USER MANUAL
FRONT END USER

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

MODUL UTAMA - MDR CLASS B, C & D

DISEDIAKAN OLEH :

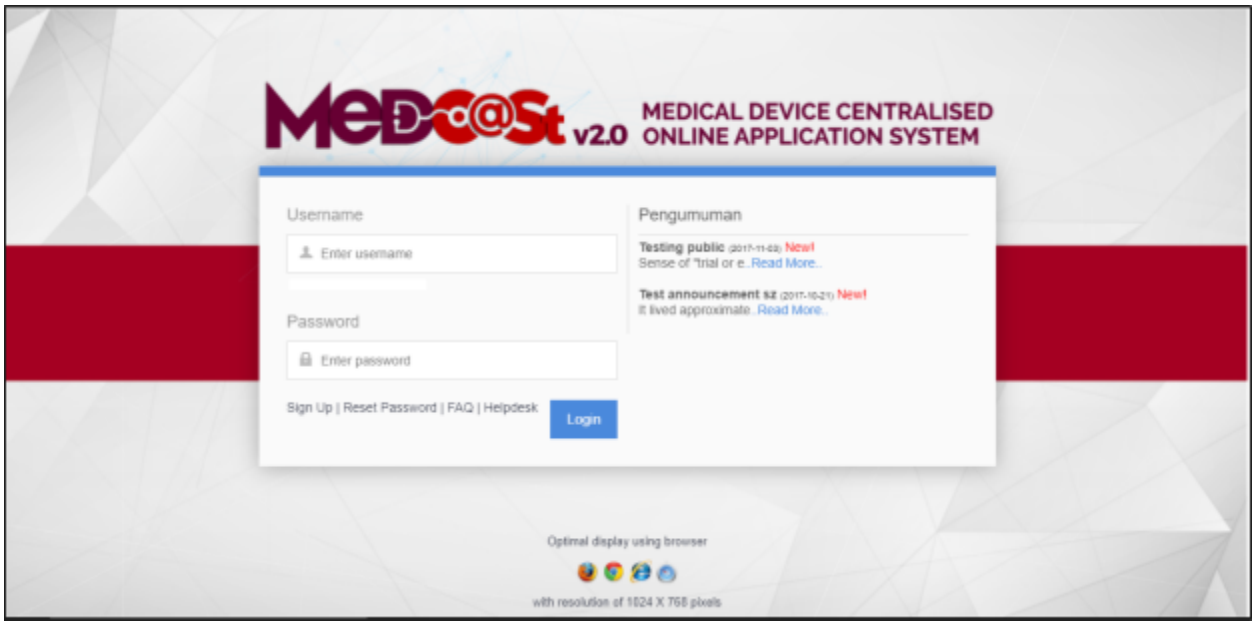
LIST OF CONTENTS

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/logivb n

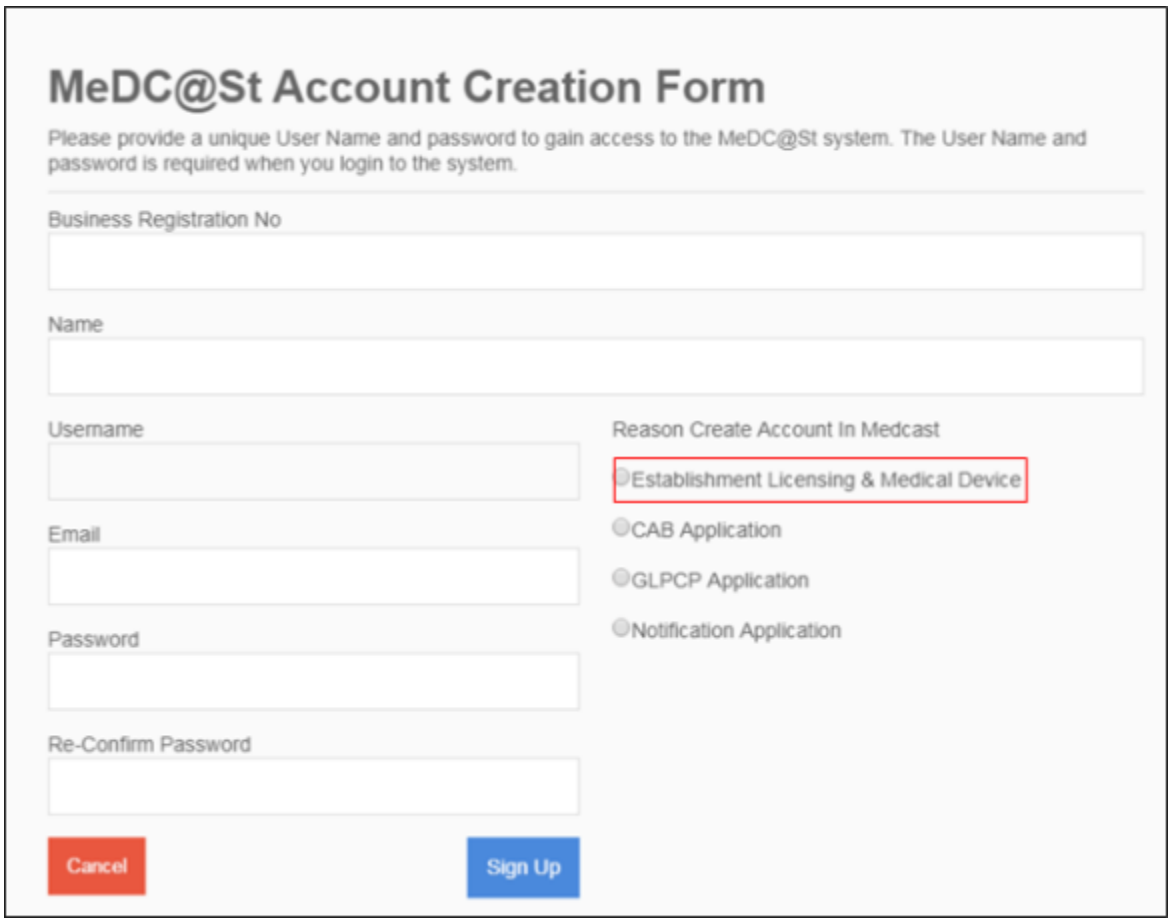
The screen below shows the expected webpage after the address has been keyed in.



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

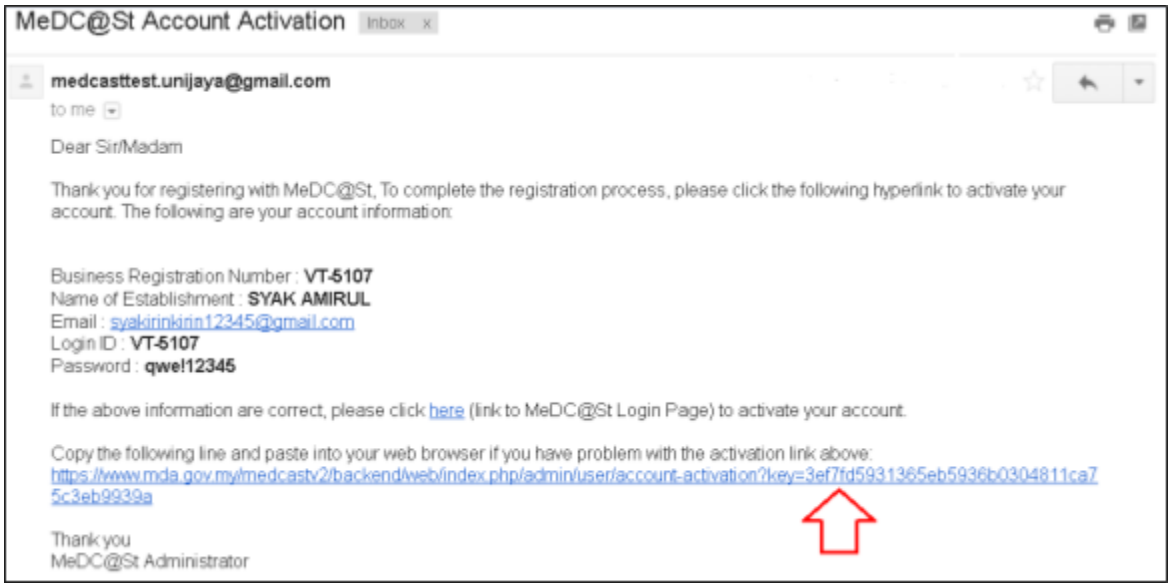
1.2 SIGN UP

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

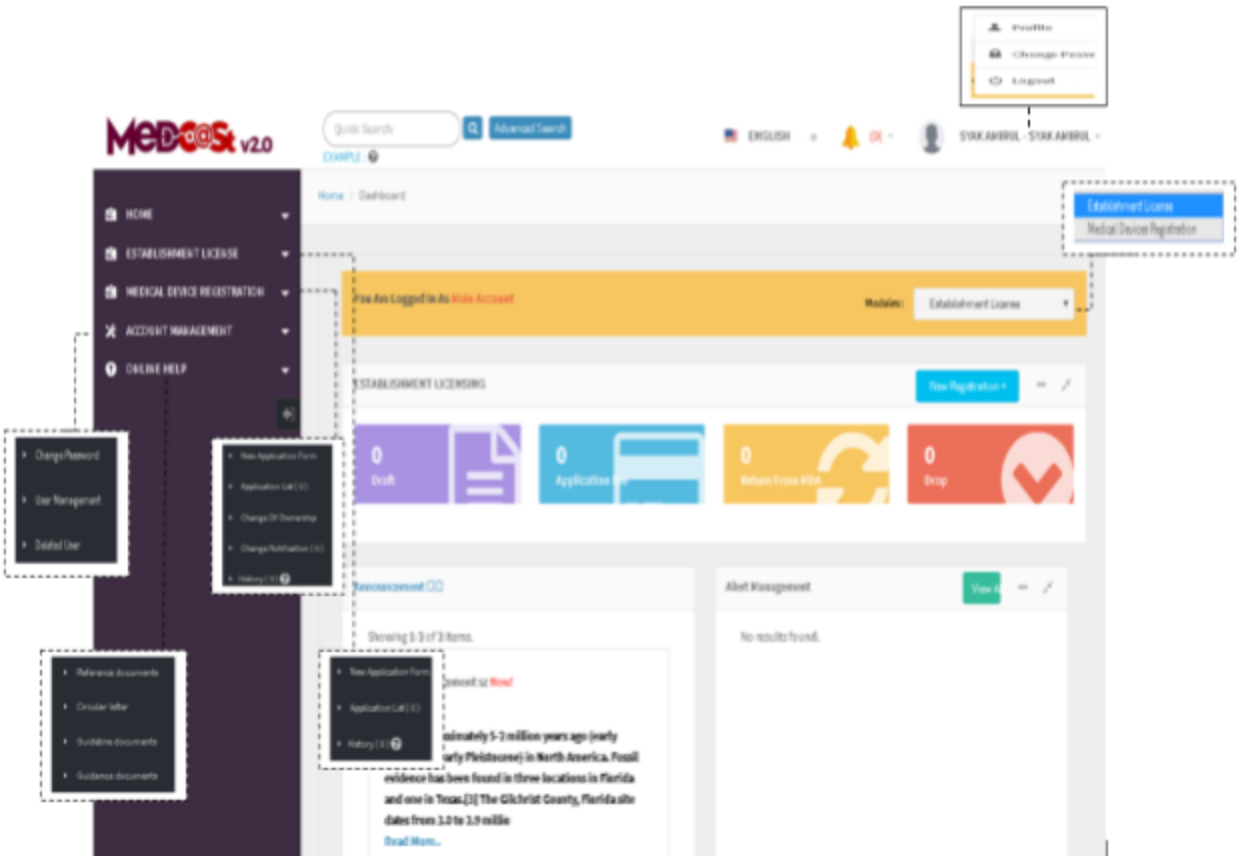
The user must verified email to completed the last step of the registration. Click at the link given to verified email in the system medcast V2.0.



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

The login screen will display.

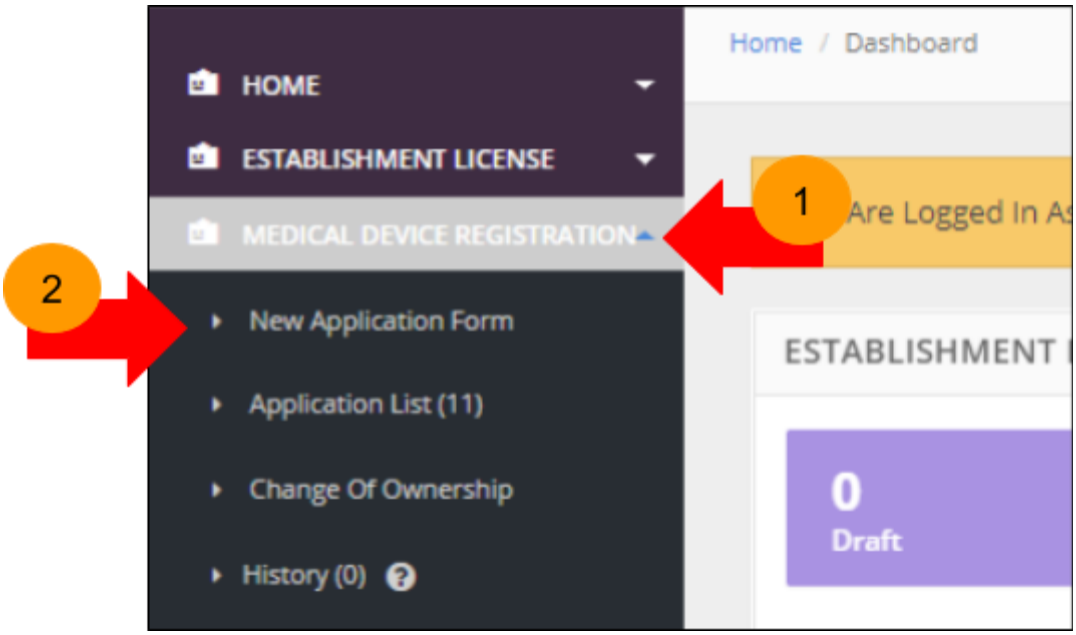
The user login successfully in the system medcast. It show the dashboard of the account.



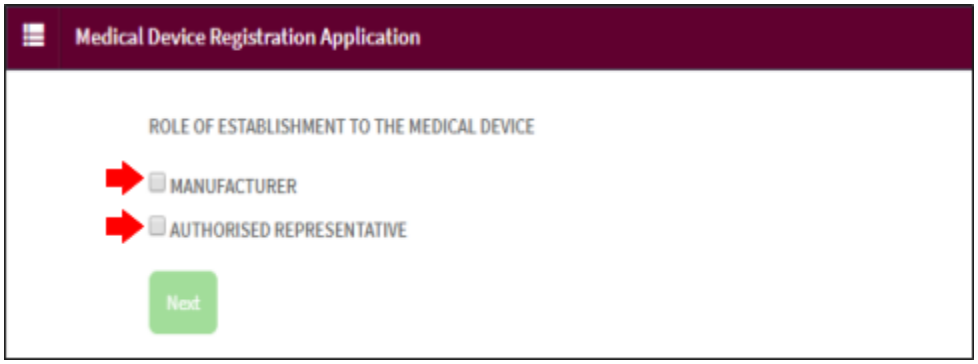
2.0 NEW REGISTRATION

****User must create new Establishment License first to create new Medical Device Registration (Refer User Manual EL Front End User)**

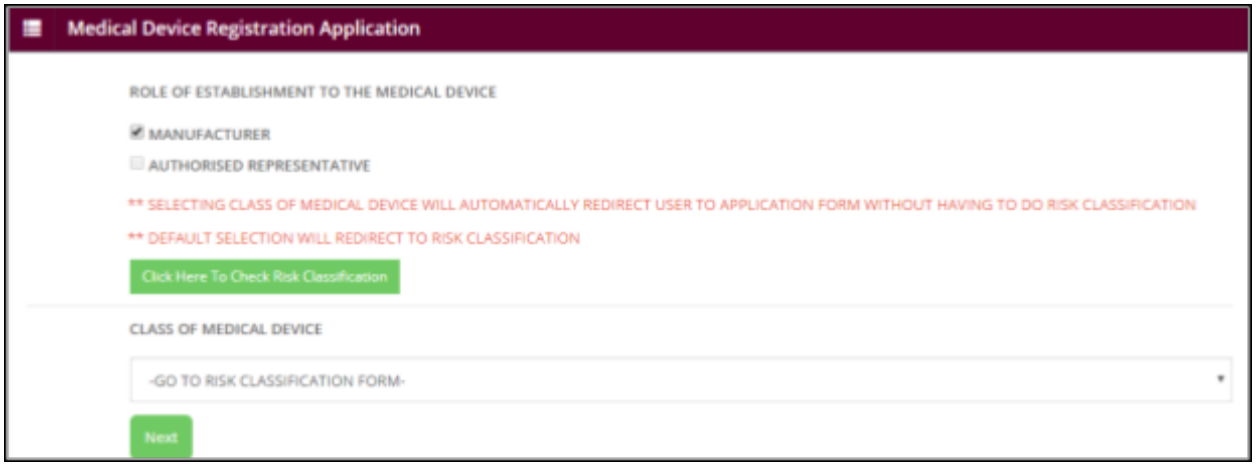
Click on the 'MEDICAL DEVICE REGISTRATION' at the left menu sidebar and click at the 'New Application Form' to create a new form.



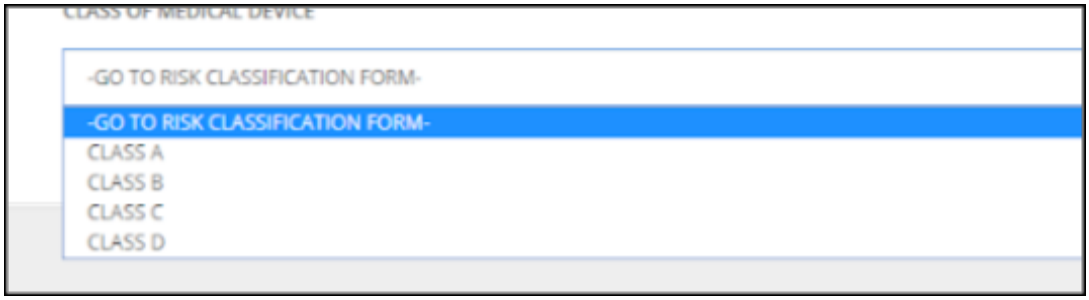
Tick on the 'MANUFACTURER' or 'AUTHORISED REPRESENTATIVE' to create new application and click on the button Next to proceed. User can make one application at one time. 'Next' button will enable after user tick applications checkbox.



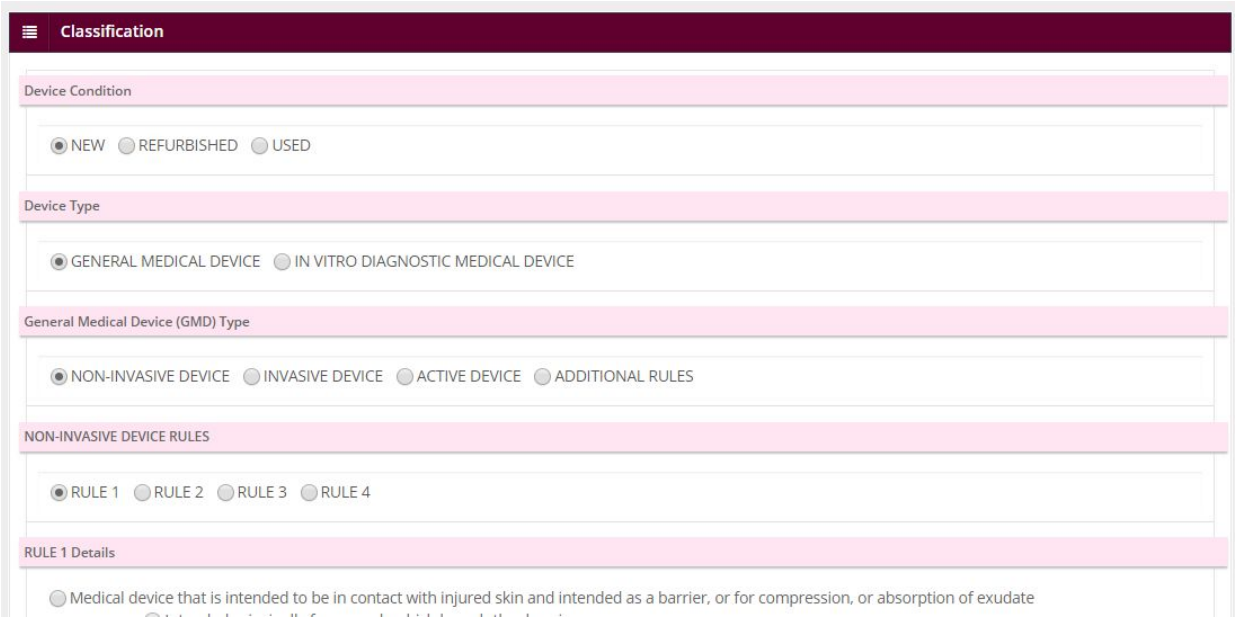
After click Next the diagram will show.



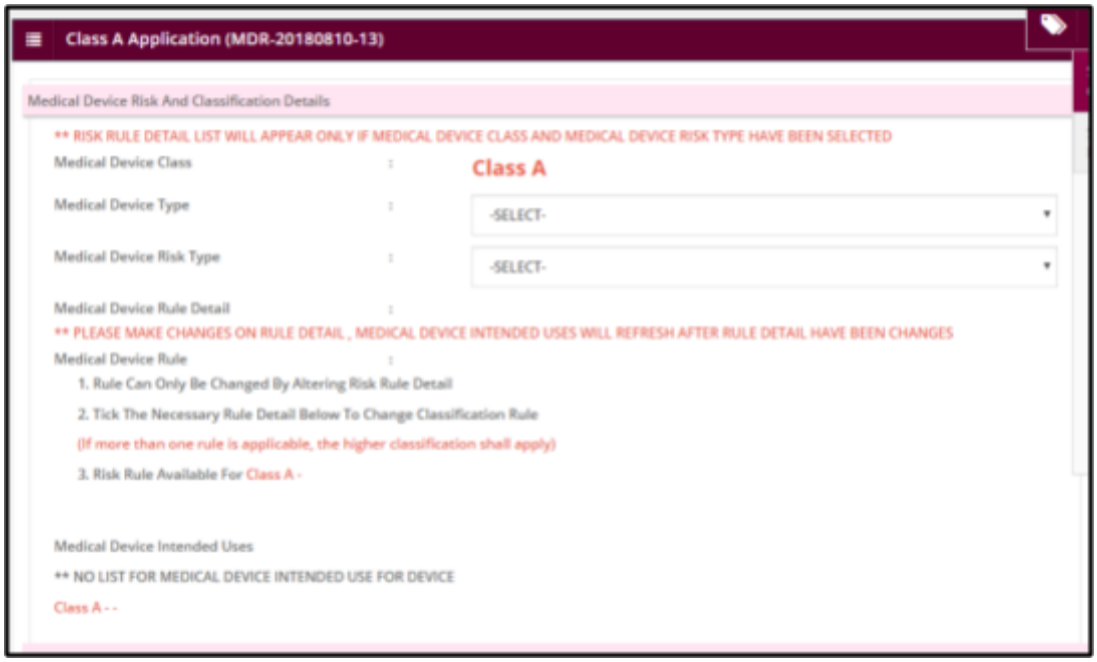
In class of medical device section you can choose CLASS A, CLASS B, CLASS C and CLASS D but also you can choose GO TO RISK CLASSIFICATION FORM.



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



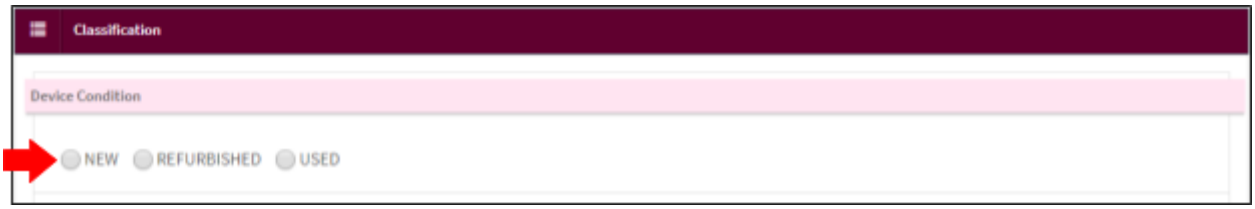
If the user choose CLASS A and click Next the Class A Application will be display.


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 - -

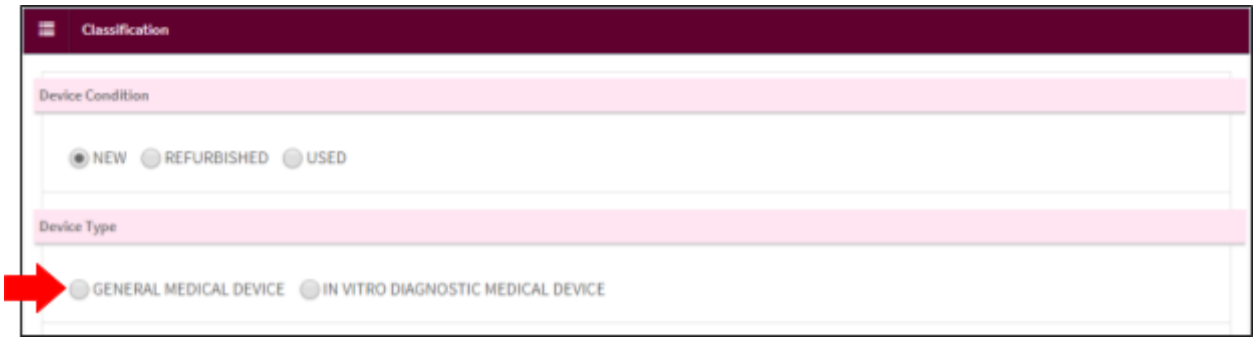
2.1 CREATE CLASS APPLICATION

2.1.1 CLASSIFICATION APPLICATION

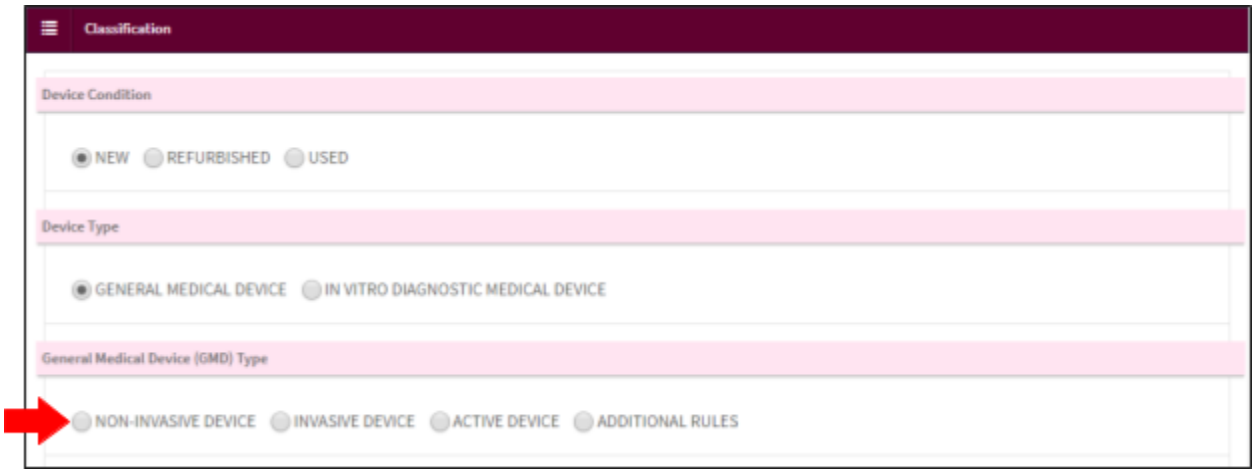
Classification form will be display. Tick at 'NEW' radio button in 'Device Conditions' field.



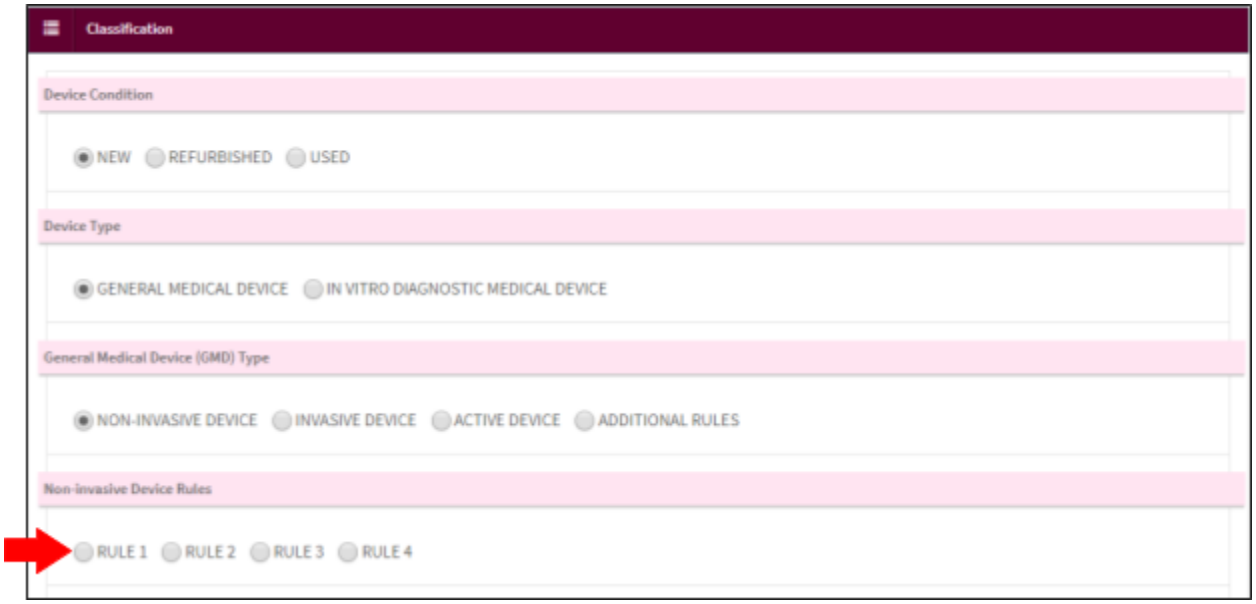
Then, tick at 'GENERAL MEDICAL DEVICE' radio button in 'Device Type' field.



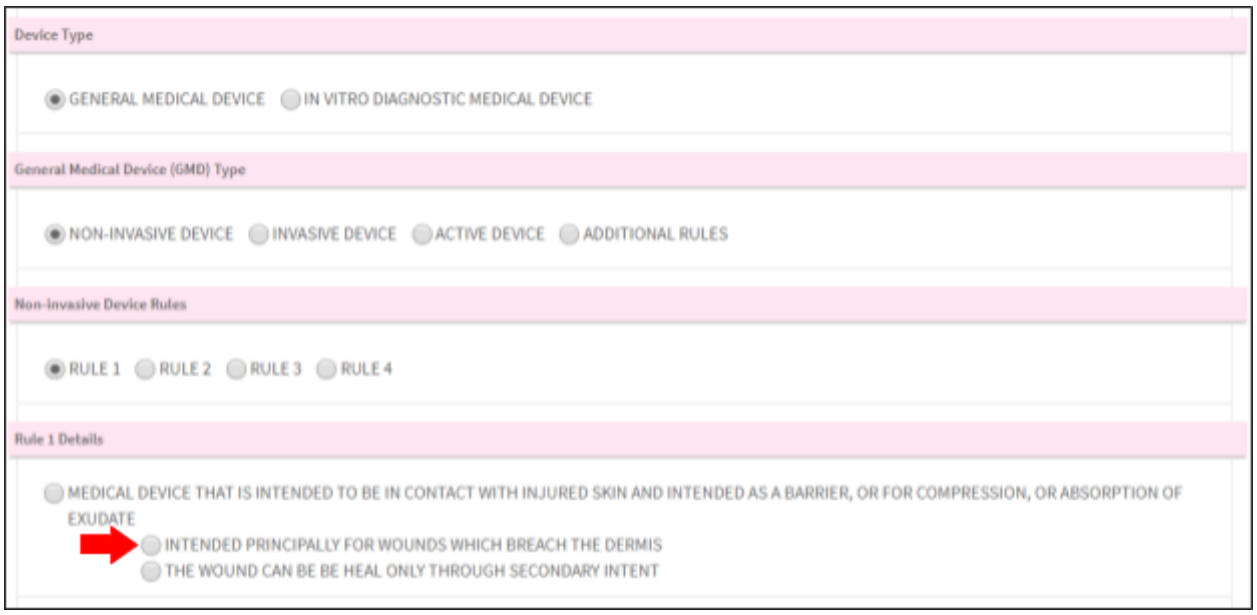
Next, tick ‘NON-INVASIVE DEVICE’ radio button in general ‘Medical Device (GMD) Type field.



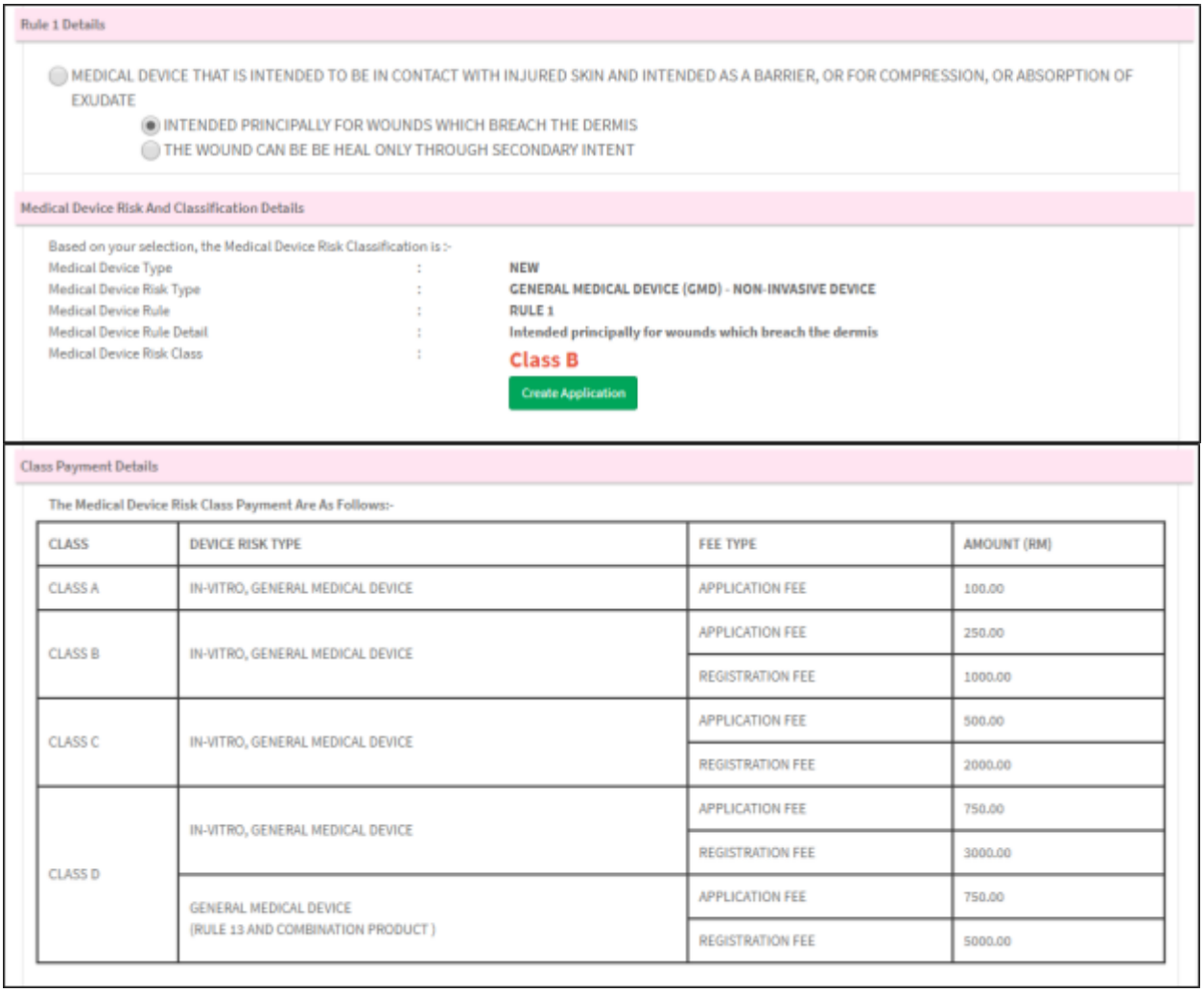
After that, tick ‘RULE 1’ radio button in ‘Non-invasive Device Rules’ field.



Next step, tick 'INTENDED PRINCIPALLY FOR WOUNDS WHICH BREACH THE DERMIS' radio button at 'Rules 1 Details' field.



Medical Device Risk And Classification Details and Class Payment Details will be display. User click Create Application to go to next step step.



Rule 1 Details

- MEDICAL DEVICE THAT IS INTENDED TO BE IN CONTACT WITH INJURED SKIN AND INTENDED AS A BARRIER, OR FOR COMPRESSION, OR ABSORPTION OF EXUDATE
  - INTENDED PRINCIPALLY FOR WOUNDS WHICH BREACH THE DERMIS
  - THE WOUND CAN BE BE HEAL ONLY THROUGH SECONDARY INTENT

Medical Device Risk And Classification Details

Based on your selection, the Medical Device Risk Classification is :-

Medical Device Type	:	NEW
Medical Device Risk Type	:	GENERAL MEDICAL DEVICE (GMD) - NON-INVASIVE DEVICE
Medical Device Rule	:	RULE 1
Medical Device Rule Detail	:	Intended principally for wounds which breach the dermis
Medical Device Risk Class	:	Class B

Create Application

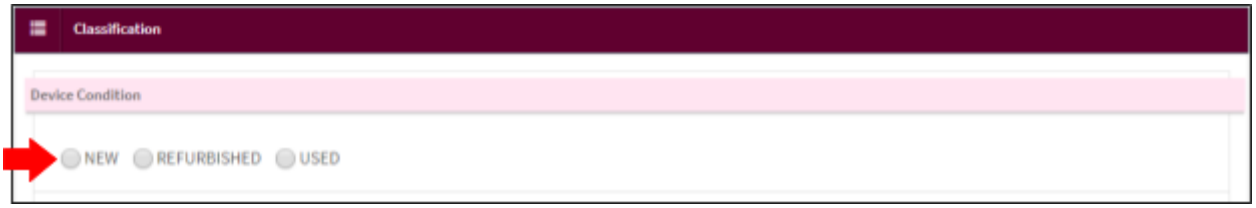
Class Payment Details

The Medical Device Risk Class Payment Are As Follows:-

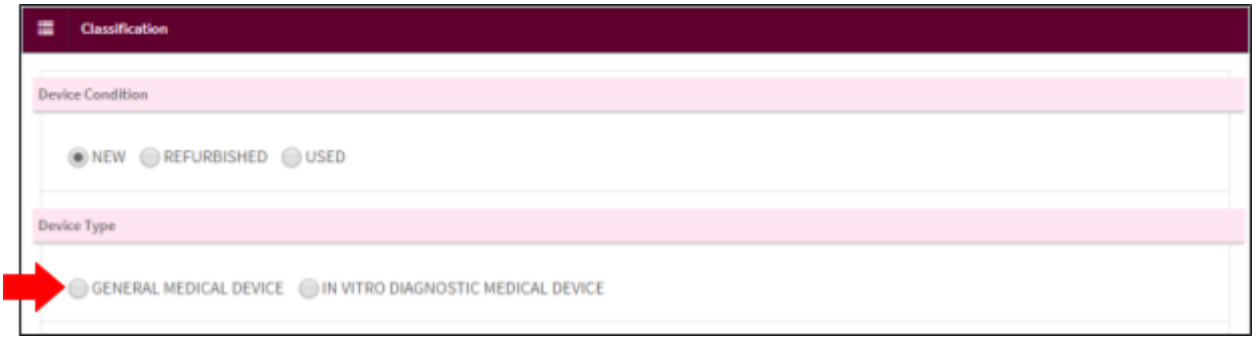
CLASS	DEVICE RISK TYPE	FEE TYPE	AMOUNT (RM)
CLASS A	IN-VITRO, GENERAL MEDICAL DEVICE	APPLICATION FEE	100.00
CLASS B	IN-VITRO, GENERAL MEDICAL DEVICE	APPLICATION FEE	250.00
		REGISTRATION FEE	1000.00
CLASS C	IN-VITRO, GENERAL MEDICAL DEVICE	APPLICATION FEE	500.00
		REGISTRATION FEE	2000.00
CLASS D	IN-VITRO, GENERAL MEDICAL DEVICE	APPLICATION FEE	750.00
		REGISTRATION FEE	3000.00
	GENERAL MEDICAL DEVICE (RULE 13 AND COMBINATION PRODUCT)	APPLICATION FEE	750.00
		REGISTRATION FEE	5000.00

2.1.2 CLASS C APPLICATION

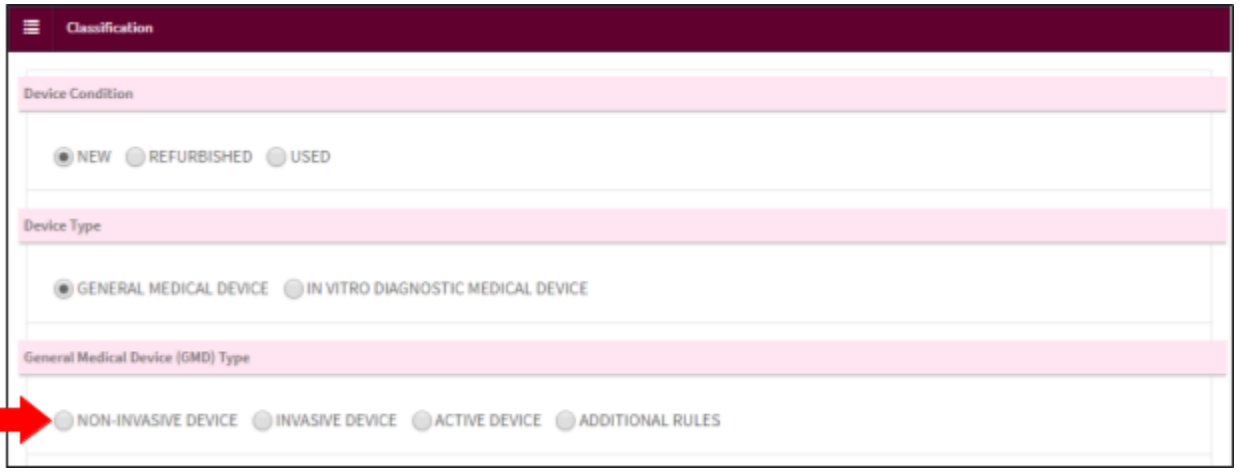
Classification form will be display. Tick at 'NEW' radio button in 'Device Conditions' field.



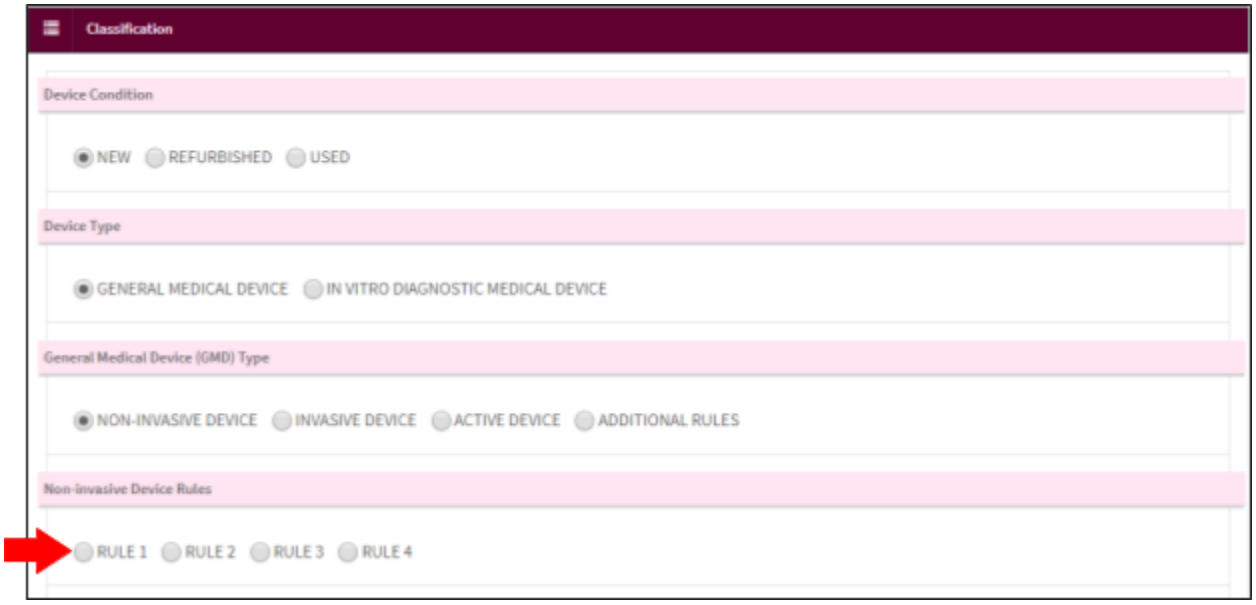
Then, tick at 'GENERAL MEDICAL DEVICE' radio button in 'Device Type' field.



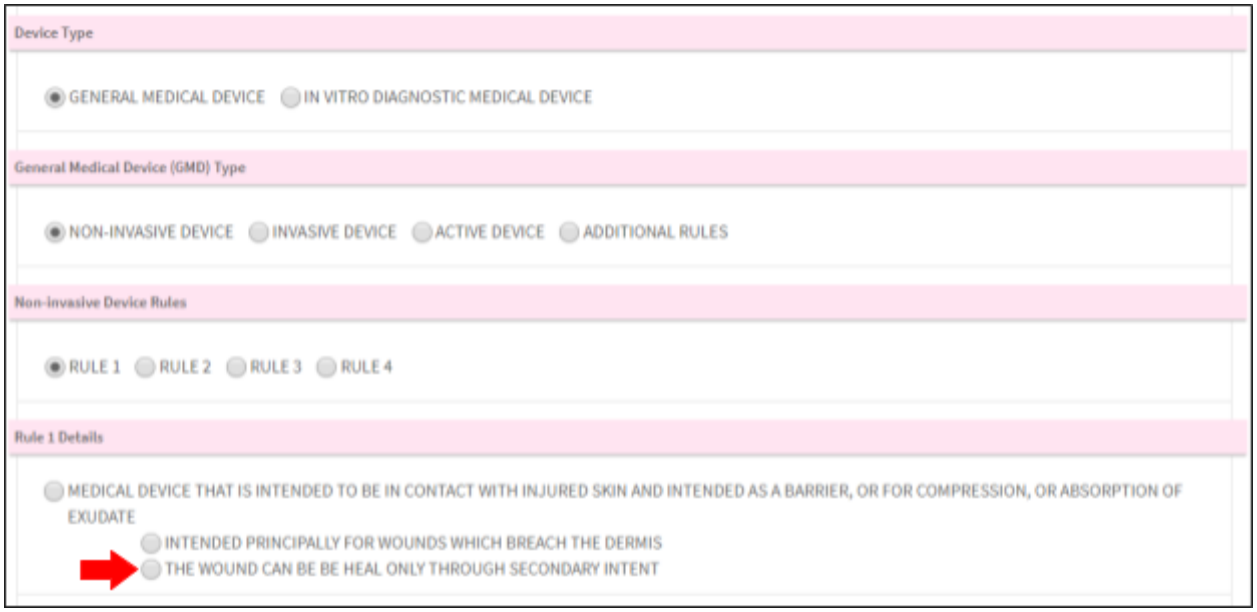
Next, tick 'NON-INVASIVE DEVICE' radio button in general 'Medical Device (GMD) Type' field.



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

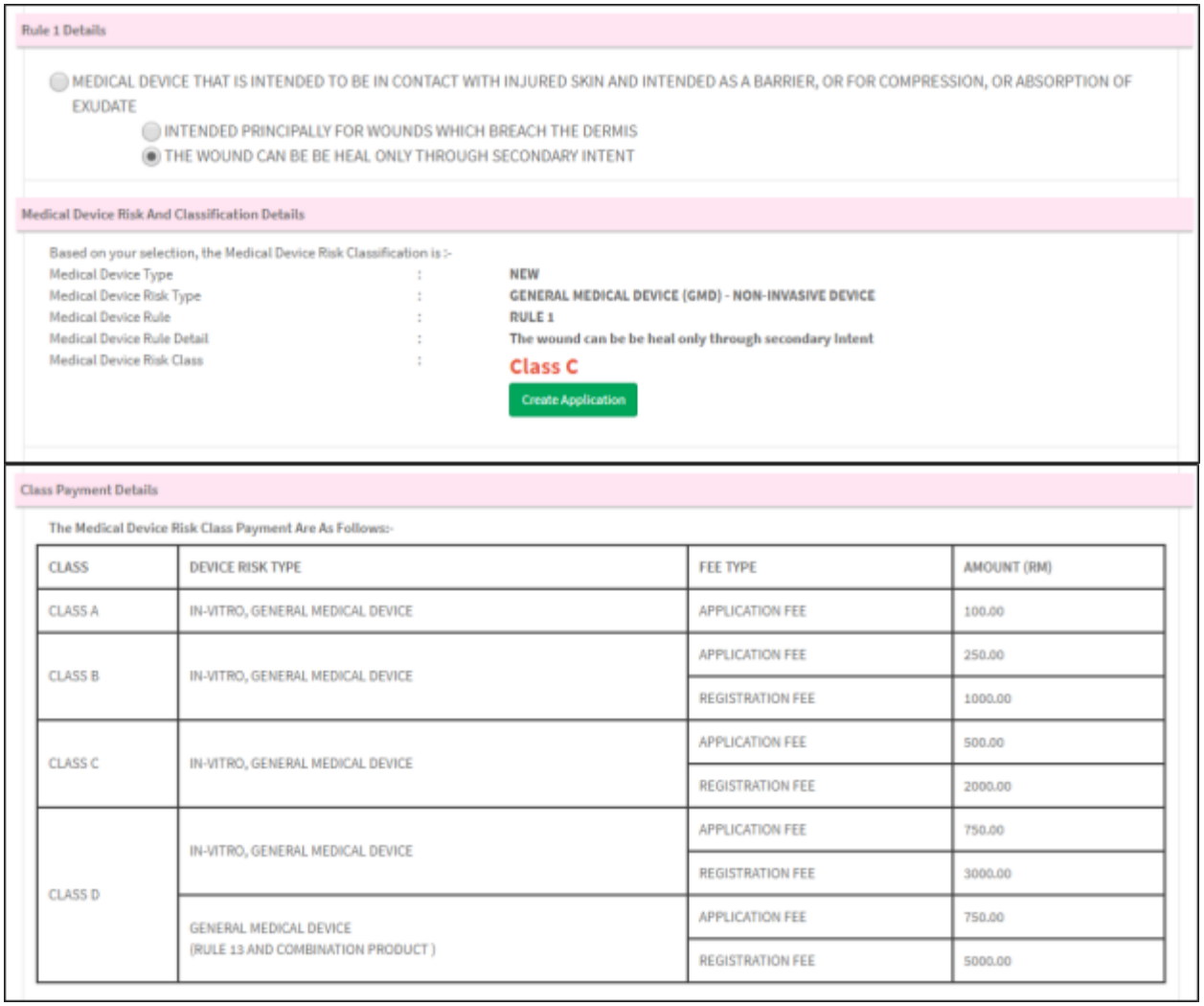


Next step, tick ‘THE WOUND CAN BE BE HEAL ONLY THROUGH SECONDARY INTENT’ radio button at ‘Rules 1 Details’ field.



Medical Device Risk Classification Details field and Class Payment Details field will be display.

User click Create Application to go to next step step.



Rule 1 Details

MEDICAL DEVICE THAT IS INTENDED TO BE IN CONTACT WITH INJURED SKIN AND INTENDED AS A BARRIER, OR FOR COMPRESSION, OR ABSORPTION OF EXUDATE

- INTENDED PRINCIPALLY FOR WOUNDS WHICH BREACH THE DERMIS
- THE WOUND CAN BE BE HEAL ONLY THROUGH SECONDARY INTENT

Medical Device Risk And Classification Details

Based on your selection, the Medical Device Risk Classification is :-

Medical Device Type	:	NEW
Medical Device Risk Type	:	GENERAL MEDICAL DEVICE (GMD) - NON-INVASIVE DEVICE
Medical Device Rule	:	RULE 1
Medical Device Rule Detail	:	The wound can be be heal only through secondary intent
Medical Device Risk Class	:	Class C

Create Application

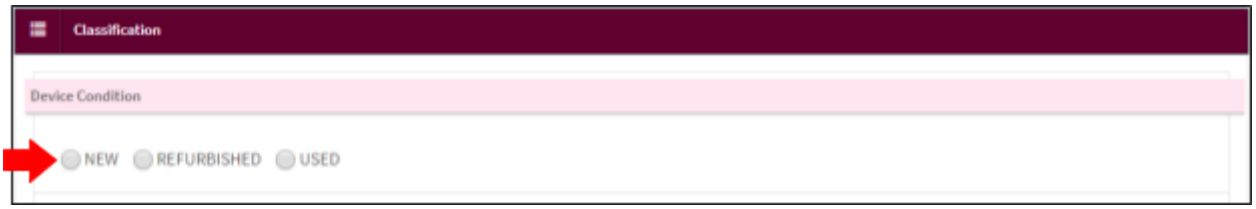
Class Payment Details

The Medical Device Risk Class Payment Are As Follows:-

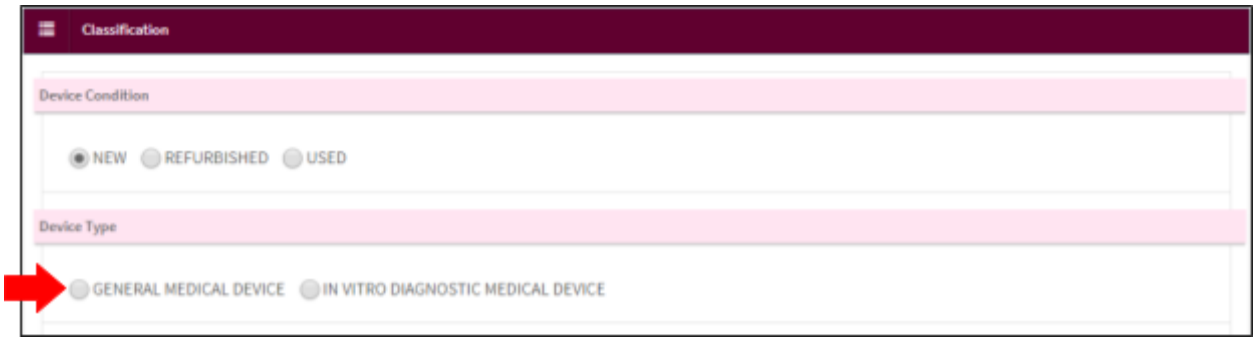
CLASS	DEVICE RISK TYPE	FEE TYPE	AMOUNT (RM)
CLASS A	IN-VITRO, GENERAL MEDICAL DEVICE	APPLICATION FEE	100.00
CLASS B	IN-VITRO, GENERAL MEDICAL DEVICE	APPLICATION FEE	250.00
		REGISTRATION FEE	1000.00
CLASS C	IN-VITRO, GENERAL MEDICAL DEVICE	APPLICATION FEE	500.00
		REGISTRATION FEE	2000.00
CLASS D	IN-VITRO, GENERAL MEDICAL DEVICE	APPLICATION FEE	750.00
		REGISTRATION FEE	3000.00
	GENERAL MEDICAL DEVICE (RULE 13 AND COMBINATION PRODUCT)	APPLICATION FEE	750.00
		REGISTRATION FEE	5000.00

2.1.3 CLASS D APPLICATION

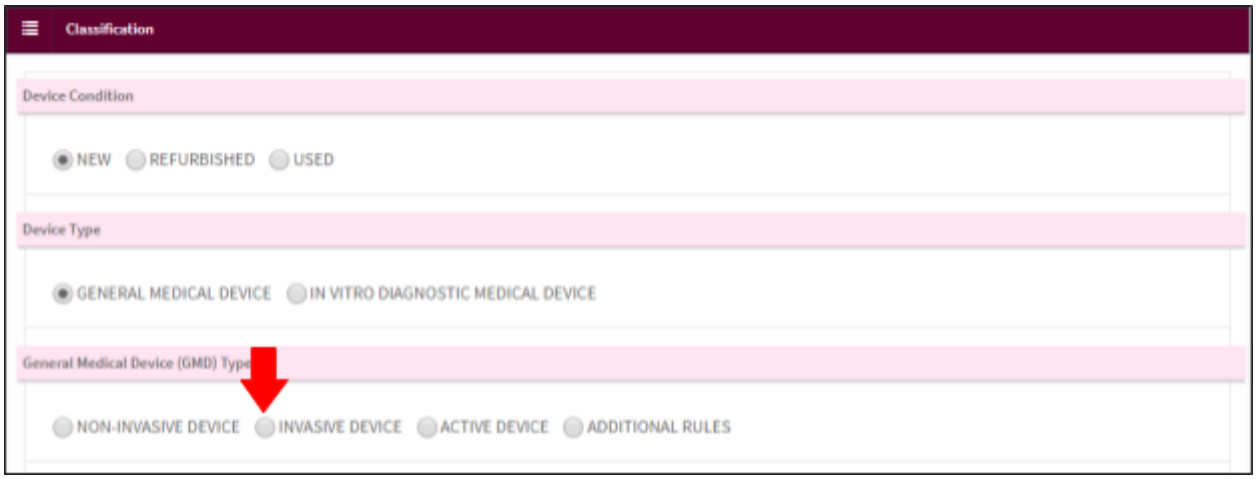
Classification form will be display. Tick at 'NEW' radio button in 'Device Conditions' field.



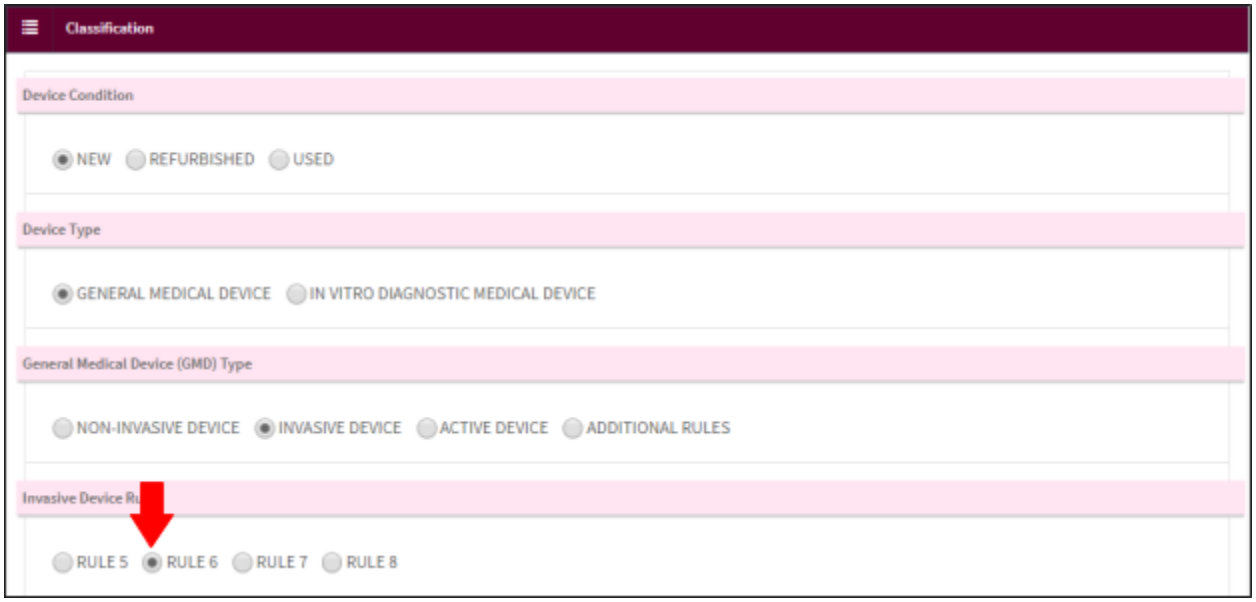
Then, tick at 'GENERAL MEDICAL DEVICE' radio button in 'Device Type' field.



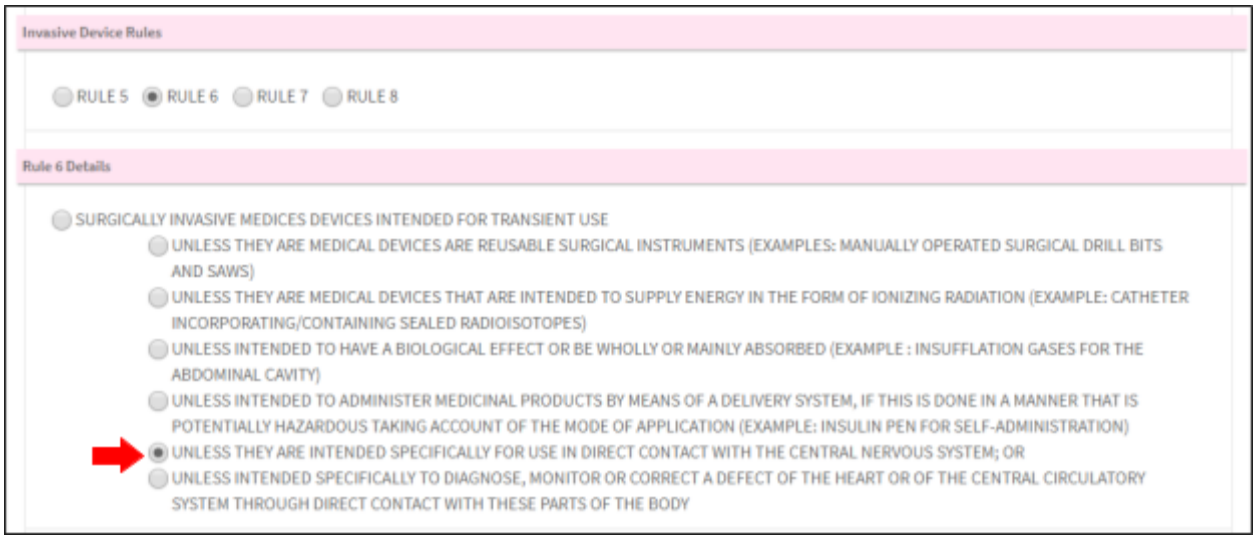
Next, tick 'INVASIVE DEVICE' radio button in general 'Medical Device (GMD) Type' field.



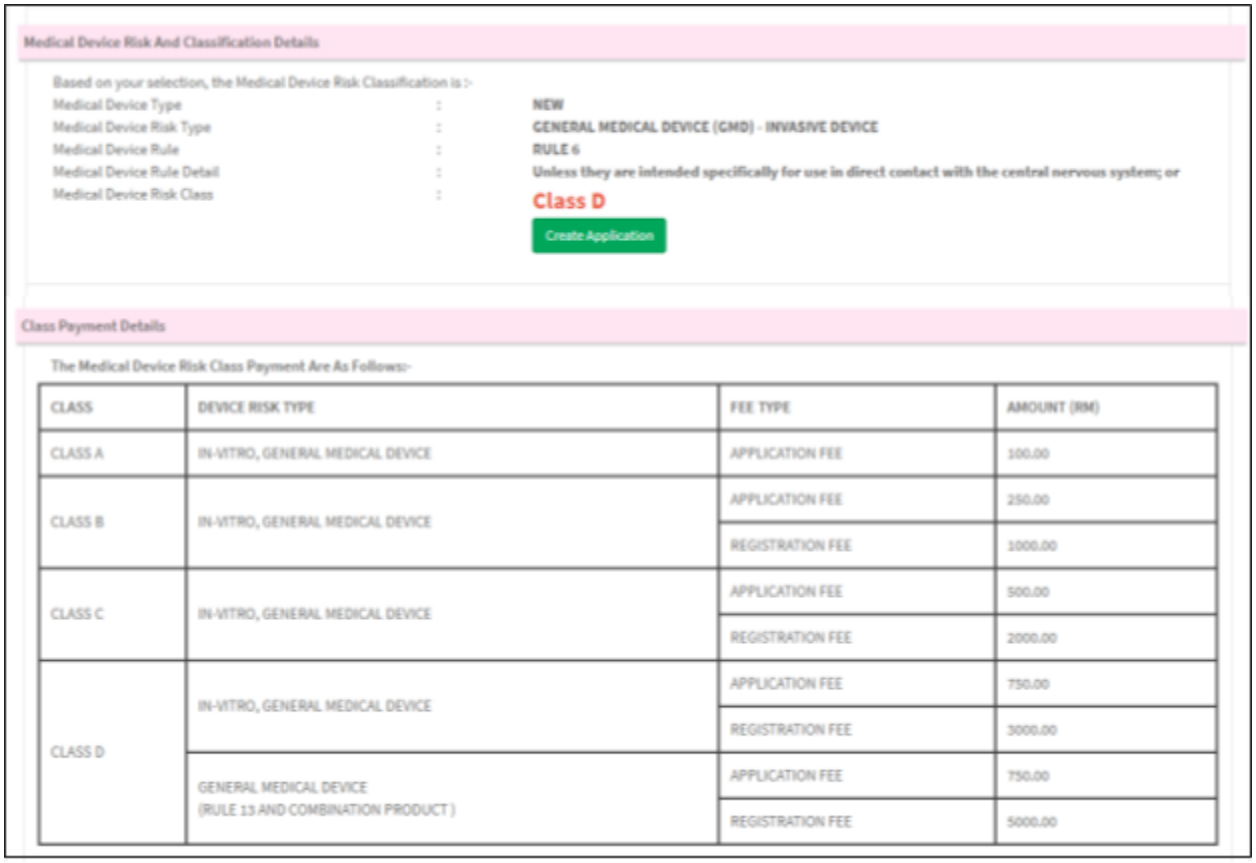
After that, tick ‘RULE 6’ radio button in ‘Non-invasive Device Rules’ field.



Next step, tick ‘UNLESS THEY ARE INTENDED SPECIFICALLY FOR USE IN DIRECT CONTACT WITH THE CENTRAL NERVOUS SYSTEM; OR’ radio button at ‘Rules 6 Details’ field.



Medical Device Risk And Classification Details and Class Payment Details will be display. User click Create Application to go to next step step.



Medical Device Risk And Classification Details

Based on your selection, the Medical Device Risk Classification is :-

Medical Device Type	:	NEW
Medical Device Risk Type	:	GENERAL MEDICAL DEVICE (GMD) - INVASIVE DEVICE
Medical Device Rule	:	RULE 6
Medical Device Rule Detail	:	Unless they are intended specifically for use in direct contact with the central nervous system; or
Medical Device Risk Class	:	Class D

Create Application

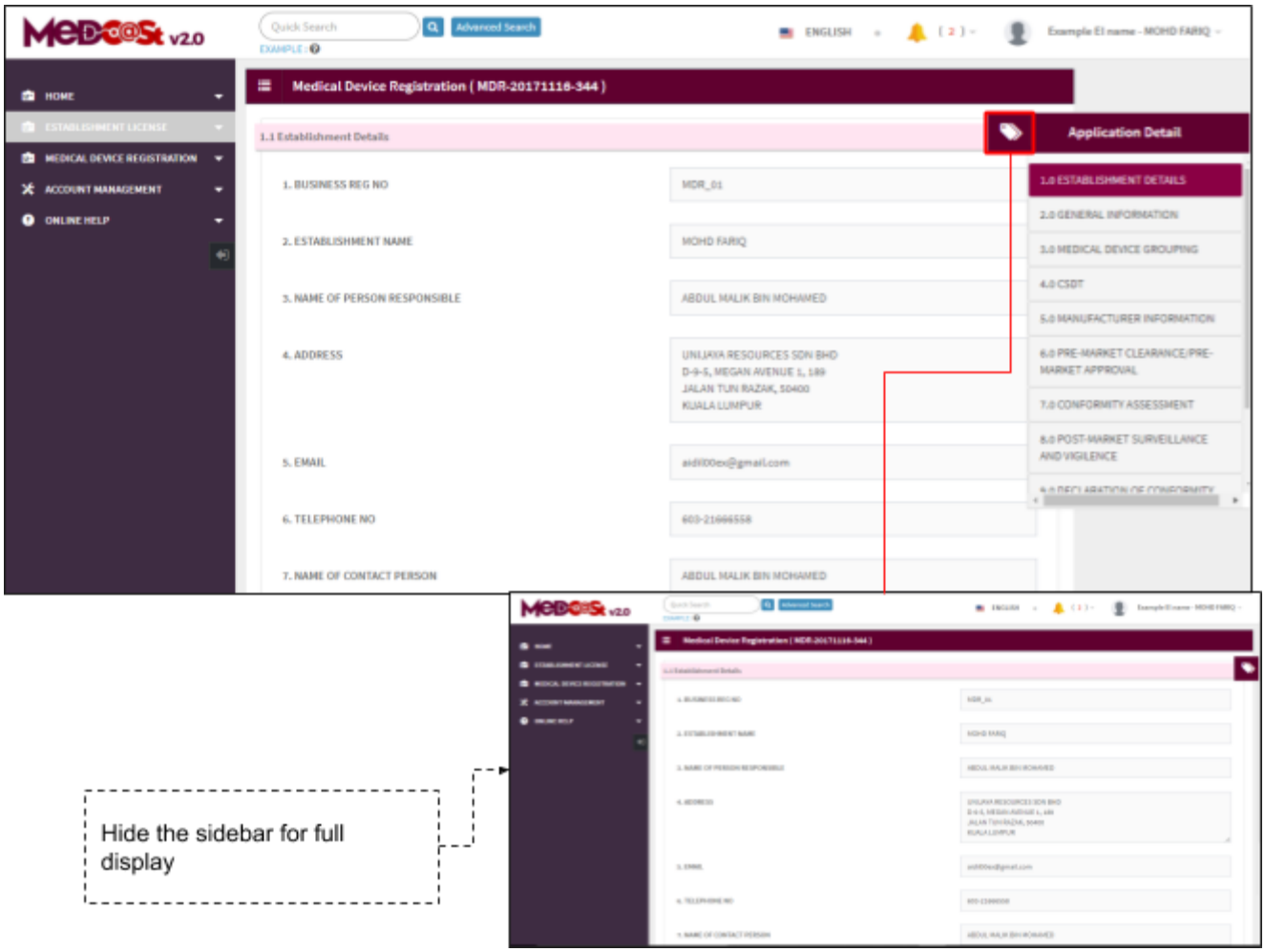
Class Payment Details

The Medical Device Risk Class Payment Are As Follows:-

CLASS	DEVICE RISK TYPE	FEE TYPE	AMOUNT (RM)
CLASS A	IN-VITRO, GENERAL MEDICAL DEVICE	APPLICATION FEE	100.00
CLASS B	IN-VITRO, GENERAL MEDICAL DEVICE	APPLICATION FEE	250.00
		REGISTRATION FEE	1000.00
CLASS C	IN-VITRO, GENERAL MEDICAL DEVICE	APPLICATION FEE	500.00
		REGISTRATION FEE	2000.00
CLASS D	IN-VITRO, GENERAL MEDICAL DEVICE	APPLICATION FEE	750.00
		REGISTRATION FEE	3000.00
	GENERAL MEDICAL DEVICE (RULE 13 AND COMBINATION PRODUCT)	APPLICATION FEE	750.00
		REGISTRATION FEE	5000.00

2.2 FILL IN THE APPLICATION FORMS

2.2.1 1.0 ESTABLISHMENT DETAILS



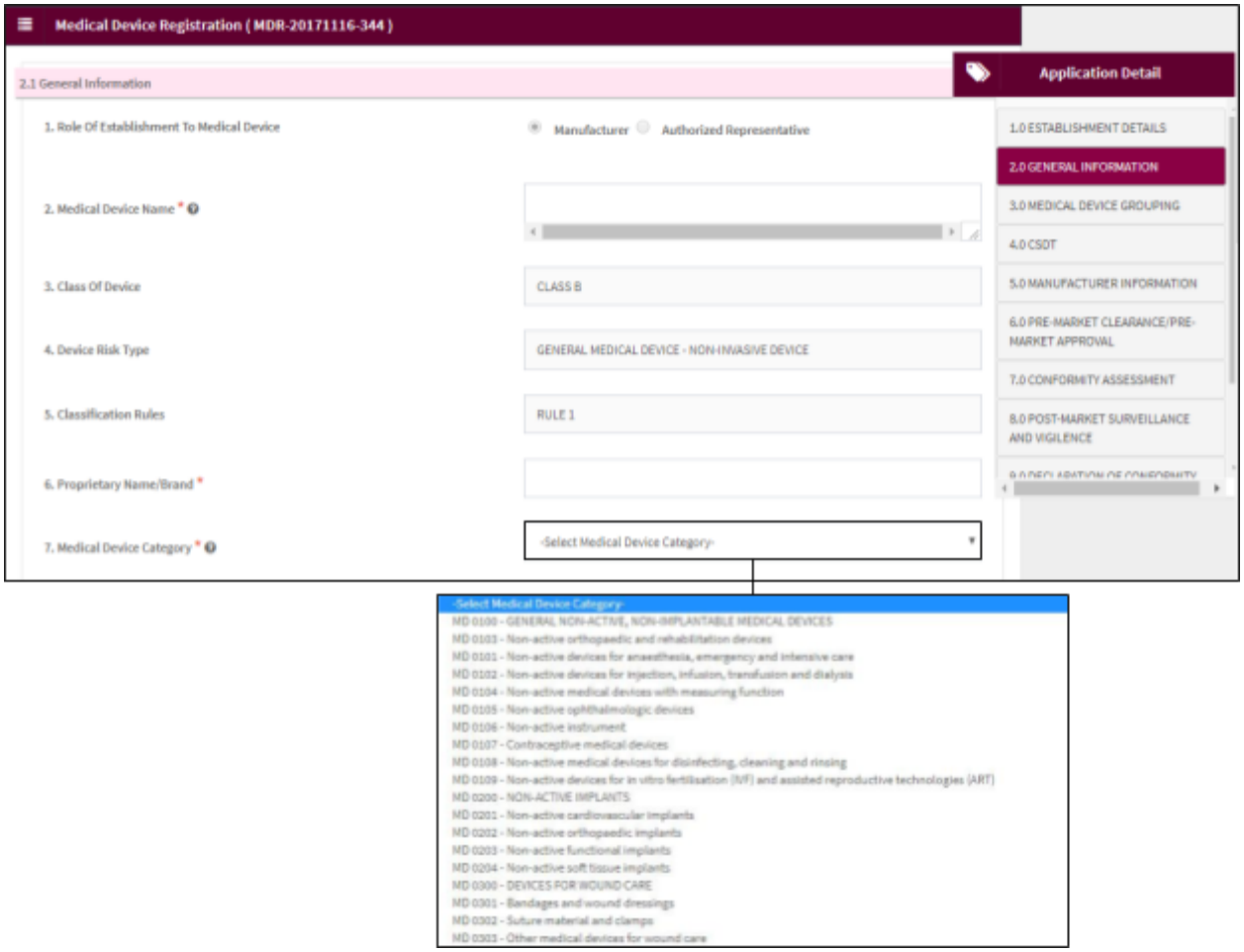
User unable to edit this section, this section only display for user. User click 

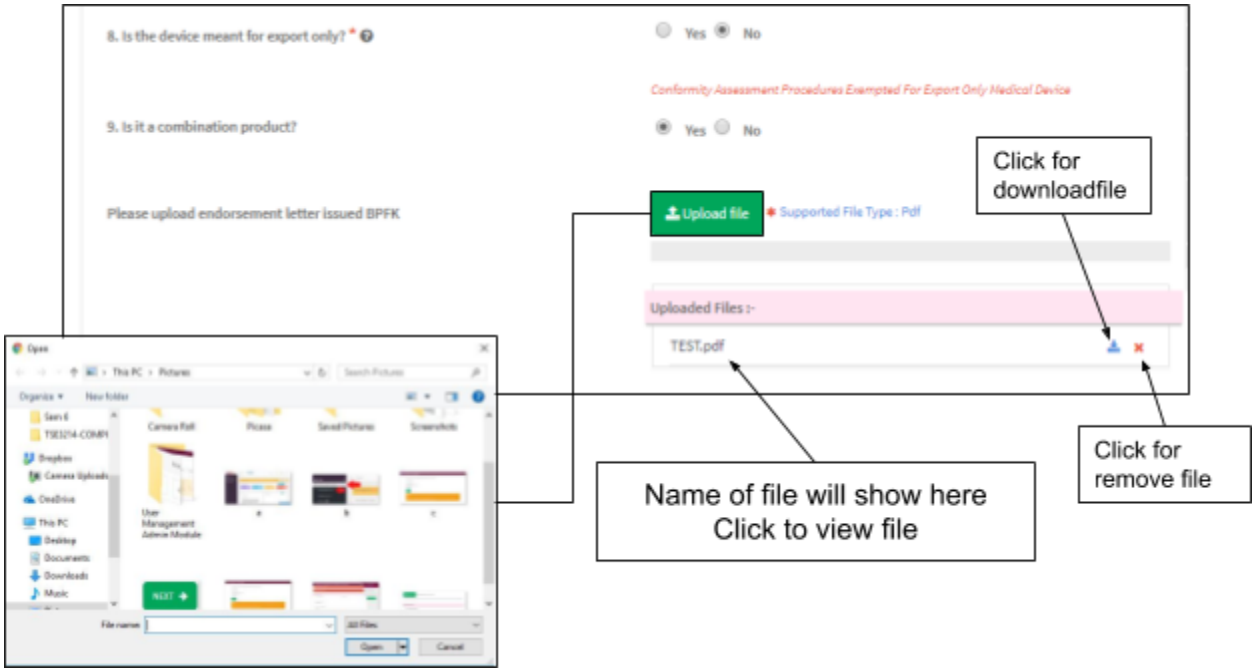
to go to the next step.

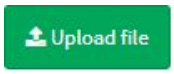
2.2.2 2.0 GENERAL INFORMATION

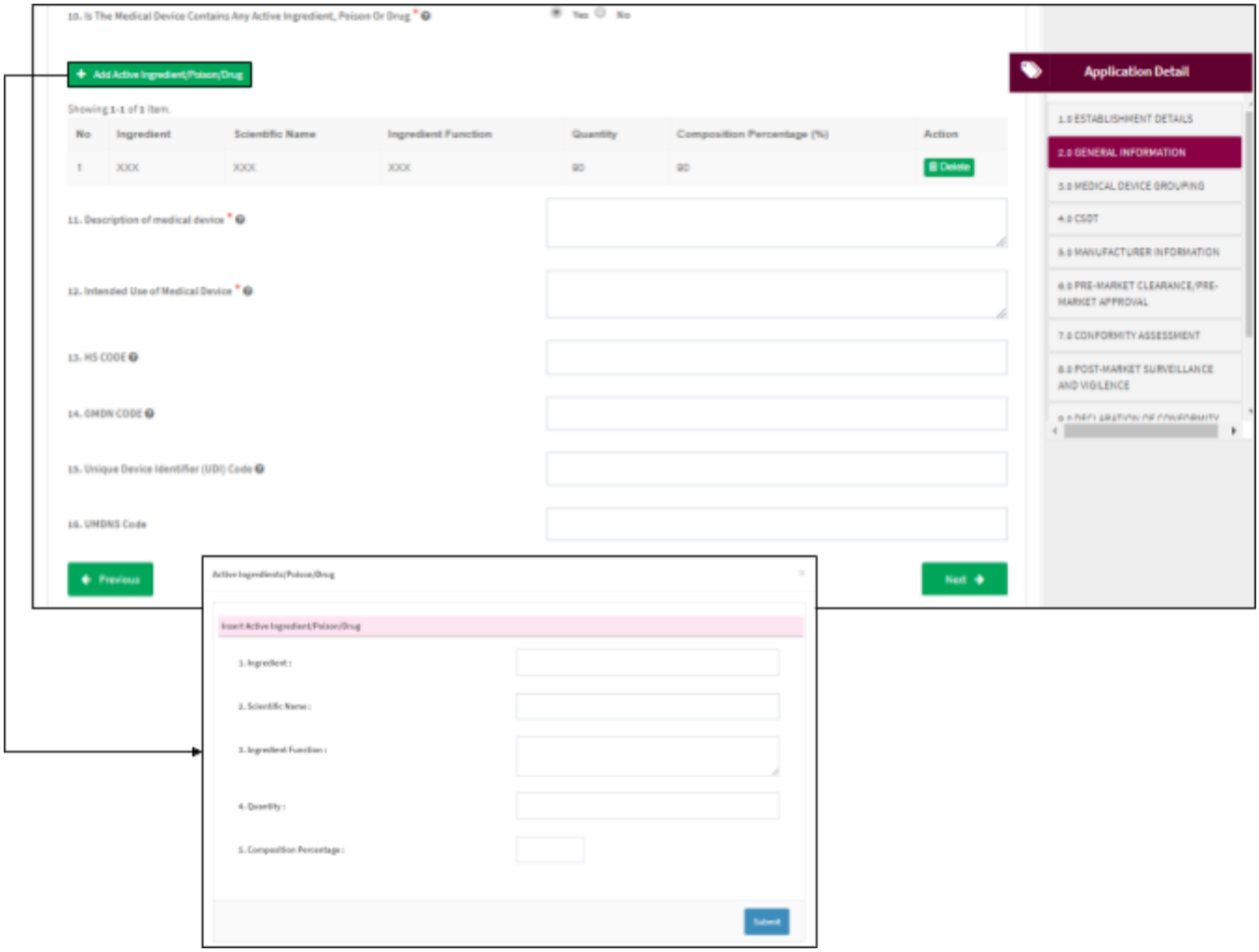
2.2.2.1 GMD APPLICATION

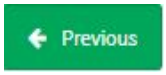
Users need to complete all fields.





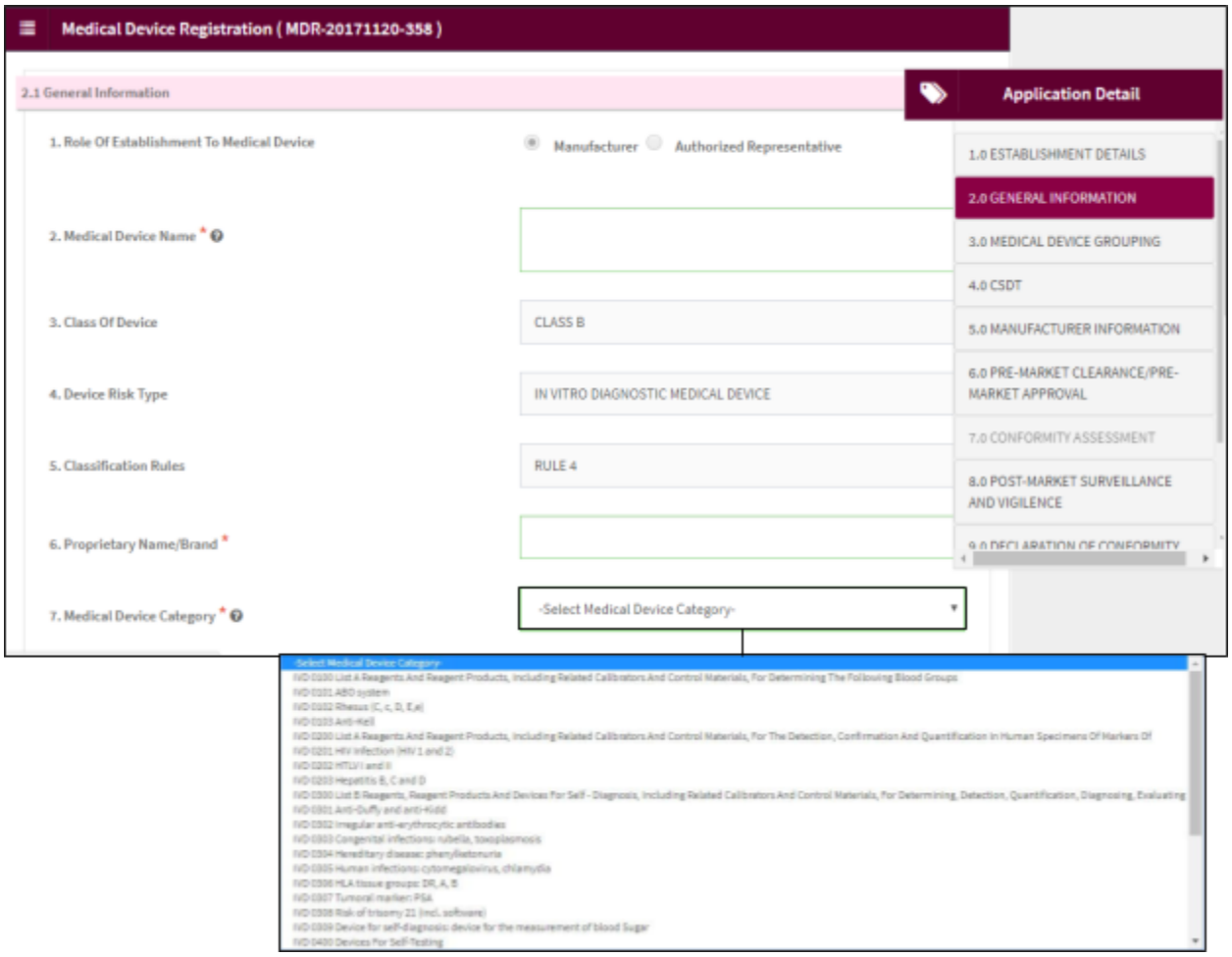
User click  to upload file'. **The file must be pdf format and size not more than 300 MB**.

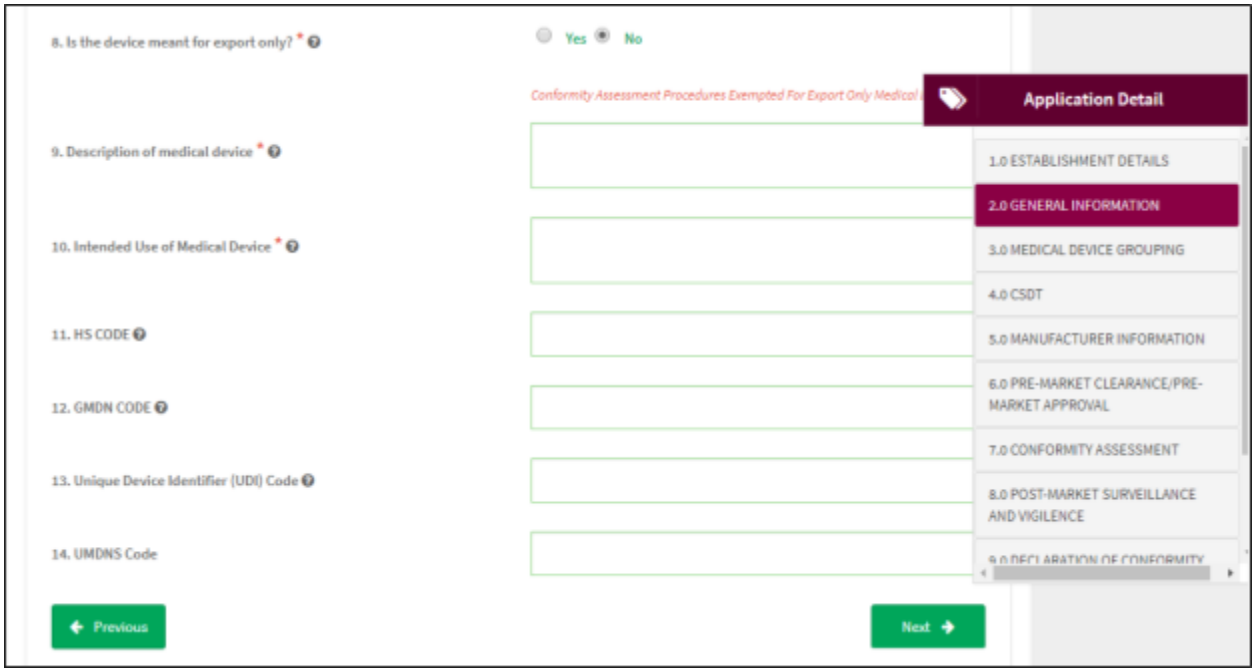


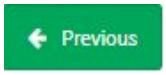
- Click  to add active ingredient/poison/drug details. Then fill the form and then click  .
- Click  to delete data in the table.
- Click  to go to the next section.
- Click  to go to the previous section.

2.2.2.2 IVD APPLICATION

Users need to complete this form



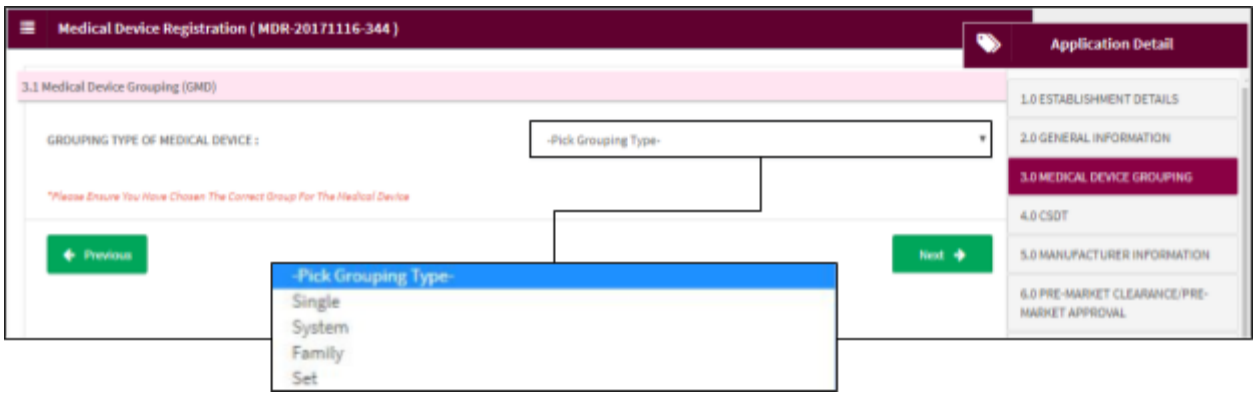


- Click  to go to the next section.
- Click  to go to the previous section.

2.2.3 3.0 MEDICAL DEVICE GROUPING

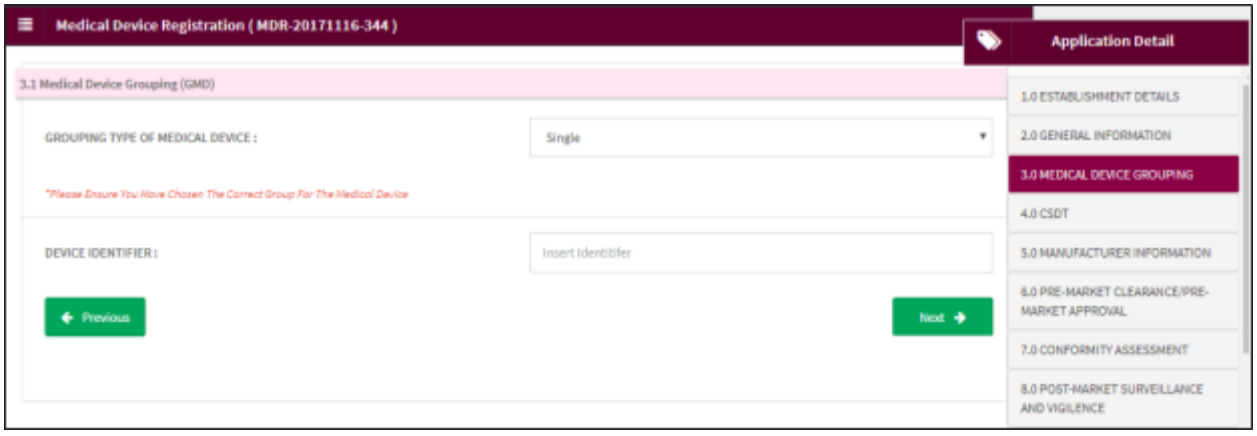
2.2.3.1 GMD APPLICATION

Users have to complete all fields.



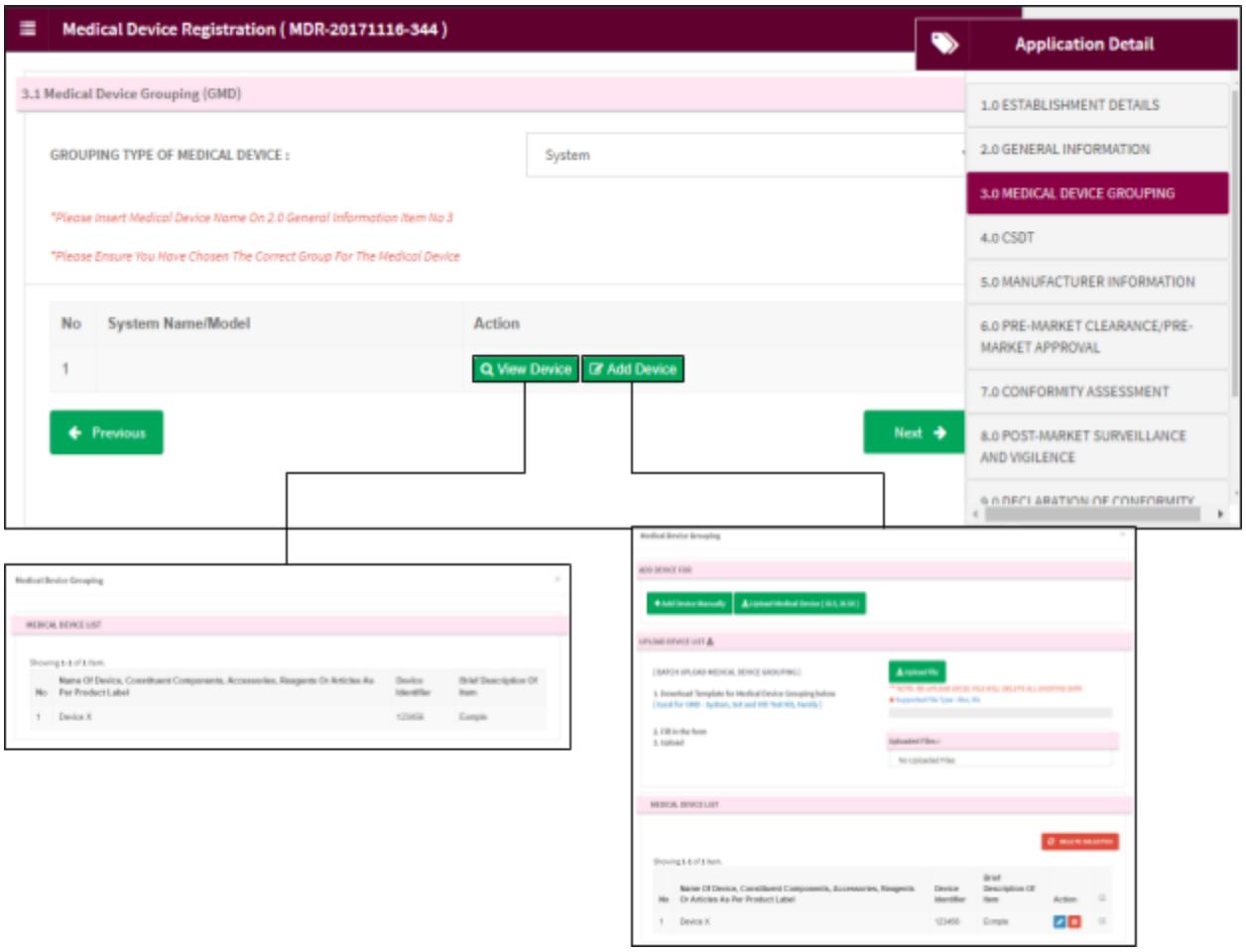
User select 'Single', 'System', 'Family' or 'Set'.

i) Single

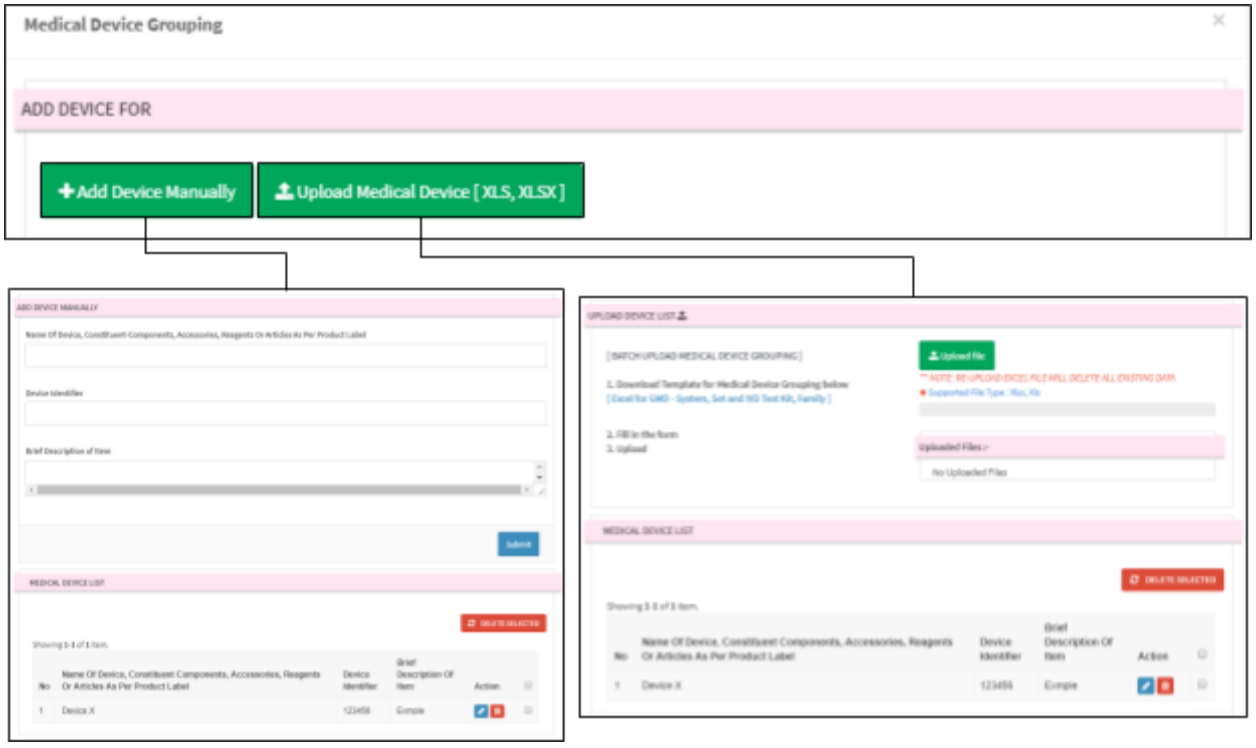


User fill 'DEVICE IDENTIFIER' textbox'. Click Next to go to the next section. Click Previous to go to the previous section.

ii) System



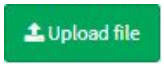
- Click Add Device to add new device. *Medical Device Grouping* field will display.
- Click View Device to view device.



- User click 

, then user have to fill the form and click 

to add device.
- User click 

, user have to upload file. User click 

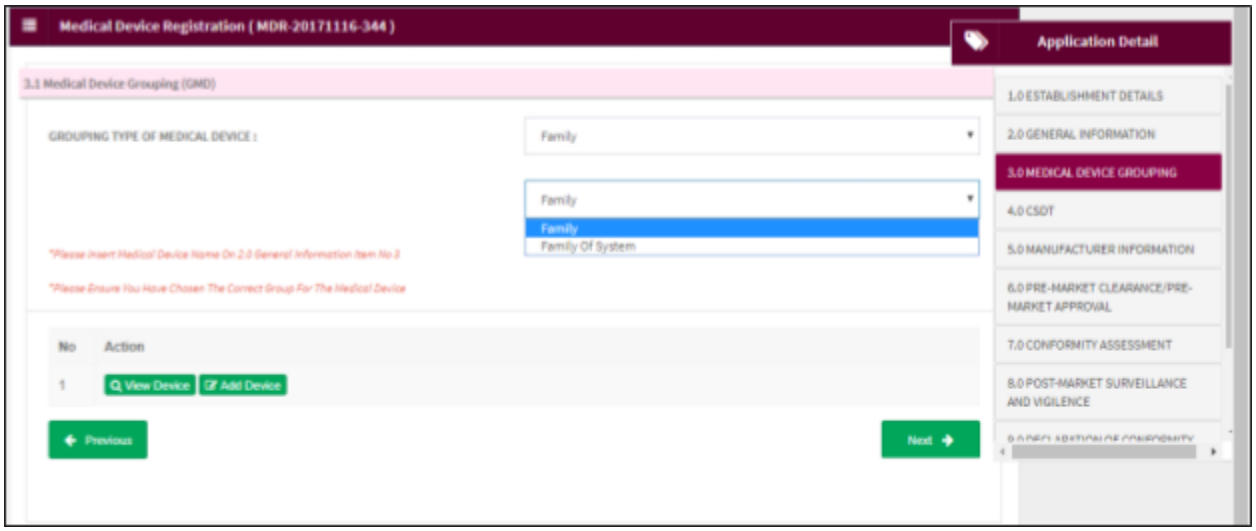
to upload excel file. **The file must be xlsx or xls format.**
-  button for user edit device details.
-  button for user delete device.
- 

button to delete selected data in the table.
- Click 

to go to the next section.
- Click 

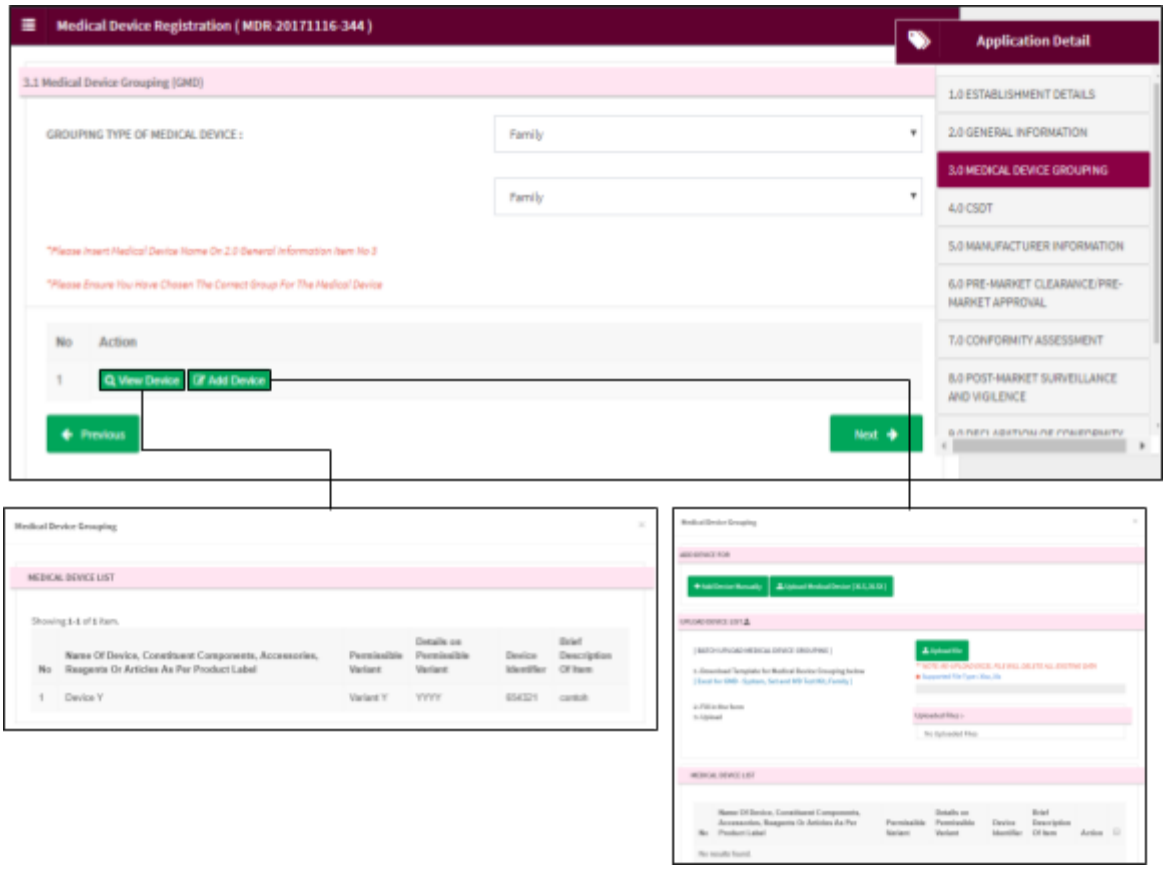
to go to the previous section.

iii) Family

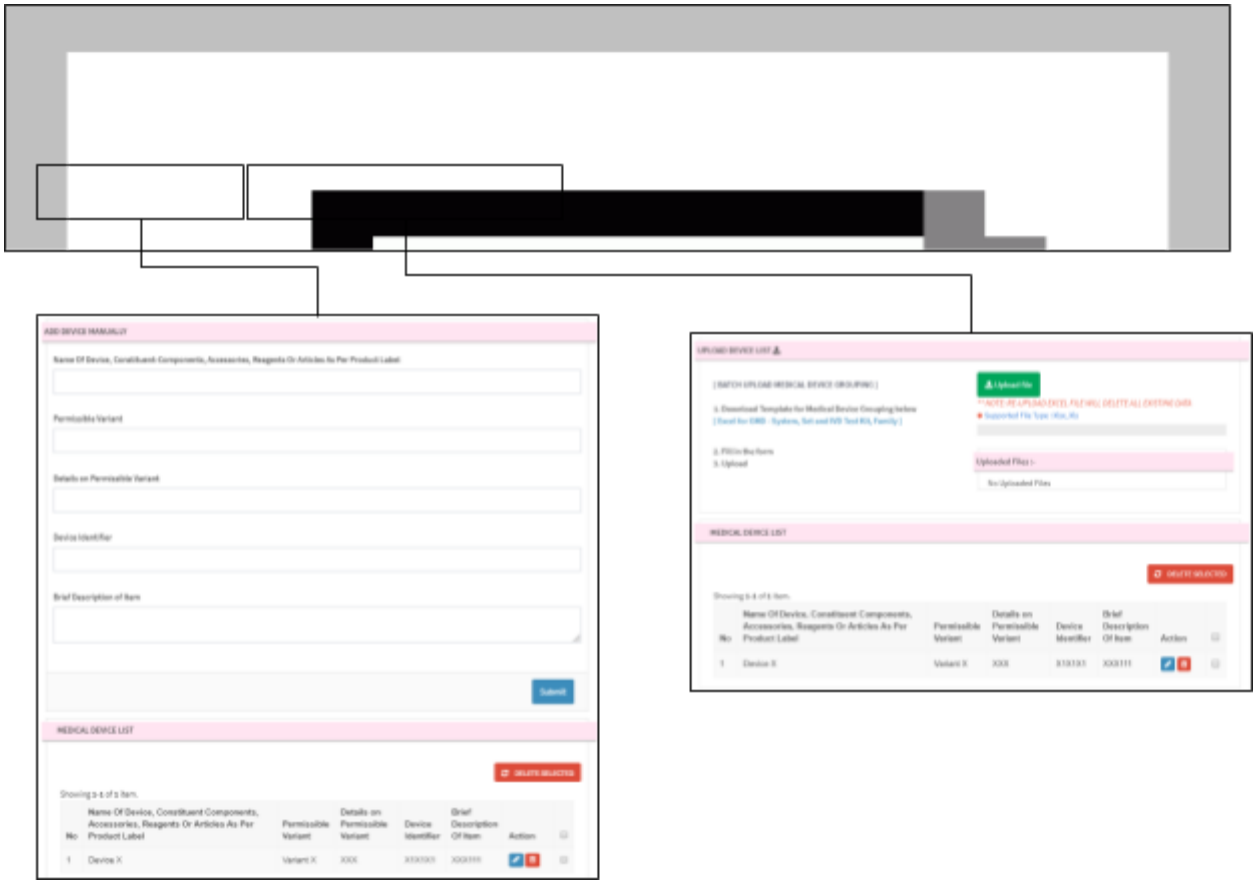


For *GROUPING TYPE OF MEDICAL DEVICE*, user select between 'Family' or 'Family Of System'.

a) Family



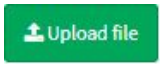
- Click  to add new device. *Medical Device Grouping* field will display.
- Click  to view device.



- User click 

, then user have to fill the form and click 

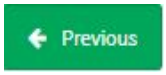
to add device.
- User click 

, user have to upload file. 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.
- 

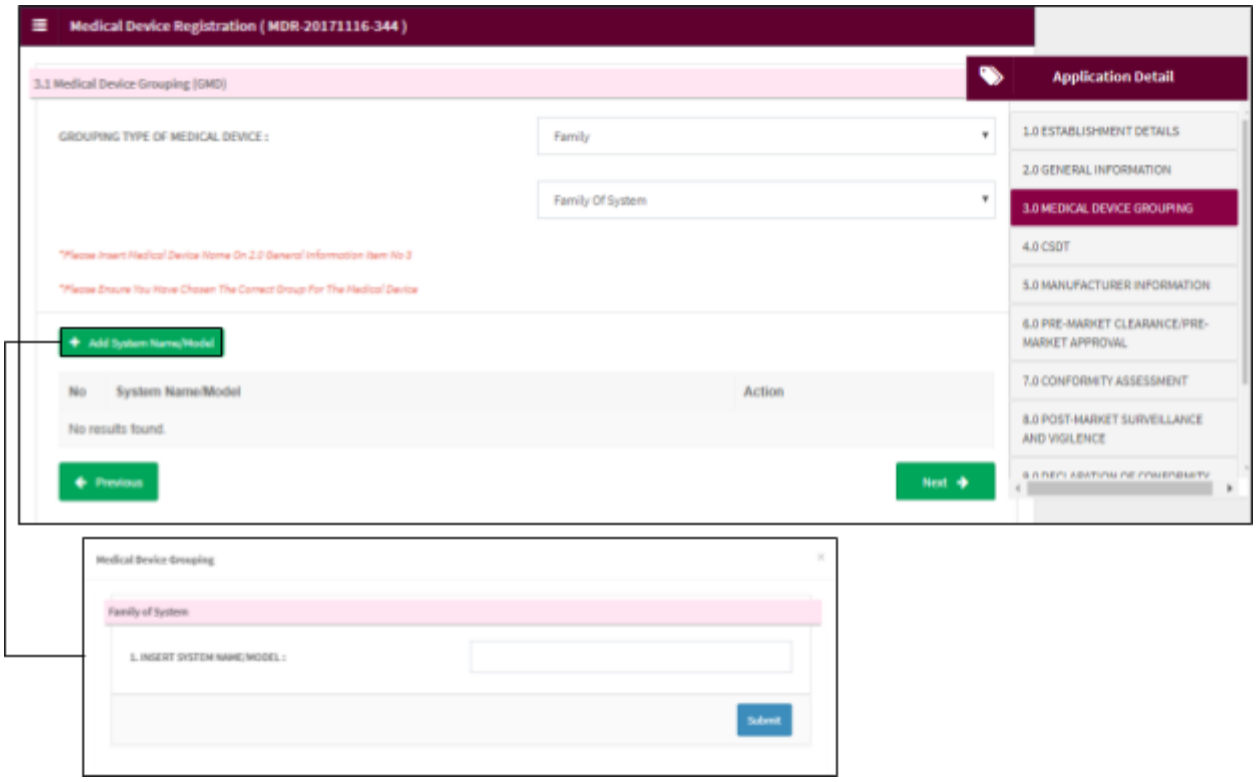
button to delete selected data in the table.
- Click 

to go to the next section.

- Click 

to go to the previous section.

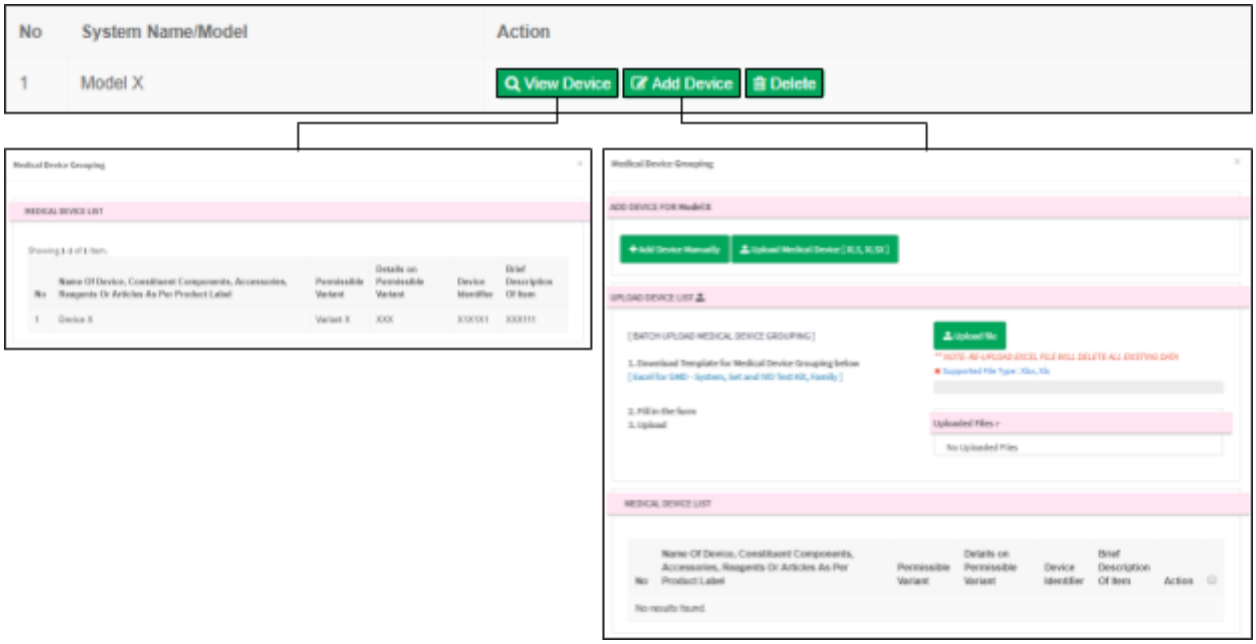
b) Family Of System



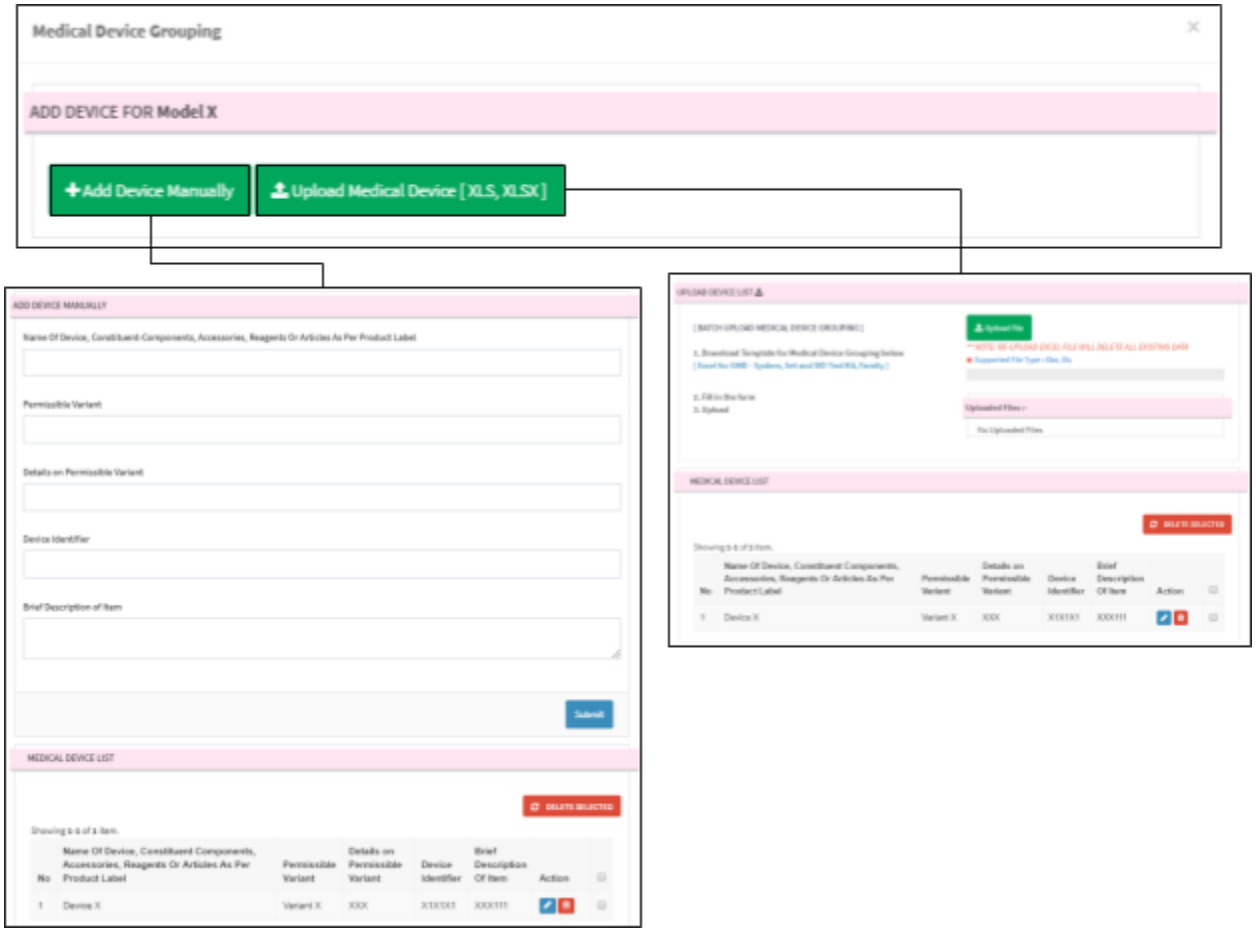
Click 

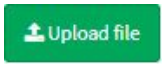
to new system name or model. User fill the form and click 

.



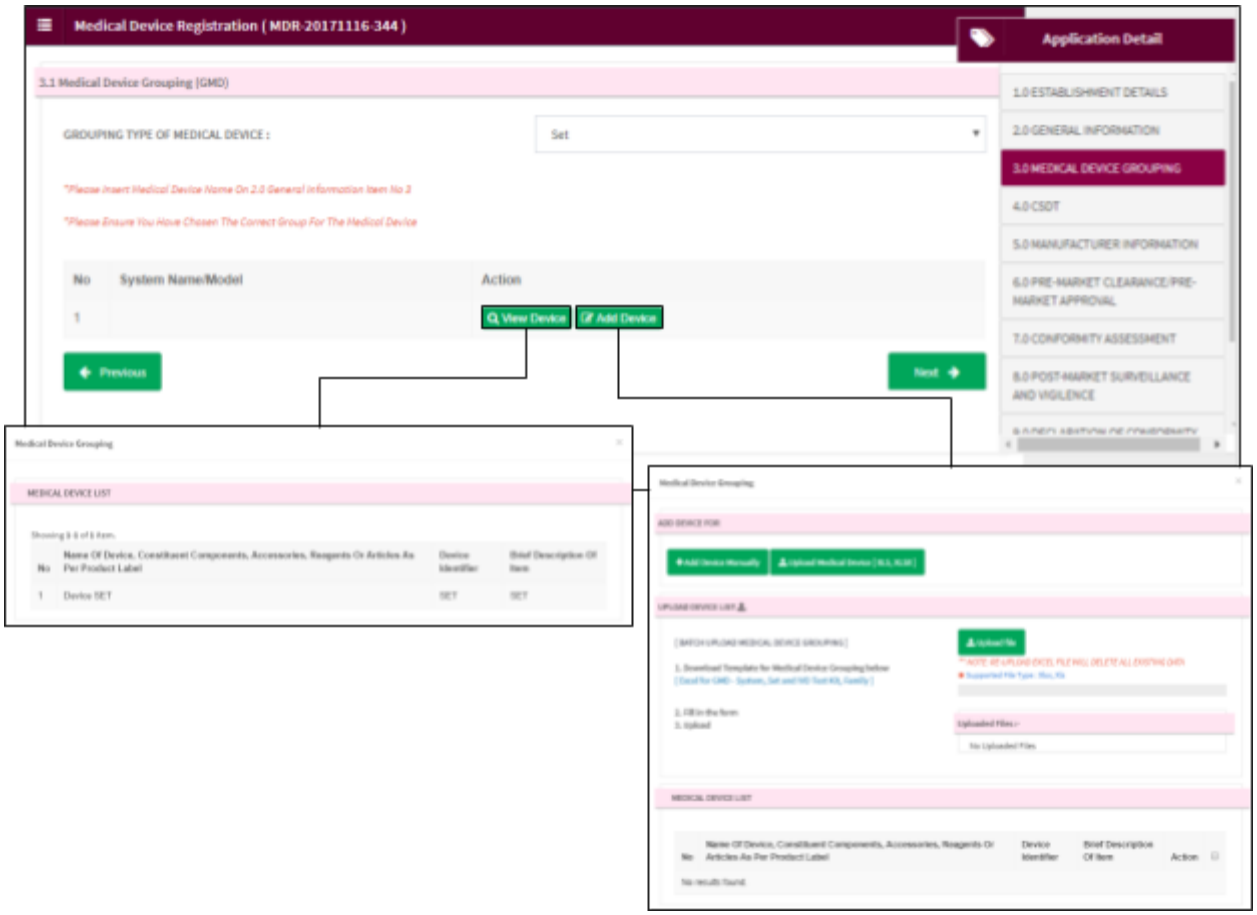
- Click  to add new device.
- Click  to view device.
- Click  to delete data in the table.



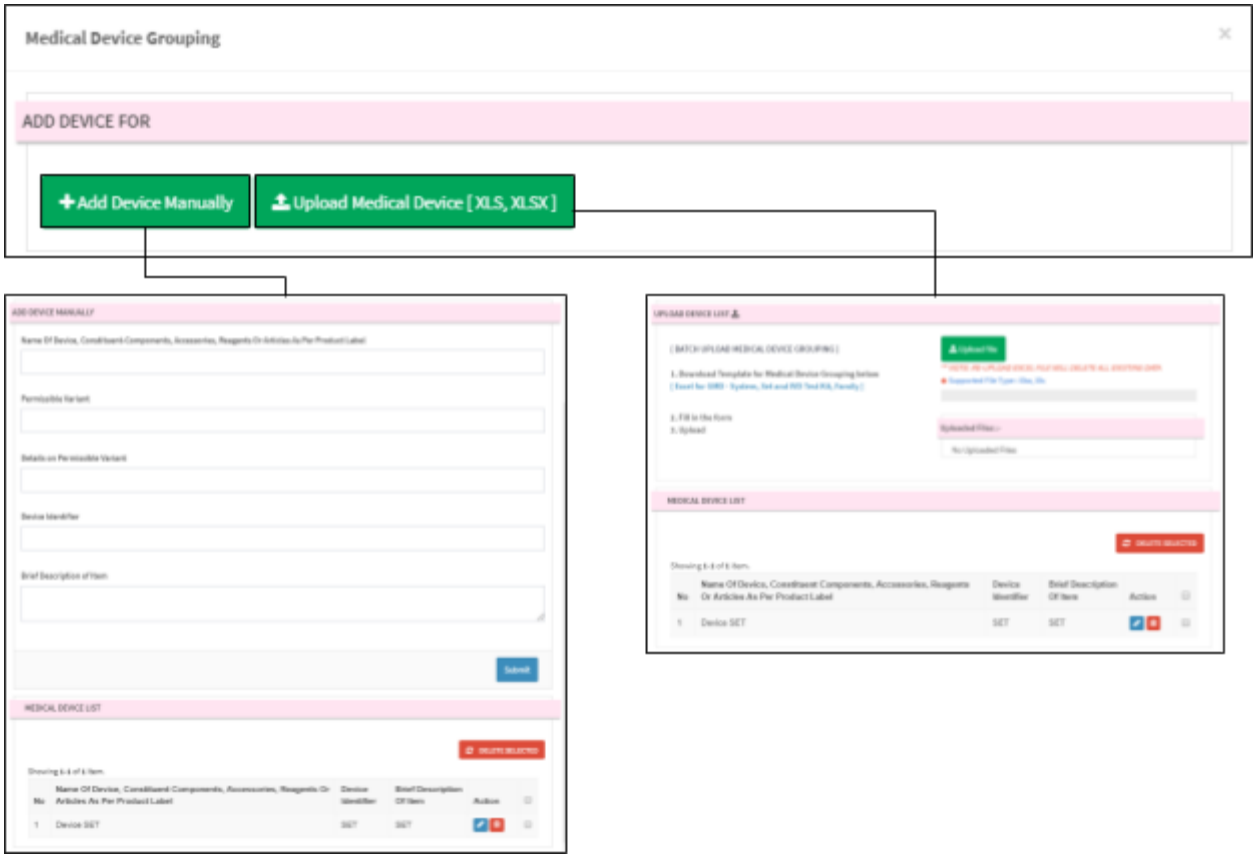
- User click  , then user have to fill the form and click  to add device.
- User click  , user have to upload file. User click  to upload excel file. **The file must be xlsx or xls format.**
-  button for user edit device details.
-  button for user delete device.
-  button to delete selected data in the table.
- Click  to go to the next section.

- Click Previous to go to the previous section.

iv) Set



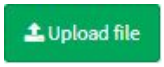
- Click Add Device to add new device.
- Click View Device to view device.



- User click 

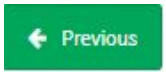
, then user have to fill the form and click 

to add device.
- User click 

, user have to upload file. User click 

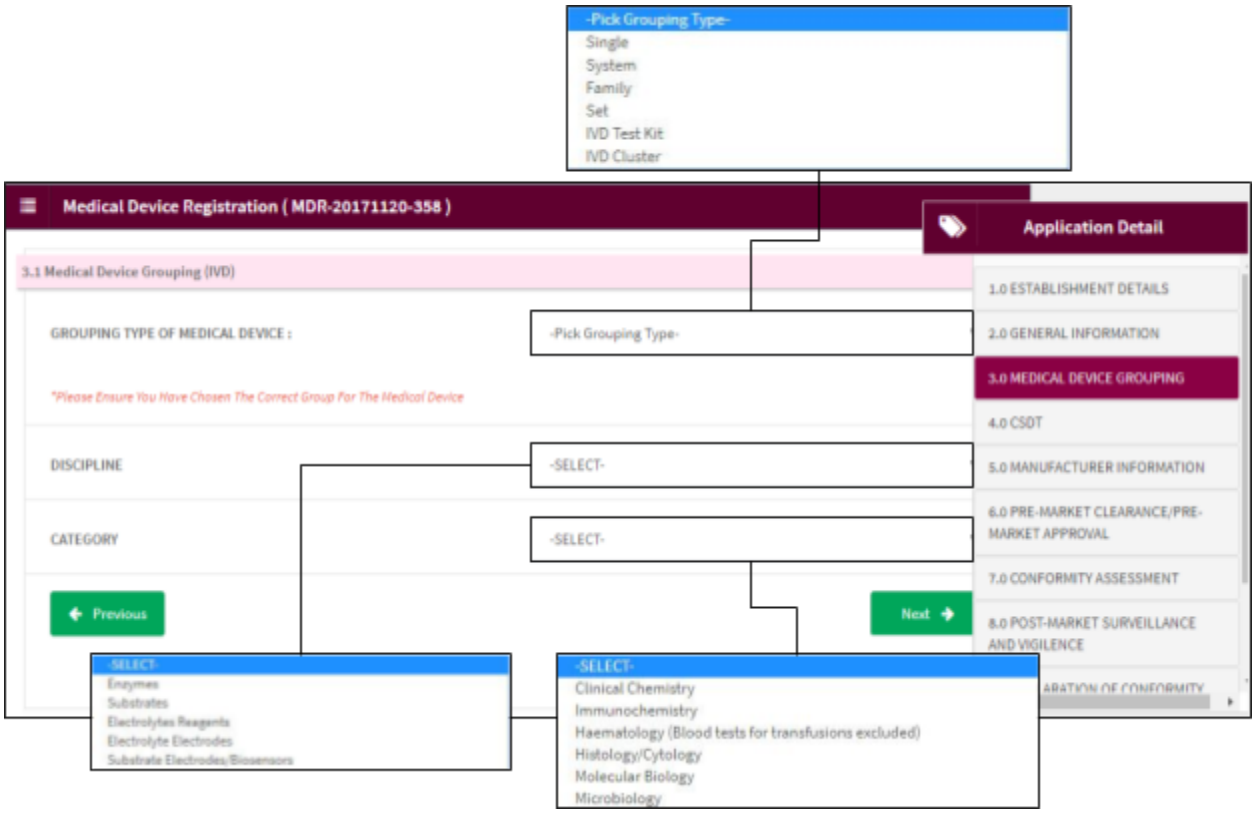
to upload excel file. **The file must be xlsx or xls format.**
-  button for user edit device details.
-  button for user delete device.
- 

button to delete selected data in the table.
- Click 

to go to the next section.
- Click 

to go to the previous section.

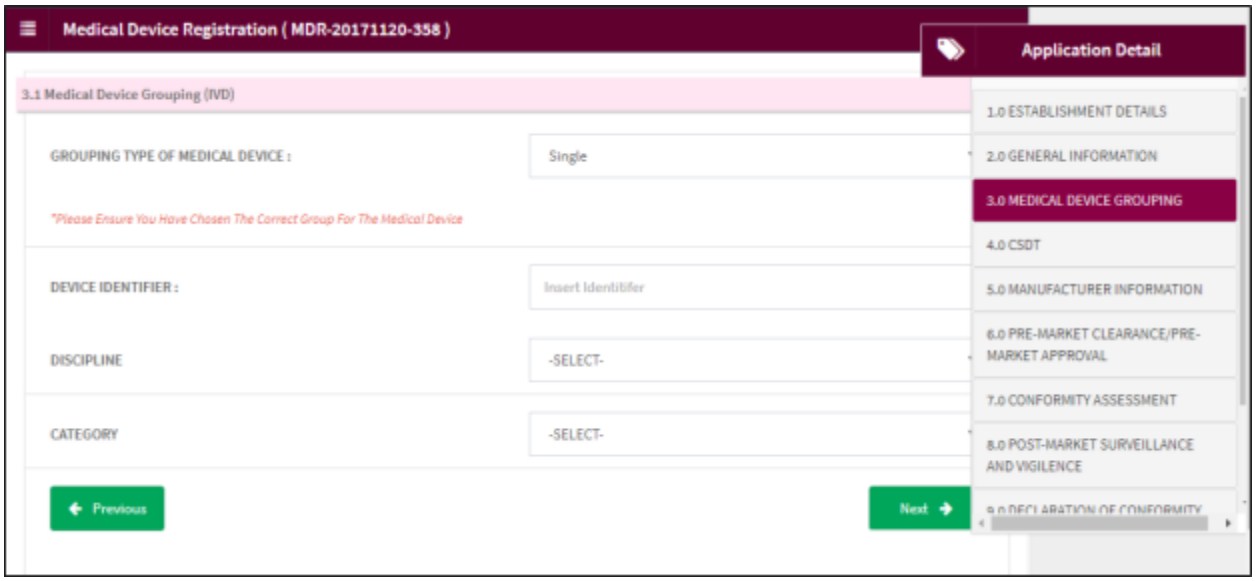
2.2.3.2 IVD APPLICATION



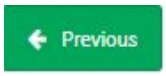
User select from ‘Single’, ’System’, ‘Family’, ‘Set’, ‘IVD Test Kit’ or ‘IVD Cluster’.

For IVD application, there to additional question, ‘DISCIPLINE’ and ‘CATEGORY’. Data from 'CATEGORY' will change according to the selected data in 'DISCIPLINE'.

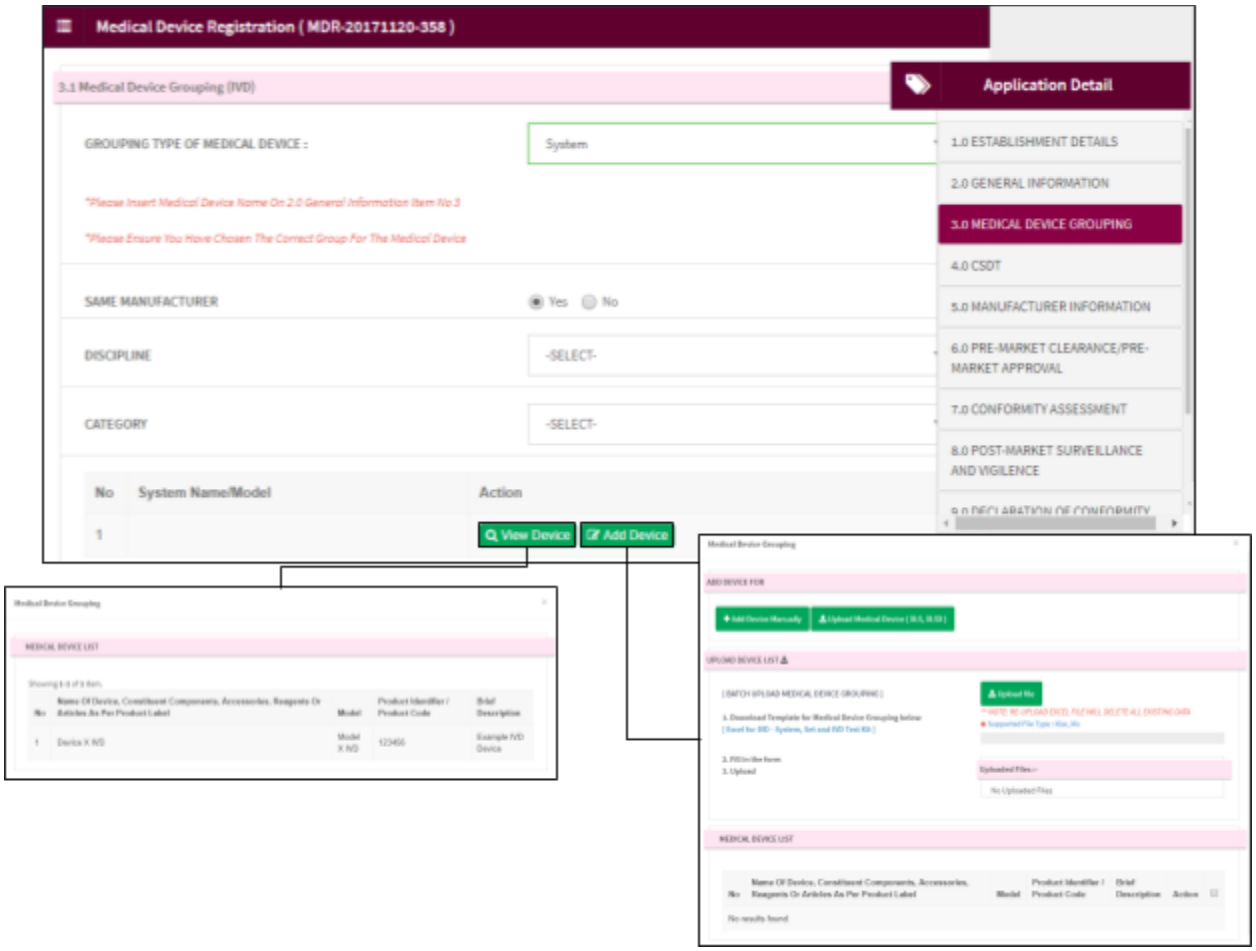
i) Single



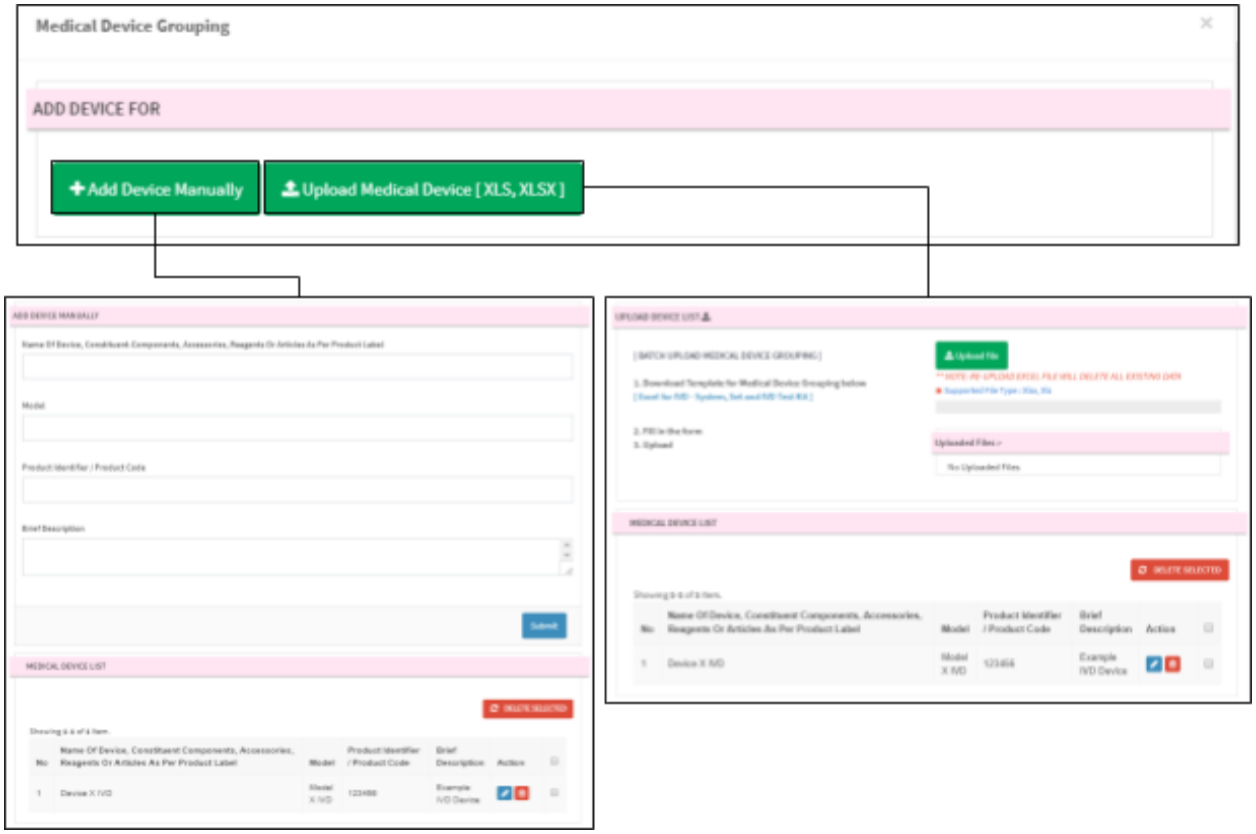
User complete Device *IDENTIFIER, DISCIPLINE* and *CATEGORY* filed.

- Click  to go to the next section.
- Click  to go to the previous section.

ii) System



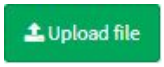
- Click Add Device to add new device.
- Click View Device to view device.



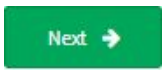
- User click 

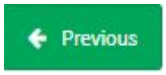
, then user have to fill the form and click 

to add device.
- User click 

, user have to upload file. User click 

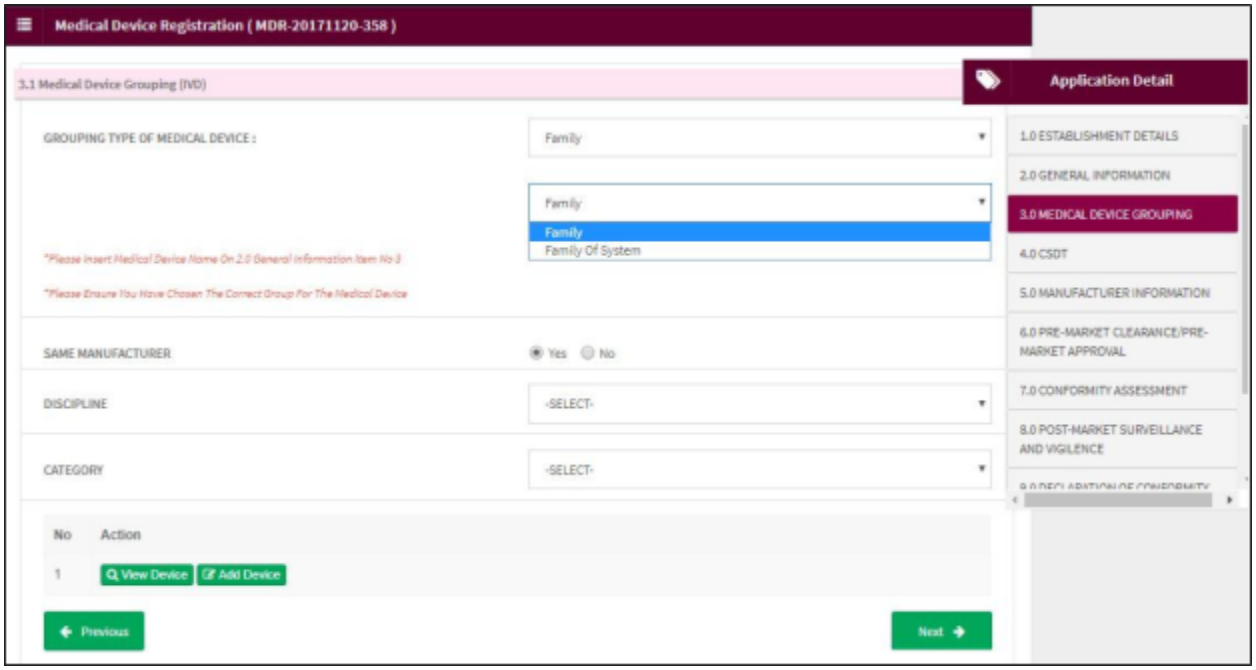
to upload excel file. **The file must be xlsx or xls format.**
-  button for user edit device details.
-  button for user delete device.
- 

button to delete selected data in the table.
- Click 

to go to the next section.
- Click 

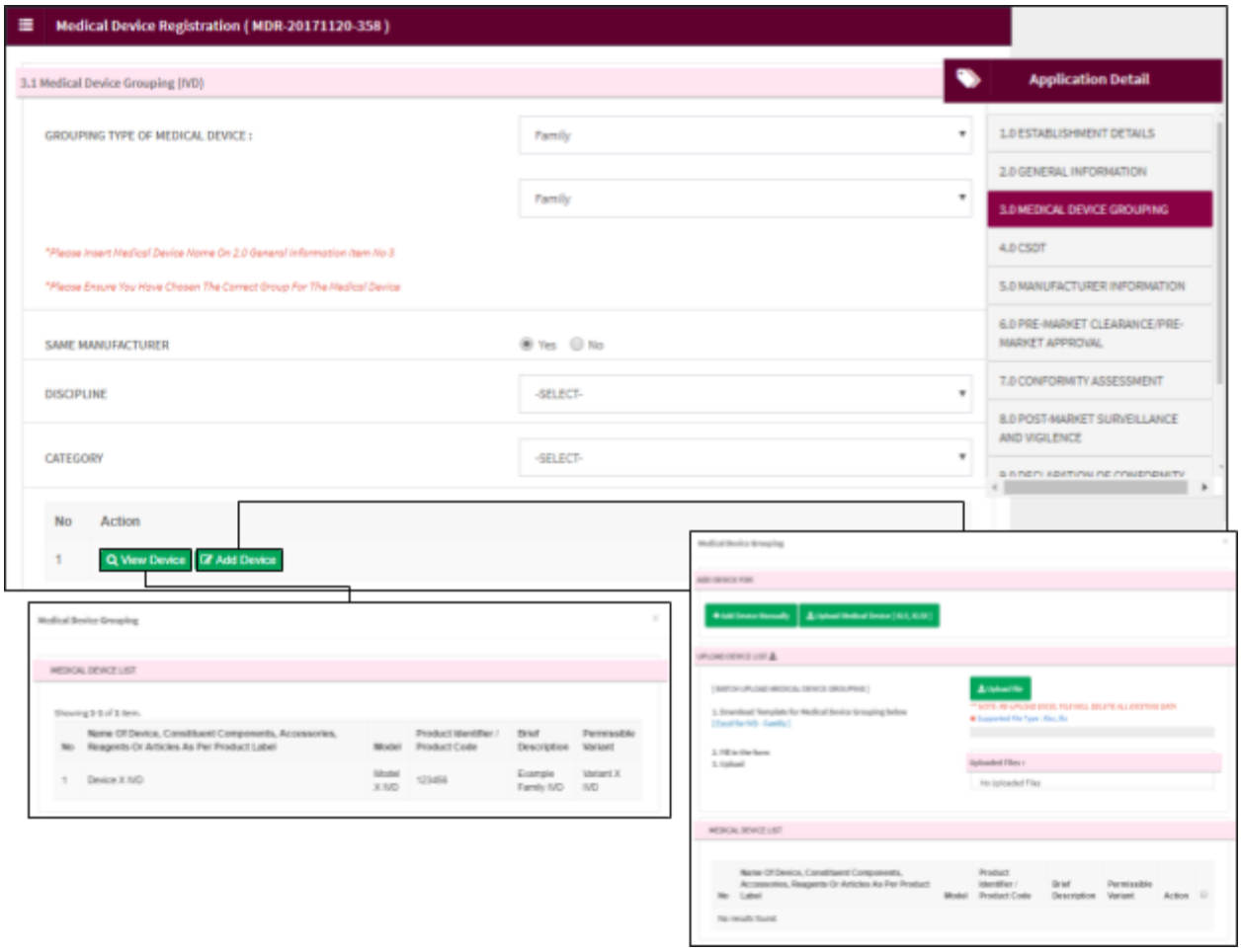
to go to the previous section.

iii) Family

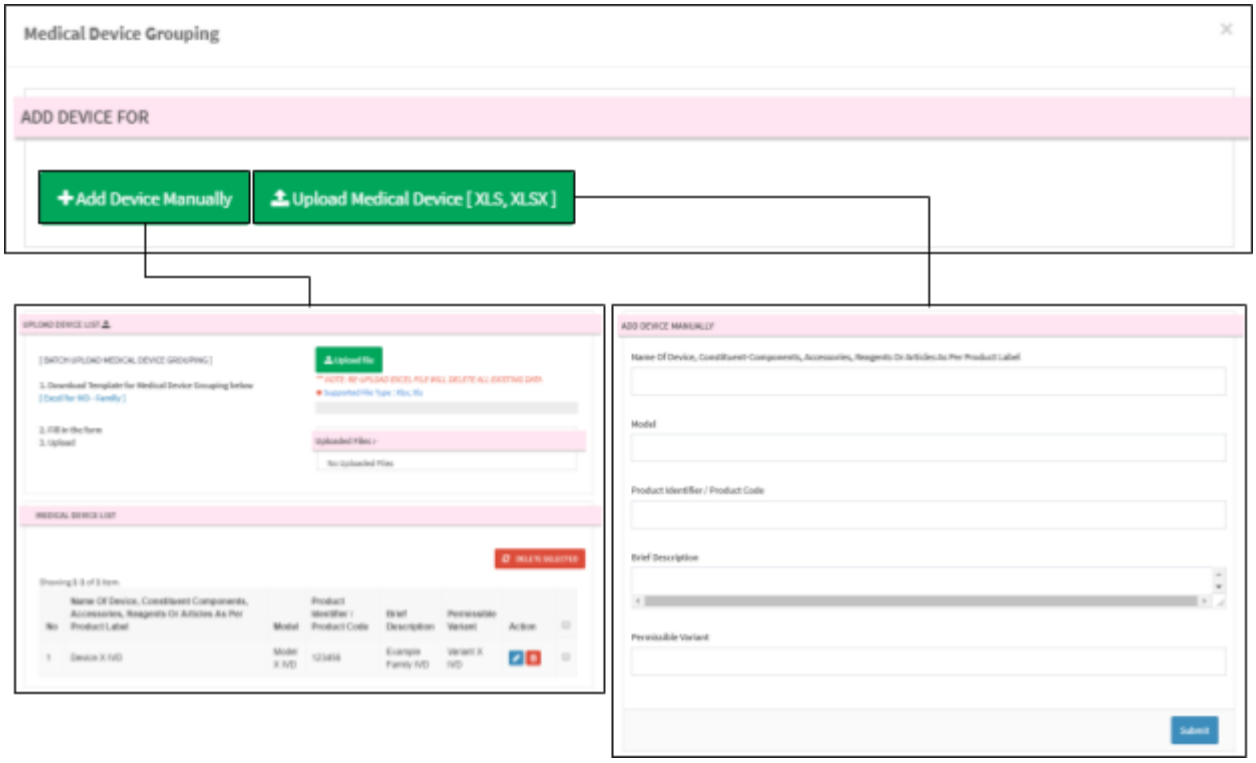


Additional drop text box will appear, user select between ‘Family’ or ‘Family Of System’.

a) Family



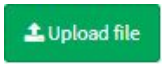
- Click  to add new device.
- Click  to view device.



- User click 

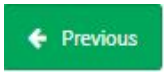
, then user have to fill the form and click 

to add device.
- User click 

, user have to upload file. User click 

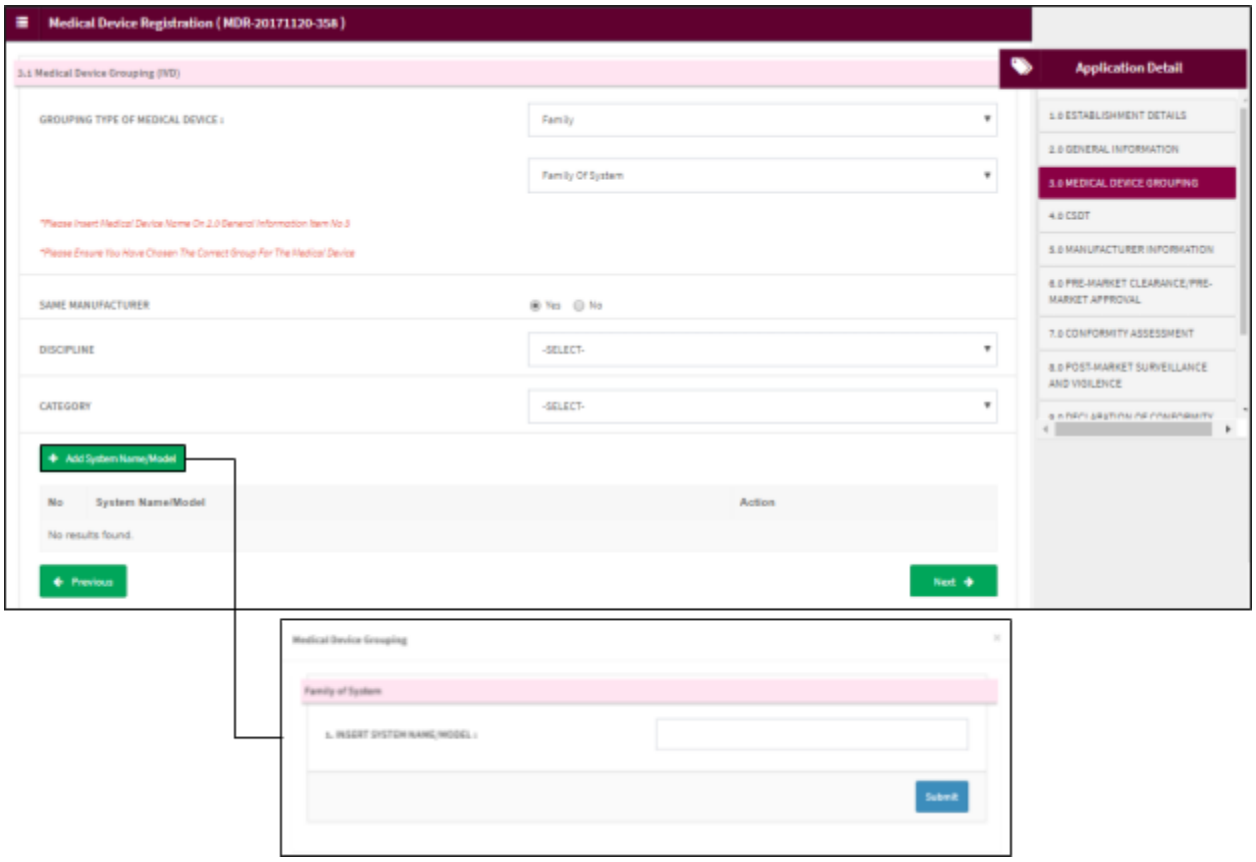
to upload excel file. **The file must be xlsx or xls format.**
-  button for user edit device details.
-  button for user delete device.
- 

button to delete selected data in the table.
- Click 

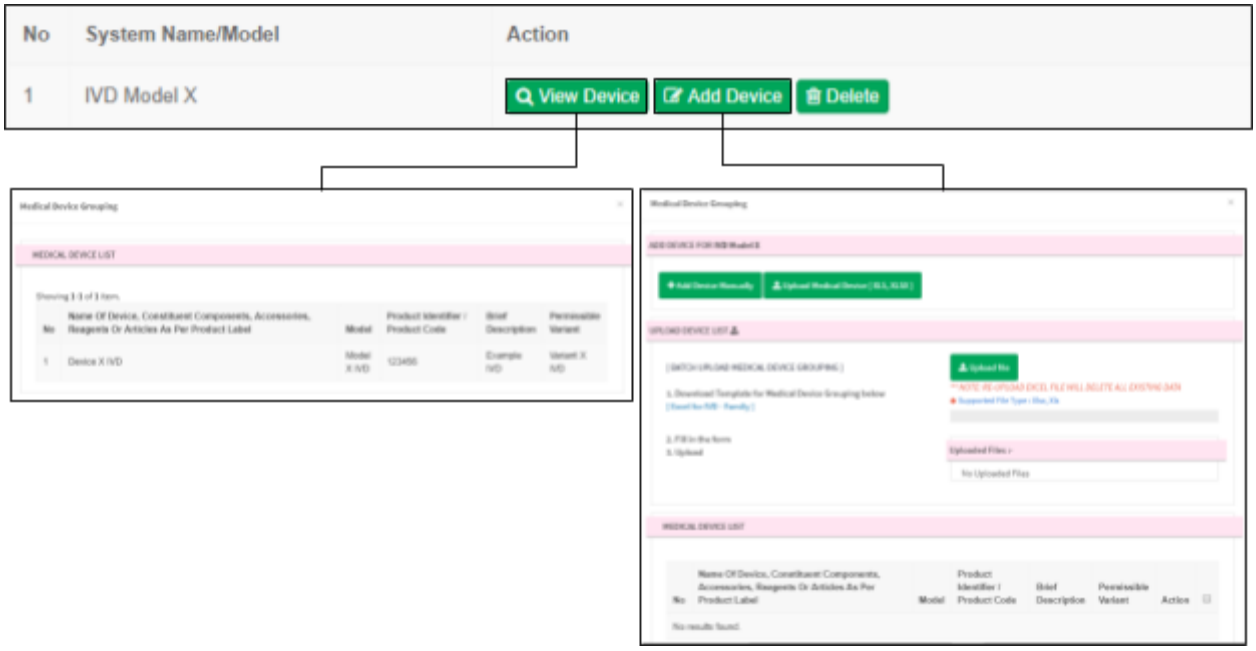
to go to the next section.
- Click 

to go to the previous section.

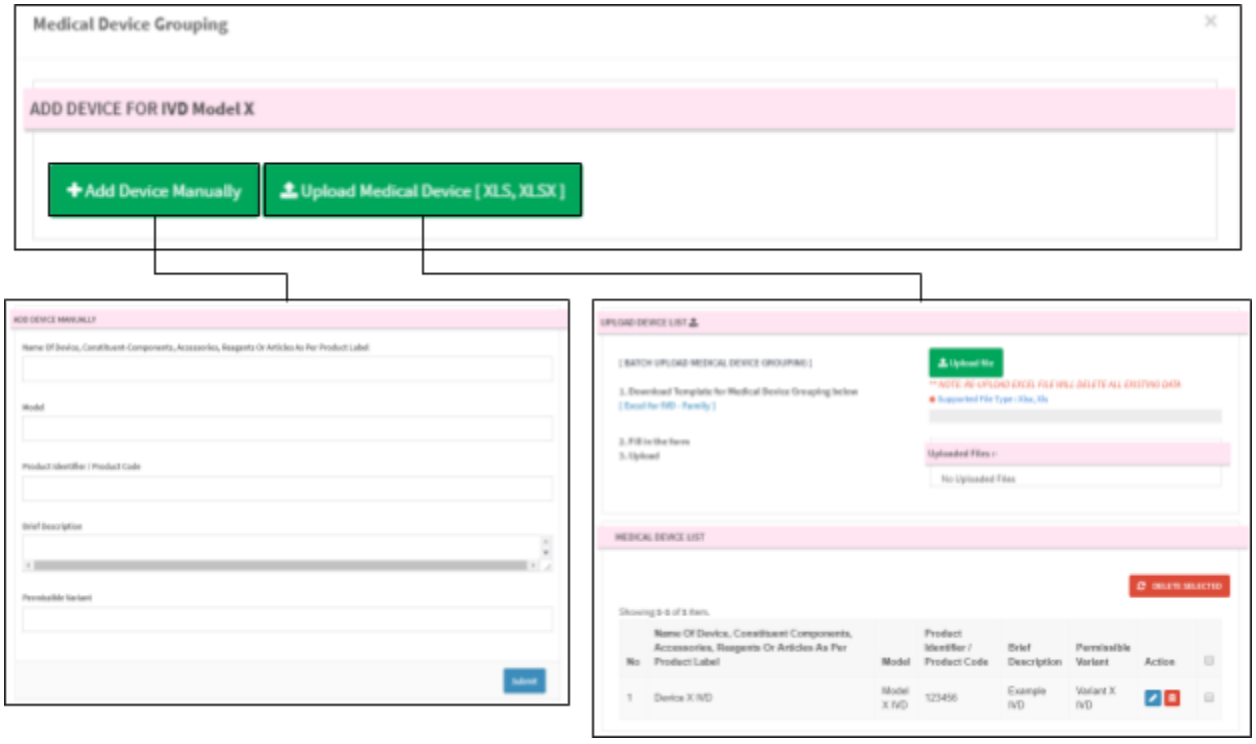
b) System



- Click  to new system name or model. Fill the form and then click  .



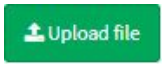
- Click  to add new device.
- Click  to view device.
- Click  to delete data in the table.



- User click 

, then user have to fill the form and click 

to add device.
- User click 

, user have to upload file. User click 

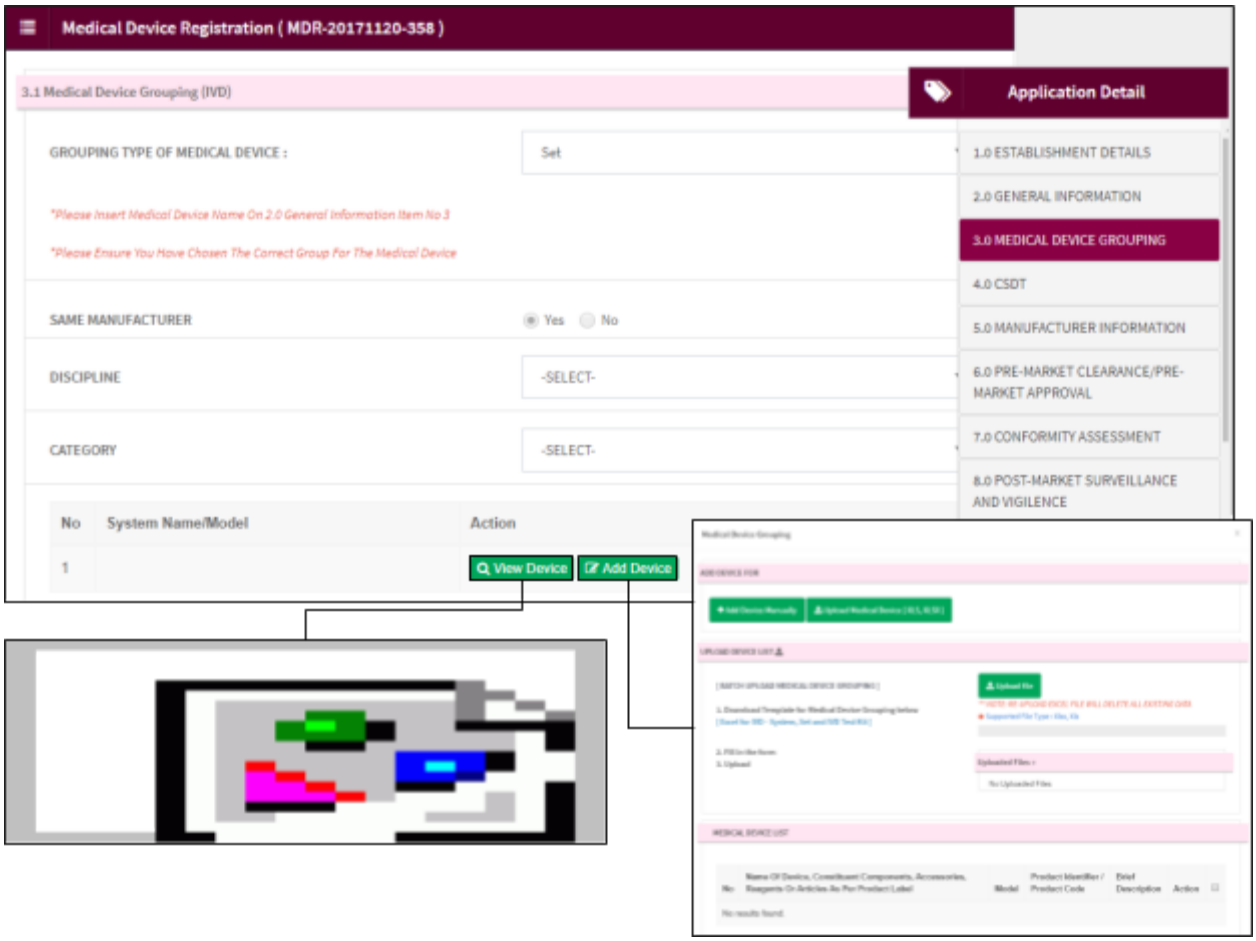
to upload excel file. **The file must be xlsx or xls format.**
-  button for user edit device details.
-  button for user delete device.
- 

button to delete selected data in the table.
- Click 

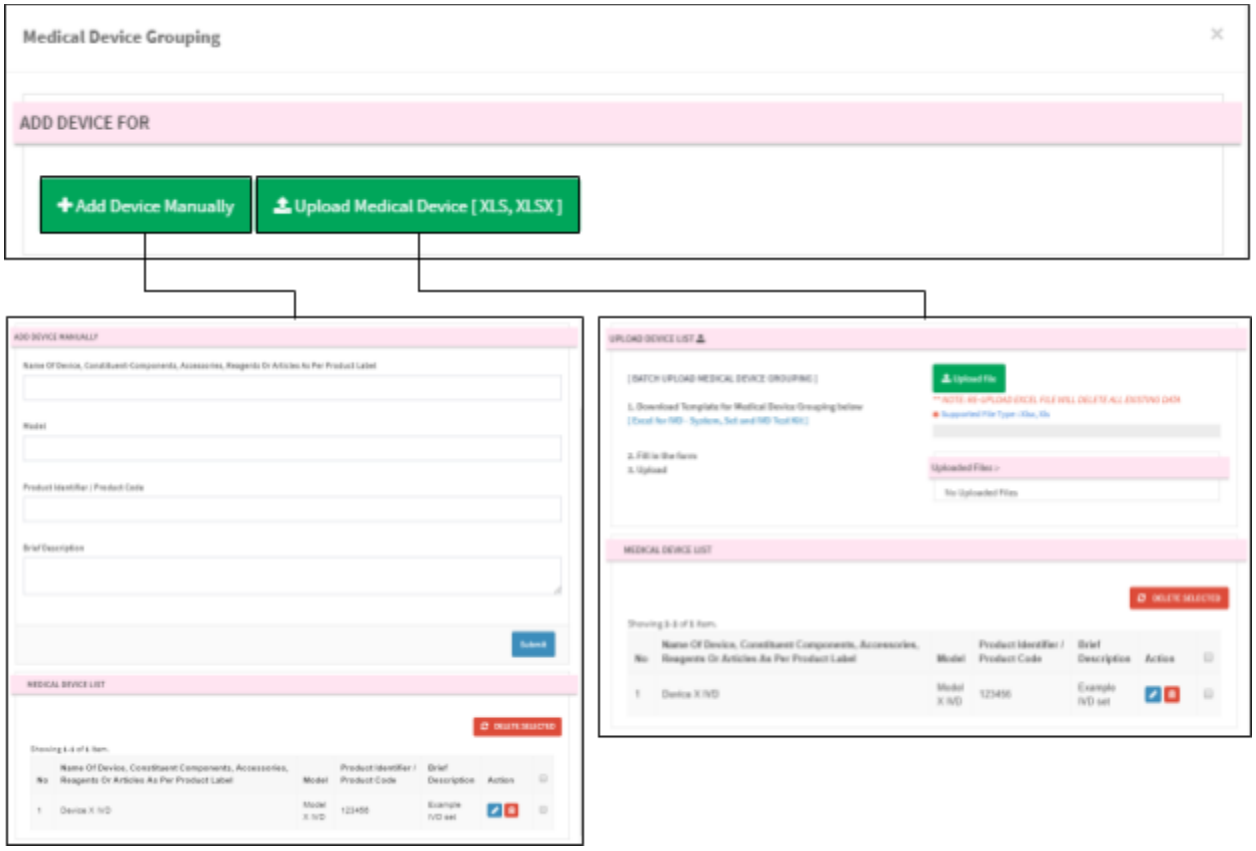
to go to the next section.
- Click 

to go to the previous section.

iv) Set



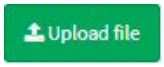
- Click Add Device to add new device.
- Click View Device to view device.



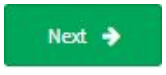
- User click 

, then user have to fill the form and click 

to add device.
- User click 

, user have to upload file. User click 

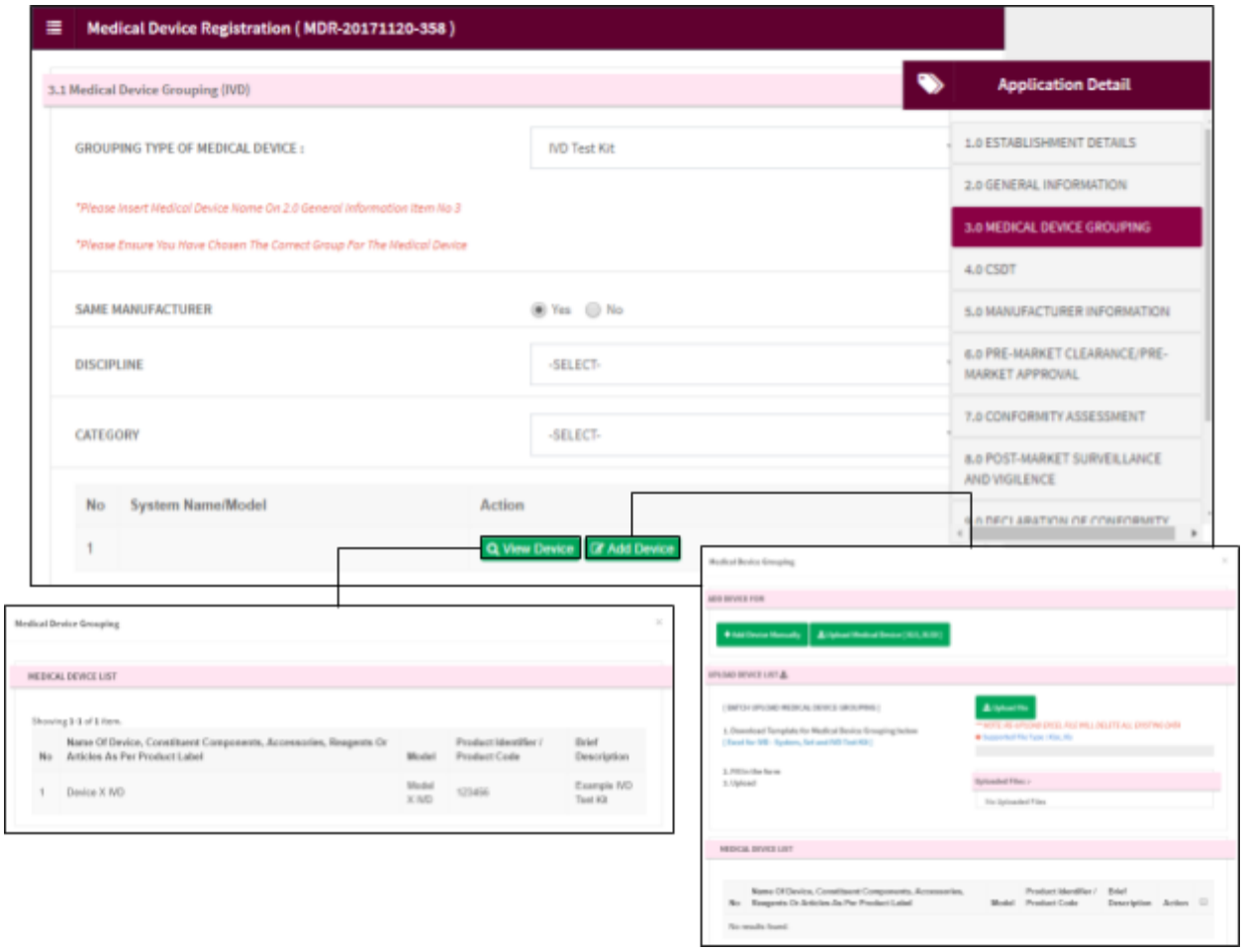
to upload excel file. **The file must be xlsx or xls format.**
-  button for user edit device details.
-  button for user delete device.
- 

button to delete selected data in the table.
- Click 

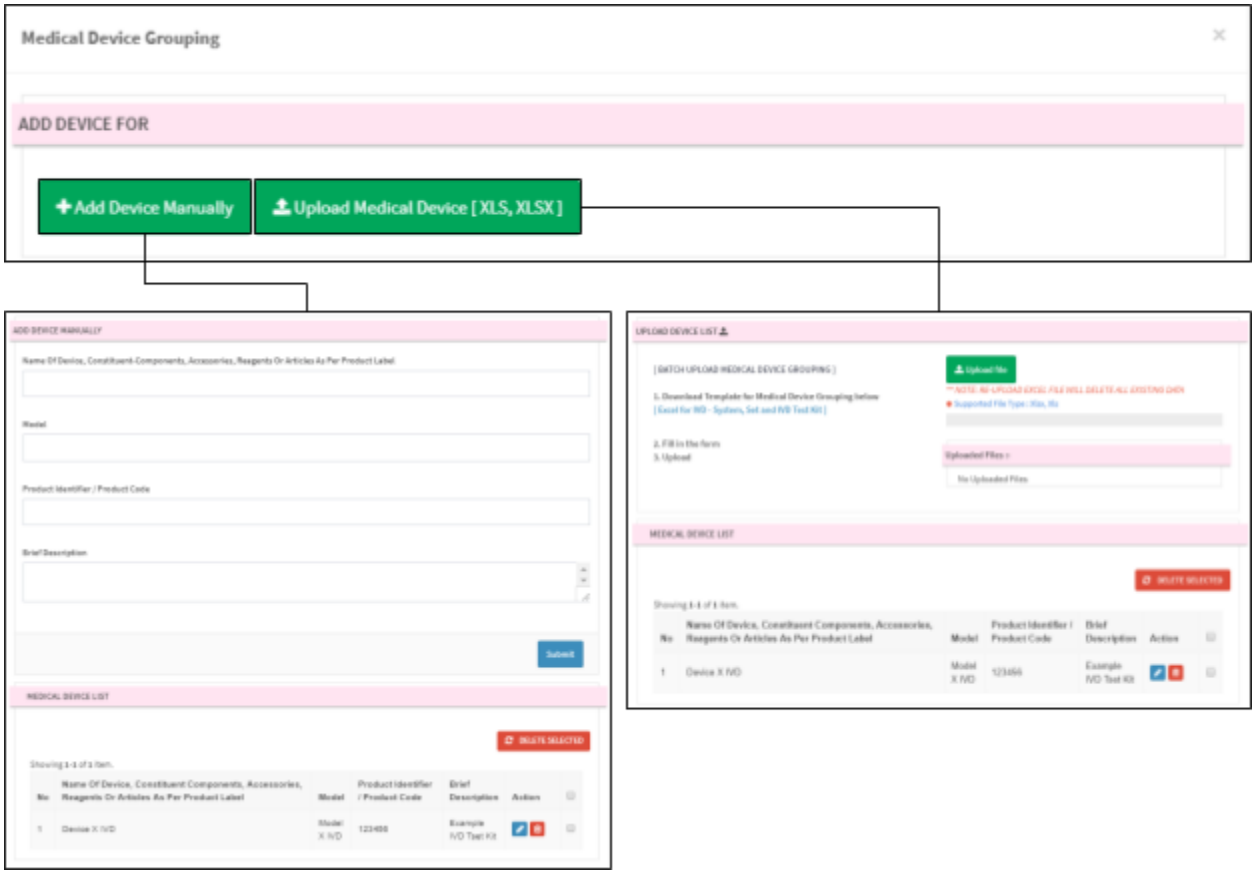
to go to the next section.
- Click 

to go to the previous section.

v) IVD Test Kit



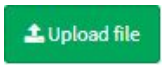
- Click Add Device to add new device.
- Click View Device to view device.



- User click 

, then user have to fill the form and click 

to add device.
- User click 

, user have to upload file. User click 

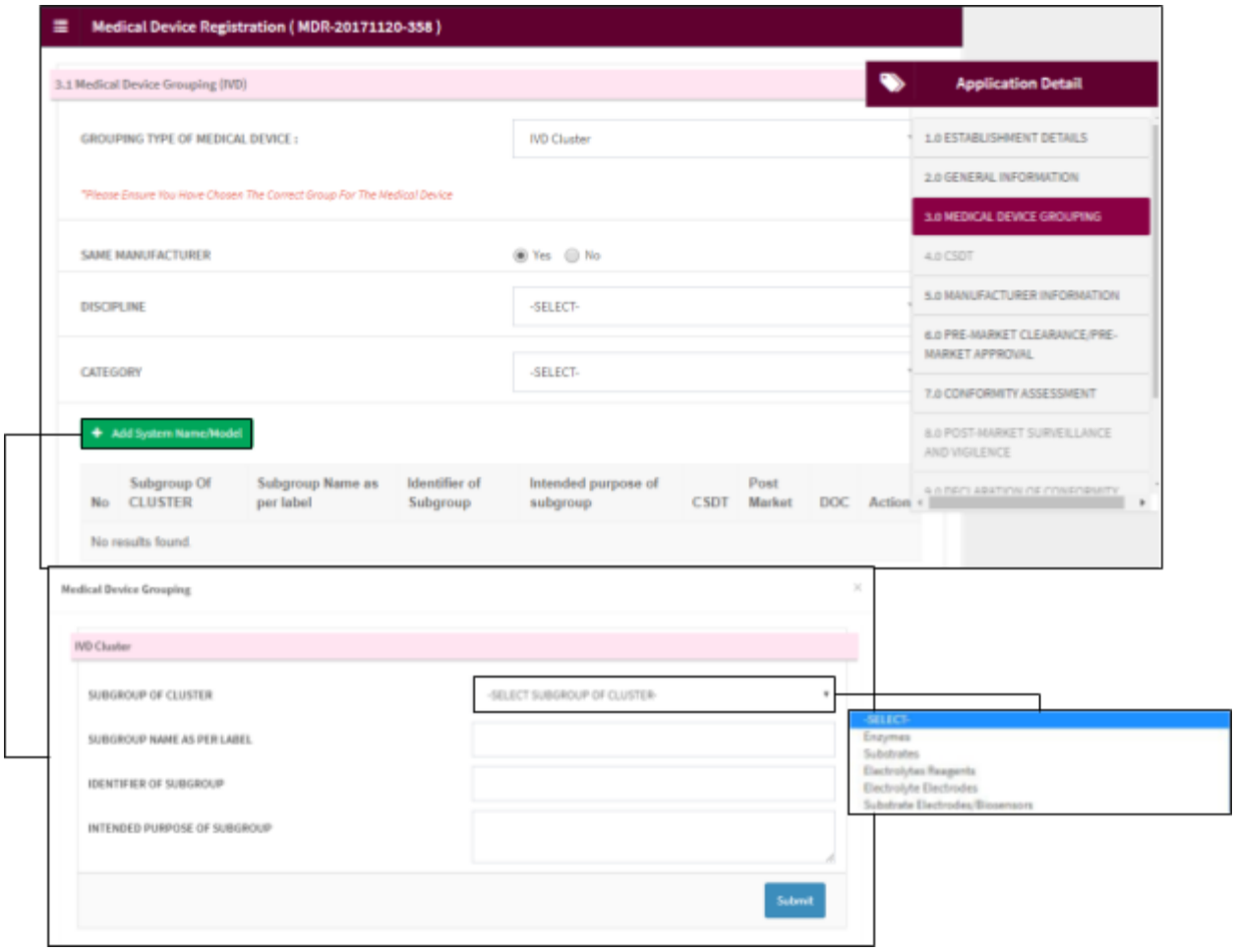
to upload excel file. **The file must be xlsx or xls format.**
-  button for user edit device details.
-  button for user delete device.
- 

button to delete selected data in the table.
- Click 

to go to the next section.
- Click 

to go to the previous section.

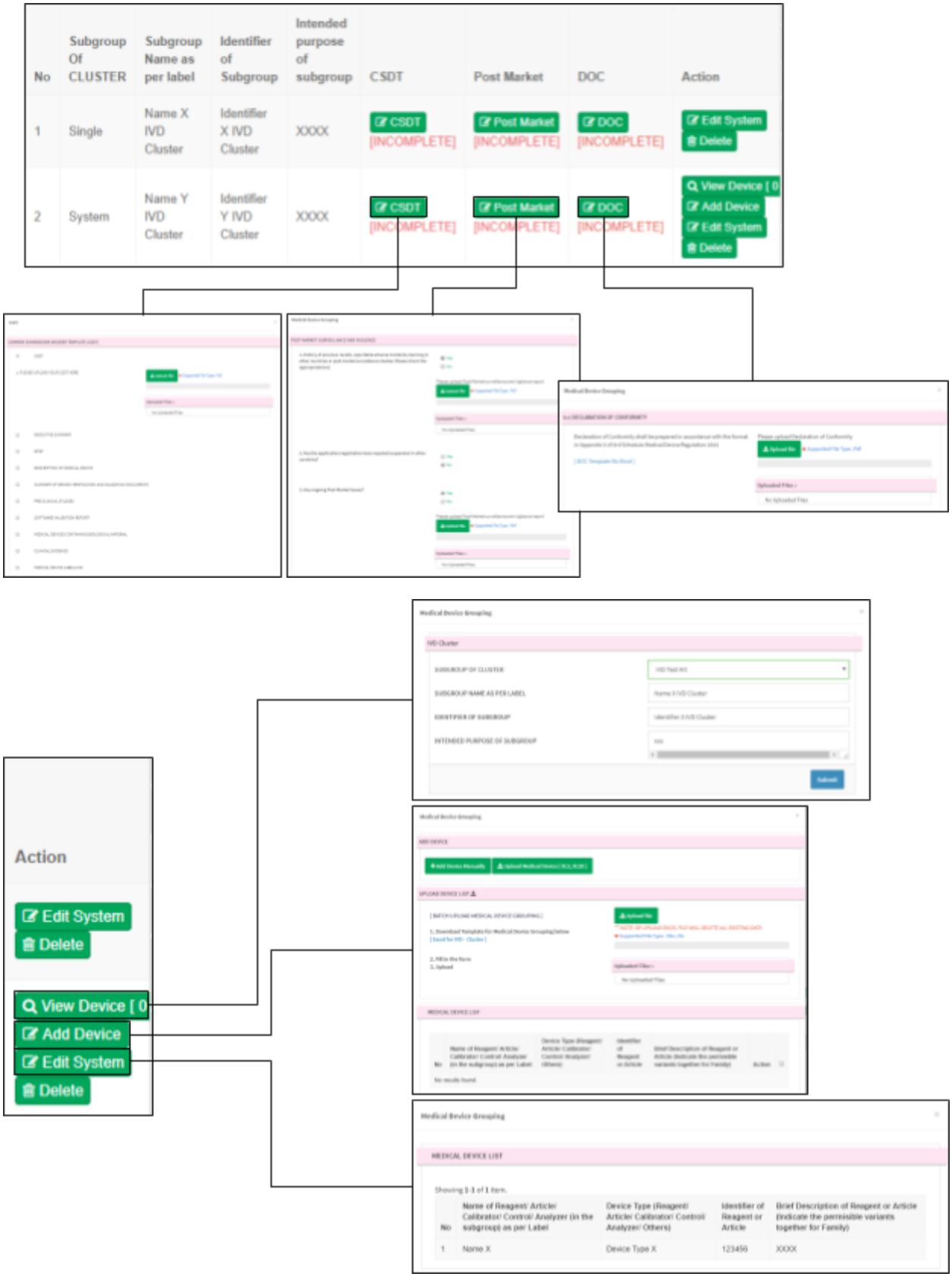
vi) IVD Cluster



- Click 

to new system name or model. Fill the form and then click 

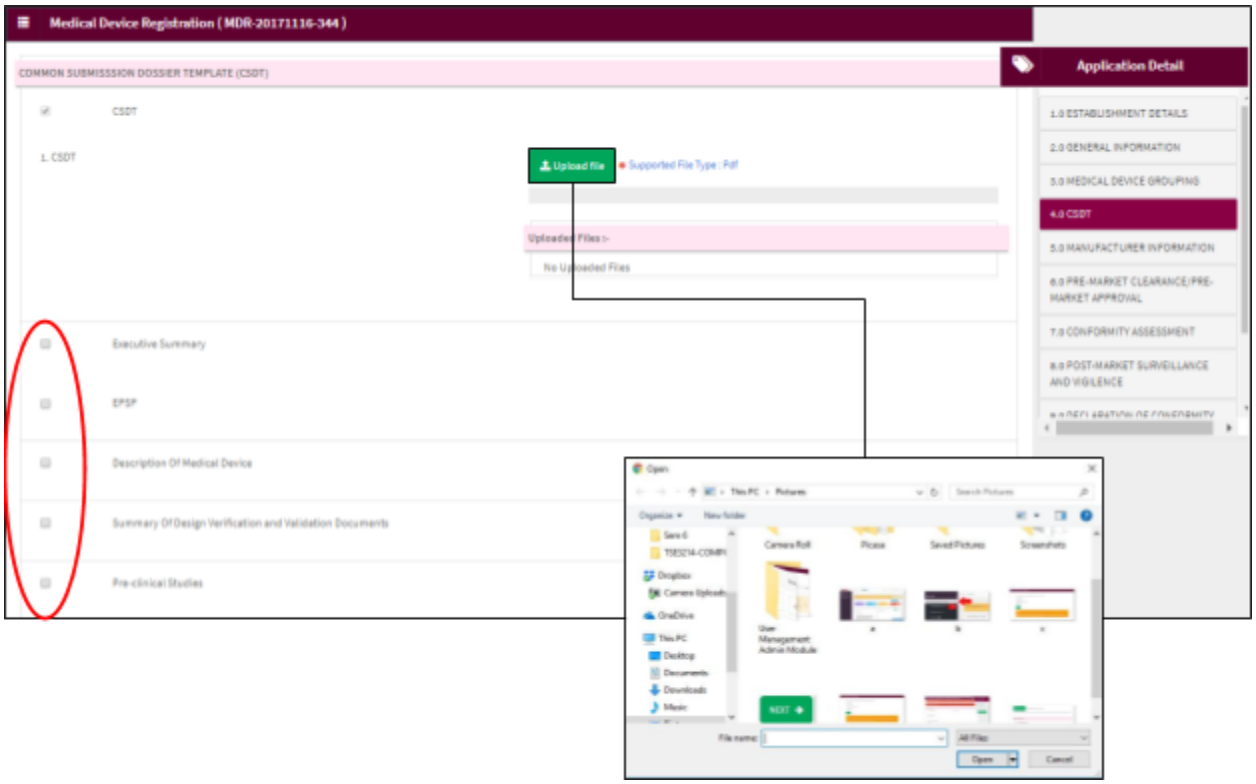
.

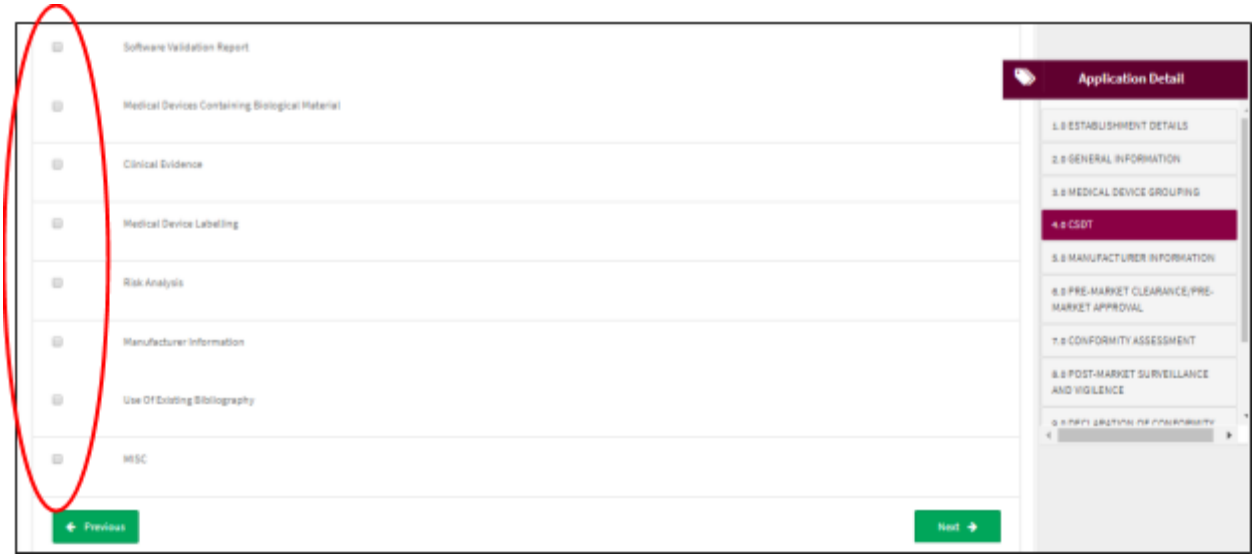

No
Subgroup Of CLUSTER
Subgroup Name as per label
Identifier of Subgroup
Intended purpose of subgroup
CSDT
Post Market
DOC
Action
1
Single
Name X IVD Cluster
Identifier X IVD Cluster
XXXX
CSDT [INCOMPLETE]
Post Market [INCOMPLETE]
DOC [INCOMPLETE]
Edit System
Delete
2
System
Name Y IVD Cluster
Identifier Y IVD Cluster
XXXX
CSDT [INCOMPLETE]
Post Market [INCOMPLETE]
DOC [INCOMPLETE]
View Device [0
Add Device
Edit System
Delete
Action
Edit System
Delete
View Device [0
Add Device
Edit System
Delete
MEDICAL DEVICE LIST

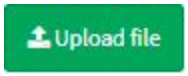
- Click Next to go to the next section.
- Click Previous to go to the previous section.

2.2.4 4.0 CSDT

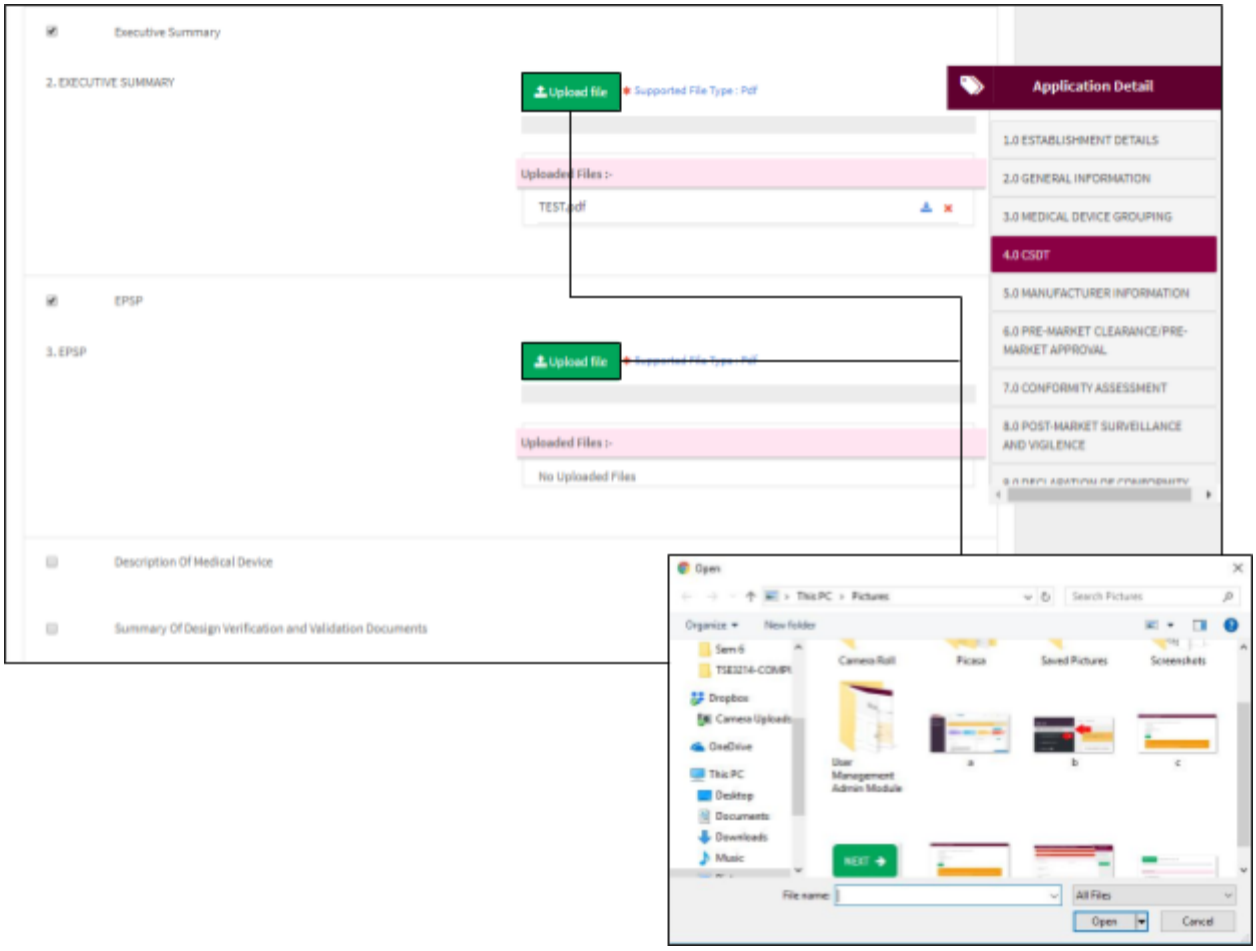
****This form not available if user GROUPING TYPE OF MEDICAL DEVICE is IVD Cluster.**





User tick any check box above. For example, user tick 'EPSP', user have to upload file. Click 

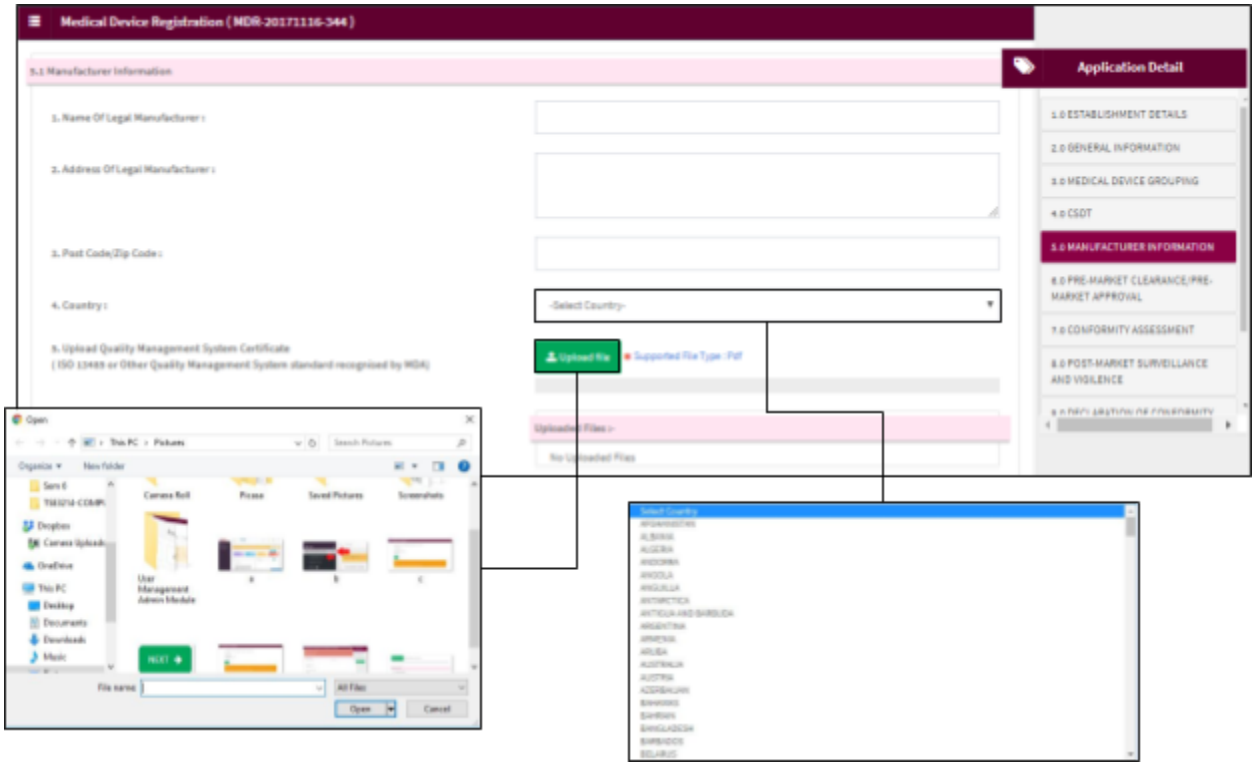
to upload file. **The file must be pdf format and size not more than 300 MB**.

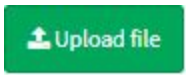


- Click Next to go to the next section.
- Click Previous to go to the previous section.

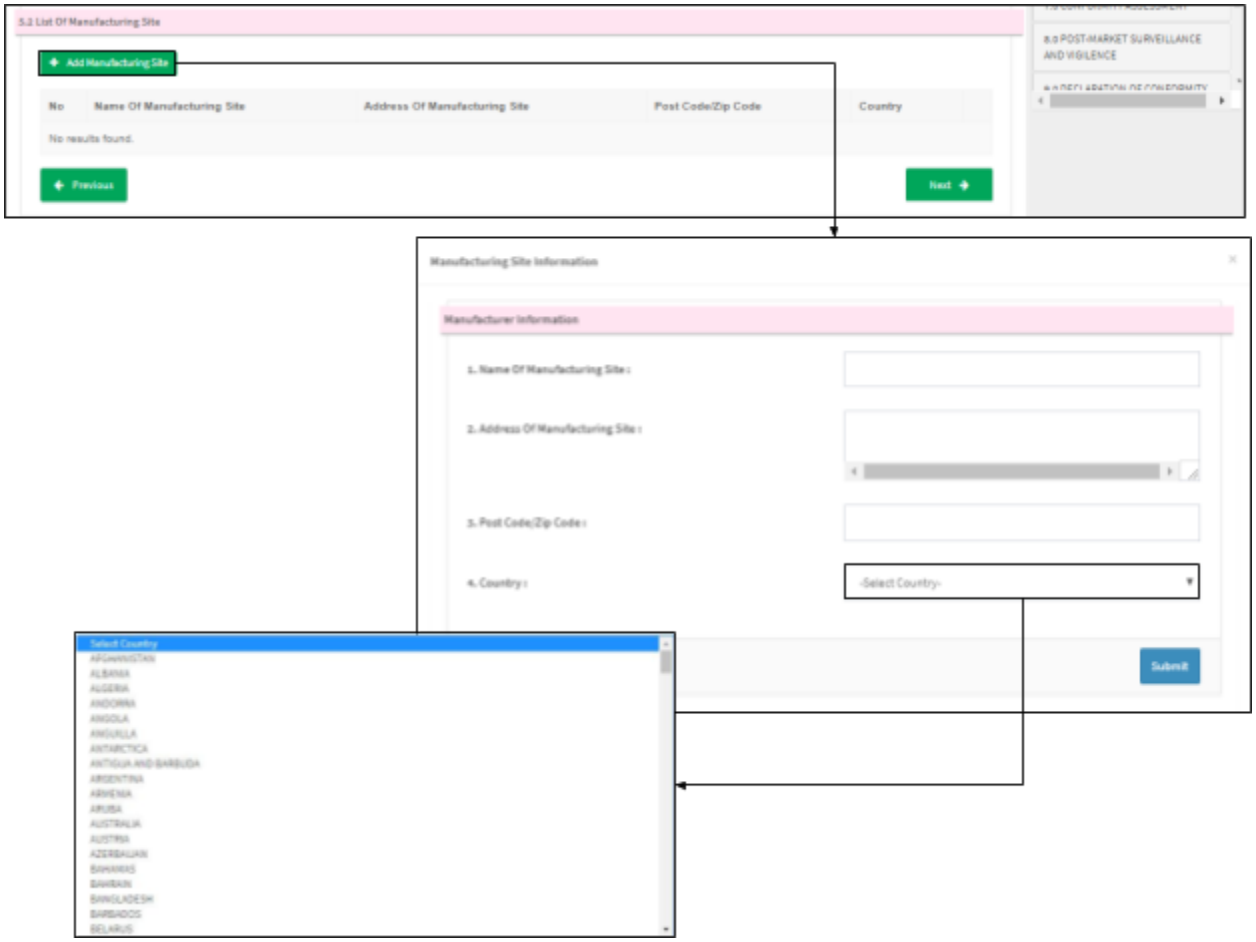
2.2.5 5.0 MANUFACTURER INFORMATION

User have to complete all field.

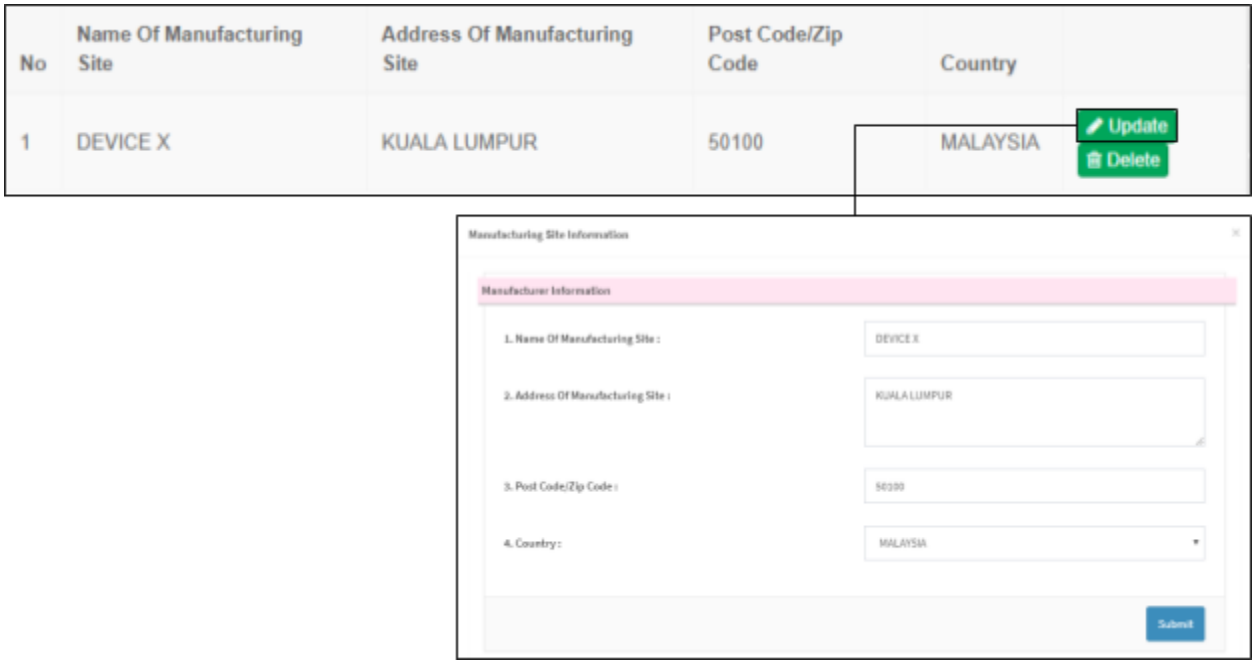


User click 

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

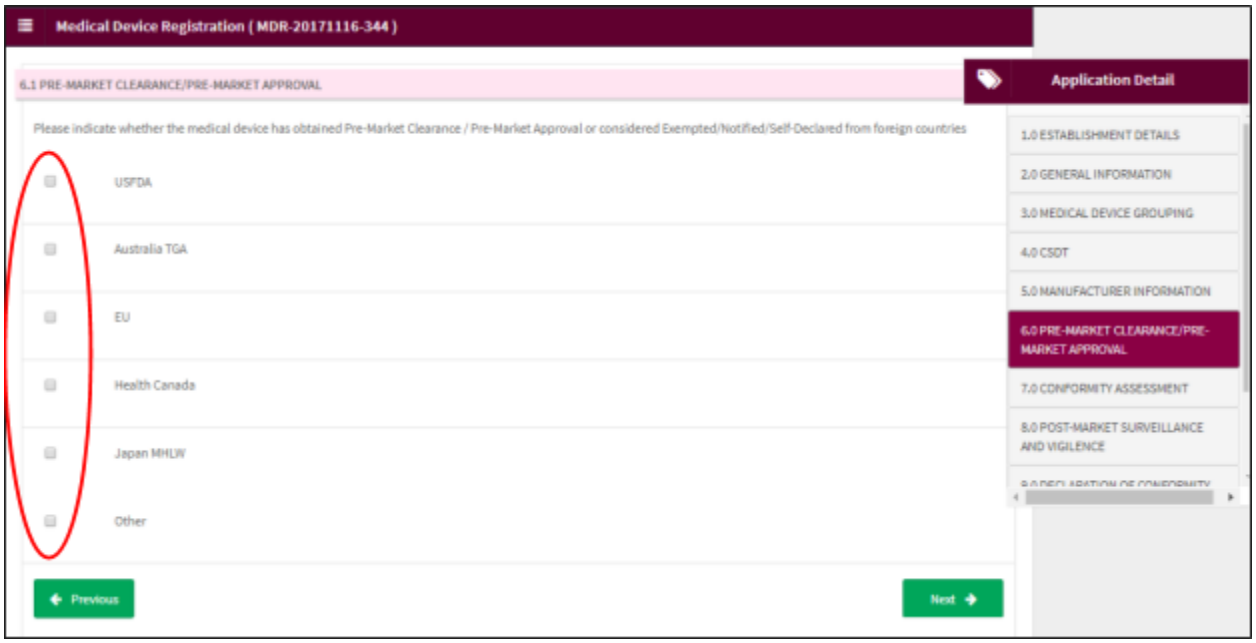


- Click  to add new manufacturing site. User fill all fields and then click  .

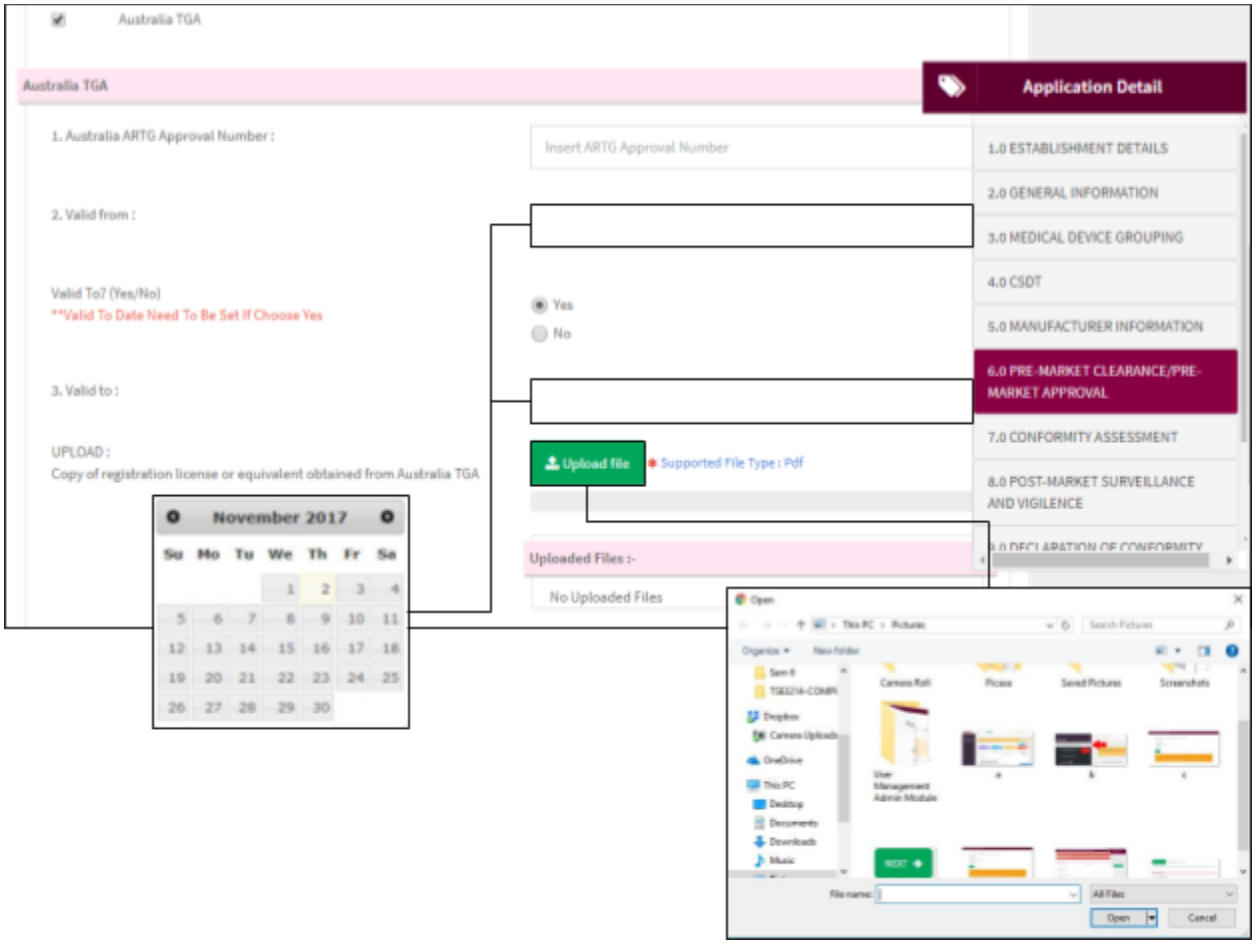


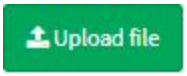
- Click Update to update data in table.
- Click Delete to delete data in table.

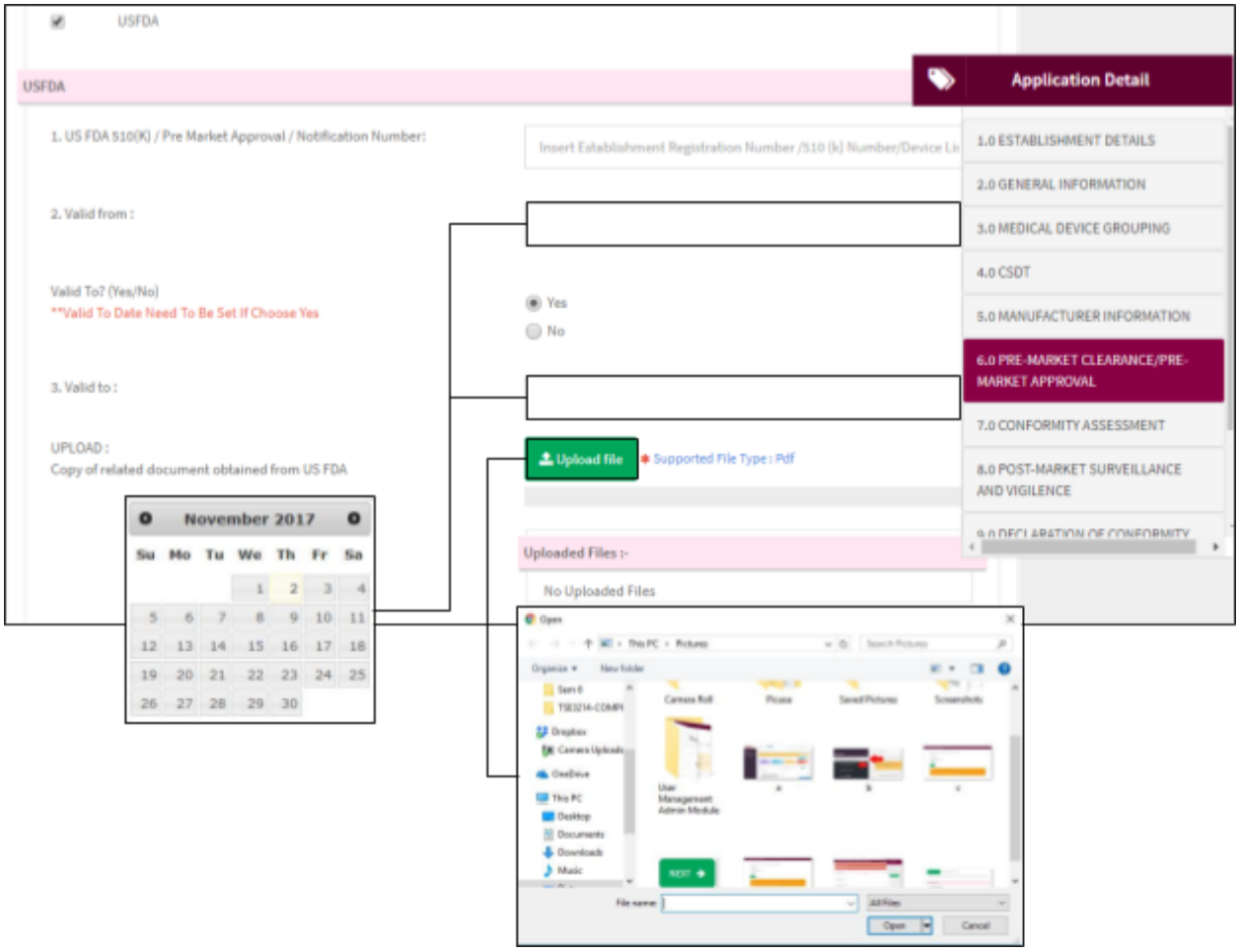
2.2.6 6.0 PRE-MARKET CLEARANCE/ PRE-MARKET APPROVAL

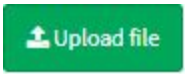


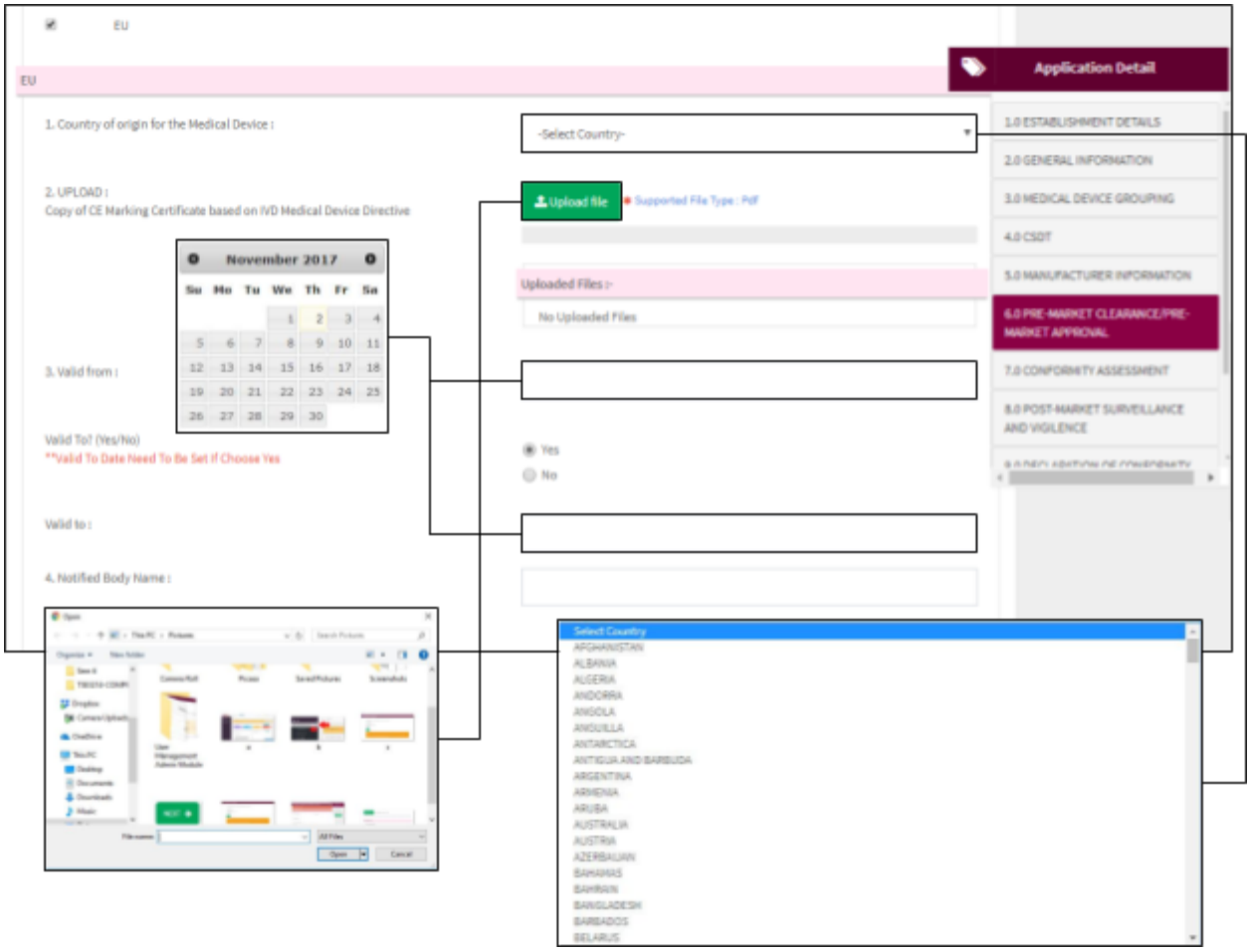
User tick any check box above.**(If necessary)**

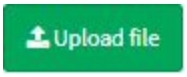


User fill the field then click  to upload file. **The file must be pdf format and size not more than 300 MB**.

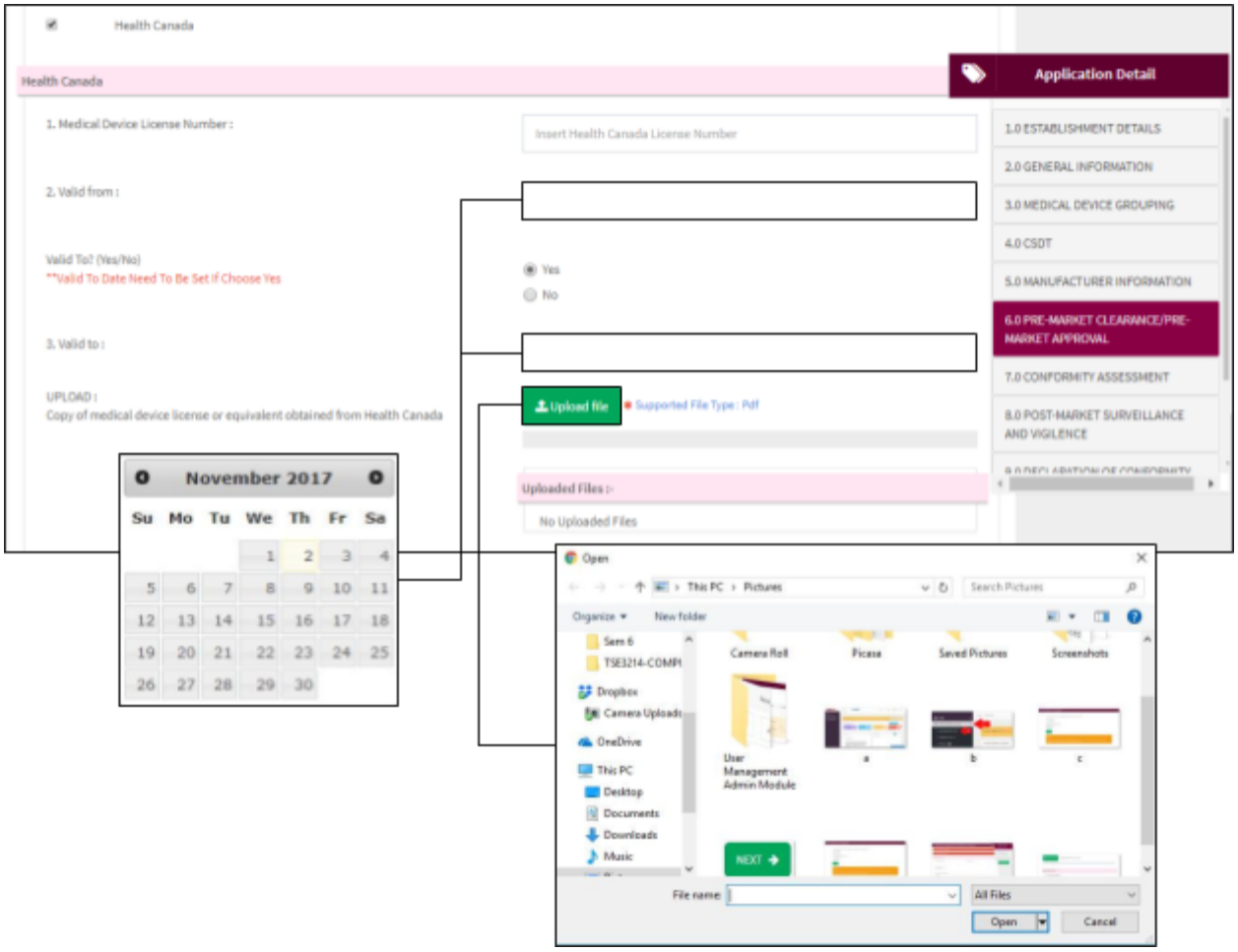


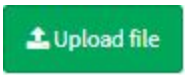
User fill the field then click  to upload file. **The file must be pdf format and size not more than 300 MB**.

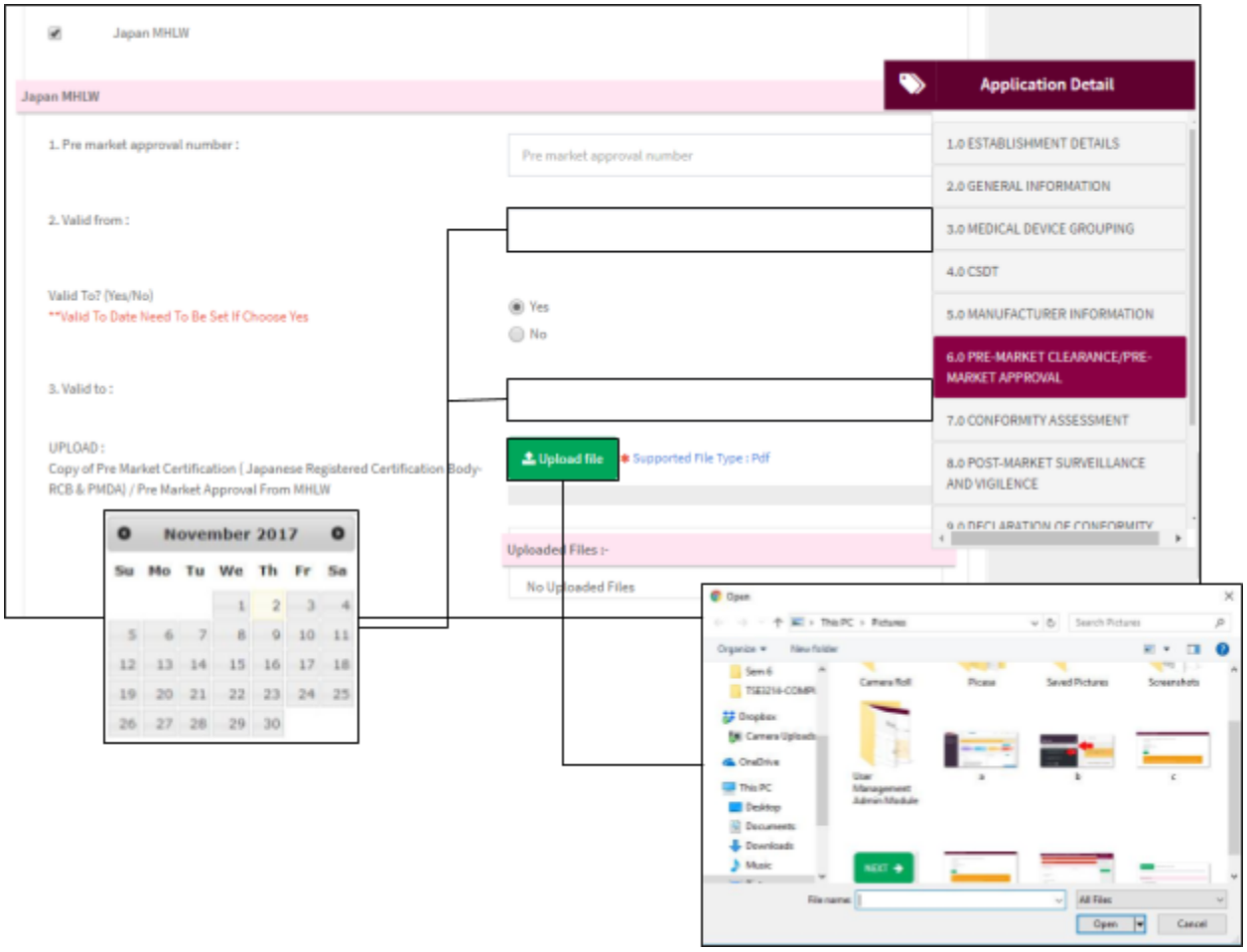


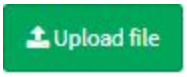
User fill the field then click 

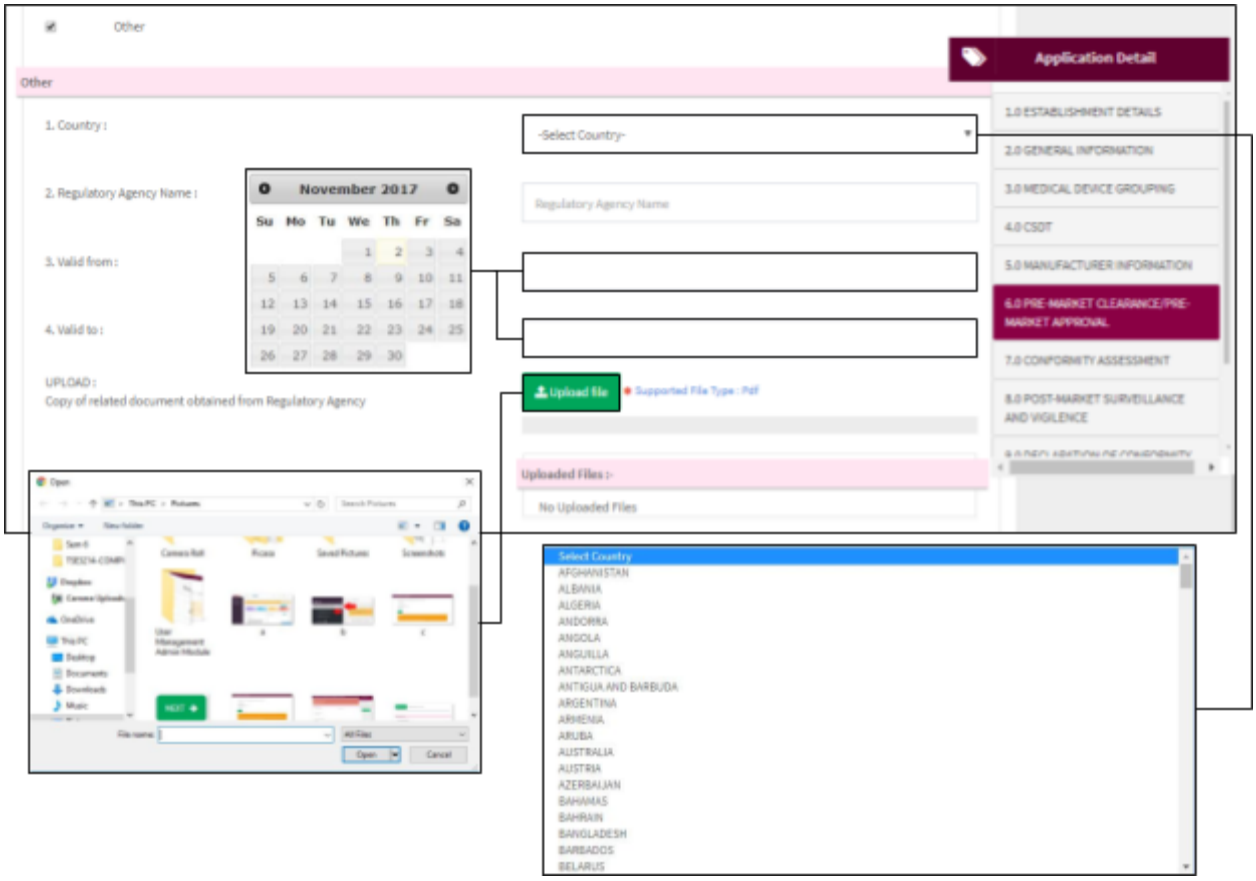
to upload file. **The file must be pdf format and size not more than 300 MB**.

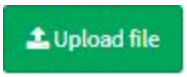


User fill the field then click  to upload file. **The file must be pdf format and size not more than 300 MB**.



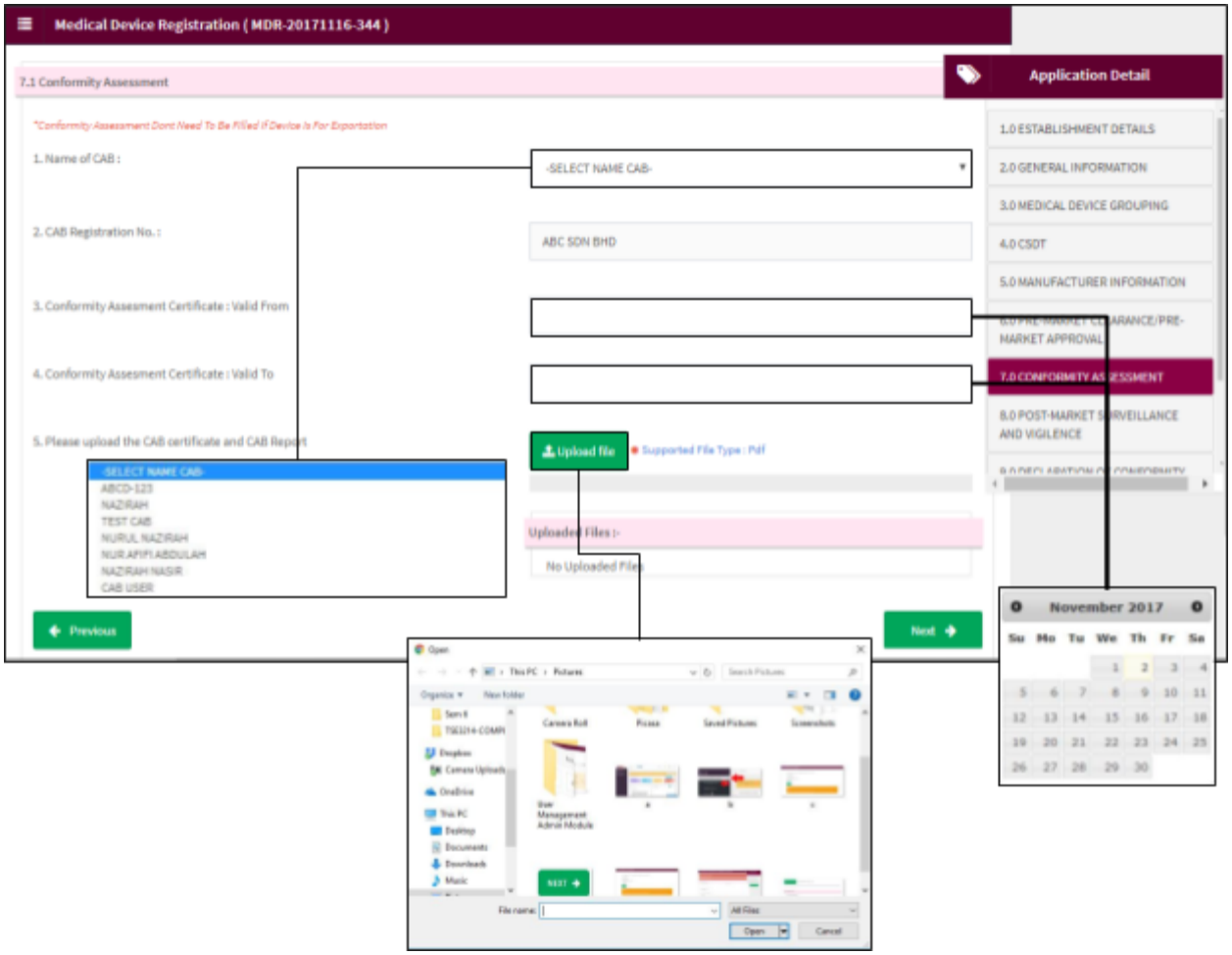
User fill the field then click  to upload file. **The file must be pdf format and size not more than 300 MB**.

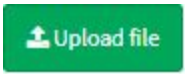


User fill the field then click 

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

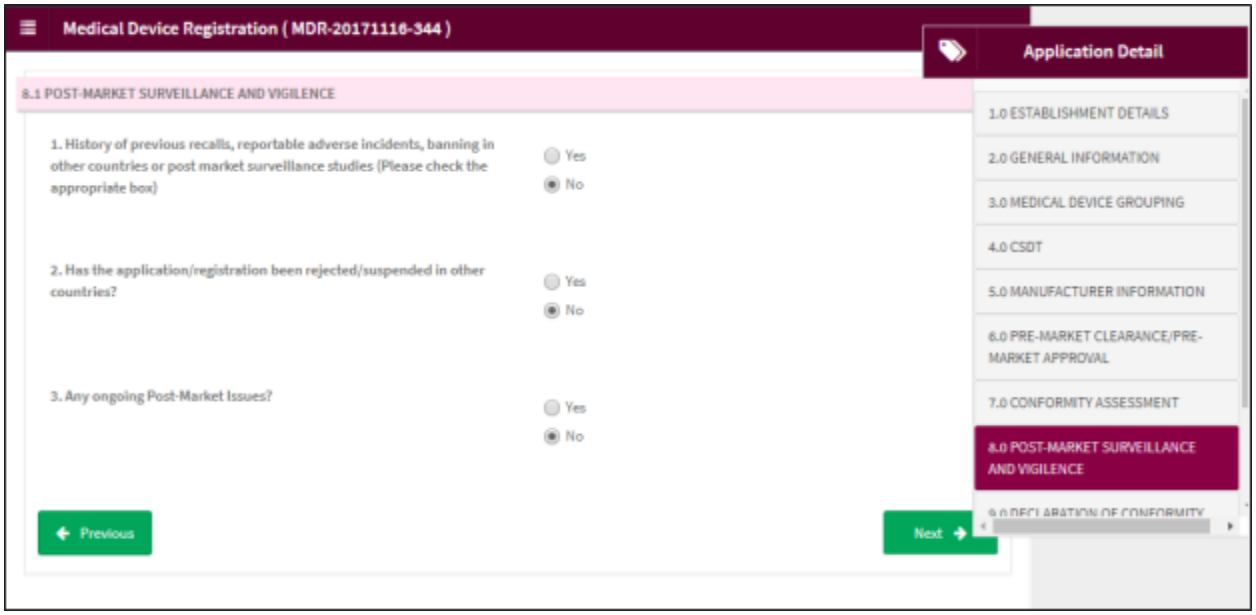
2.2.7 7.0 CONFORMITY ASSESSMENT

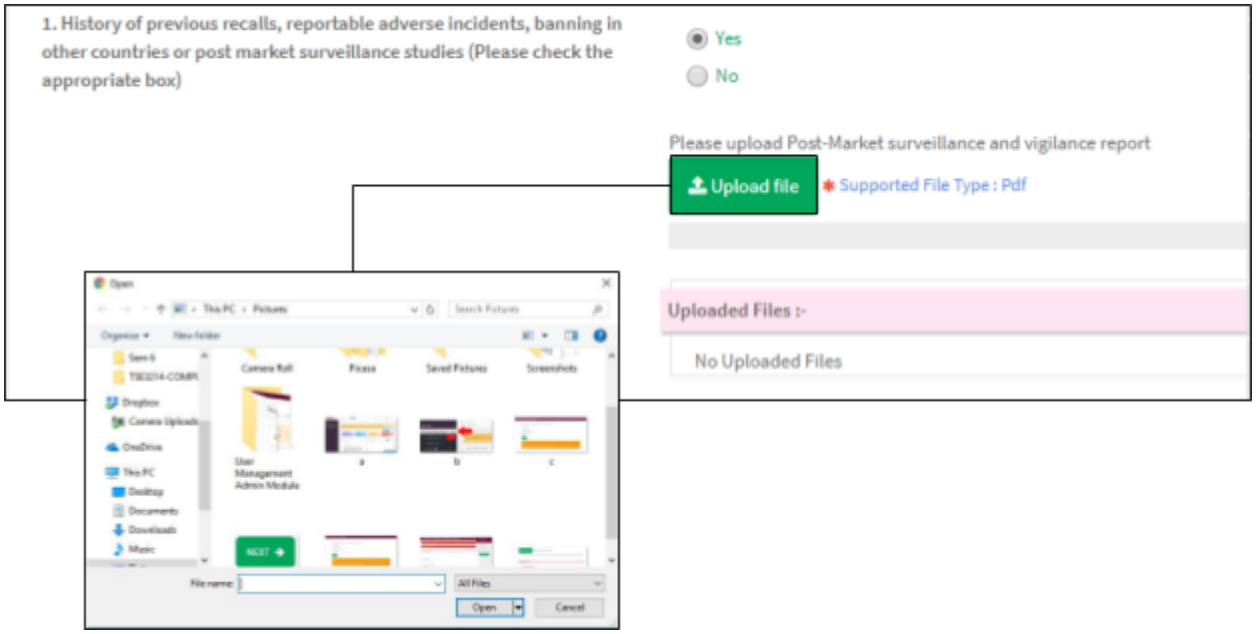


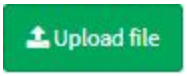
User fill the field then click  to upload file. **The file must be pdf format and size not more than 300 MB**.

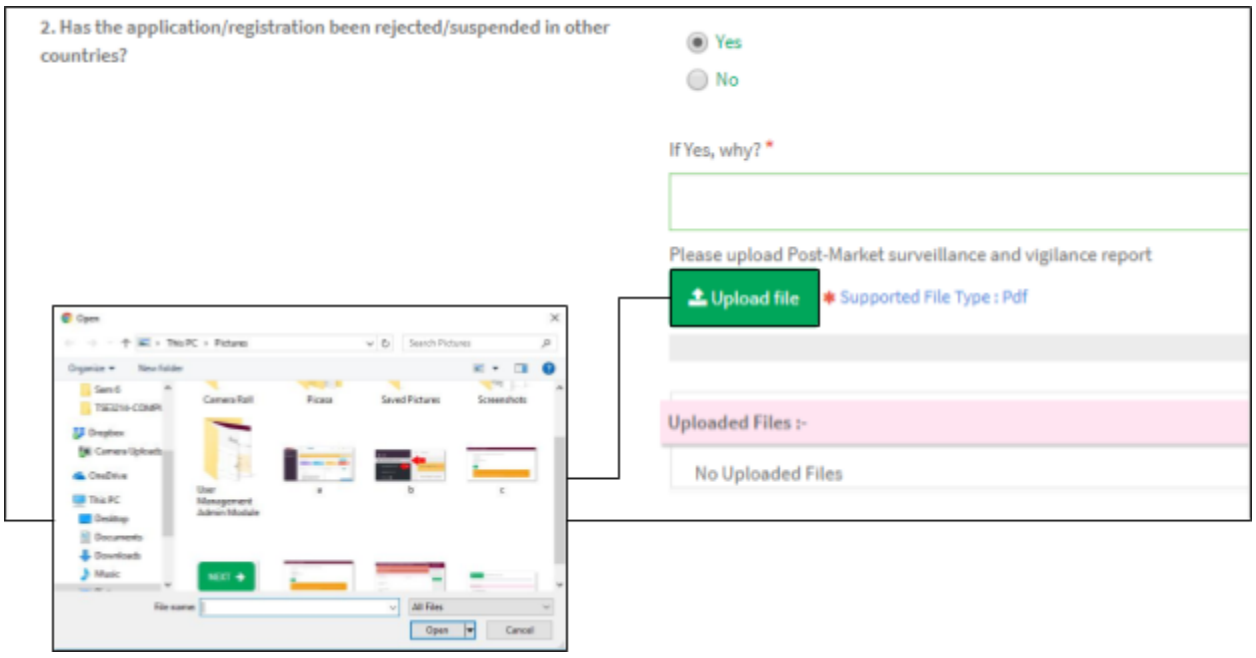
2.2.8 8.0 POST-MARKET SURVEILLANCE AND VIGILENCE

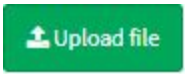
User have to complete the field.

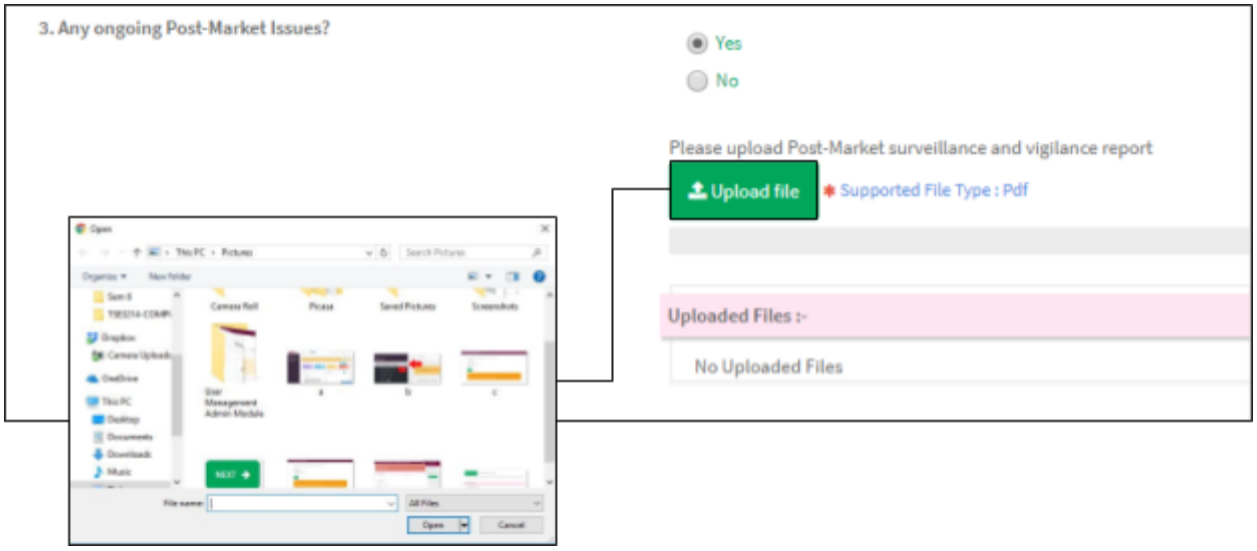


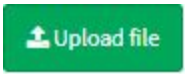


If user tick 'Yes', user have to upload file. Click  to upload file. **The file must be pdf format and size not more than 300 MB**.



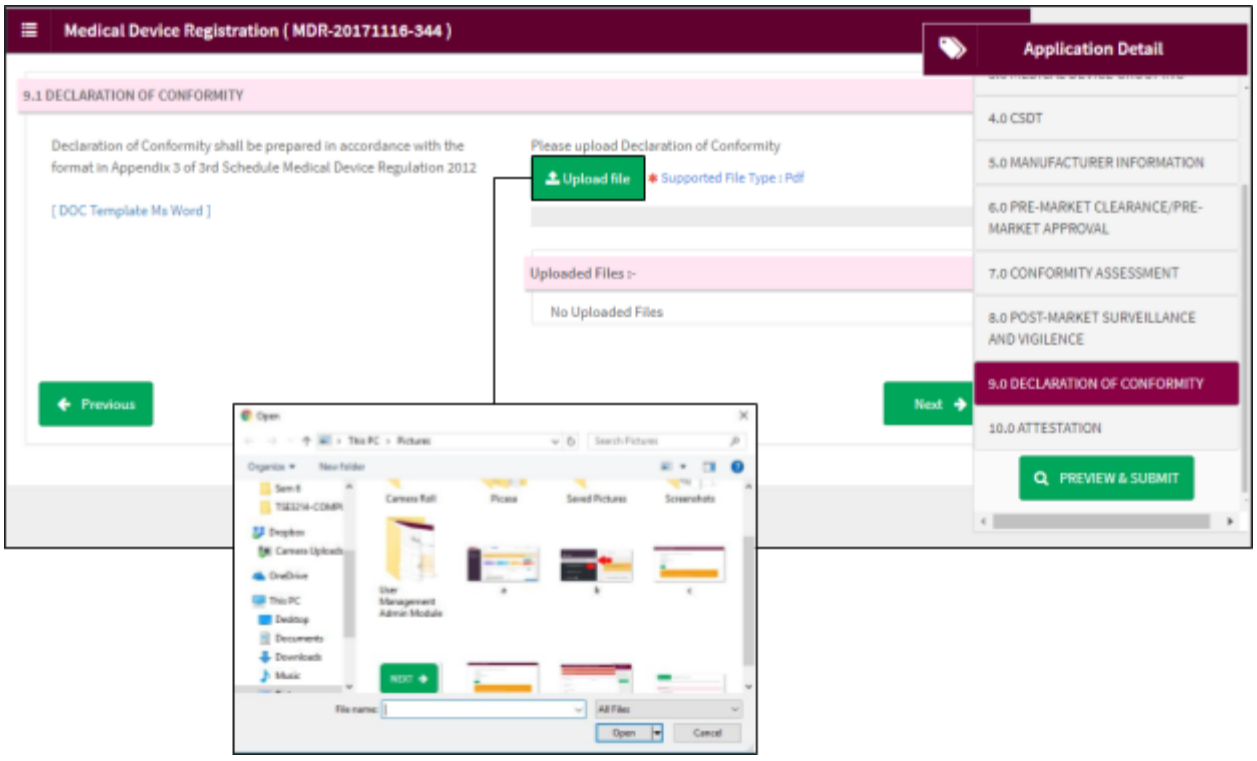
If user tick 'Yes', user have to upload file. Click  to upload file. **The file must be pdf format and size not more than 300 MB**.

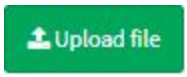


If user tick 'Yes', user have to upload file. Click 

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

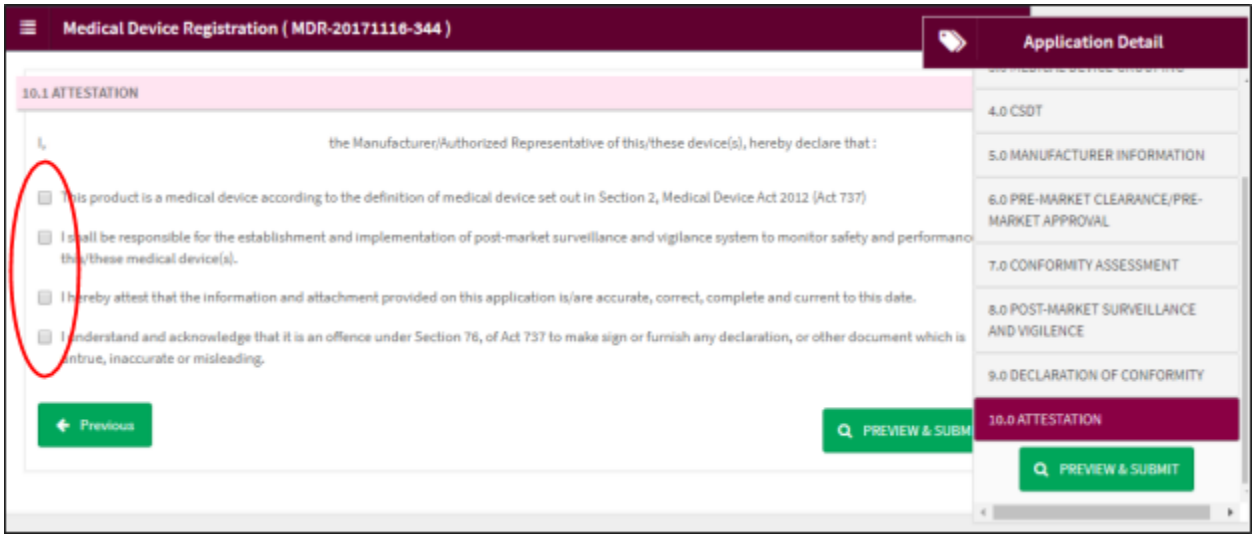
2.2.9 9.0 DECLARATION OF CONFORMITY



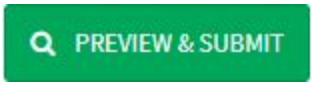
User click 

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

2.2.10 10.0 ATTESTATION

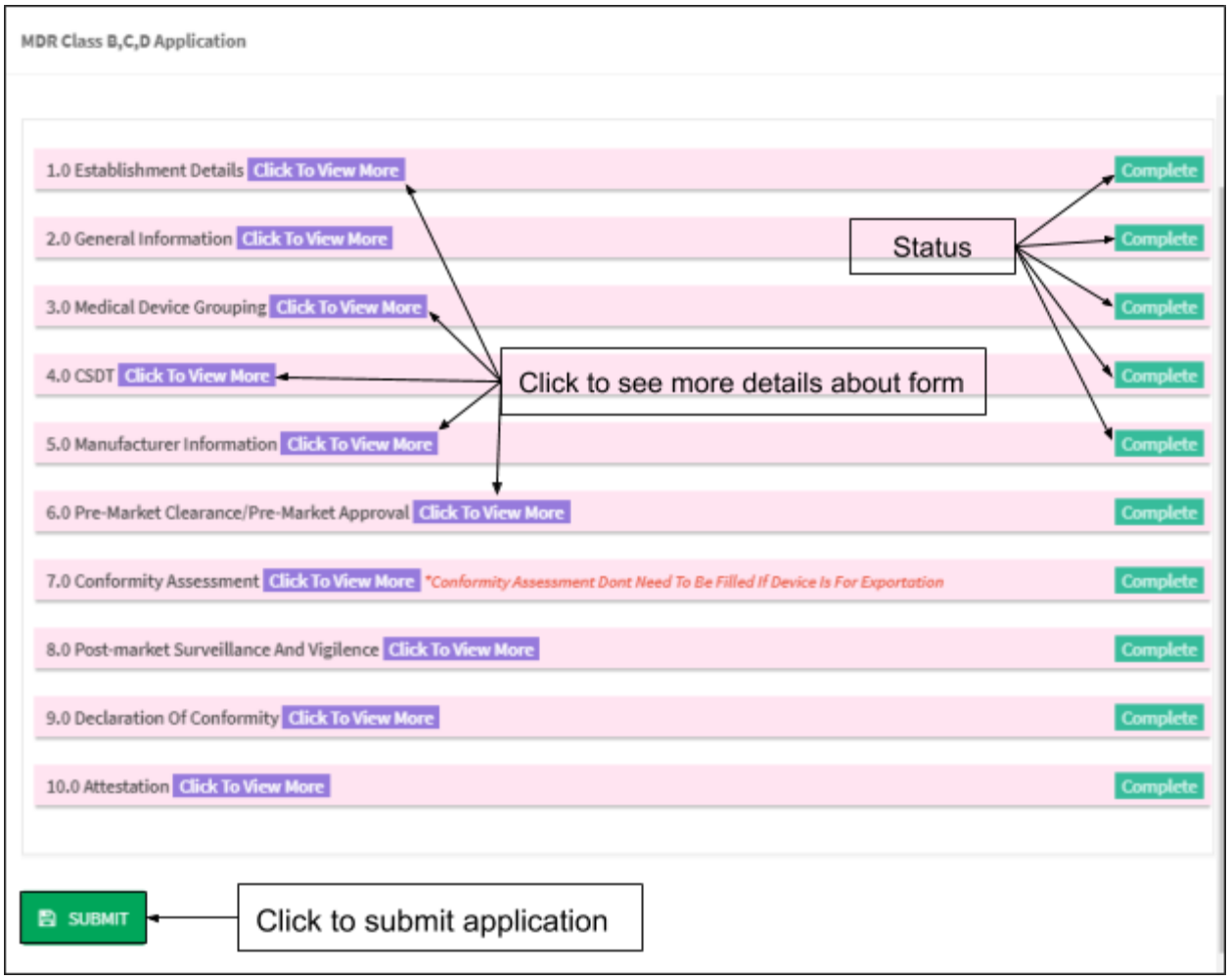


User have to tick all the checkbox before user can submit application. User click



to preview before submit application.

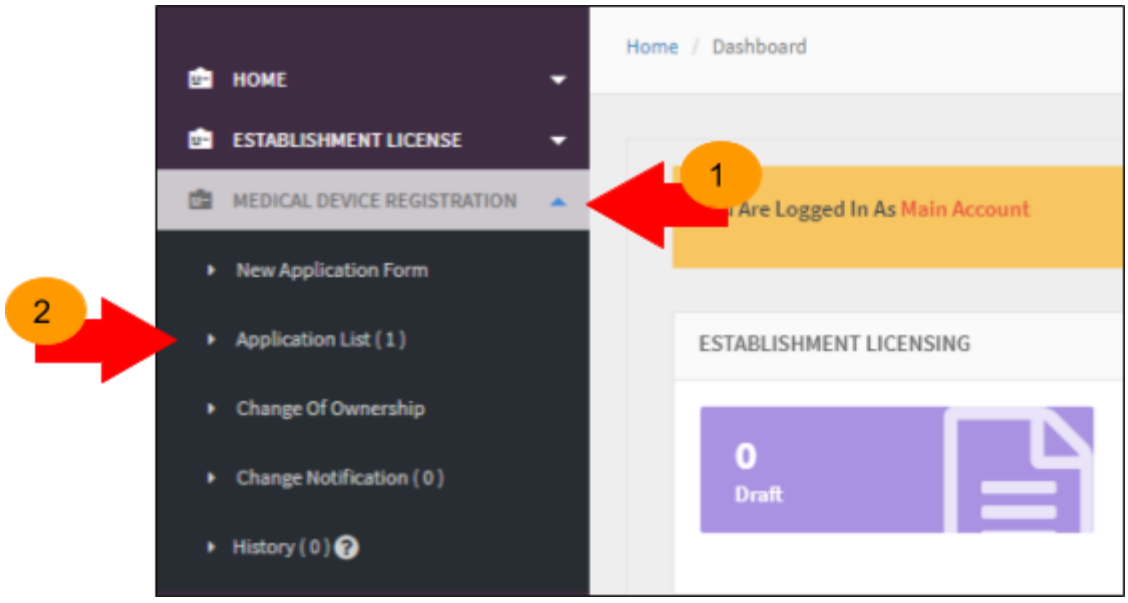
The diagram below will appear after user click [PREVIEW AND SUBMIT] button.



Submission only can do if all form status is Complete . If status Not Complete , user have to complete the form. Then, click Submit to submit application.

3.0 RE-REGISTRATION

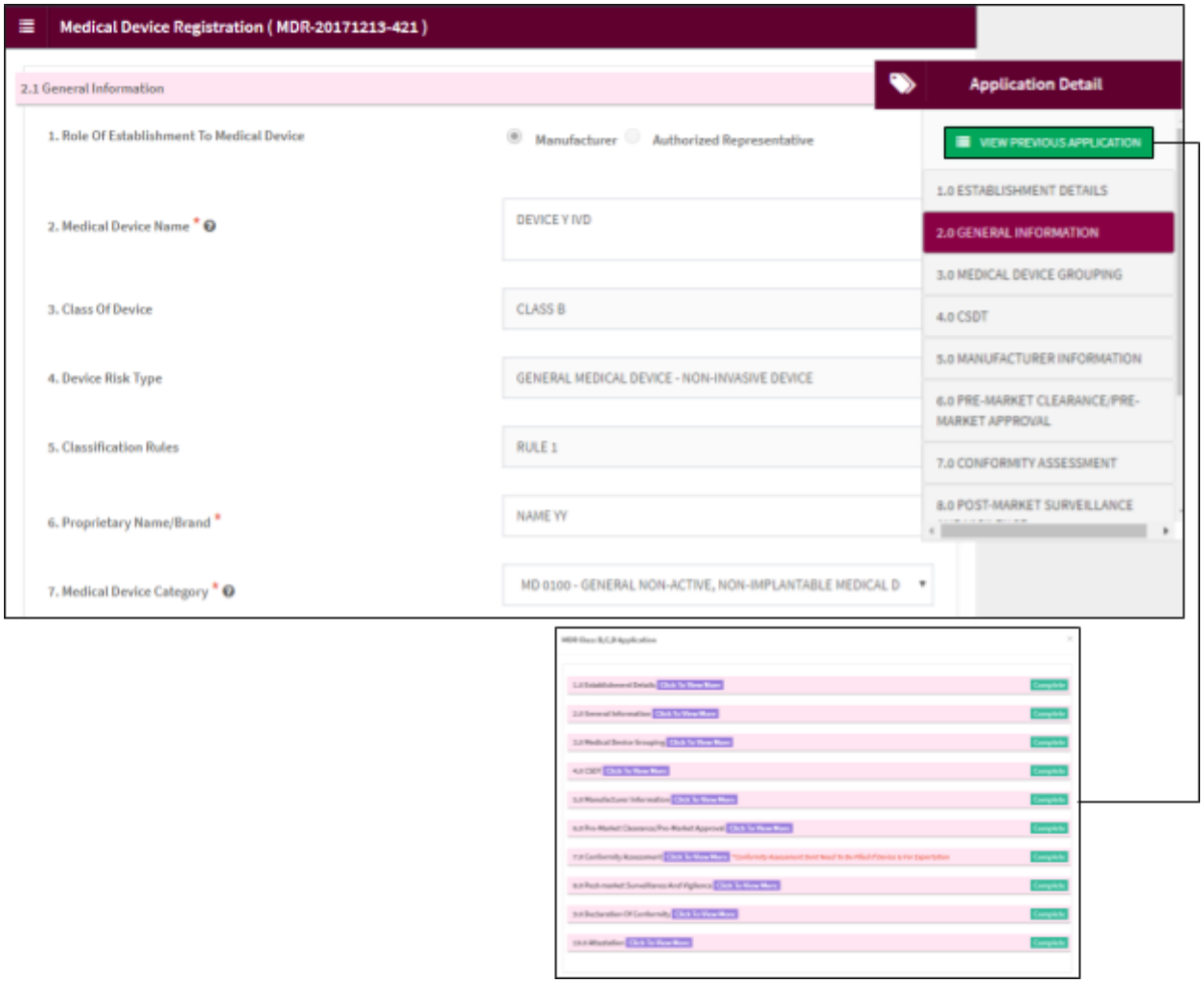
Click on the 'MEDICAL DEVICE REGISTRATION' at the left menu sidebar and click at the 'Application List' to create new form.



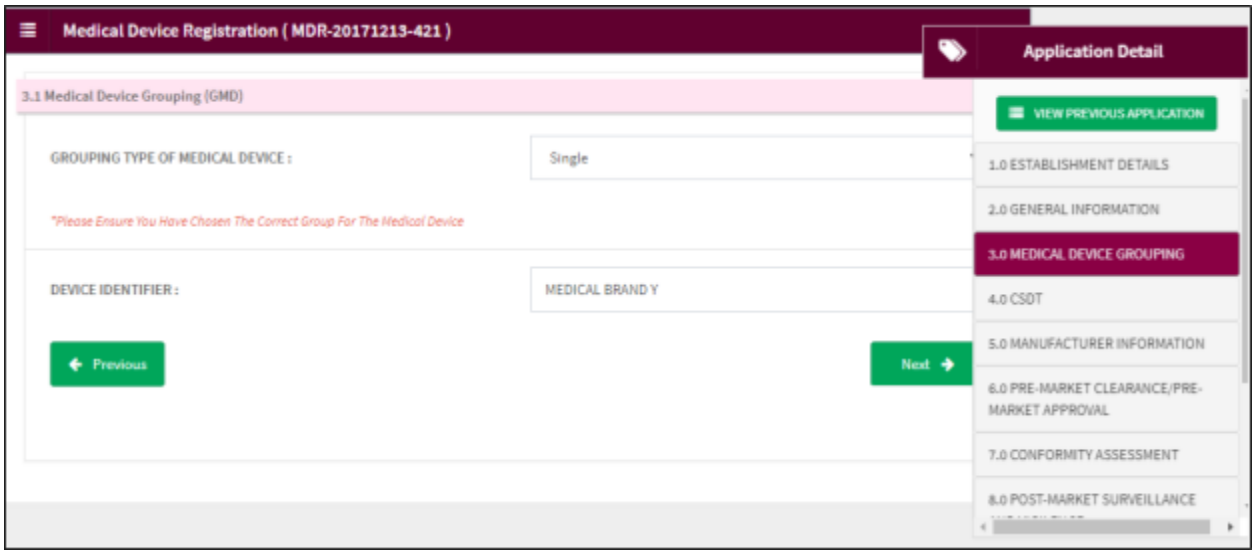
The diagram below show Application List page. Click ReRegister to re-register application.

Next, user will go to 2.0 GENERAL INFORMATION page. User have to complete all fields with (*). User click 

to go to the next step.

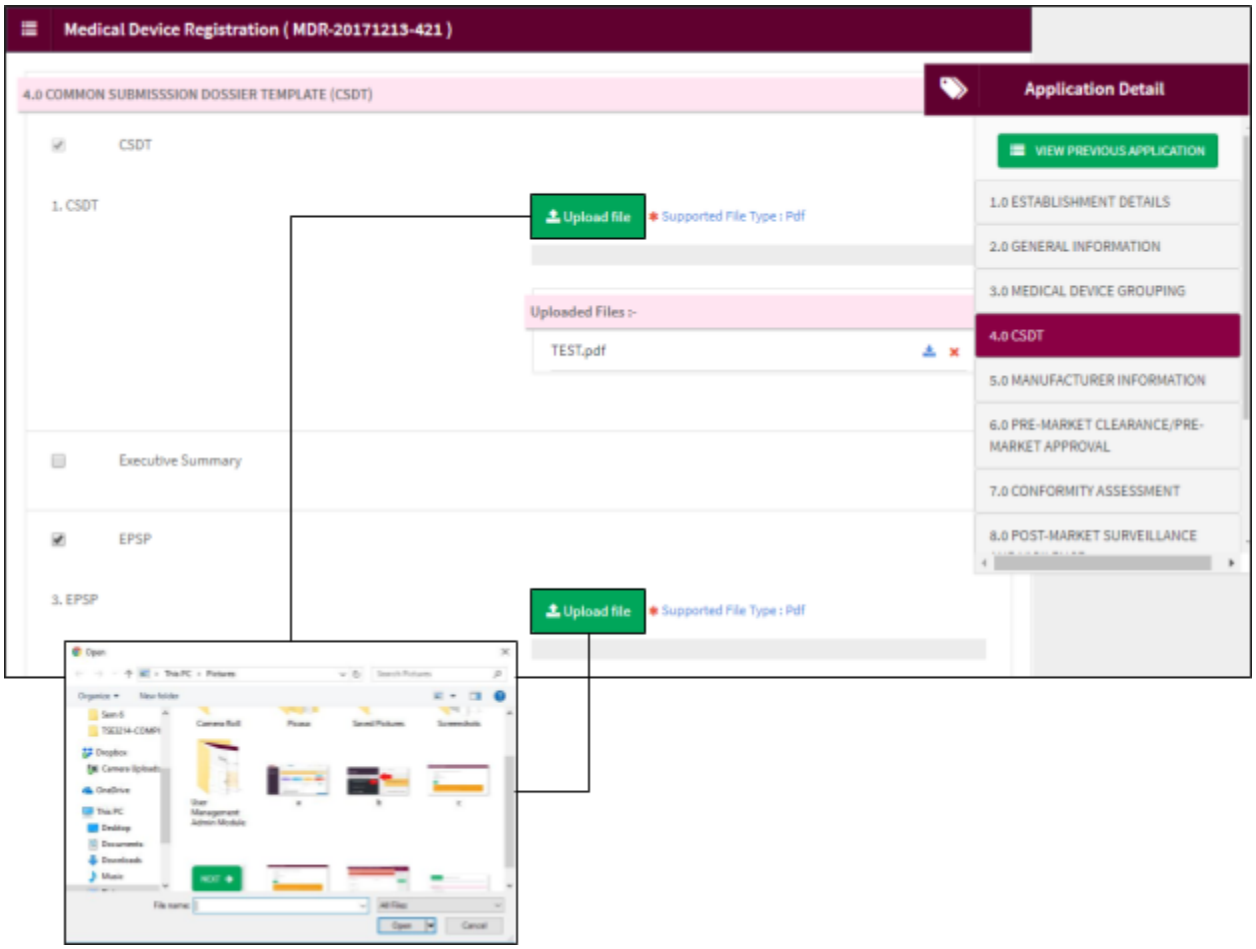


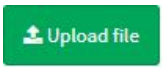
The diagram below show 2.0 PERSON RESPONSIBLE DETAILS form. User have to complete all fields with (*).



User click Next to go to the next step. User click Previous to go to the previous form.

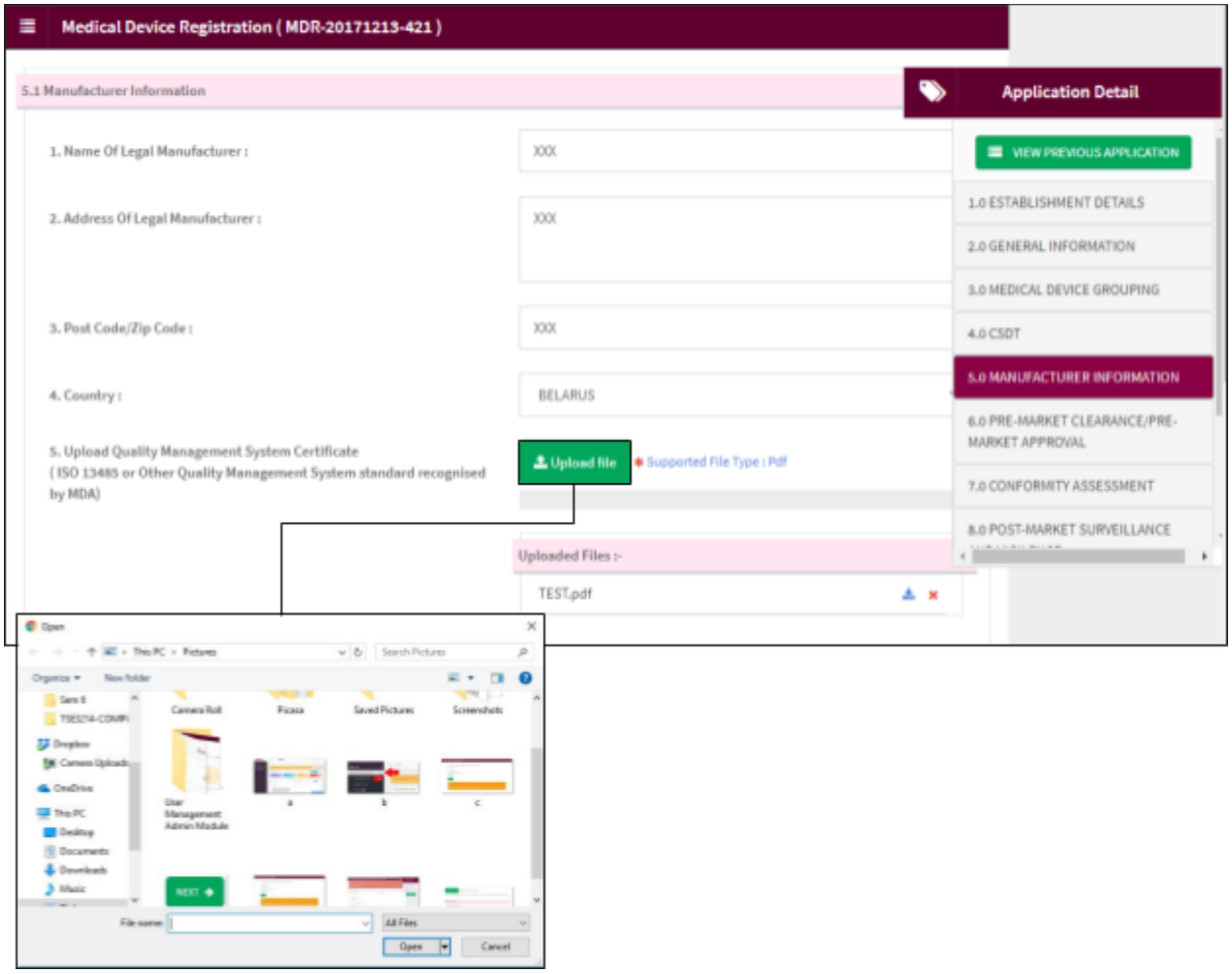
The diagram below show 4.0 CSDT form. User have to fill all fields with (*).

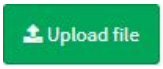


Click  to upload. **The file must be pdf format and size not more than 300 MB**.

User click  to go to the next step.User click  to go to the previous form.

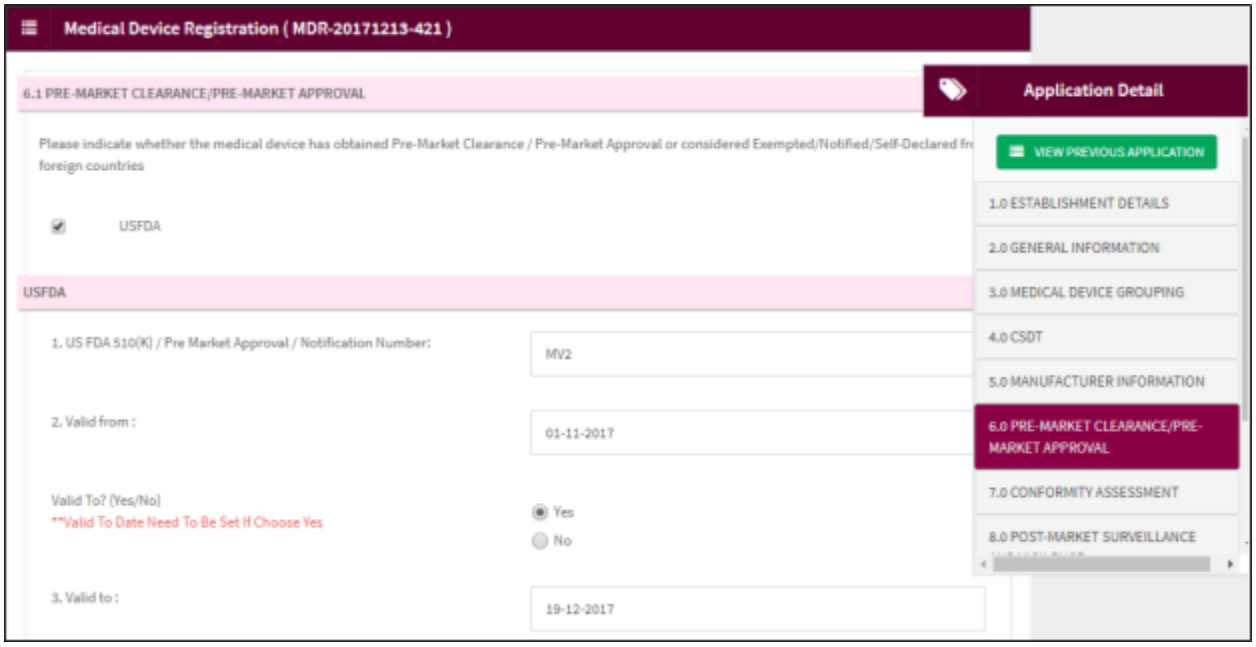
The diagram below show 5.0 MANUFACTURER INFORMATION form. User have to complete all fields with (*).



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

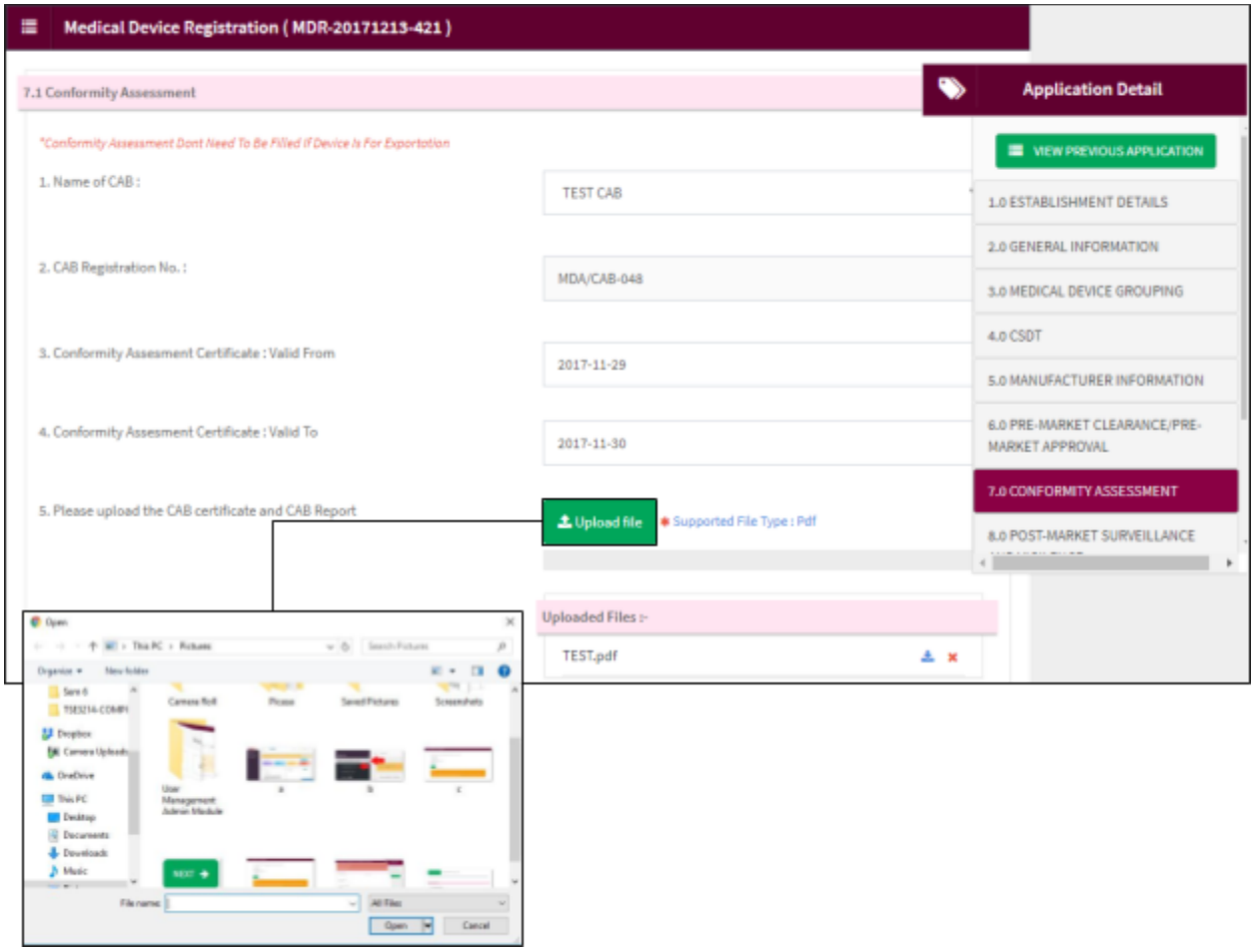
User click  to go to the next step.User click  to go to the previous form.

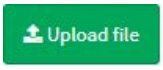
The diagram below show 6.0 PRE-MARKET CLEARANCE/PRE-MARKET APPROVAL form. User have to complete all fields with (*).



User click  to go to the next step.User click  to go to the previous form.

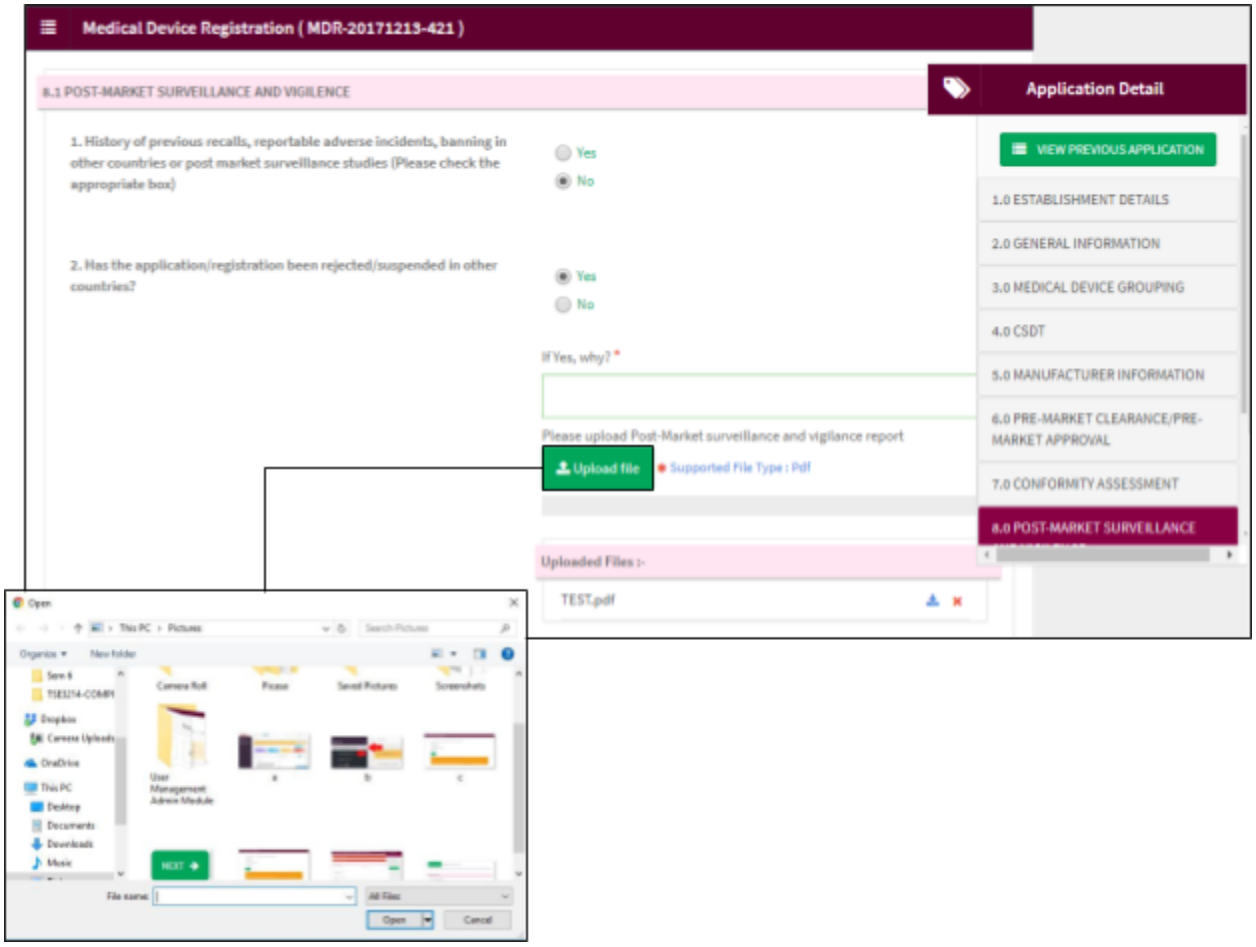
The diagram below show 6.0 PRE-MARKET CLEARANCE/PRE-MARKET APPROVAL form. User have to complete all fields with (*).

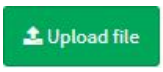


Click  to upload. **The file must be pdf format and size not more than 300 MB**.

User click  to go to the next step.User click  to go to the previous form.

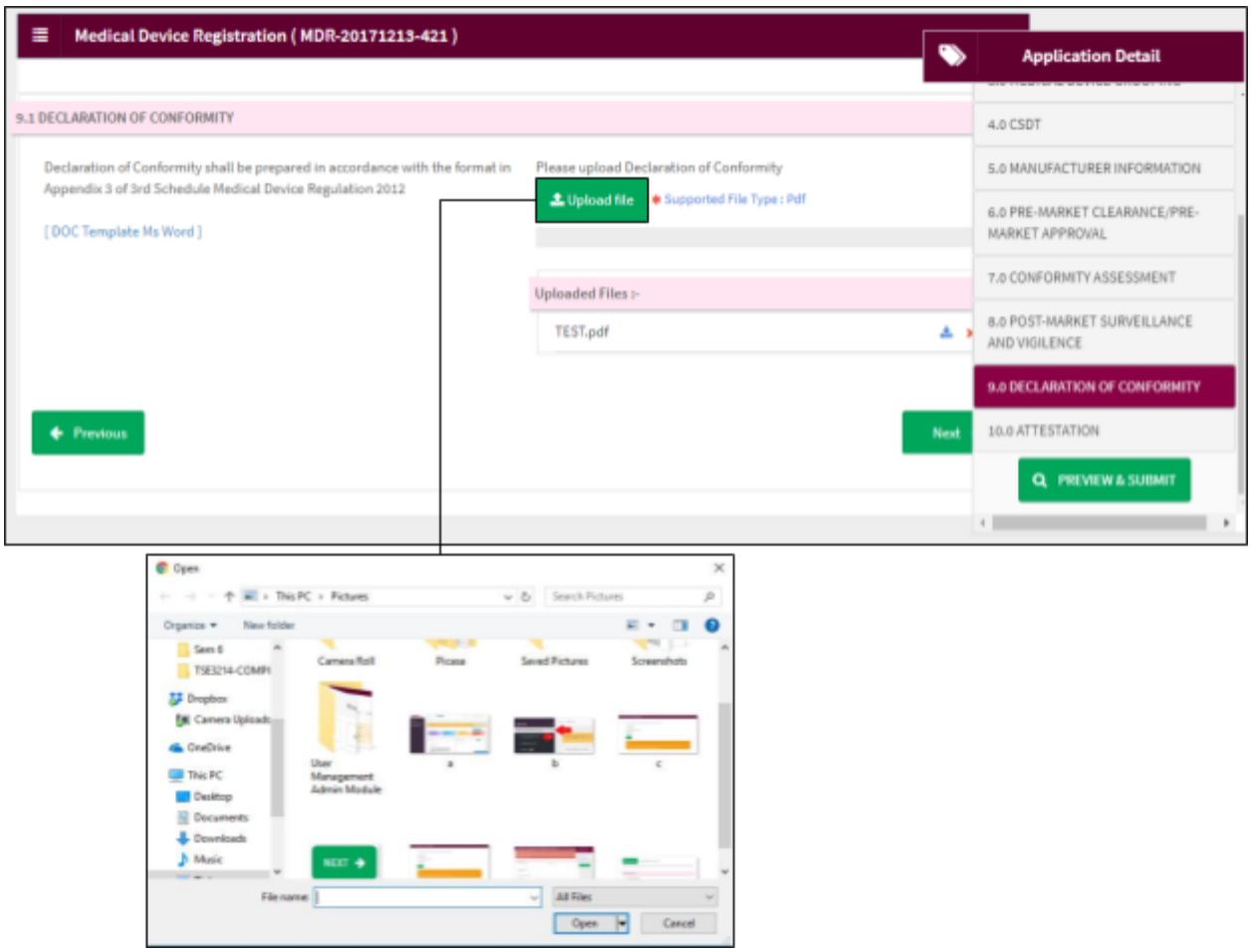
The diagram below show SURVEILLANCE AND VIGILENCE form. User have to complete all fields with (*).

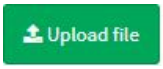


Click  to upload. **The file must be pdf format and size not more than 300 MB**.

User click  to go to the next step.User click  to go to the previous form.

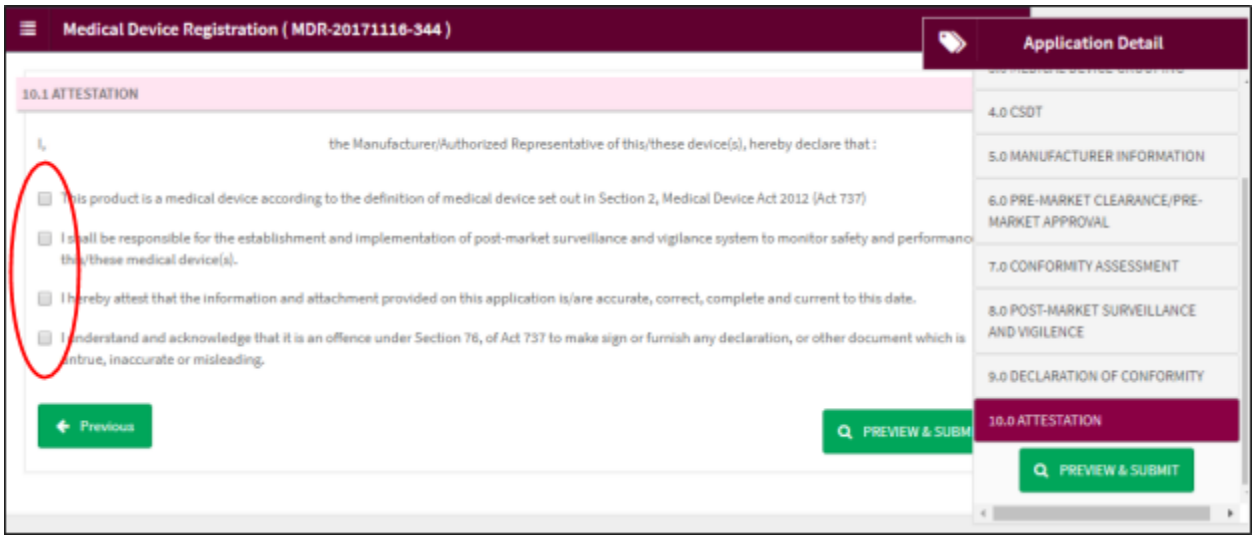
The diagram below show 9.0 DECLARATION OF CONFORMITY form. User have to complete all fields with (*).



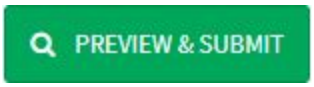
Click  to upload. **The file must be pdf format and size not more than 300 MB**.

User click  to go to the next step.User click  to go to the previous form.

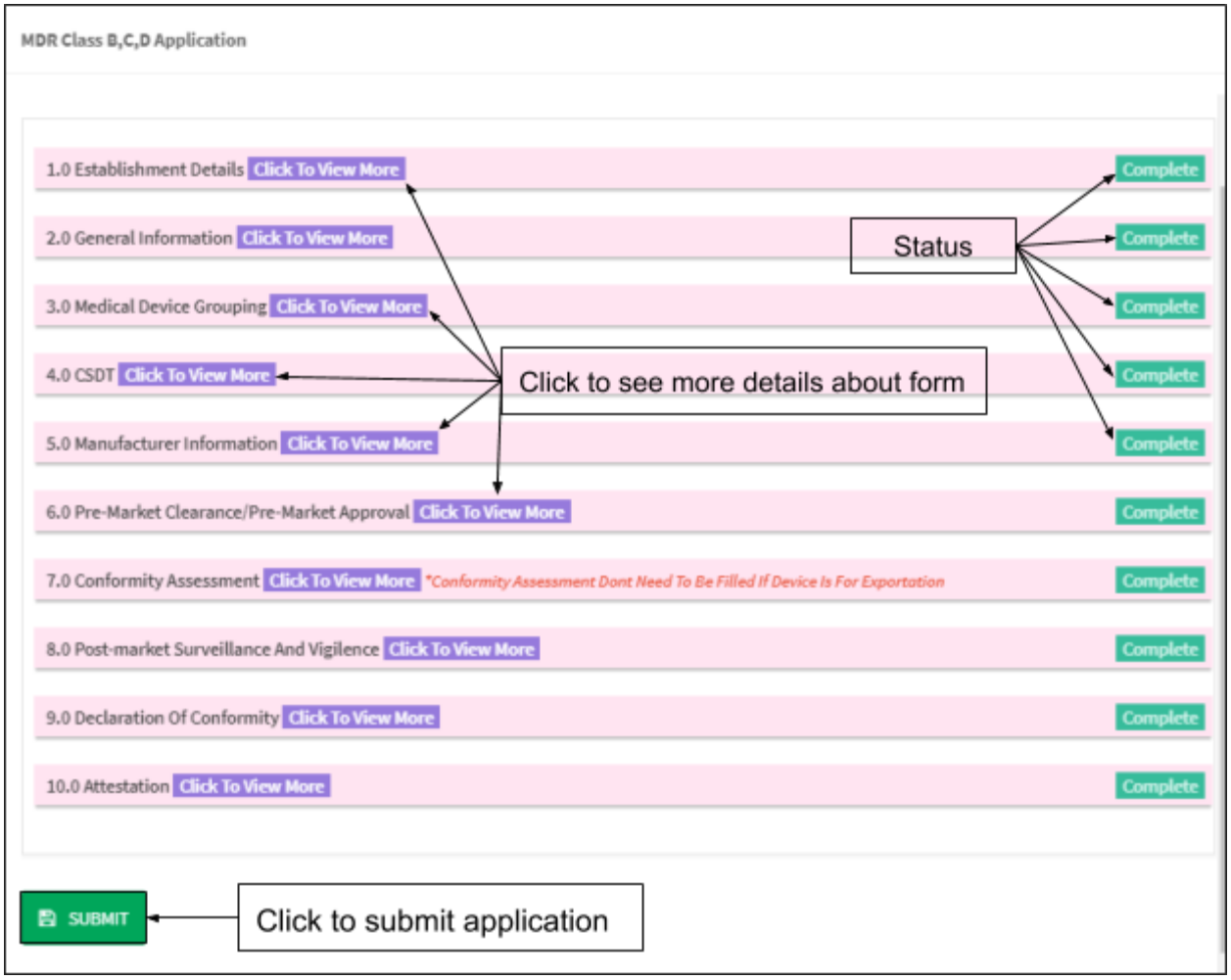
The diagram below show 10.0 ATTESTATION form. User have to complete all fields with (*).



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



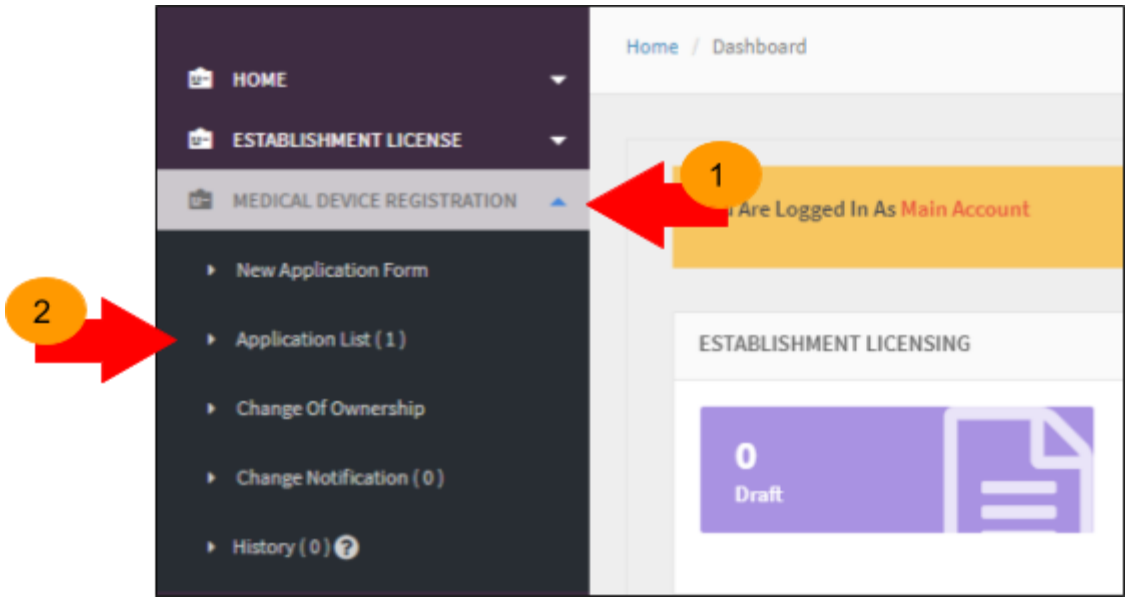
to preview before submit application.



Submission only can do if all form status is Complete . If status Not Complete , user have to complete the form. Then, click Submit to submit application.

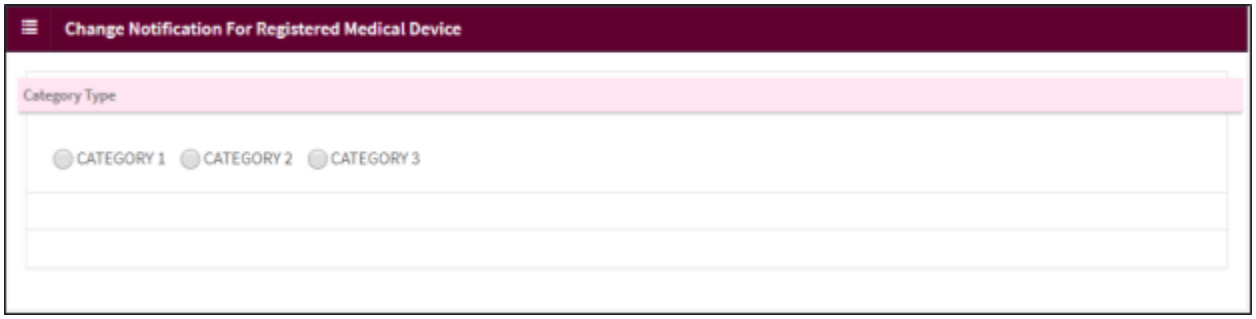
4.0 CHANGE OF NOTIFICATION

Click on the 'MEDICAL DEVICE REGISTRATION' at the left menu sidebar and click at the 'Application List' to create new form.

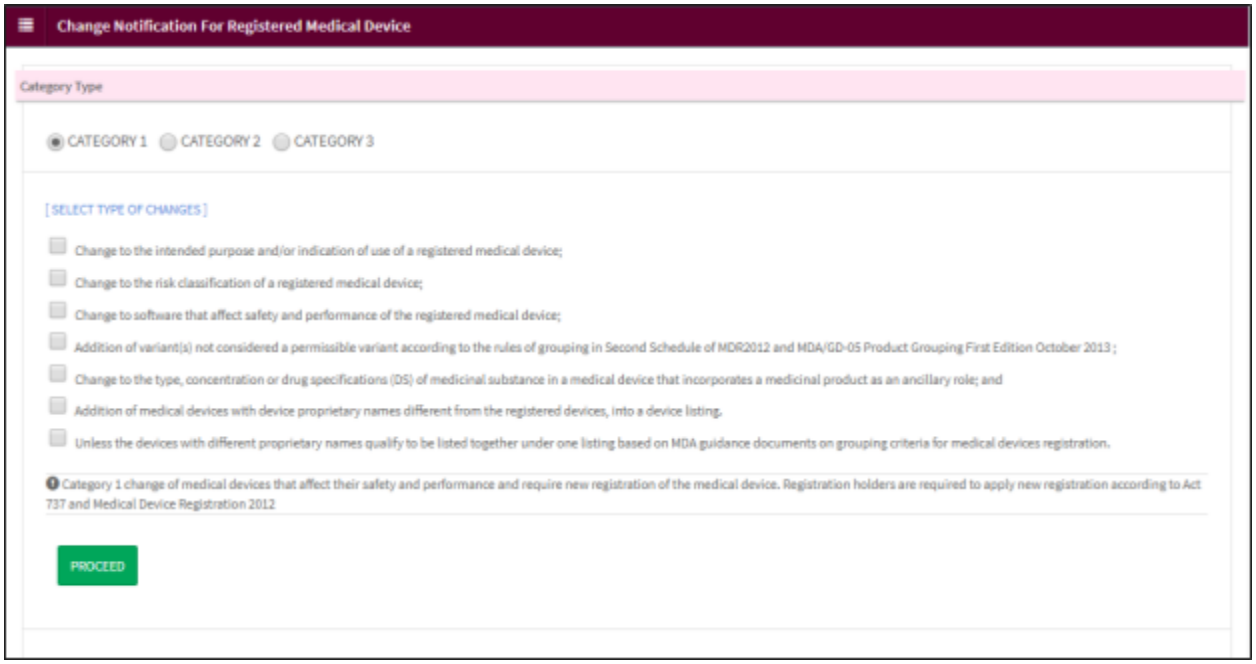


The diagram below show Application List page. Click Change Notification to re-register application.

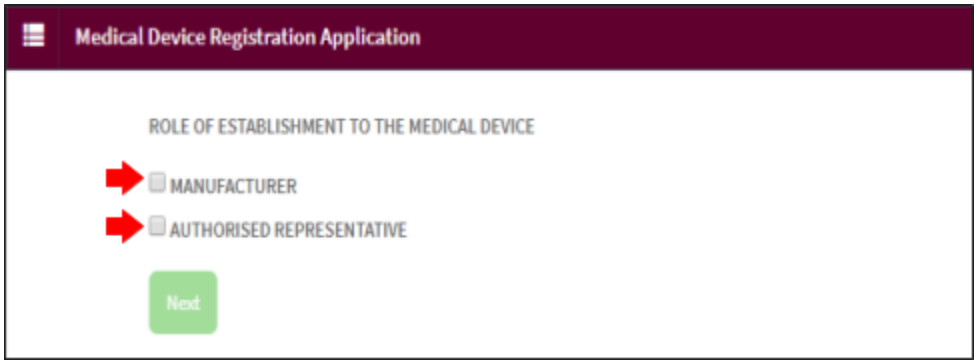
The diagram below show Change Notification For Registered Medical Device field after user click [Change Notification] button.



1) **Category 1, changes of medical devices that affect their safety and performance and require new registration of the medical device.**

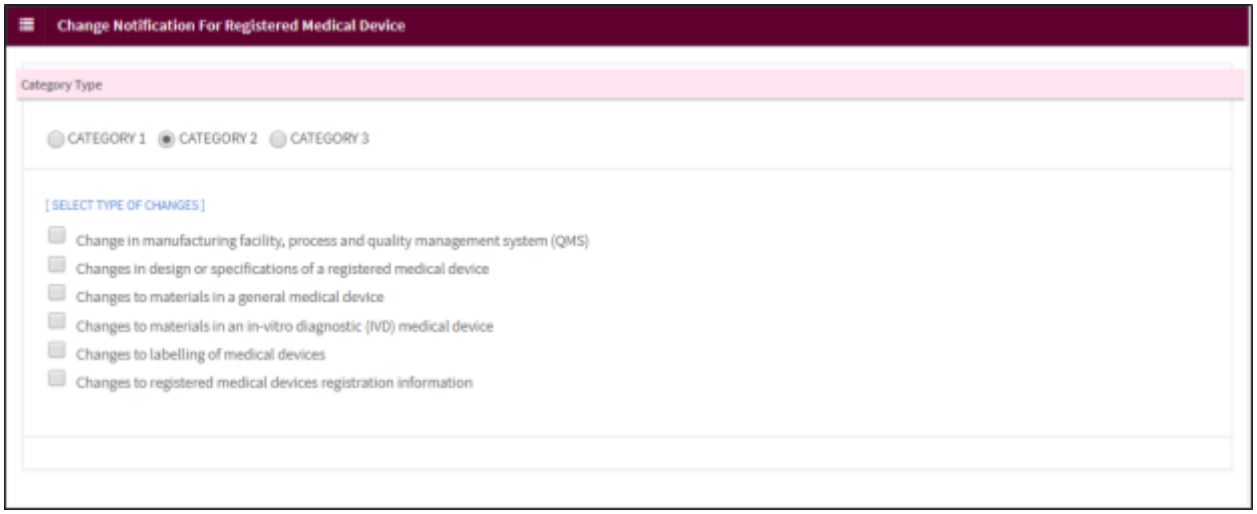


Next, user will go Medical Device Registration Application field. Tick on the 'MANUFACTURER' or 'AUTHORISED REPRESENTATIVE' to create new application and click on the button Next to proceed. User can make one application at one time. 'Next' button will enable after user tick applications checkbox.

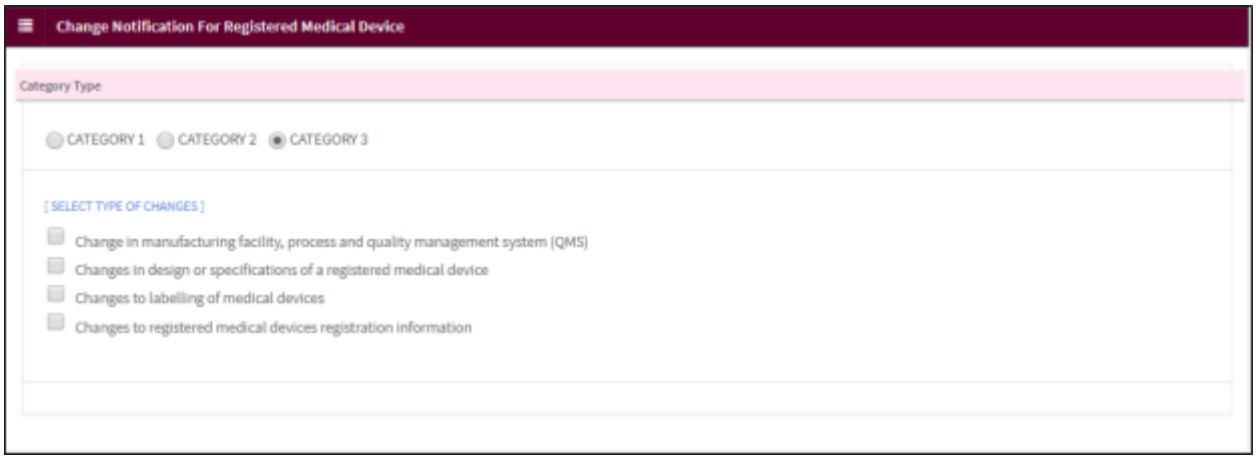


- **For complete step refer 2.2 FILL IN THE APPLICATION FORMS**

2) **Category 2, changes that require evaluation and endorsement from the MDA prior to implementation of the changes and before placing the market.**

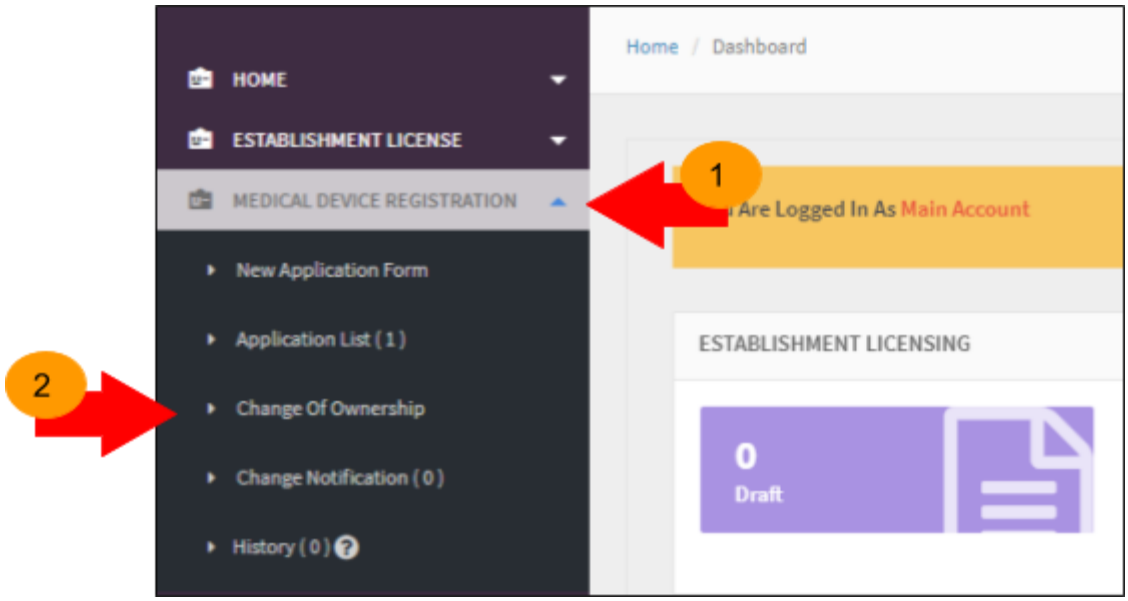


3) **Category 3, changes may be implemented immediately upon receipt of the acknowledgment from the Authority.**

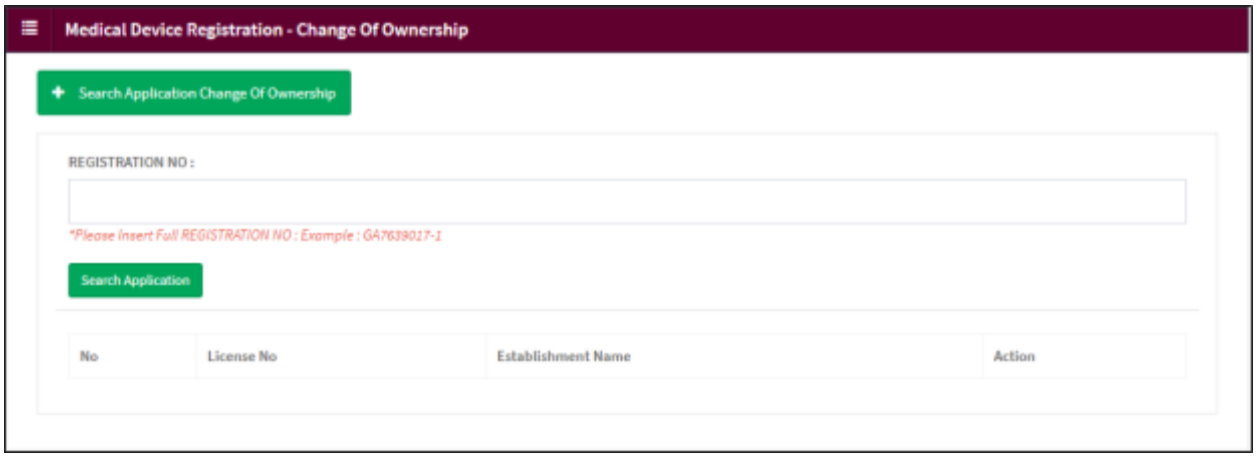


5.0 CHANGE OF OWNERSHIP

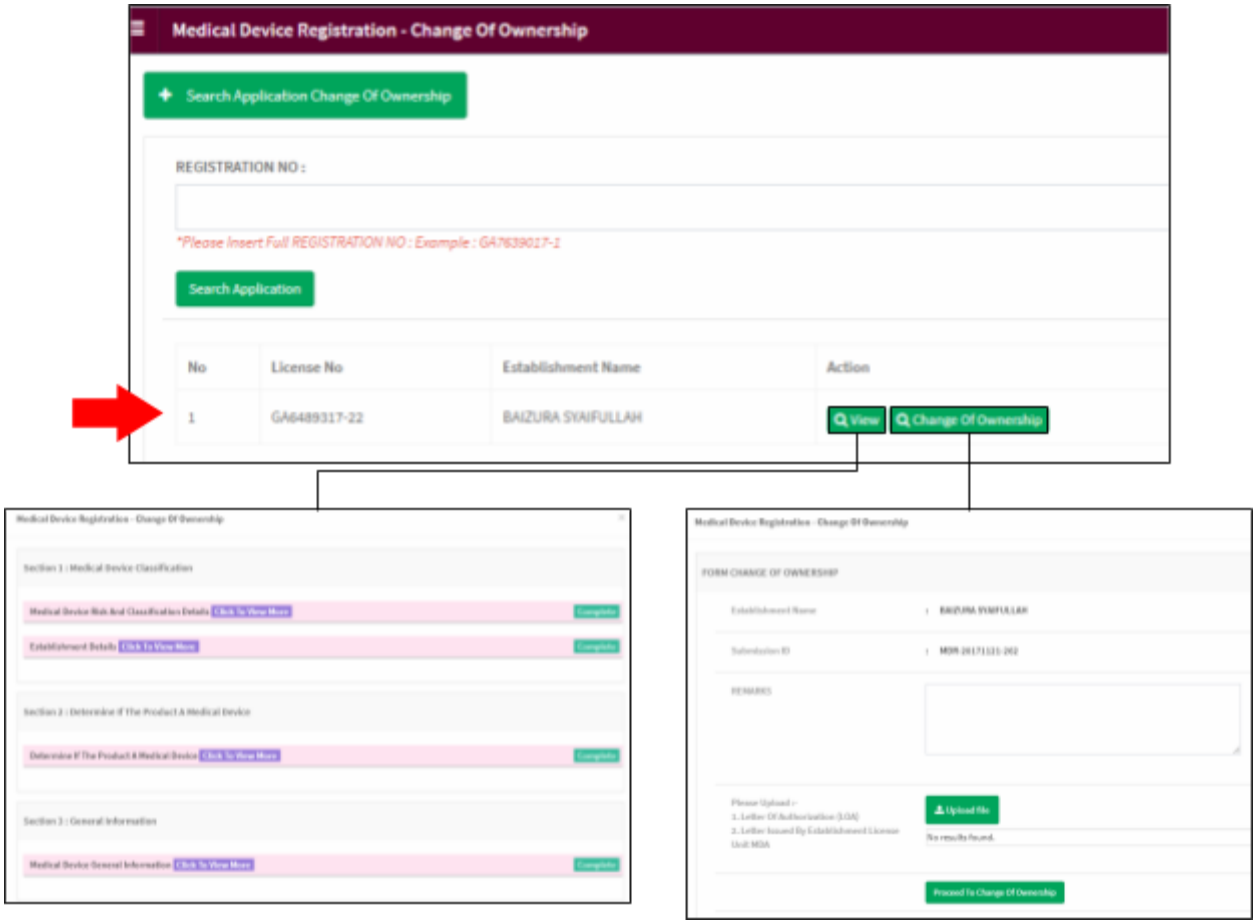
Click on the 'MEDICAL DEVICE REGISTRATION' at the left menu sidebar and click at the 'Change Of Ownership' to create new form.



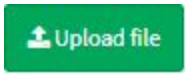
The diagram below show *Change of Ownership* page.

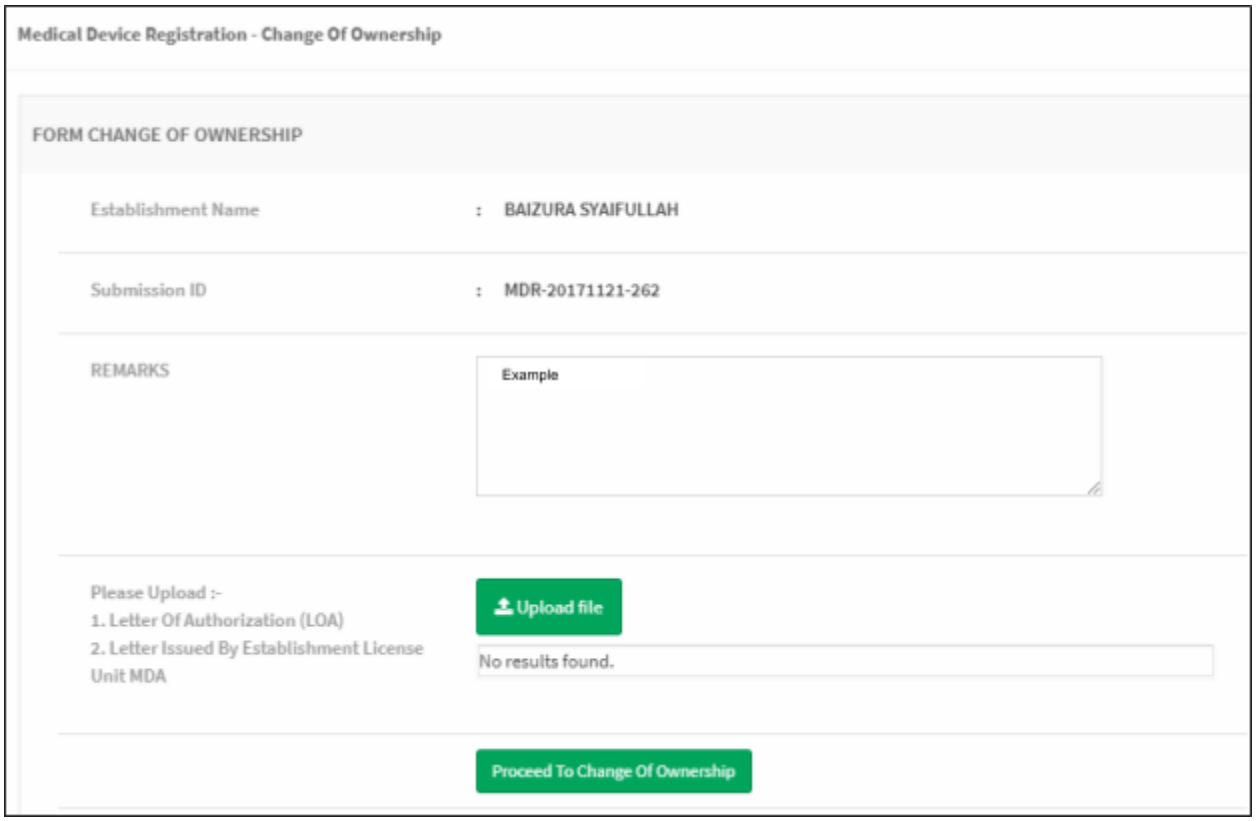


User fill the '*REGISTRATION NO*' text boxes and click Search Application to search the registration number. The registration number must be from other establishment user.



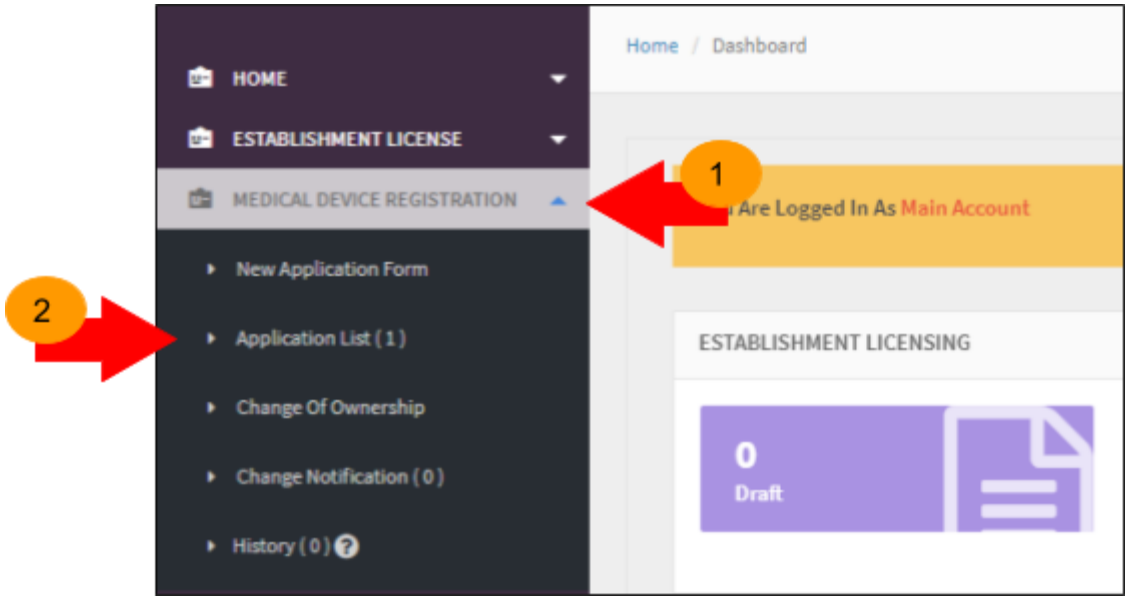
- Click View to view the application.
- Click Change Of Ownership to proceed the process change of ownership

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.

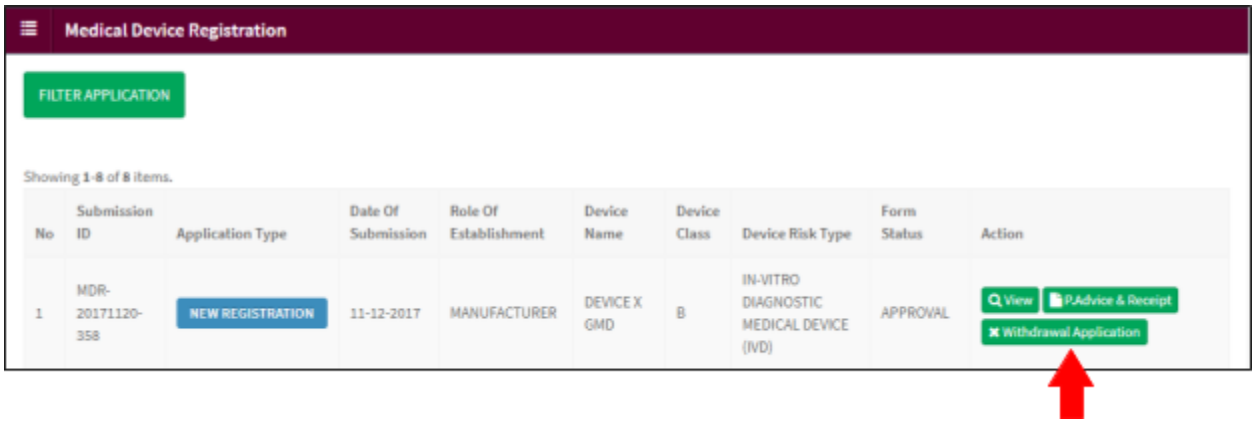


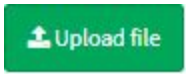
6.0 WITHDRAWAL APPLICATION

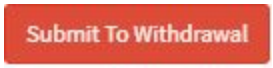
Click on the 'MEDICAL DEVICE REGISTRATION' at the left menu sidebar and click at the 'Application List' to create new form.



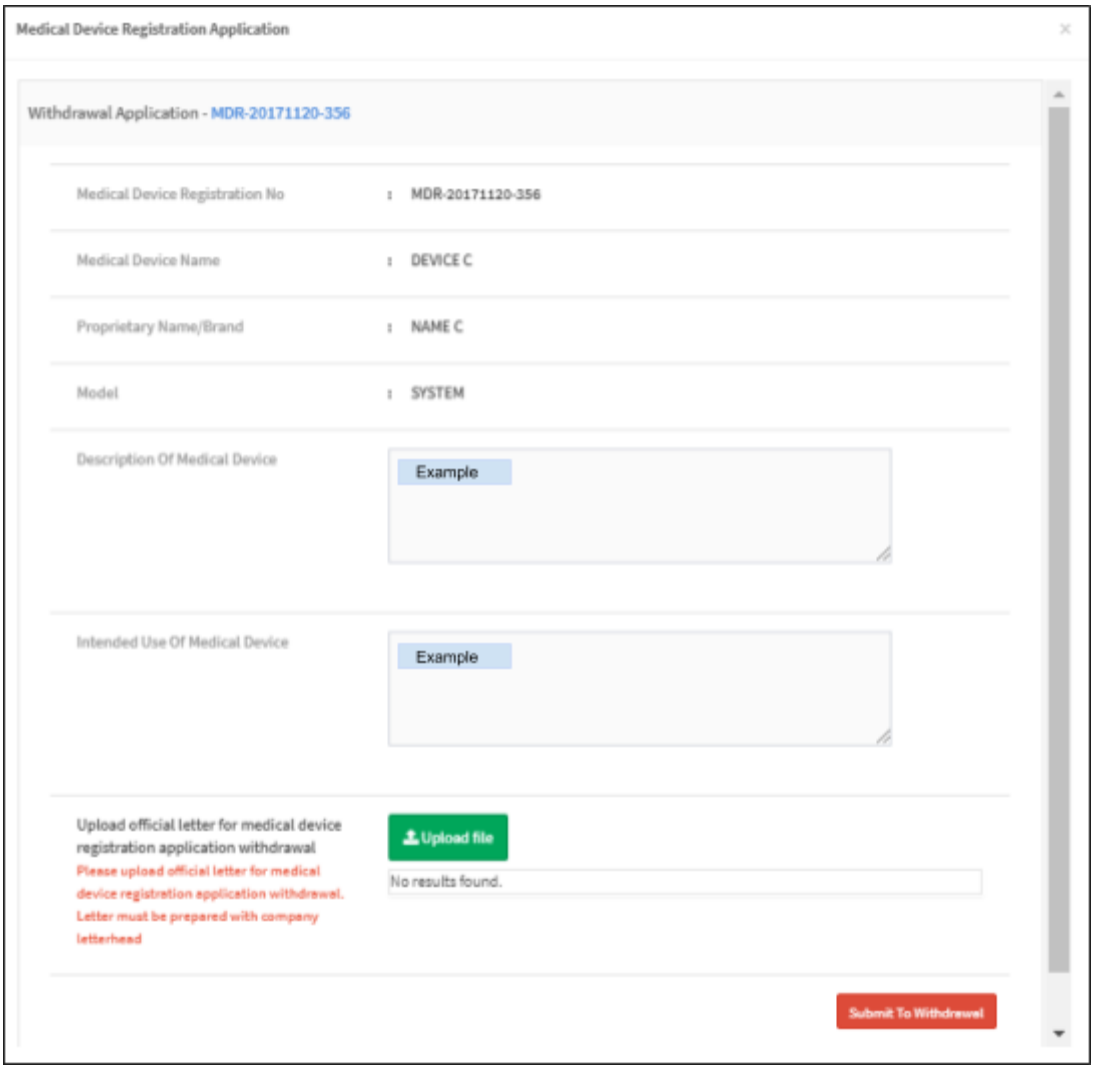
The diagram below show Application List page. Click ✖ Withdrawal Application to withdrawal application.



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

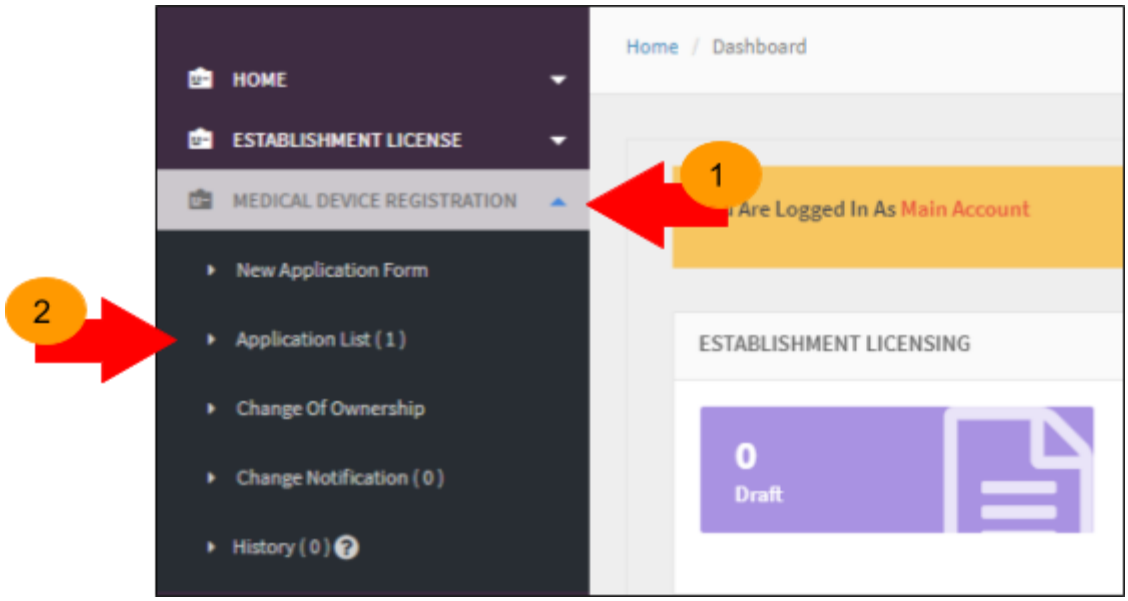
to upload file. **The file must be pdf format and size not more than 300 MB**. Next, click 

to submit.

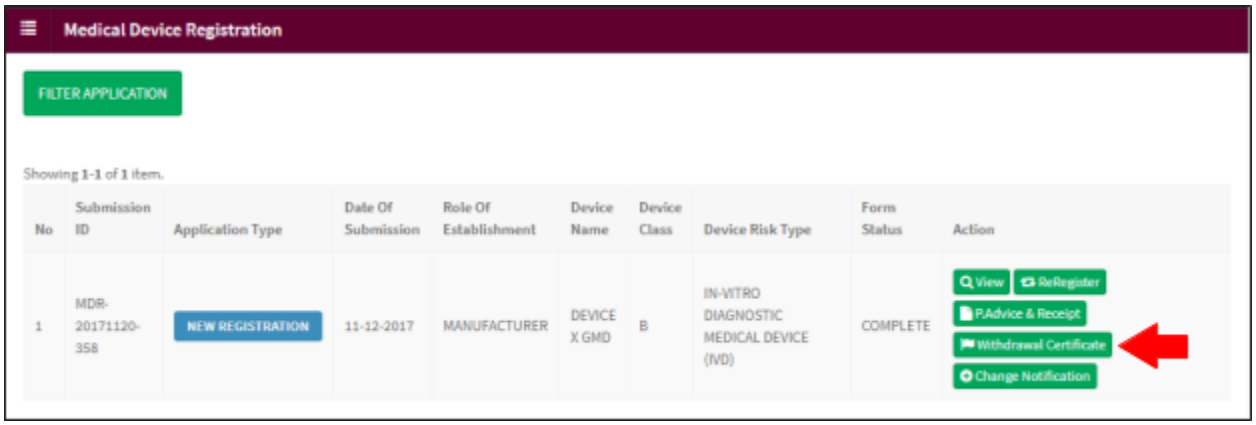


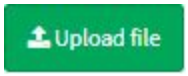
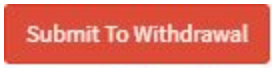
7.0 WITHDRAWAL CERTIFICATION

Click on the 'MEDICAL DEVICE REGISTRATION' at the left menu sidebar and click at the 'Application List' to create new form.



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



The diagram below appear after user click [Withdrawal] button. Click click  to upload file. **The file must be pdf format and size not more than 300 MB**. Next, click  to submit.