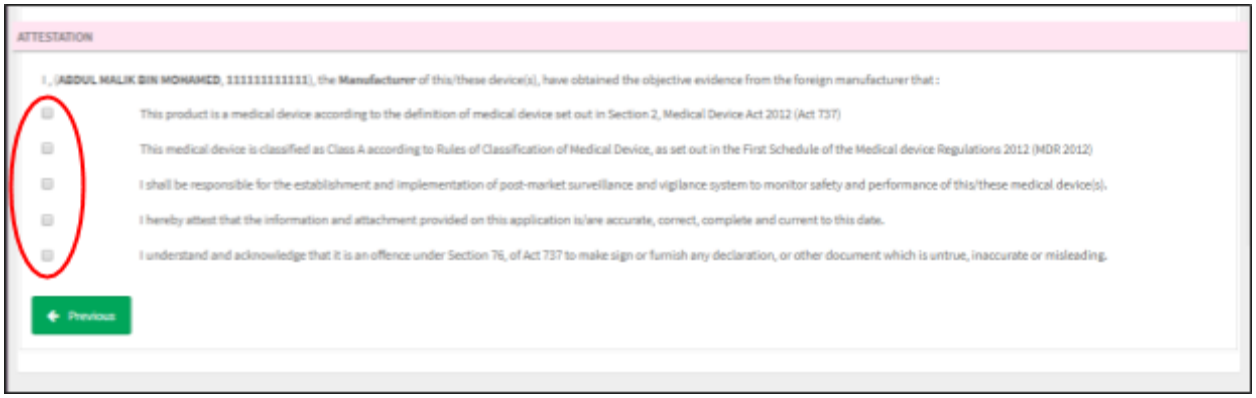


User click  to add new data or click  to change the old data. User has to fill all the text box then click  . The new data will display in 'List Of Manufacturing Site' table.

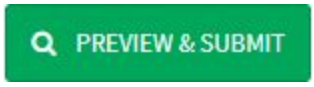
User click  to change the old upload file or to new upload files.

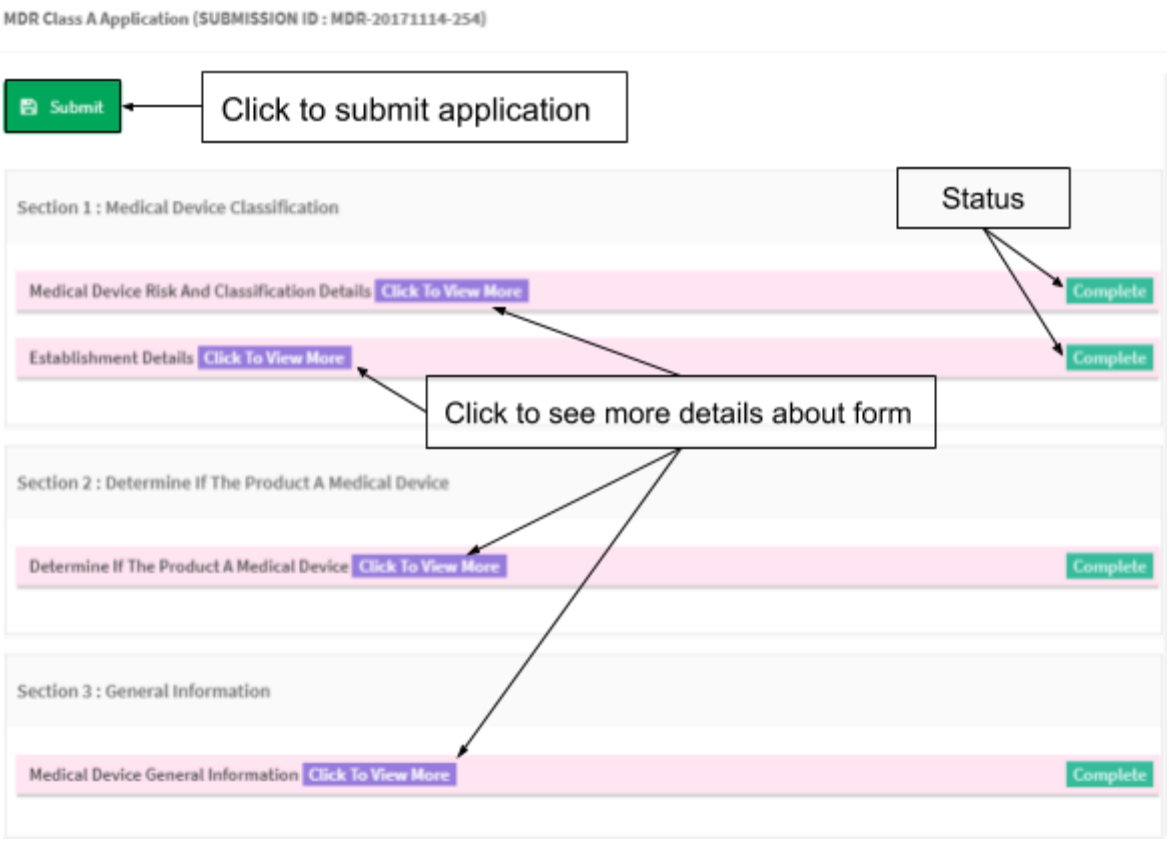

List Of Manufacturing Site
Add Manufacturing Site
Showing 1-1 of 1 item.
No
Name Of Manufacturing Site
Address Of Manufacturing Site
Post Code/Zip Code
Manufacturing Site Upload File
Action
1
M33H0N
LOT M 12, MEZZANINE CENTRE, AMPANG POINT, SHOPPING CENTRE, JALAN MAMANDA 3,
54300
150537297259ba2b2c300cc5 41407858.pdf
Update
Delete

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.

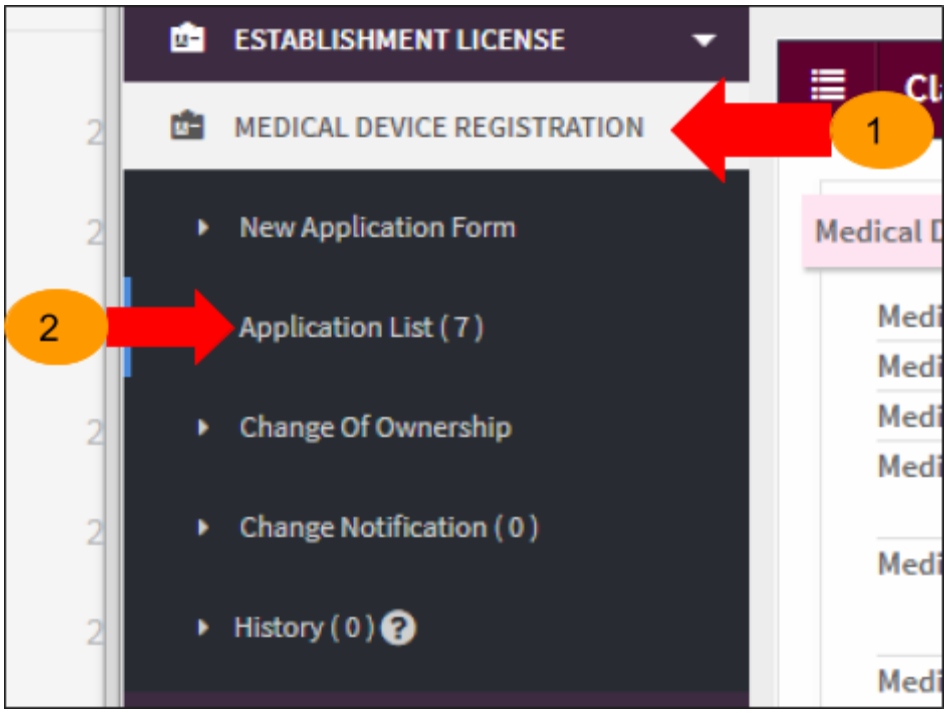



Submission only can do if all form status is Complete. If status Not Complete, user has to complete the form.

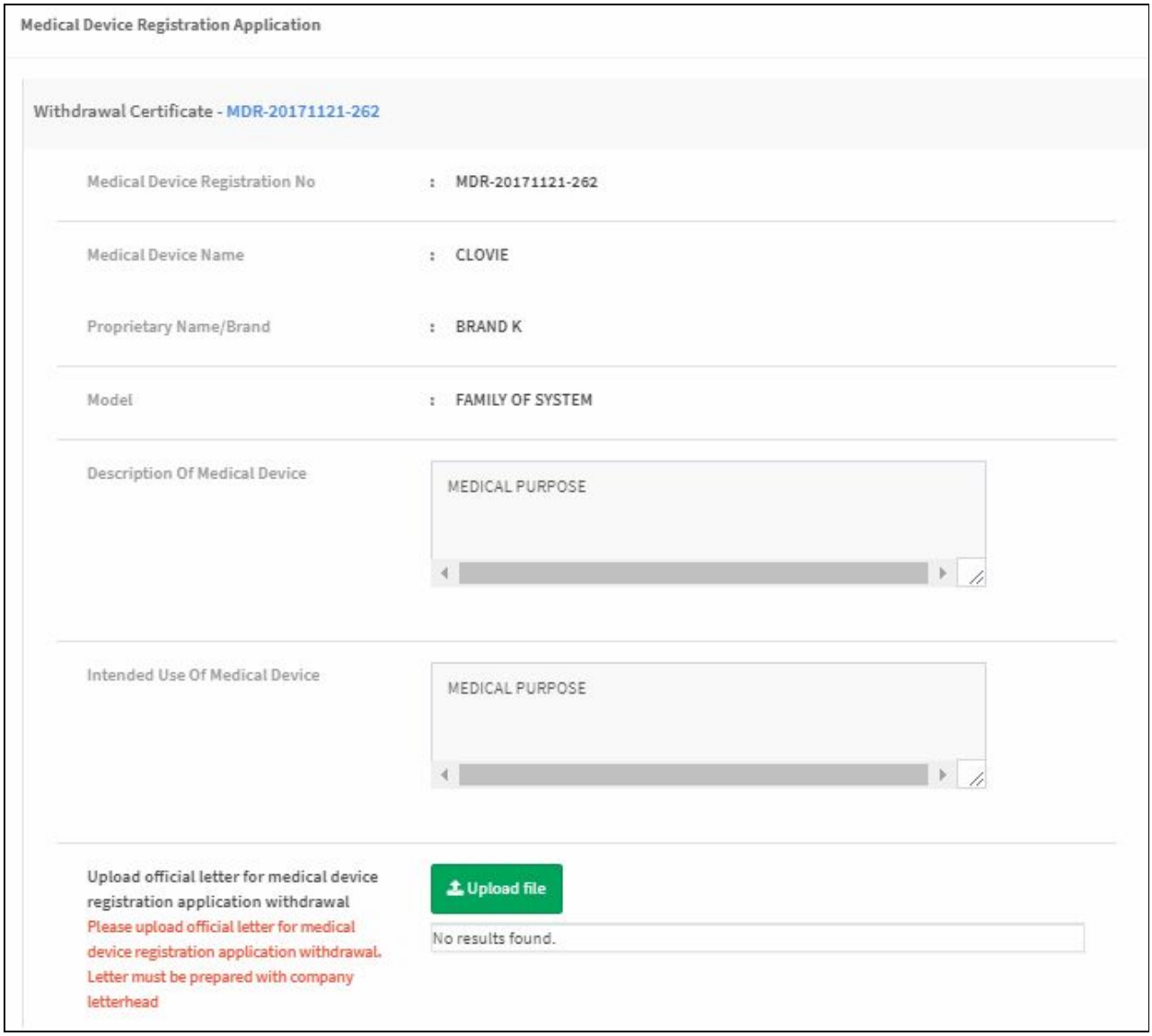
Then, click Submit to submit application.

## 5.0 WITHDRAWAL CERTIFICATE

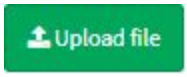
User go to *Application List* page to withdrawal certificate



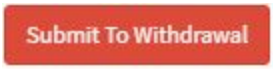

The diagram below show *Application List* page. Click Withdrawal Certificate to withdrawal certificate.


Medical Device Registration Application
Withdrawal Certificate - MDR-20171121-262
Medical Device Registration No : MDR-20171121-262
Medical Device Name : CLOVIE
Proprietary Name/Brand : BRAND K
Model : FAMILY OF SYSTEM
Description Of Medical Device
MEDICAL PURPOSE
Intended Use Of Medical Device
MEDICAL PURPOSE
Upload official letter for medical device registration application withdrawal
Please upload official letter for medical device registration application withdrawal. Letter must be prepared with company letterhead
Upload file
No results found.

User must upload file to proceed withdrawal application

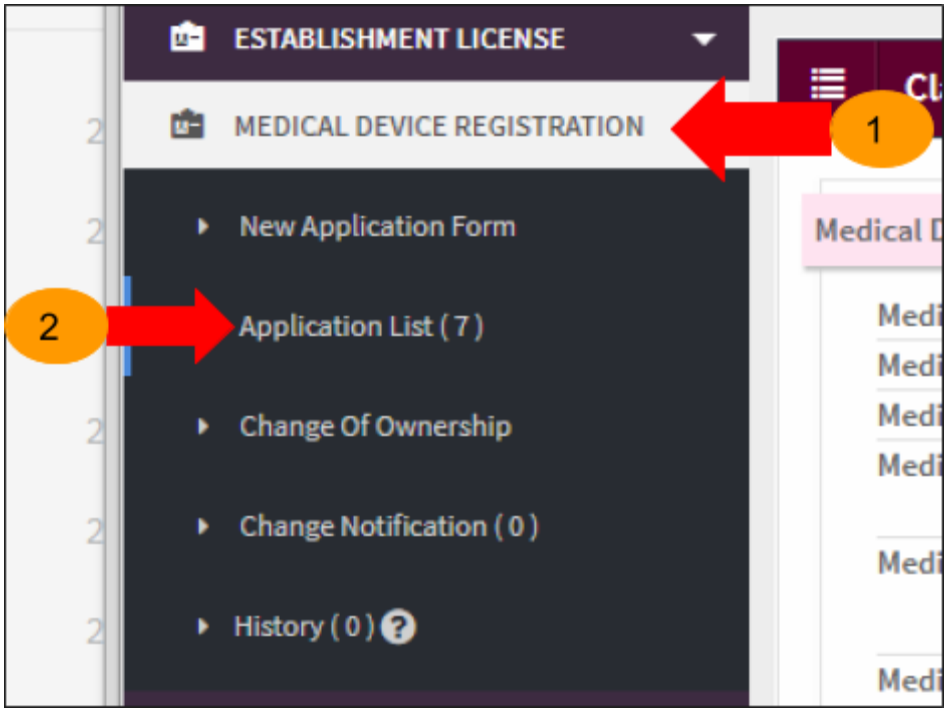
User click  to upload file. **The file must be pdf format and size not more than 300 MB**.



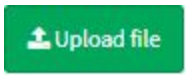
Then, click  to submit withdrawal certificate application.

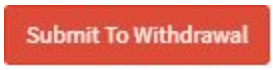
## 6.0 WITHDRAWAL APPLICATION

User go to *Application List* page to withdrawal application

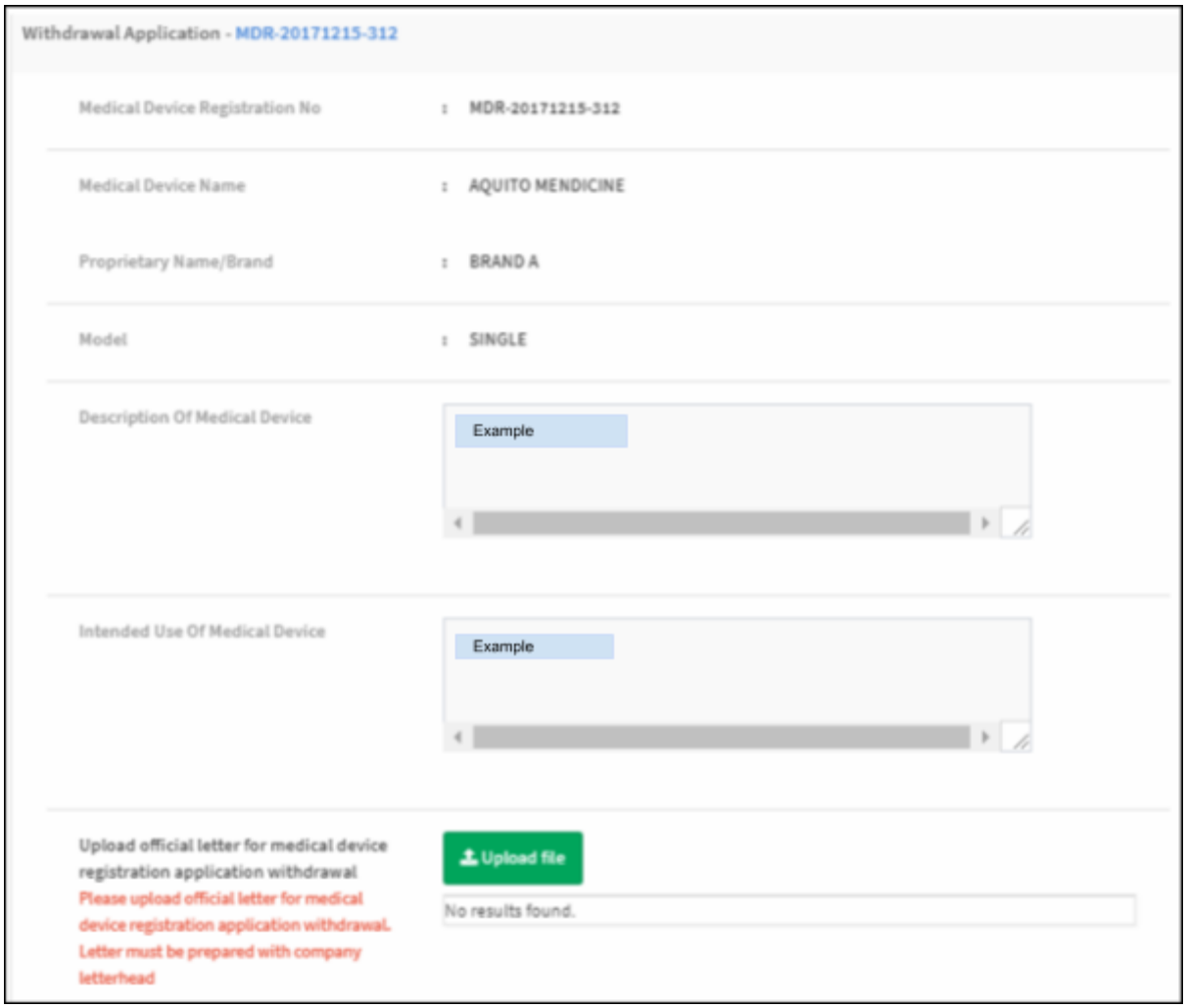



The diagram below show *Application List* page. Click ✖ Withdrawal Application to withdrawal application.

The diagram below appear after user click [Withdrawal Application] button. Click 

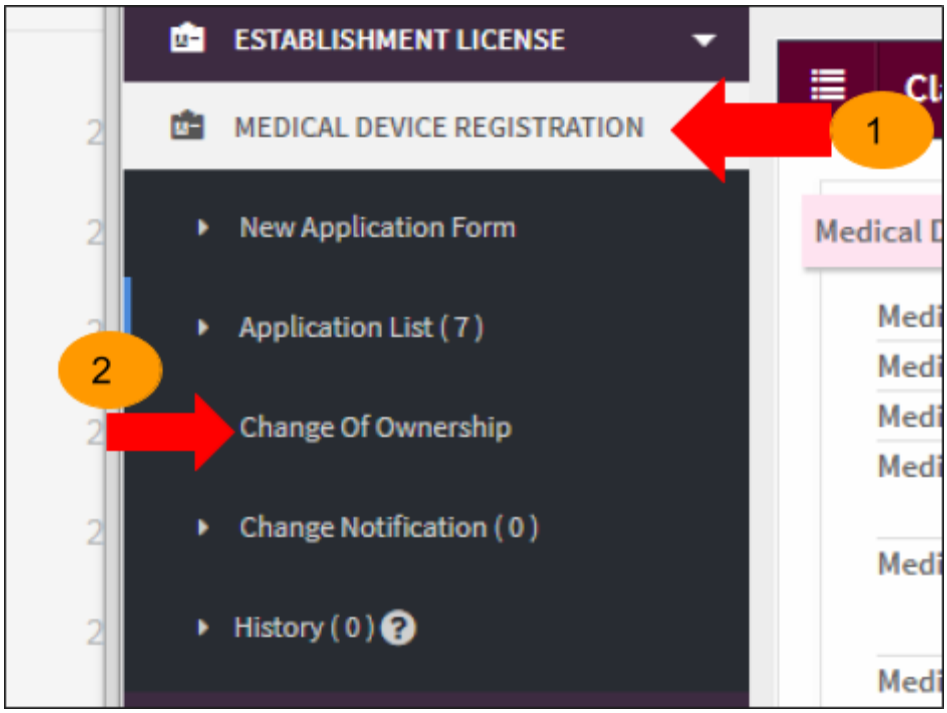
to upload file. **The file must be pdf format and size not more than 300 MB**. Next, click 

to submit.



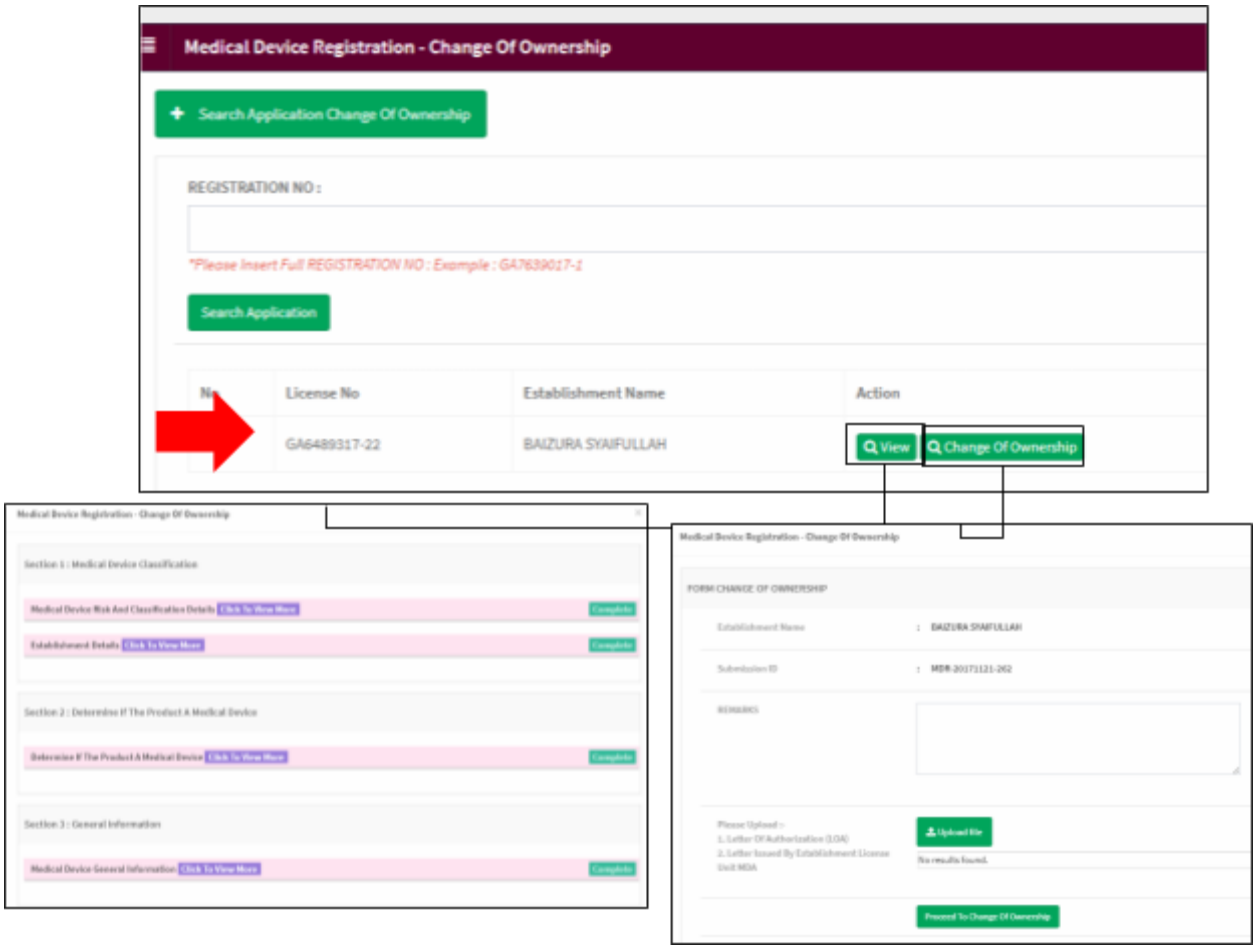
## 7.0 CHANGE OF AR

User go to *Change of Ownership* page to change of AR

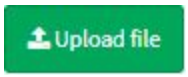



The diagram below show *Change of Ownership* page.

User fill the '*REGISTRATION NO*' text boxes and click Search Application to search the registration number. The registration number must be from other establishment user.




- Click View to view the application.
- Click Change Of Ownership to proceed the process change of ownership

The diagram below appear after user click [Change Of Ownership] button. Click 

to upload file. **The file must be pdf format and size not more than 300 MB**. Next, click 

to submit.