

USER MANUAL FRONT END USER

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



MODUL UTAMA - MDR CLASS B, C & D

DISEDIAKAN OLEH :



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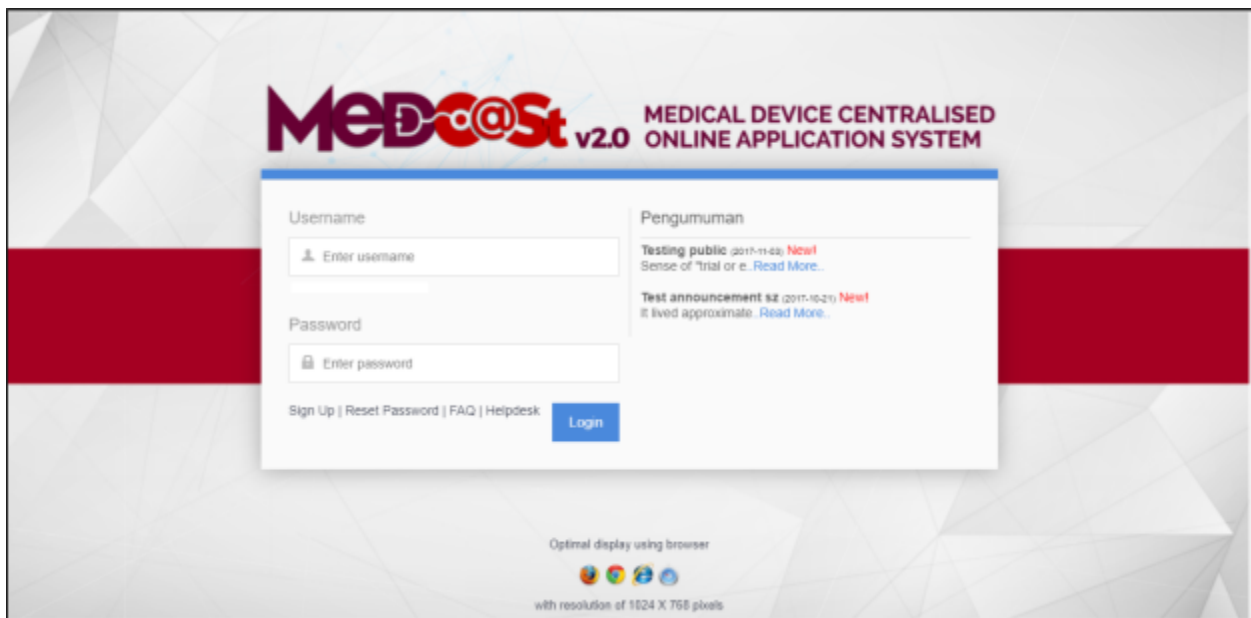
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1.0 INTRODUCTION

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

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

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



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

1.2 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.

MeDC@St Account Creation Form

Please provide a unique User Name and password to gain access to the MeDC@St system. The User Name and password is required when you login to the system.

Business Registration No

Name

Username

Email

Password

Re-Confirm Password

Reason Create Account in Medcast

Establishment Licensing & Medical Device

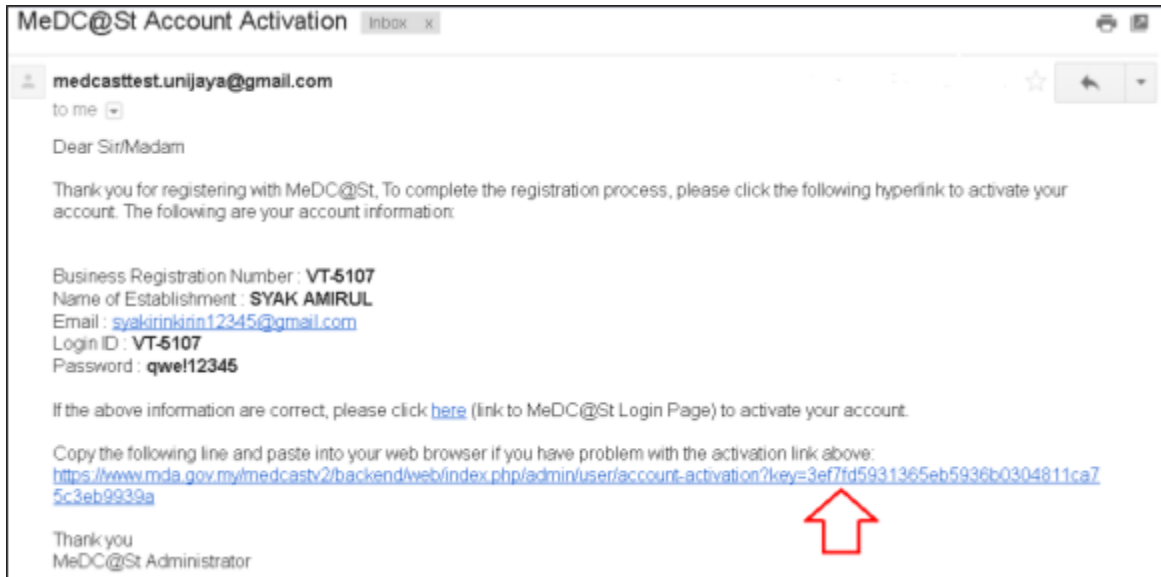
CAB Application

GLPCP Application

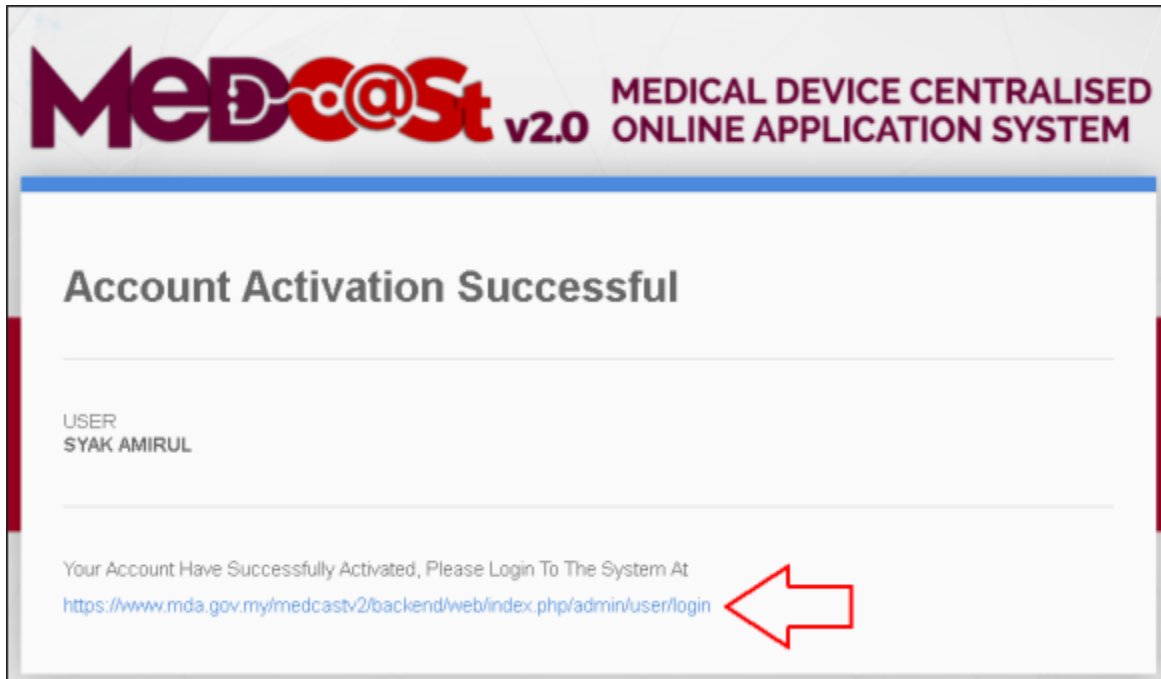
Notification Application

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.



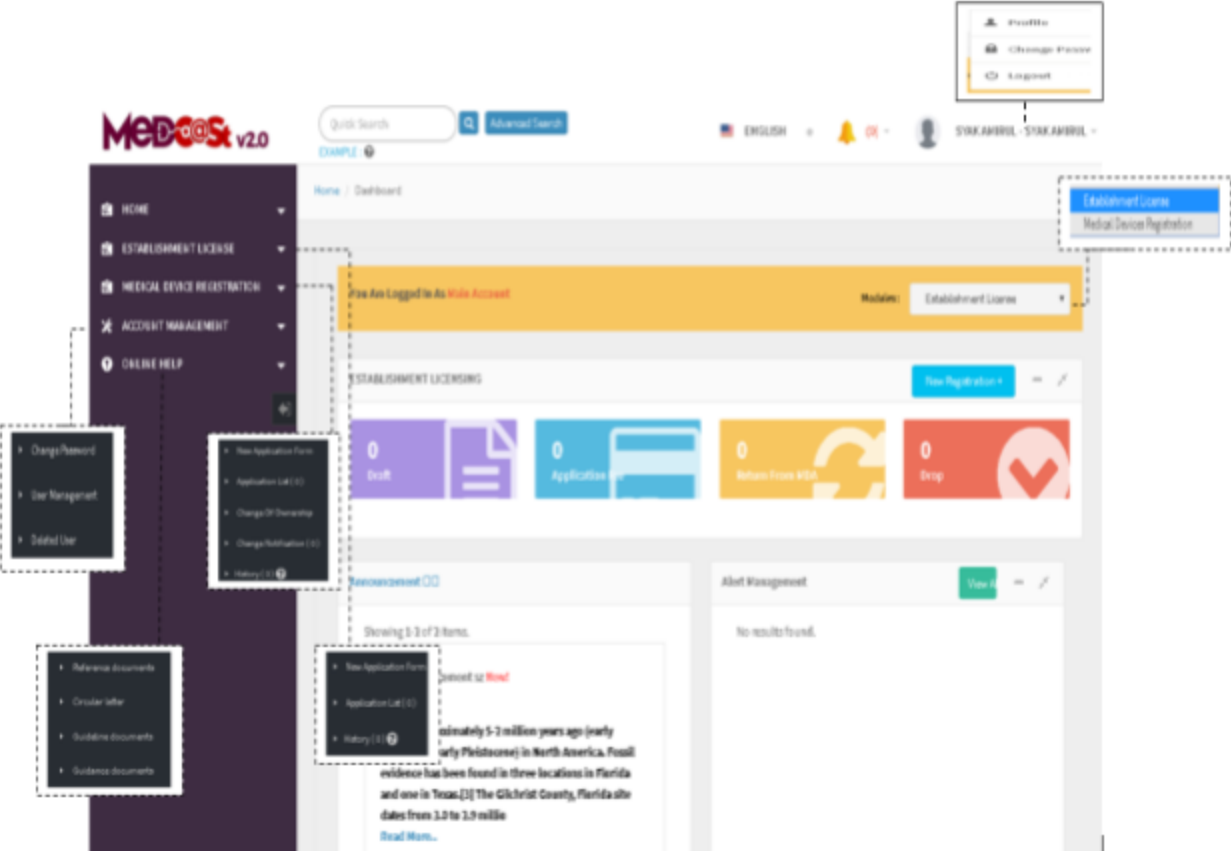
The account activation screen will display. The user must click at the link to login into the account.



The login screen will display.



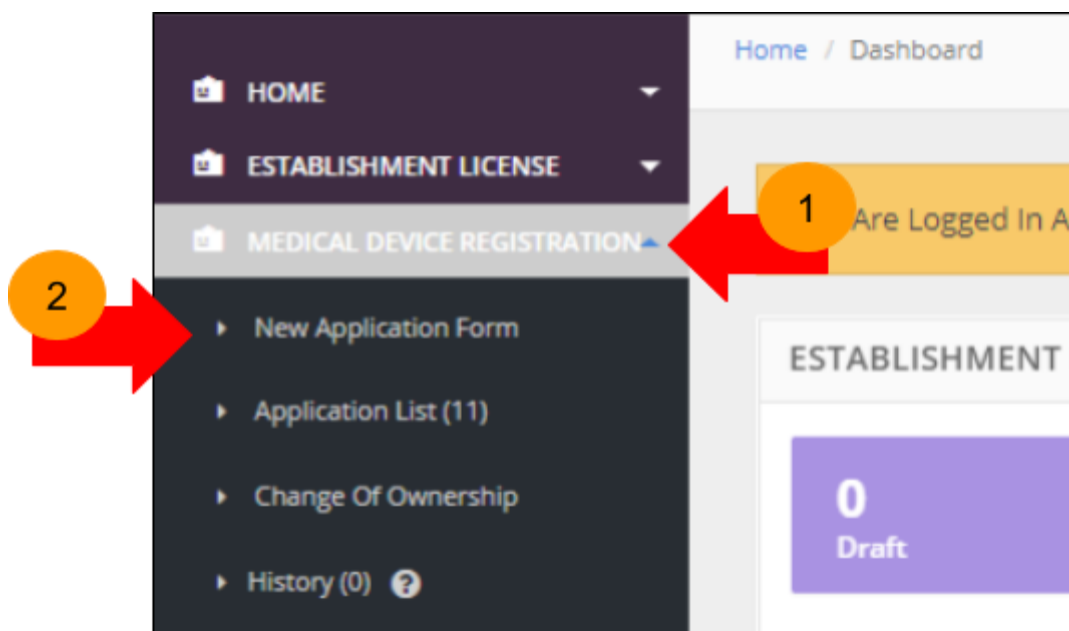
The user login successfully in the system medcast. It show the dashboard of the account.




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



Medical Device Registration Application

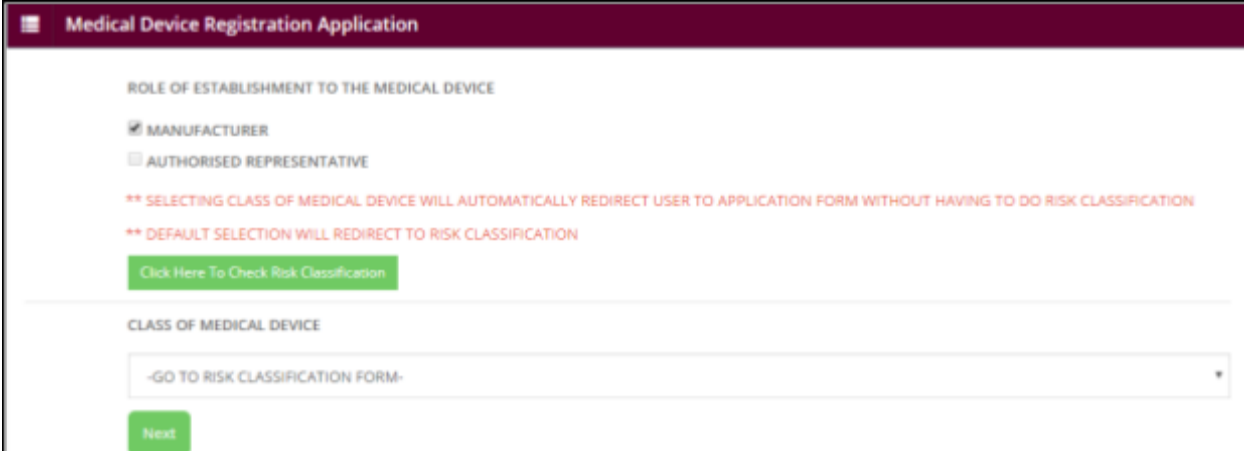
ROLE OF ESTABLISHMENT TO THE MEDICAL DEVICE

MANUFACTURER

AUTHORISED REPRESENTATIVE

[Next](#)

After click  the diagram will show.



Medical Device Registration Application

ROLE OF ESTABLISHMENT TO THE MEDICAL DEVICE

MANUFACTURER

AUTHORISED REPRESENTATIVE

** SELECTING CLASS OF MEDICAL DEVICE WILL AUTOMATICALLY REDIRECT USER TO APPLICATION FORM WITHOUT HAVING TO DO RISK CLASSIFICATION

** DEFAULT SELECTION WILL REDIRECT TO RISK CLASSIFICATION

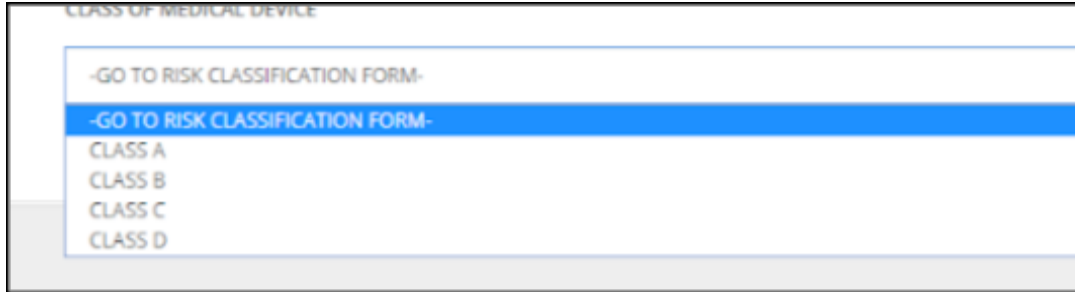
[Click Here To Check Risk Classification](#)


CLASS OF MEDICAL DEVICE

-GO TO RISK CLASSIFICATION FORM-

[Next](#)

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  the classification section will be display.

If the user choose CLASS A and click  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 :

Medical Device Risk Type :

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

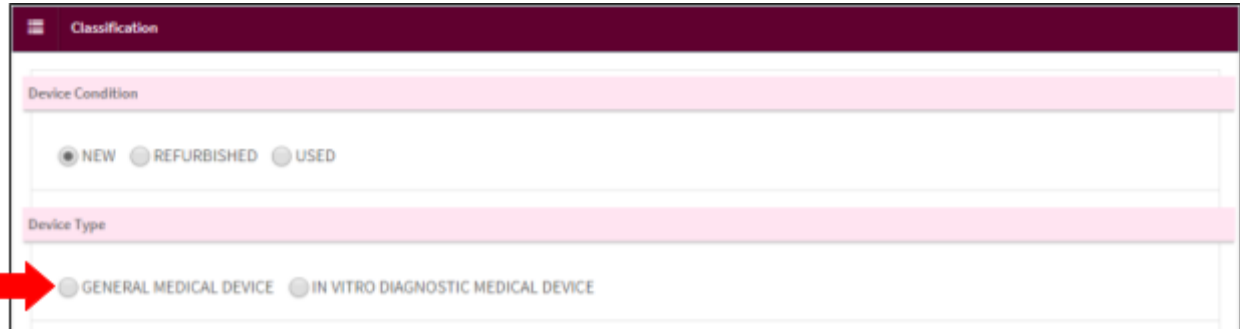
2.1.1 CLASSIFICATION APPLICATION

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



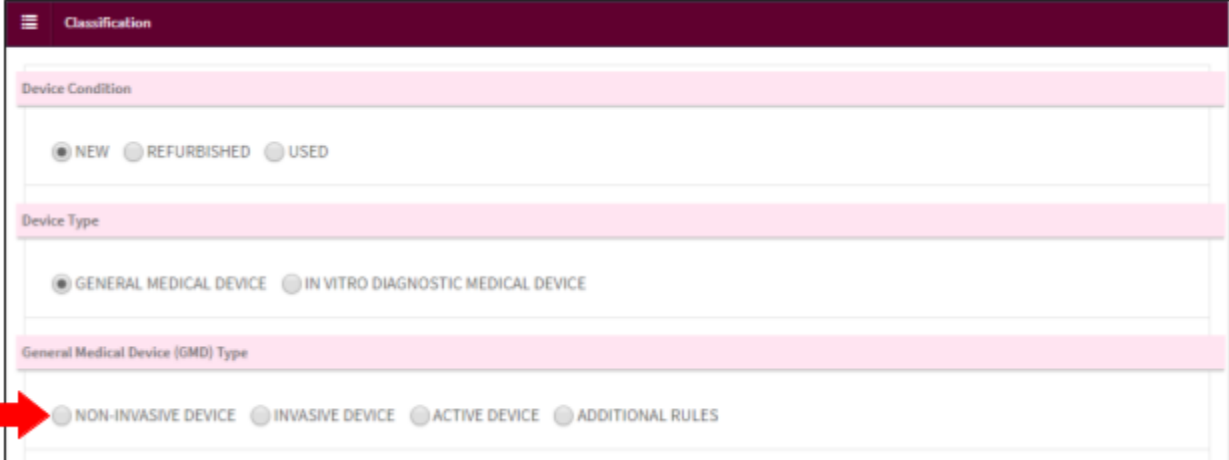
The screenshot shows the 'Classification' form with a dark red header. Below the header is a light pink bar labeled 'Device Condition'. Underneath, there are three radio buttons: 'NEW', 'REFURBISHED', and 'USED'. A red arrow points to the 'NEW' radio button, which is selected.

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



The screenshot shows the 'Classification' form with a dark red header. Below the header is a light pink bar labeled 'Device Condition'. Underneath, there are three radio buttons: 'NEW', 'REFURBISHED', and 'USED'. Below this is another light pink bar labeled 'Device Type'. Underneath, there are two radio buttons: 'GENERAL MEDICAL DEVICE' and 'IN VITRO DIAGNOSTIC MEDICAL DEVICE'. A red arrow points to the 'GENERAL MEDICAL DEVICE' radio button, which is selected.

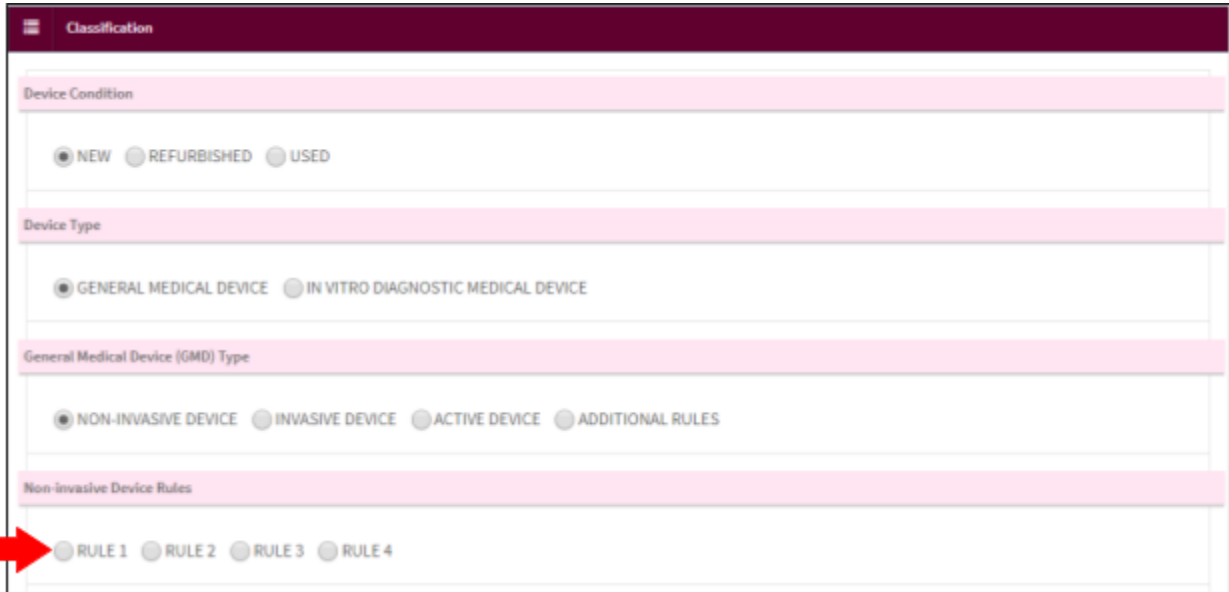
Next, tick 'NON-INVASIVE DEVICE' radio button in general 'Medical Device (GMD) Type' field.



The screenshot shows the 'Classification' form with the following sections:

- Device Condition:** Radio buttons for NEW (selected), REFURBISHED, and USED.
- Device Type:** Radio buttons for GENERAL MEDICAL DEVICE (selected) and IN VITRO DIAGNOSTIC MEDICAL DEVICE.
- General Medical Device (GMD) Type:** Radio buttons for NON-INVASIVE DEVICE (selected), INVASIVE DEVICE, ACTIVE DEVICE, and ADDITIONAL RULES. A red arrow points to the 'NON-INVASIVE DEVICE' button.

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



The screenshot shows the 'Classification' form with the following sections:

- Device Condition:** Radio buttons for NEW (selected), REFURBISHED, and USED.
- Device Type:** Radio buttons for GENERAL MEDICAL DEVICE (selected) and IN VITRO DIAGNOSTIC MEDICAL DEVICE.
- General Medical Device (GMD) Type:** Radio buttons for NON-INVASIVE DEVICE (selected), INVASIVE DEVICE, ACTIVE DEVICE, and ADDITIONAL RULES.
- Non-invasive Device Rules:** Radio buttons for RULE 1 (selected), RULE 2, RULE 3, and RULE 4. A red arrow points to the 'RULE 1' button.

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

Device Type

GENERAL MEDICAL DEVICE IN VITRO DIAGNOSTIC MEDICAL DEVICE

General Medical Device (GMD) Type

NON-INVASIVE DEVICE INVASIVE DEVICE ACTIVE DEVICE ADDITIONAL RULES

Non-invasive Device Rules

RULE 1 RULE 2 RULE 3 RULE 4

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 HEAL ONLY THROUGH SECONDARY INTENT

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

click  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 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**



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.



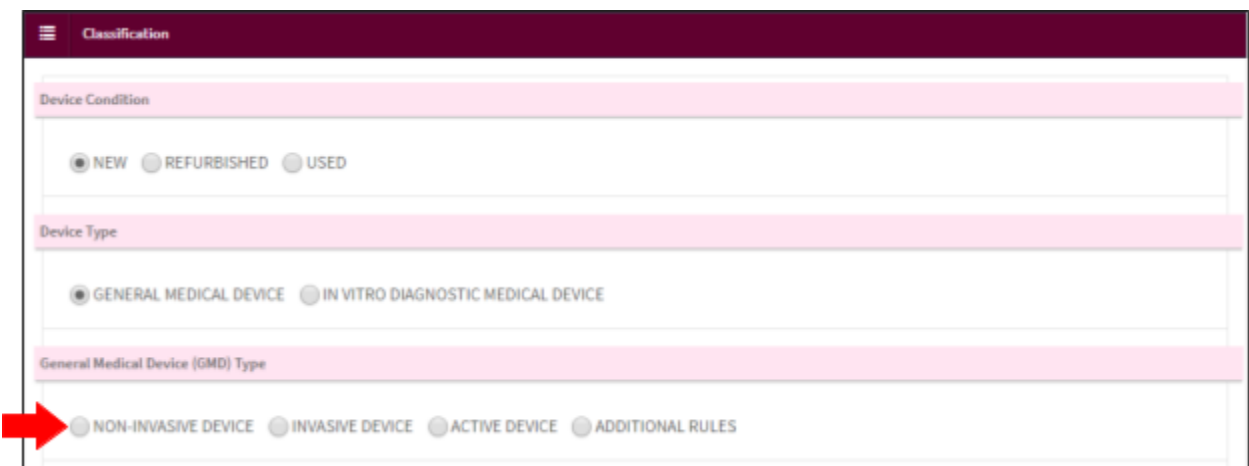
The screenshot shows the 'Classification' form with a dark purple header. Below the header is a pink bar labeled 'Device Condition'. Underneath, there are three radio buttons: 'NEW', 'REFURBISHED', and 'USED'. A red arrow points to the 'NEW' radio button, which is selected.

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



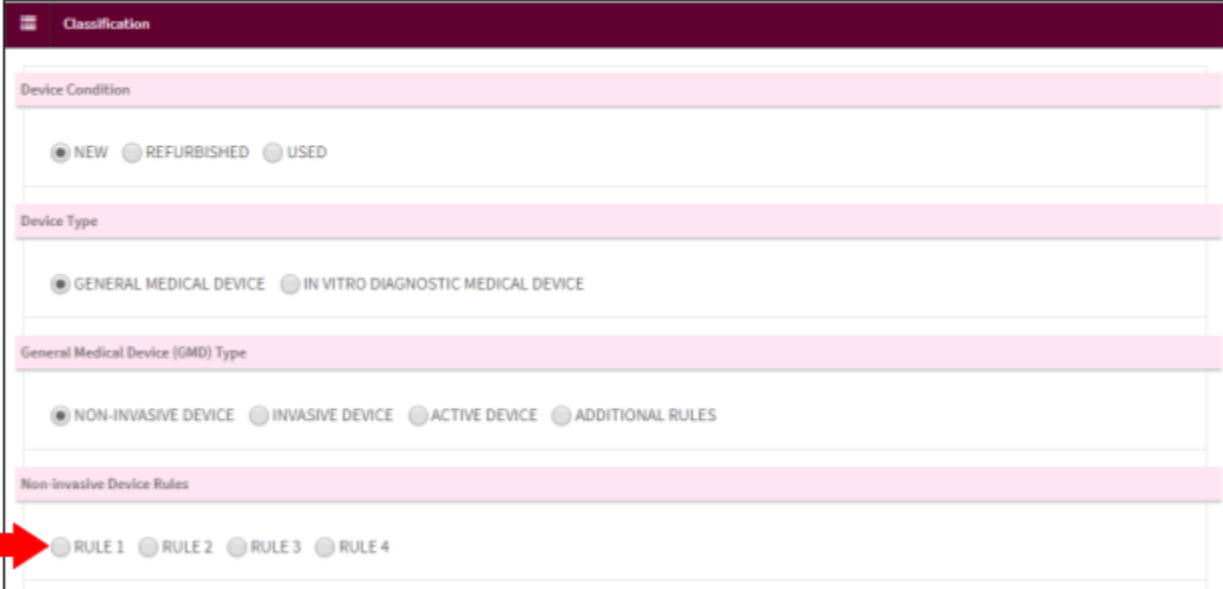
The screenshot shows the 'Classification' form with a dark purple header. Below the header is a pink bar labeled 'Device Condition'. Underneath, there are three radio buttons: 'NEW', 'REFURBISHED', and 'USED'. Below this is another pink bar labeled 'Device Type'. Underneath, there are two radio buttons: 'GENERAL MEDICAL DEVICE' and 'IN VITRO DIAGNOSTIC MEDICAL DEVICE'. A red arrow points to the 'GENERAL MEDICAL DEVICE' radio button, which is selected.

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



The screenshot shows the 'Classification' form with a dark purple header. Below the header is a pink bar labeled 'Device Condition'. Underneath, there are three radio buttons: 'NEW', 'REFURBISHED', and 'USED'. Below this is another pink bar labeled 'Device Type'. Underneath, there are two radio buttons: 'GENERAL MEDICAL DEVICE' and 'IN VITRO DIAGNOSTIC MEDICAL DEVICE'. Below this is a third pink bar labeled 'General Medical Device (GMD) Type'. Underneath, there are four radio buttons: 'NON-INVASIVE DEVICE', 'INVASIVE DEVICE', 'ACTIVE DEVICE', and 'ADDITIONAL RULES'. A red arrow points to the 'NON-INVASIVE DEVICE' radio button, which is selected.

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




The screenshot shows the 'Classification' form with the following sections:

- Device Condition:** NEW REFURBISHED USED
- Device Type:** GENERAL MEDICAL DEVICE IN VITRO DIAGNOSTIC MEDICAL DEVICE
- General Medical Device (GMD) Type:** NON-INVASIVE DEVICE INVASIVE DEVICE ACTIVE DEVICE ADDITIONAL RULES
- Non-invasive Device Rules:** RULE 1 RULE 2 RULE 3 RULE 4

A red arrow points to the 'RULE 1' radio button in the 'Non-invasive Device Rules' section.

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



The screenshot shows the 'Rules 1 Details' section of the form with the following options:

- 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 HEAL ONLY THROUGH SECONDARY INTENT

A red arrow points to the 'THE WOUND CAN BE HEAL ONLY THROUGH SECONDARY INTENT' radio button.

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

User click  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 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 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

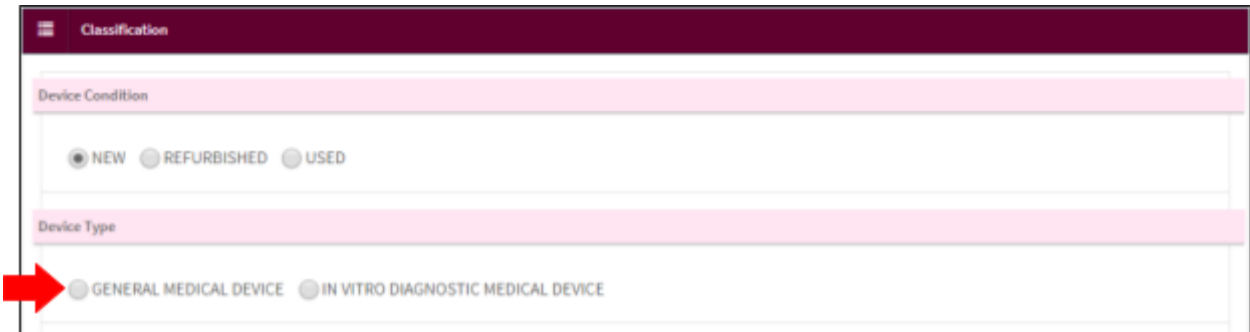
2.1.3 CLASS D APPLICATION

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



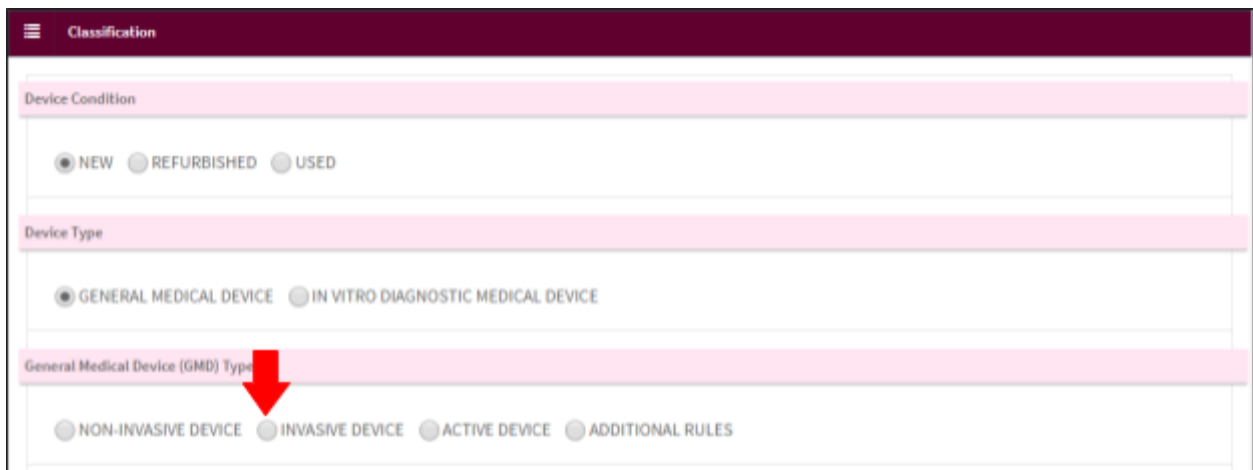
The screenshot shows the 'Classification' form with the 'Device Condition' field highlighted in pink. The field contains three radio buttons: 'NEW', 'REFURBISHED', and 'USED'. A red arrow points to the 'NEW' radio button, which is selected.

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



The screenshot shows the 'Classification' form with the 'Device Type' field highlighted in pink. The field contains two radio buttons: 'GENERAL MEDICAL DEVICE' and 'IN VITRO DIAGNOSTIC MEDICAL DEVICE'. A red arrow points to the 'GENERAL MEDICAL DEVICE' radio button, which is selected.

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



The screenshot shows the 'Classification' form with the 'General Medical Device (GMD) Type' field highlighted in pink. The field contains four radio buttons: 'NON-INVASIVE DEVICE', 'INVASIVE DEVICE', 'ACTIVE DEVICE', and 'ADDITIONAL RULES'. A red arrow points to the 'INVASIVE DEVICE' radio button, which is selected.

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

The screenshot shows a 'Classification' form with several sections. The 'Invasive Device Rules' section is highlighted with a red arrow pointing to the 'RULE 6' radio button, which is selected. Other sections include 'Device Condition' (NEW, REFURBISHED, USED), 'Device Type' (GENERAL MEDICAL DEVICE, IN VITRO DIAGNOSTIC MEDICAL DEVICE), and 'General Medical Device (GMD) Type' (NON-INVASIVE DEVICE, INVASIVE DEVICE, ACTIVE DEVICE, ADDITIONAL RULES).

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.

The screenshot shows the 'Invasive Device Rules' form with 'RULE 6' selected. Below it is the 'Rule 6 Details' section, which contains a list of options. The second option, 'UNLESS THEY ARE INTENDED SPECIFICALLY FOR USE IN DIRECT CONTACT WITH THE CENTRAL NERVOUS SYSTEM; OR', is selected and highlighted with a red arrow. Other options include 'SURGICALLY INVASIVE MEDICES DEVICES INTENDED FOR TRANSIENT USE' and 'UNLESS INTENDED SPECIFICALLY TO DIAGNOSE, MONITOR OR CORRECT A DEFECT OF THE HEART OR OF THE CENTRAL CIRCULATORY SYSTEM THROUGH DIRECT CONTACT WITH THESE PARTS OF THE BODY'.

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](#)

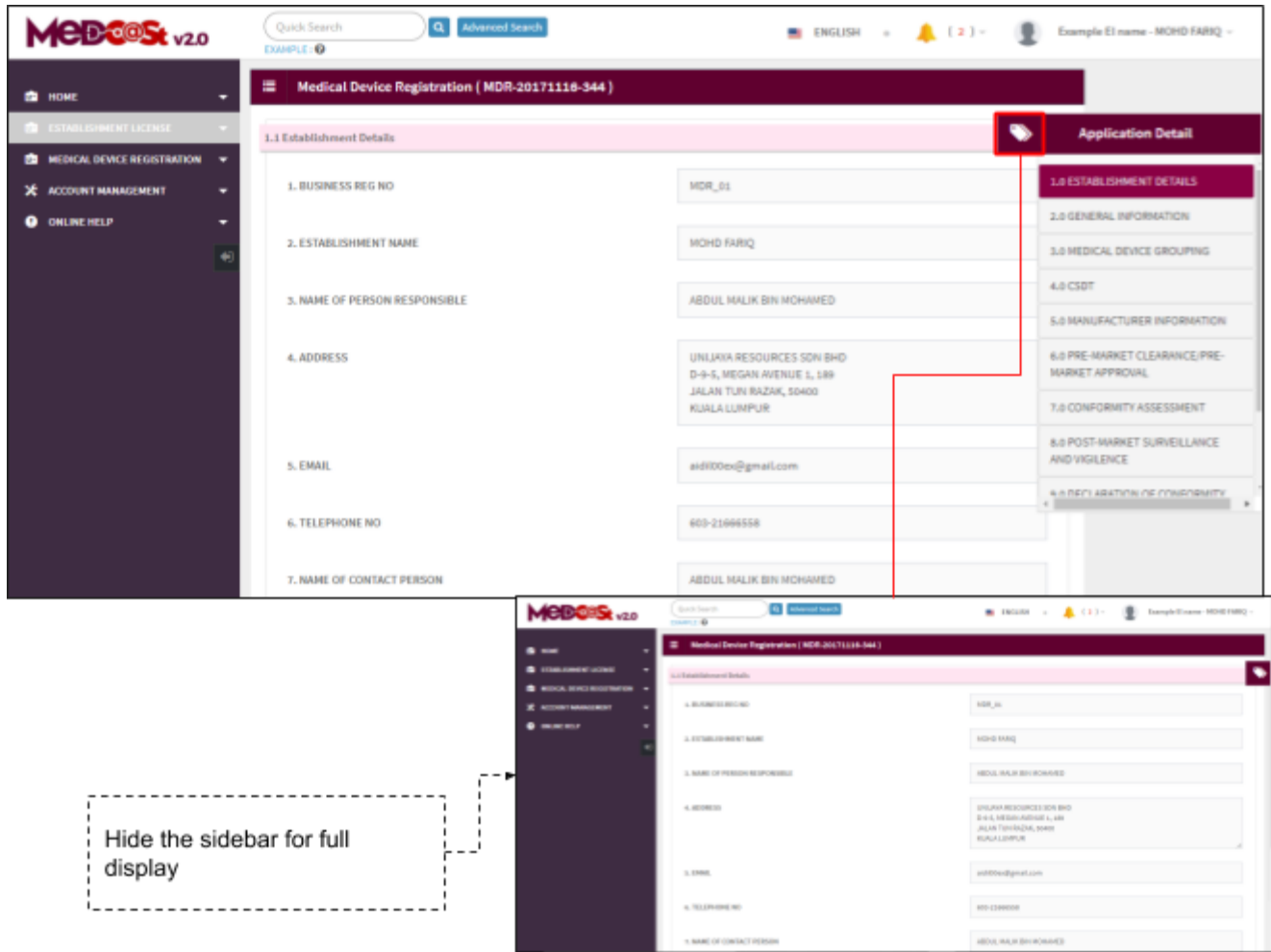
Class Payment Details

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 [Next](#) 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.

Medical Device Registration (MDR-20171116-344)

2.1 General Information

1. Role Of Establishment To Medical Device Manufacturer Authorized Representative

2. Medical Device Name *

3. Class Of Device
CLASS B

4. Device Risk Type
GENERAL MEDICAL DEVICE - NON-INVASIVE DEVICE

5. Classification Rules
RULE 1

6. Proprietary Name/Brand *

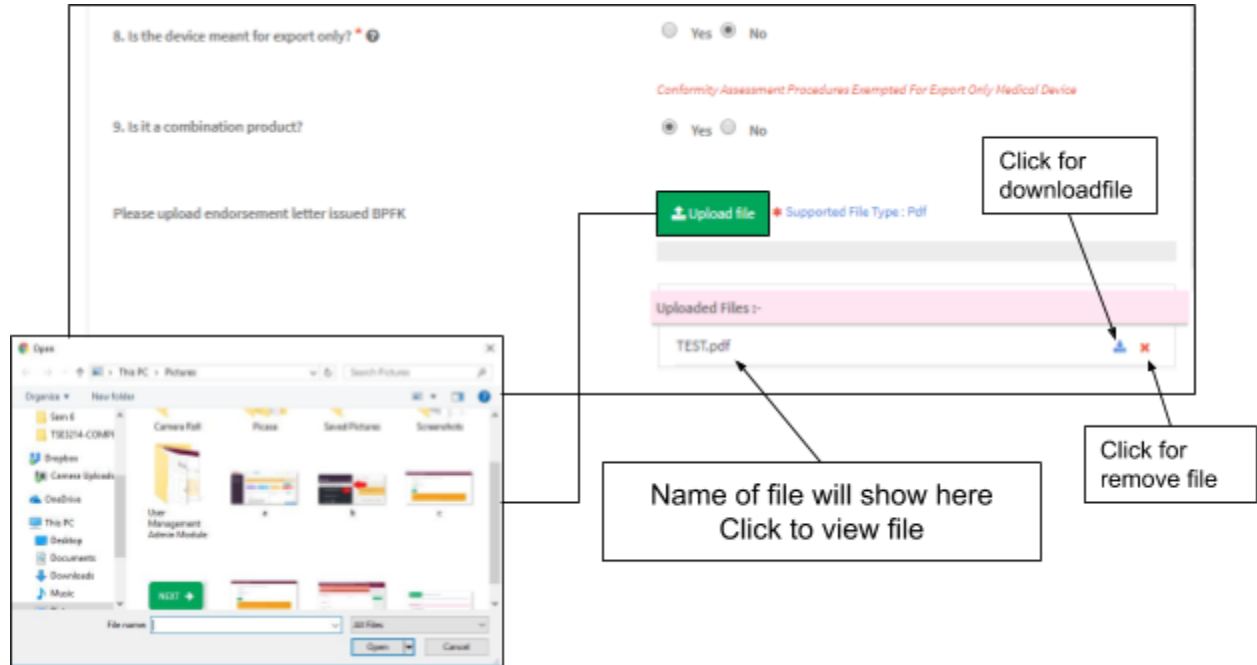
7. Medical Device Category *


Application Detail

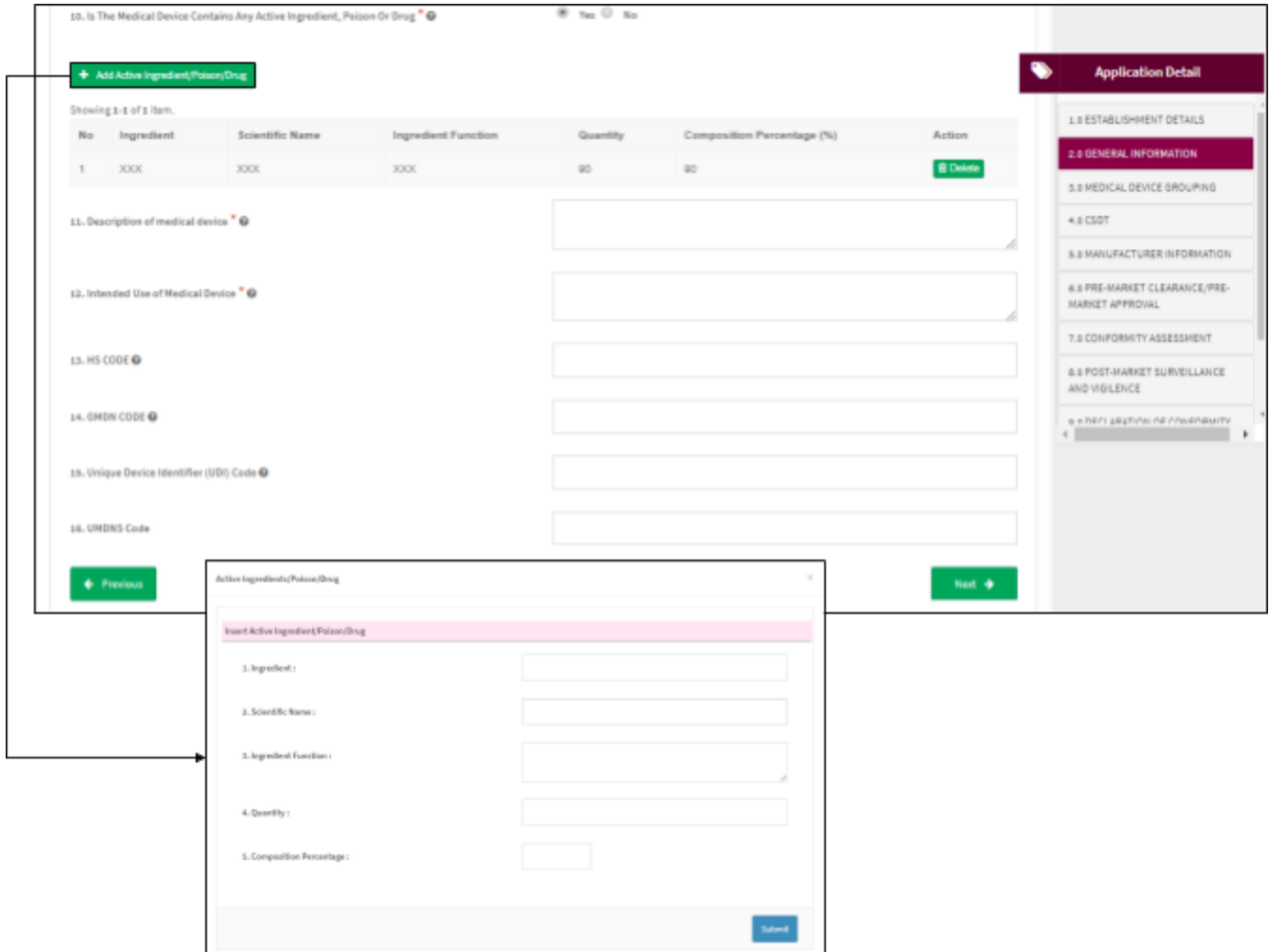
- 1.0 ESTABLISHMENT DETAILS
- 2.0 GENERAL INFORMATION**
- 3.0 MEDICAL DEVICE GROUPING
- 4.0 CSOT
- 5.0 MANUFACTURER INFORMATION
- 6.0 PRE-MARKET CLEARANCE/PRE-MARKET APPROVAL
- 7.0 CONFORMITY ASSESSMENT
- 8.0 POST-MARKET SURVEILLANCE AND VIGILANCE
- 9.0 SPECIFICATION OF CONFORMITY






Select Medical Device Category:

- MD 0100 - GENERAL NON-ACTIVE, NON-IMPLANTABLE MEDICAL DEVICES
- MD 0101 - Non-active orthopaedic and rehabilitation devices
- MD 0102 - Non-active devices for anaesthesia, emergency and intensive care
- MD 0103 - Non-active devices for injection, infusion, transfusion and dialysis
- MD 0104 - Non-active medical devices with measuring function
- MD 0105 - Non-active ophthalmologic devices
- MD 0106 - Non-active instrument
- MD 0107 - Contraceptive medical devices
- MD 0108 - Non-active medical devices for disinfecting, cleaning and rinsing
- MD 0109 - Non-active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART)
- MD 0200 - NON-ACTIVE IMPLANTS
- MD 0201 - Non-active cardiovascular implants
- MD 0202 - Non-active orthopaedic implants
- MD 0203 - Non-active functional implants
- MD 0204 - Non-active soft tissue implants
- MD 0300 - DEVICES FOR WOUND CARE
- MD 0301 - Bandages and wound dressings
- MD 0302 - Suture material and clamps
- MD 0303 - Other medical devices for wound care



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

Medical Device Registration (MDR-20171120-358)

2.1 General Information

1. Role Of Establishment To Medical Device Manufacturer Authorized Representative

2. Medical Device Name *

3. Class Of Device CLASS B

4. Device Risk Type IN VITRO DIAGNOSTIC MEDICAL DEVICE

5. Classification Rules RULE 4

6. Proprietary Name/Brand *

7. Medical Device Category *



Application Detail

- 1.0 ESTABLISHMENT DETAILS
- 2.0 GENERAL INFORMATION**
- 3.0 MEDICAL DEVICE GROUPING
- 4.0 CSDT
- 5.0 MANUFACTURER INFORMATION
- 6.0 PRE-MARKET CLEARANCE/PRE-MARKET APPROVAL
- 7.0 CONFORMITY ASSESSMENT
- 8.0 POST-MARKET SURVEILLANCE AND VIGILANCE
- 9.0 DECLARATION OF CONFORMITY

Select Medical Device Category

- IVD 0200 List A Reagents And Reagent Products, Including Related Calibrators And Control Materials, For Determining The Following Blood Groups
- IVD 0201 ASO system
- IVD 0202 Rhesus (C, c, D, E, e)
- IVD 0203 Anti-Hel
- IVD 0204 List A Reagents And Reagent Products, Including Related Calibrators And Control Materials, For The Detection, Confirmation And Quantification In Human Specimens Of Markers Of
- IVD 0205 HIV Infection (HIV 1 and 2)
- IVD 0206 HTLV1 and II
- IVD 0207 Hepatitis B, C and D
- IVD 0208 List B Reagents, Reagent Products And Devices For Self-Diagnosis, Including Related Calibrators And Control Materials, For Determining, Detection, Quantification, Diagnosing, Evaluating
- IVD 0209 Anti-Duffy and anti-Kidd
- IVD 0210 Irregular anti-erythrocytic antibodies
- IVD 0211 Congenital infections: rubella, toxoplasmosis
- IVD 0212 Hereditary diseases: phenylketonuria
- IVD 0213 Human infections: cytomegalovirus, chlamydia
- IVD 0214 HLA tissue groups: DR, A, B
- IVD 0215 Tumoral marker: PSA
- IVD 0216 Risk of trisomy 21 (incl. software)
- IVD 0217 Device for self-diagnosis device for the measurement of blood Sugar
- IVD 0400 Devices For Self-Testing

The screenshot displays a web form for medical device registration. On the left, there are several input fields with labels: '8. Is the device meant for export only?' (with radio buttons for 'Yes' and 'No'), '9. Description of medical device', '10. Intended Use of Medical Device', '11. HS CODE', '12. GMDN CODE', '13. Unique Device Identifier (UDI) Code', and '14. UMDNS Code'. Below these fields are 'Previous' and 'Next' navigation buttons. On the right, a sidebar titled 'Application Detail' contains a list of sections: '1.0 ESTABLISHMENT DETAILS', '2.0 GENERAL INFORMATION' (highlighted in dark red), '3.0 MEDICAL DEVICE GROUPING', '4.0 CSDT', '5.0 MANUFACTURER INFORMATION', '6.0 PRE-MARKET CLEARANCE/PRE-MARKET APPROVAL', '7.0 CONFORMITY ASSESSMENT', '8.0 POST-MARKET SURVEILLANCE AND VIGILANCE', and '9.0 DECLARATION OF CONFORMITY'. A red banner above the sidebar reads 'Conformity Assessment Procedures Exempted For Export Only Medical'.

- 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.


The screenshot shows the '3.1 Medical Device Grouping (GMD)' section of the application. The 'GROUPING TYPE OF MEDICAL DEVICE' dropdown menu is open, showing the following options: Single, System, Family, and Set. The 'next' button is highlighted in green, indicating the user is ready to proceed to the next step.

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

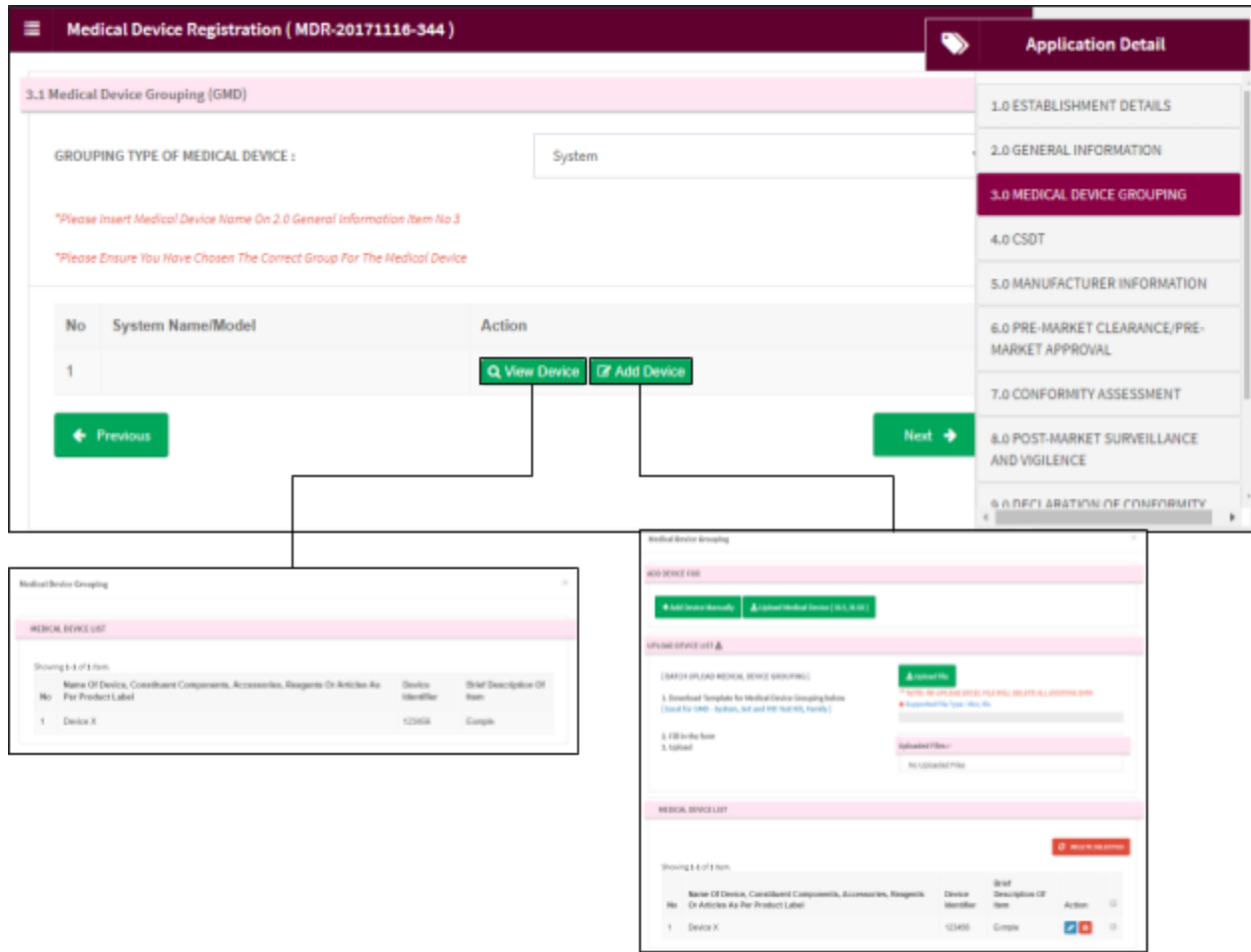
i) Single

The screenshot shows the '3.1 Medical Device Grouping (GMD)' section of the application. The 'GROUPING TYPE OF MEDICAL DEVICE' dropdown menu is set to 'Single'. The 'DEVICE IDENTIFIER' text box contains the placeholder text 'Insert Identifier'. The 'next' button is highlighted in green, indicating the user is ready to proceed to the next step.

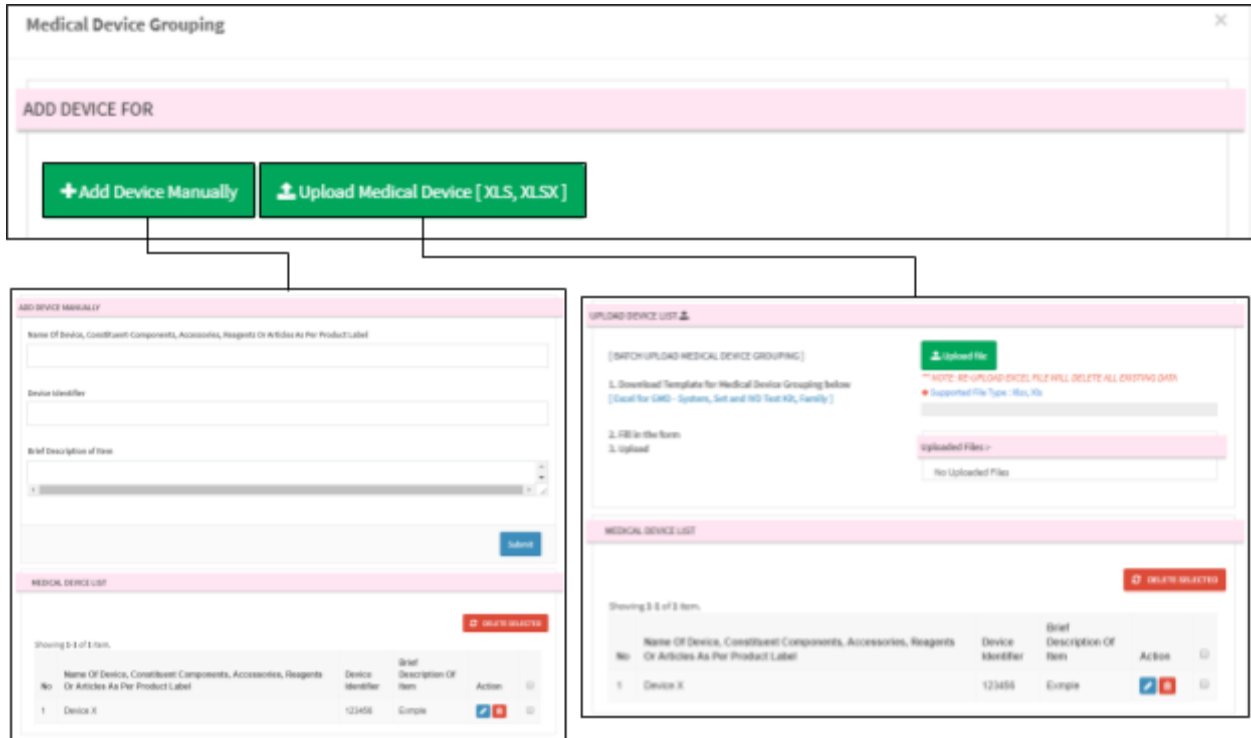
User fill 'DEVICE IDENTIFIER' textbox'. Click  to go to the next section. Click










 to go to the previous section.

ii) System

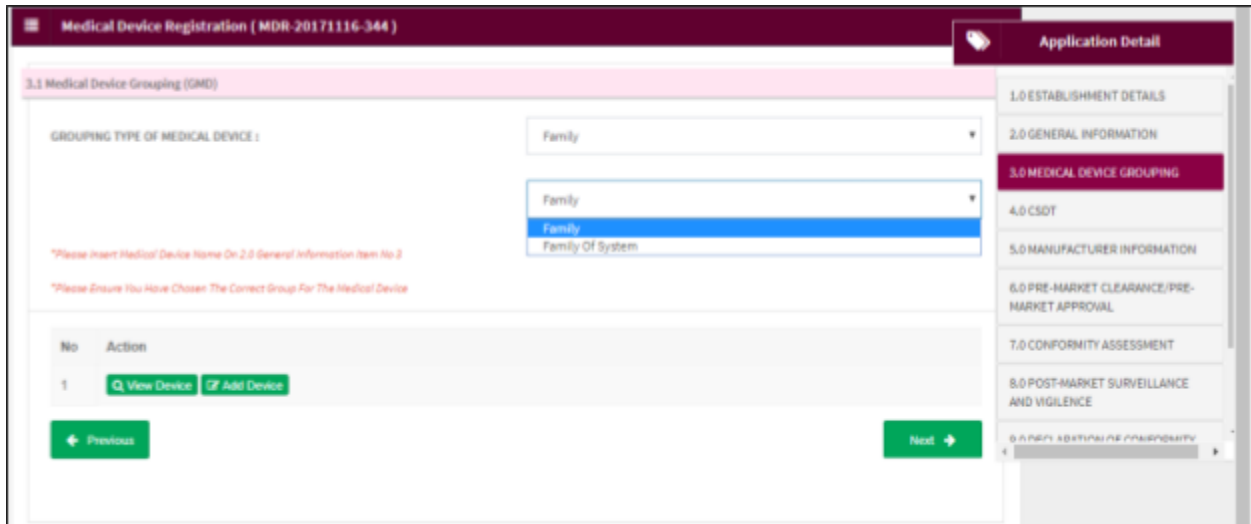


- Click **Add Device** to add new device. *Medical Device Grouping* field will display.
- Click **View Device** to view device.



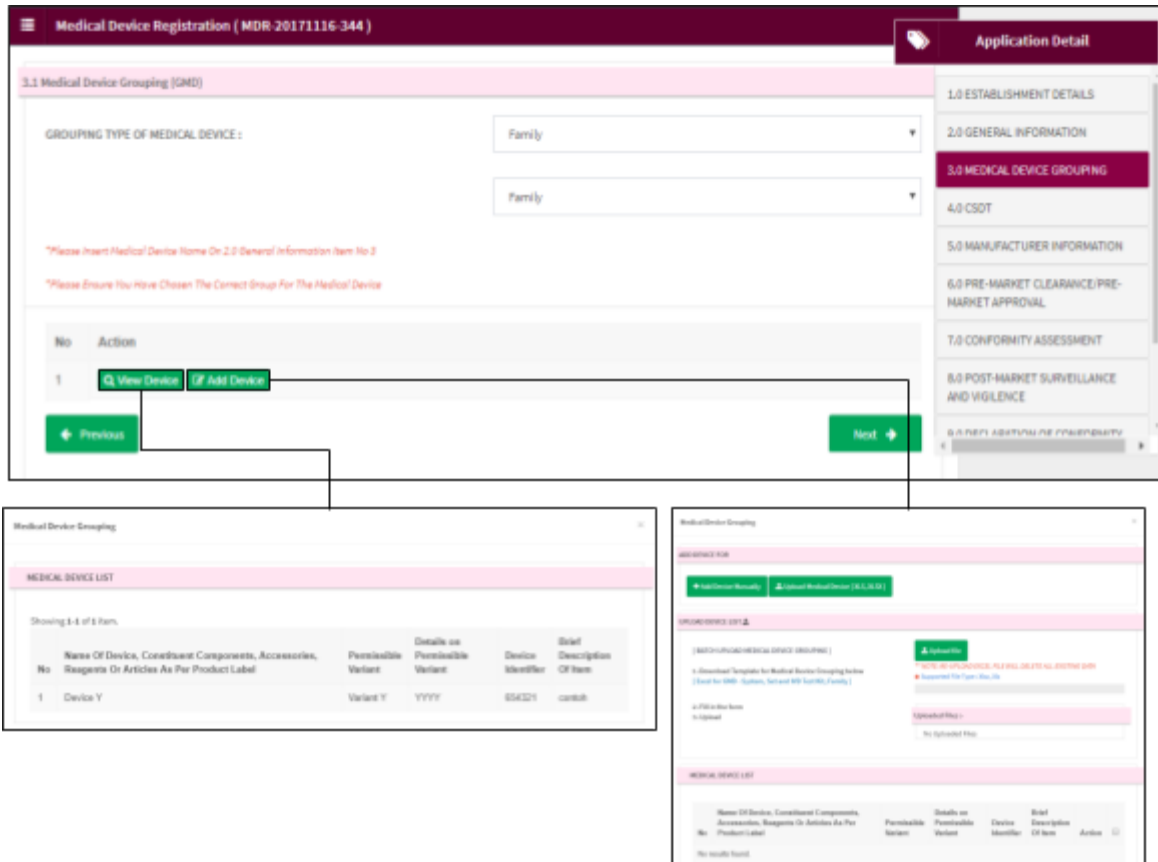
- User click  , then user have to fill the form and click  to add device.
- User click  , user have to upload file. User click  to upload excel file. **The file must be xlsx or xls format.**
-  button for user edit device details.
-  button for user delete device.
-  button to delete selected data in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



iii) Family

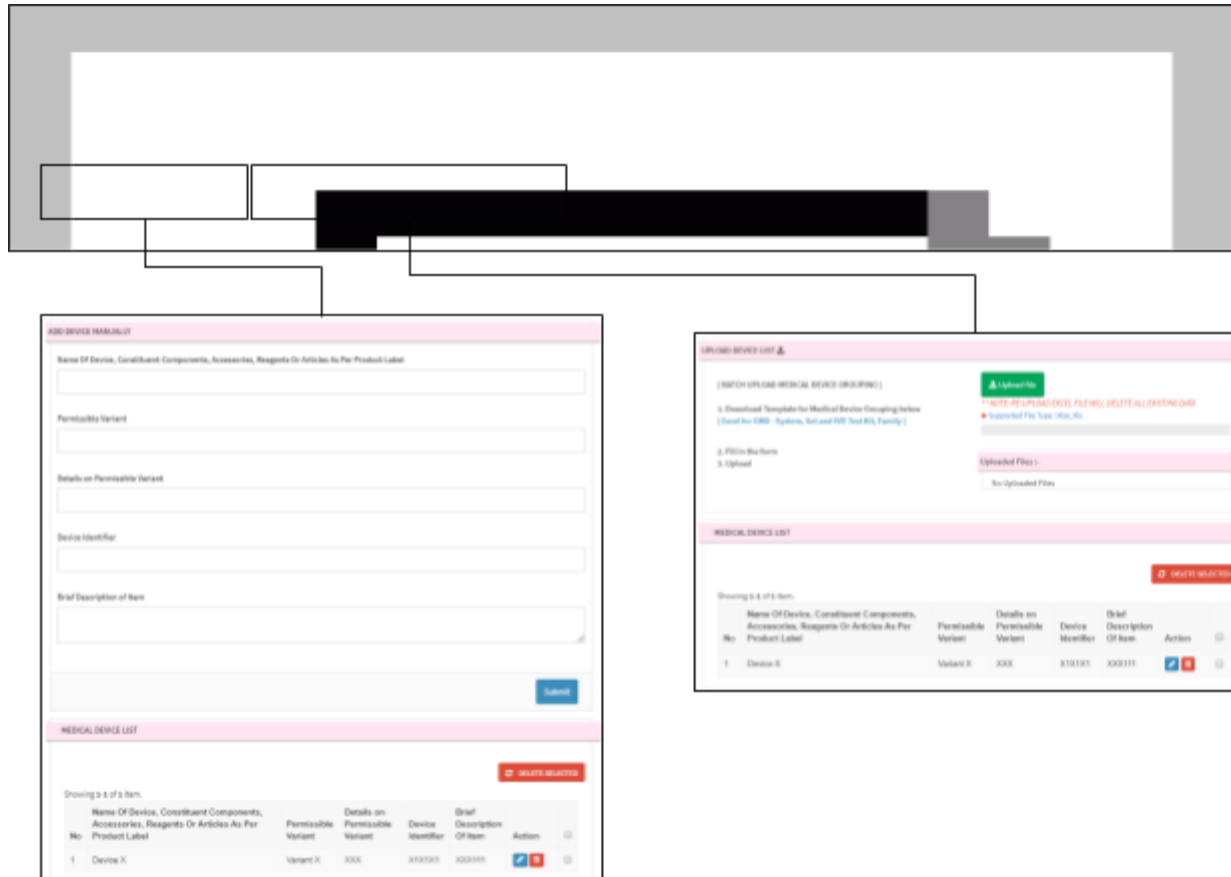










For *GROUPING TYPE OF MEDICAL DEVICE*, user select between 'Family' or 'Family Of System'.


a) Family



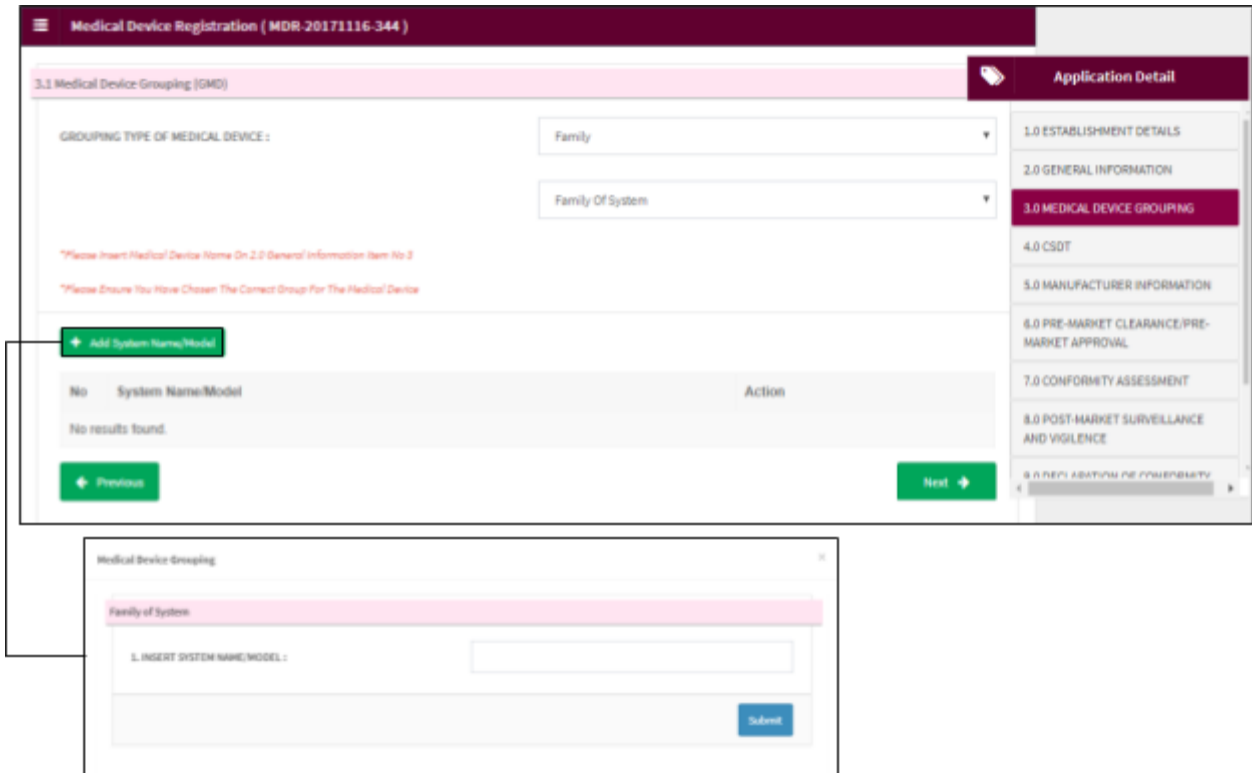
- Click  to add new device. *Medical Device Grouping* field will display.
- Click  to view device.

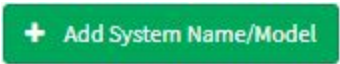


- User click  , then user have to fill the form and click  to add device.
- User click  , user have to upload file. User click  to upload excel file. **The file must be xlsx or xls format.**
-  button for user edit device details.
-  button for user delete device.
-  button to delete selected data in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



No	System Name/Model	Action
1	Model X	 View Device  Add Device  Delete

Medical Device Grouping



MEDICAL DEVICE LIST

Showing 1 of 1 item.

No	Name Of Device, Constituent Components, Accessories, Reagents Or Articles As Per Product Label	Permissible Variant	Details on Permissible Variant	Device Identifier	Brief Description Of Item
1	Device X	Variant X	XXX	X1X1X1	X3X111


Medical Device Grouping

ADD DEVICE FOR MODEL

 Add Device Manually
  Upload Medical Device [PLS, XLS]

UPLOAD DEVICE LIST

[BATCH UPLOAD MEDICAL DEVICE GROUPING]

 Upload File

****NOTE: AN UPLOAD-ORICE FILE WILL DELETE ALL EXISTING DATA**

Supported File Type: Xls, Xlsx

1. Download Template for Medical Device Grouping below
 [Click for GMD - System, Set and ID Tool Kit, Family]

2. Fill in the form

3. Upload

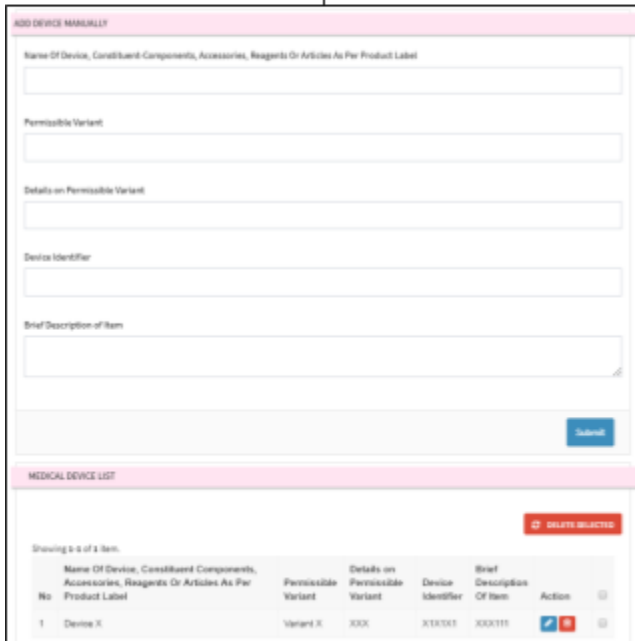
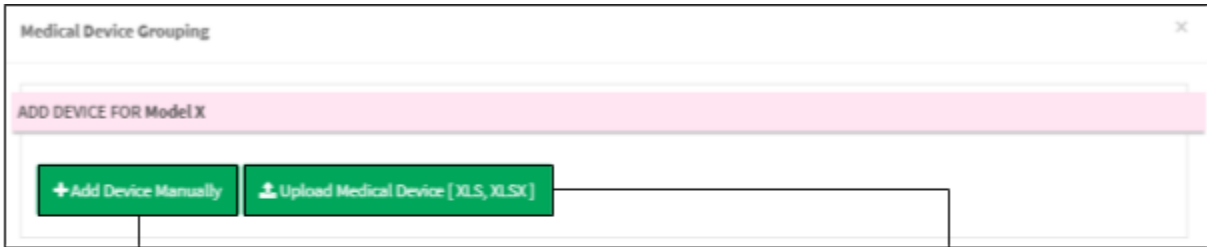
Uploaded Files >









No Uploaded Files


MEDICAL DEVICE LIST

No	Name Of Device, Constituent Components, Accessories, Reagents Or Articles As Per Product Label	Permissible Variant	Details on Permissible Variant	Device Identifier	Brief Description Of Item	Action
No results found.						

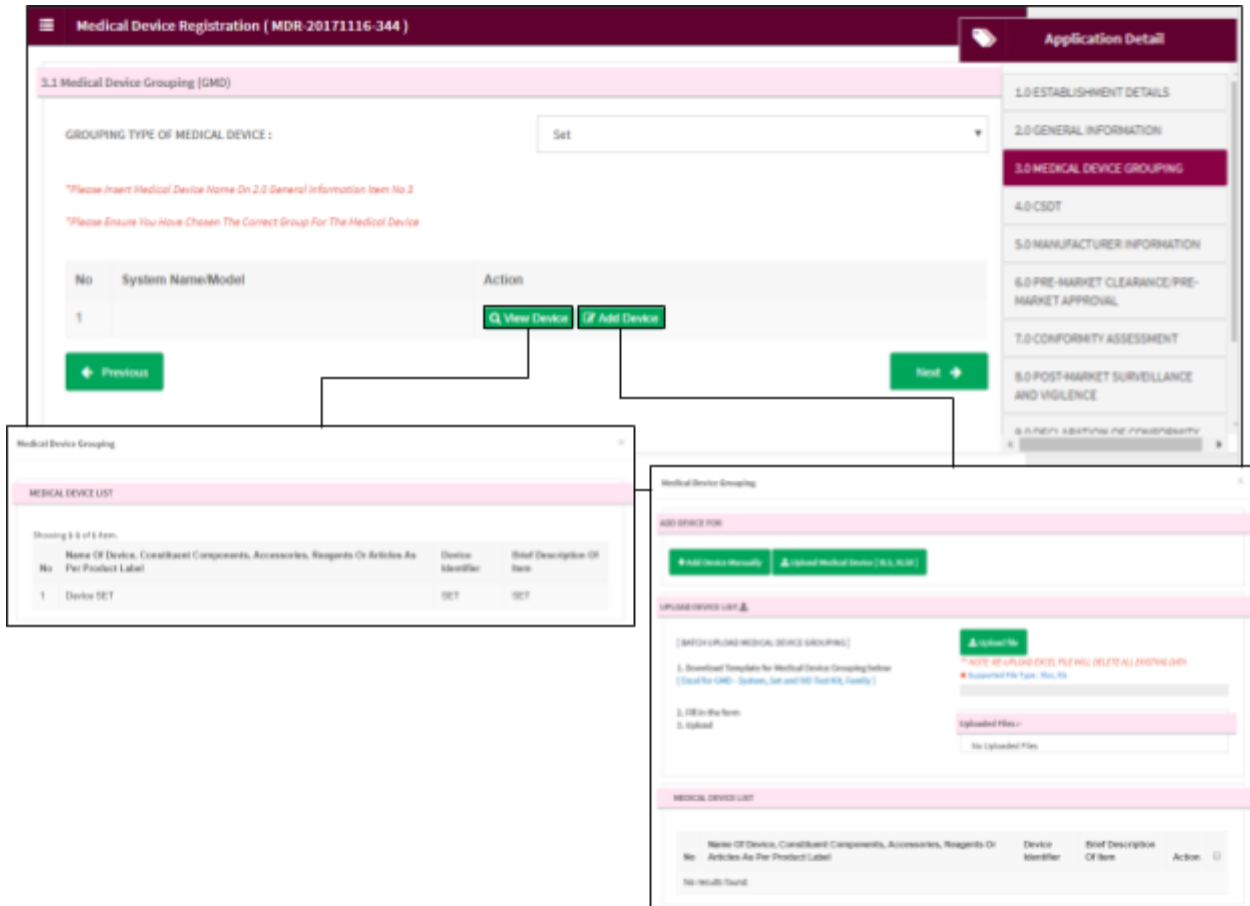
- Click  **Add Device** to add new device.
- Click  **View Device** to view device.
- Click  **Delete** to delete data in the table.



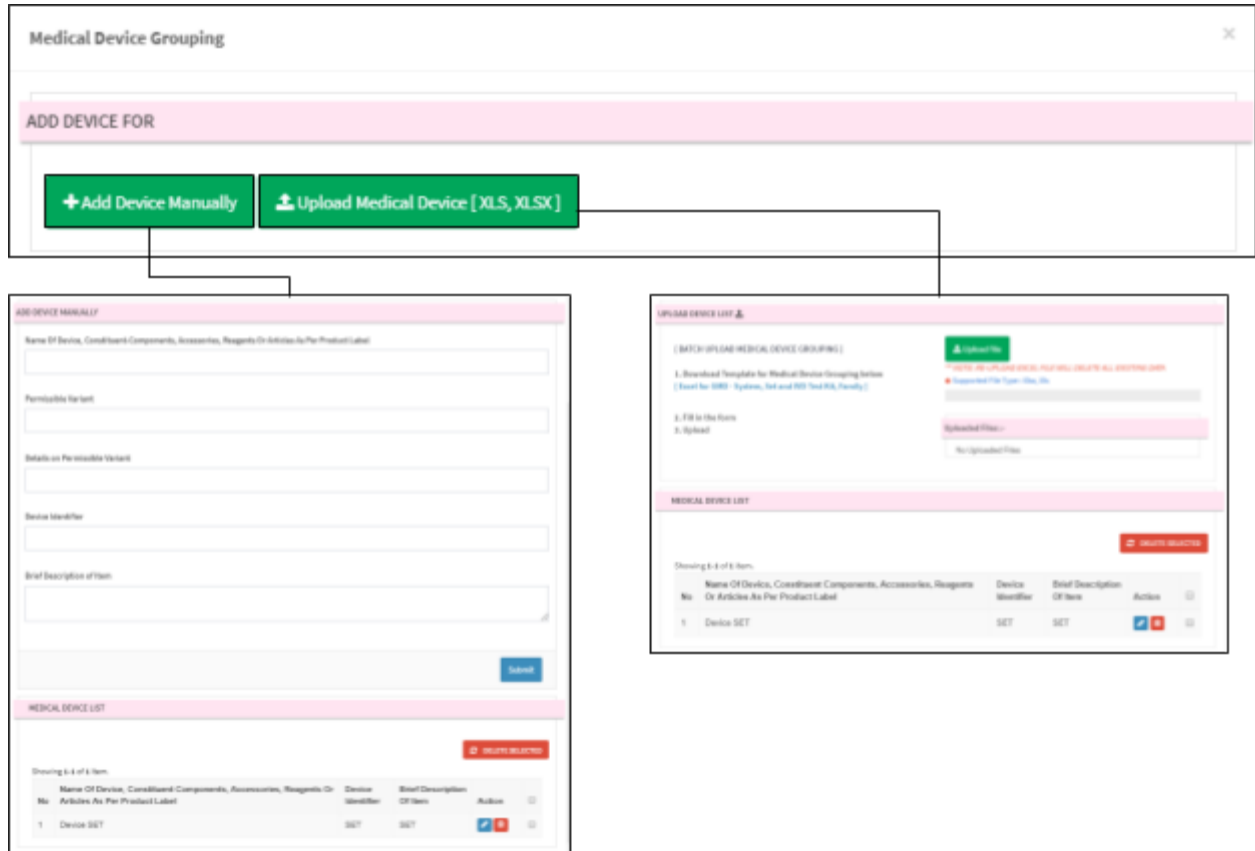
- User click  , then user have to fill the form and click  to add device.
- User click  , user have to upload file. User click  to upload excel file. **The file must be xlsx or xls format.**
-  button for user edit device details.
-  button for user delete device.
-  button to delete selected data in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










- Click  to go to the previous section.

iv) Set

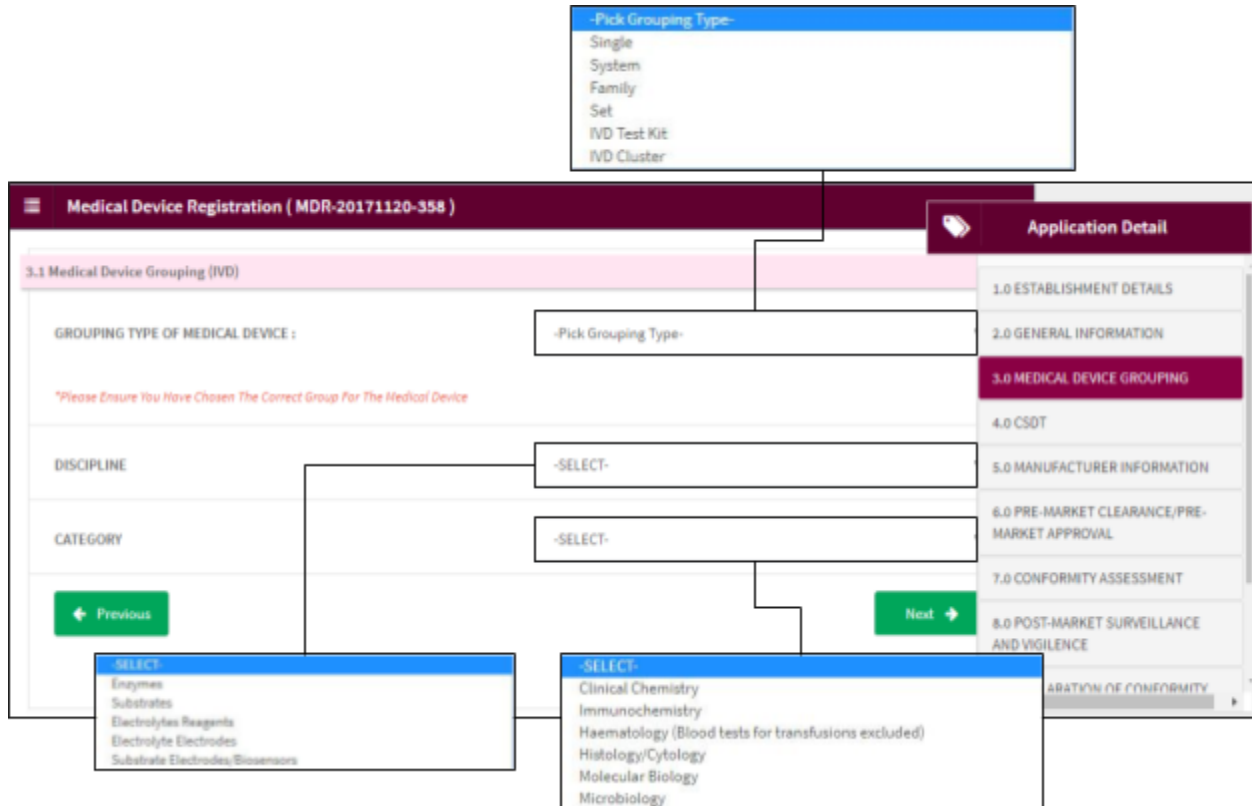


- Click  to add new device.
- Click  to view device.



- 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.

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

Medical Device Registration (MDR-20171120-358)

Application Detail

3.1 Medical Device Grouping (IVD)

GROUPING TYPE OF MEDICAL DEVICE : Single

*Please Ensure You Have Chosen The Correct Group For The Medical Device

DEVICE IDENTIFIER : Insert Identifier

DISCIPLINE : -SELECT-

CATEGORY : -SELECT-

1.0 ESTABLISHMENT DETAILS

2.0 GENERAL INFORMATION

3.0 MEDICAL DEVICE GROUPING

4.0 CSDT

5.0 MANUFACTURER INFORMATION

6.0 PRE-MARKET CLEARANCE/PRE-MARKET APPROVAL

7.0 CONFORMITY ASSESSMENT



8.0 POST-MARKET SURVEILLANCE AND VIGILANCE

9.0 DECLARATION OF CONFORMITY

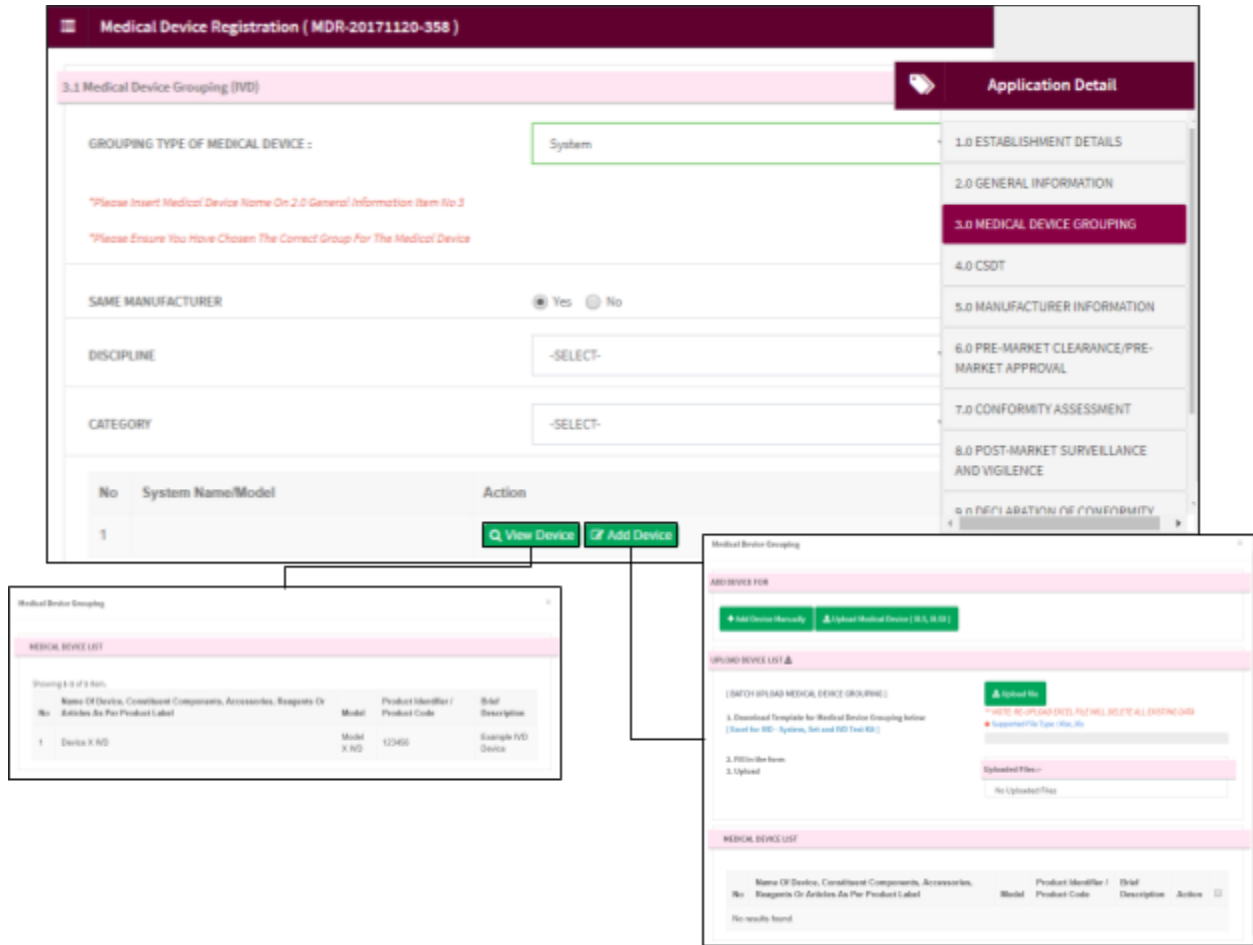
← Previous

Next →

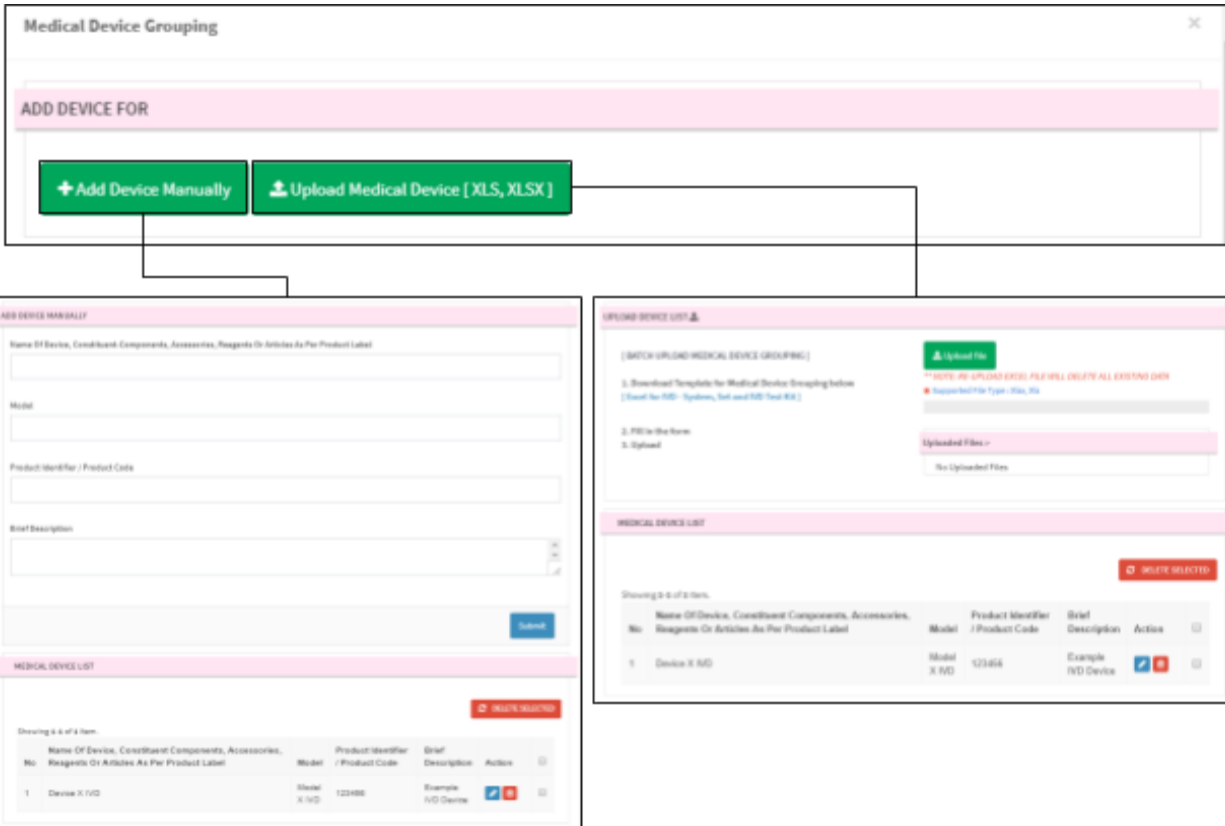
User complete Device *IDENTIFIER*, *DISCIPLINE* and *CATEGORY* filed.







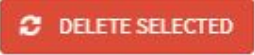


- Click  to go to the next section.
- Click  to go to the previous section.

ii) System



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



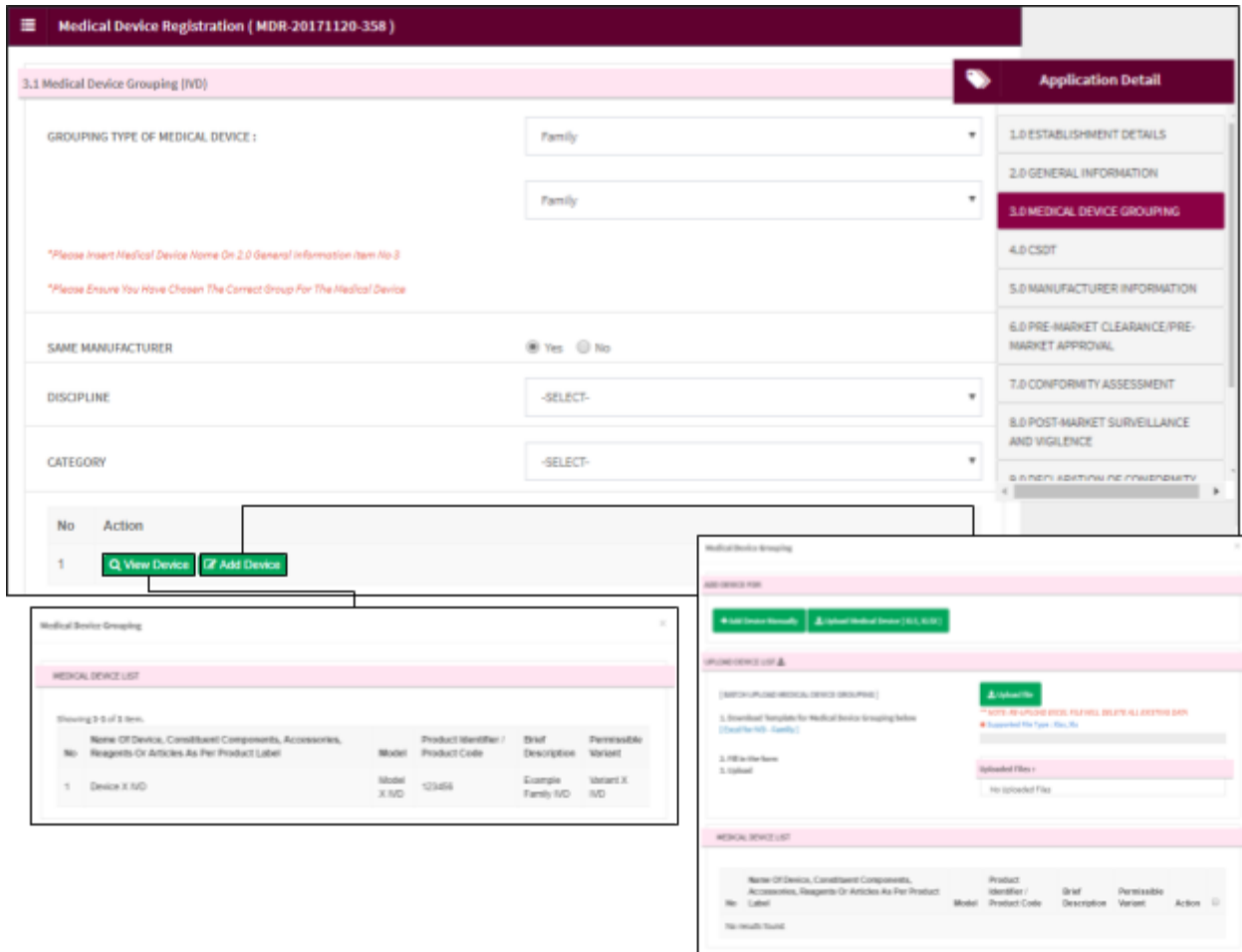
- User click  , then user have to fill the form and click  to add device.
- User click  , user have to upload file. User click  to upload excel file. **The file must be xlsx or xls format.**
-  button for user edit device details.
-  button for user delete device.
-  button to delete selected data in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

iii) Family

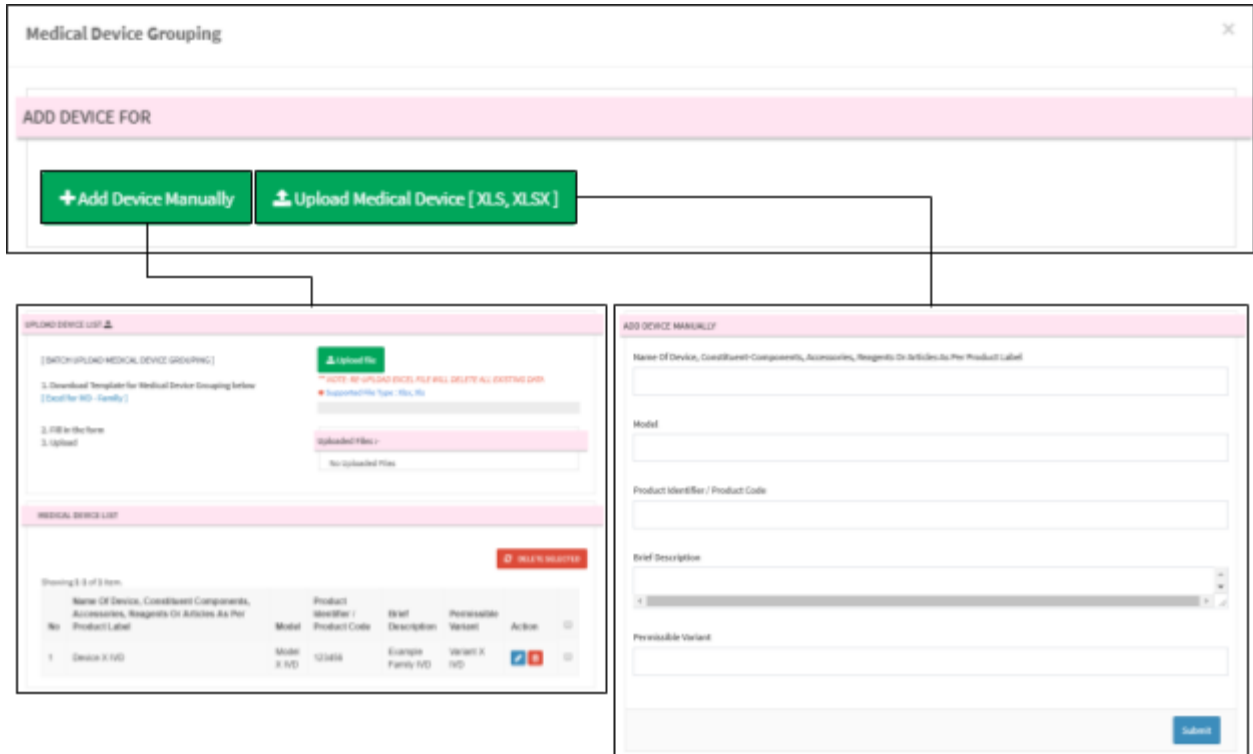
The screenshot displays the '3.1 Medical Device Grouping (IVD)' section of the application. The 'GROUPING TYPE OF MEDICAL DEVICE' dropdown menu is open, showing 'Family' as the selected option and 'Family Of System' as an alternative. Below this, the 'SAME MANUFACTURER' field has radio buttons for 'Yes' and 'No'. The 'DISCIPLINE' and 'CATEGORY' fields are currently set to '-SELECT-'. At the bottom, a table lists one device with 'View Device' and 'Add Device' buttons. A 'Next' button is located at the bottom right of the form.










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

a) Family

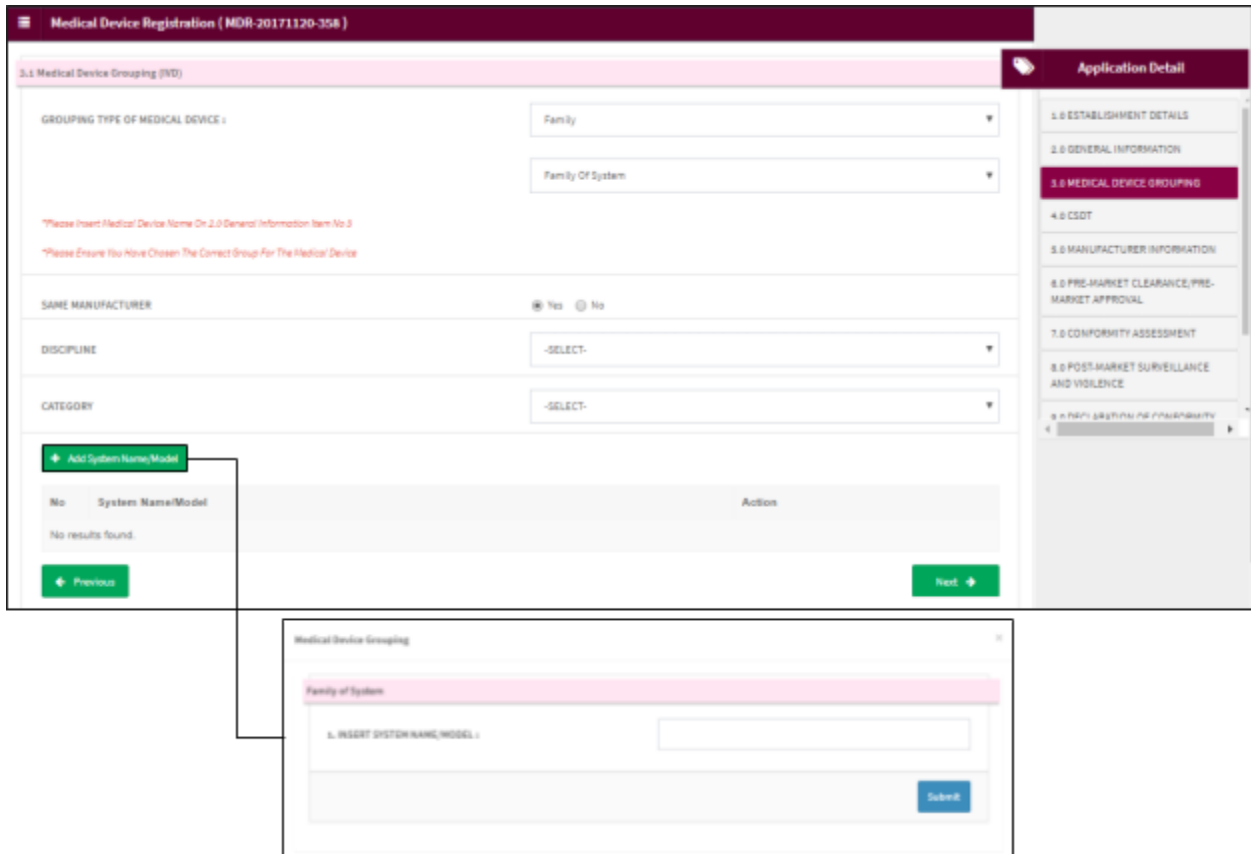


- Click  to add new device.
- Click  to view device.



- 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 **+ Add System Name/Model** to new system name or model. Fill the form and then click **Submit**.

No	System Name/Model	Action
1	IVD Model X	  

Medical Device Grouping



MEDICAL DEVICE LIST

Showing 1 of 1 item.

No	Name Of Device, Constituent Components, Accessories, Reagents Or Articles As Per Product Label	Model	Product Identifier / Product Code	Brief Description	Permissible Variant
1	Device X IVD	Model X IVD	123456	Example IVD	Variant X IVD


Medical Device Grouping

ADD DEVICE FOR NEW MODEL

 Add Device icon
 Upload Product Device (S1, S2, S3)

UPLOAD DEVICE LIST

[S1]-[S3] UPLOAD MEDICAL DEVICE GROUPING

 Upload File

1. Download Template for Medical Device Grouping below
 [Download MDR Ready]

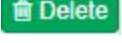
2. Fill in the form
 3. Upload

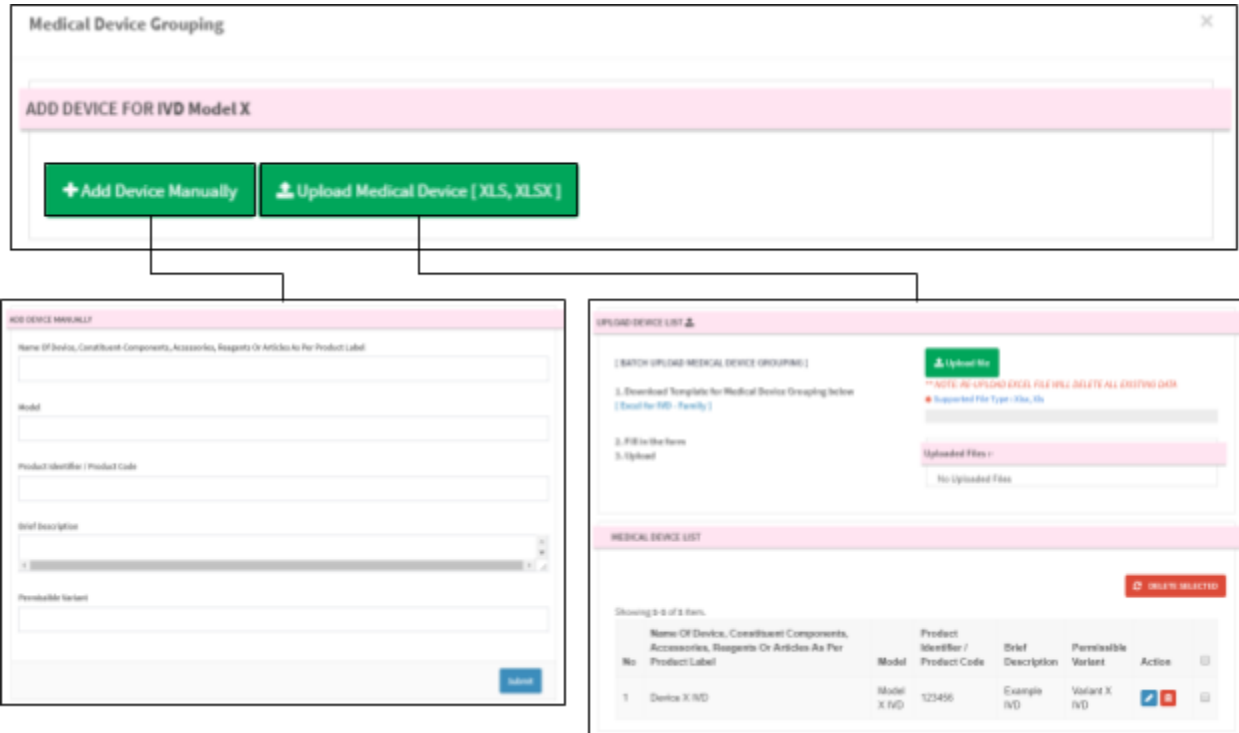
*NOTE: UP-LOAD EXCEL FILE WILL DELETE ALL EXISTING DATA
 *Supported File Type : xls, xlsx










Uploaded File: No Uploaded File

MEDICAL DEVICE LIST

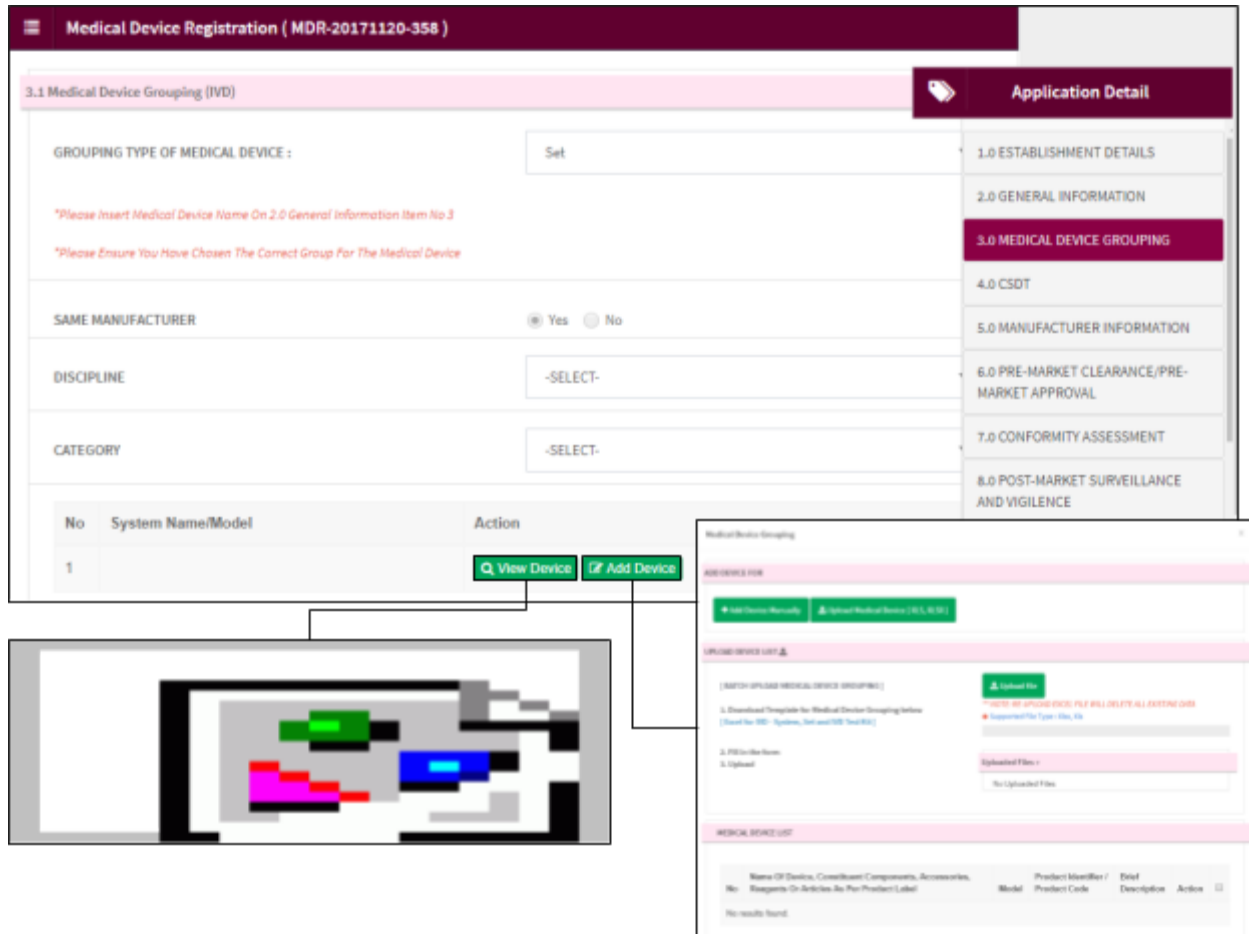
No	Name Of Device, Constituent Components, Accessories, Reagents Or Articles As Per Product Label	Model	Product Identifier / Product Code	Brief Description	Permissible Variant	Action
No results found.						

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

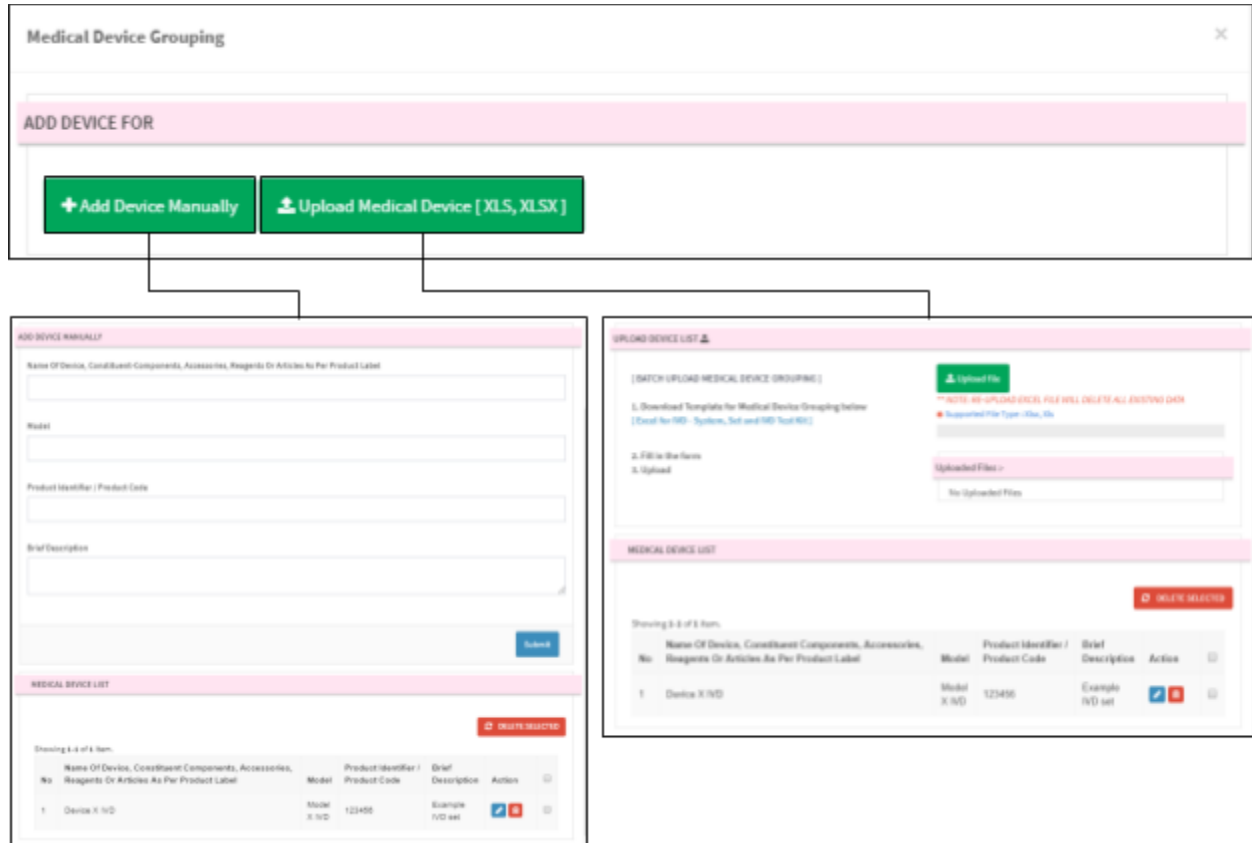











- User click  , then user have to fill the form and click  to add device.
- User click  , user have to upload file. User click  to upload excel file. **The file must be xlsx or xls format.**
-  button for user edit device details.
-  button for user delete device.
-  button to delete selected data in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

iv) Set

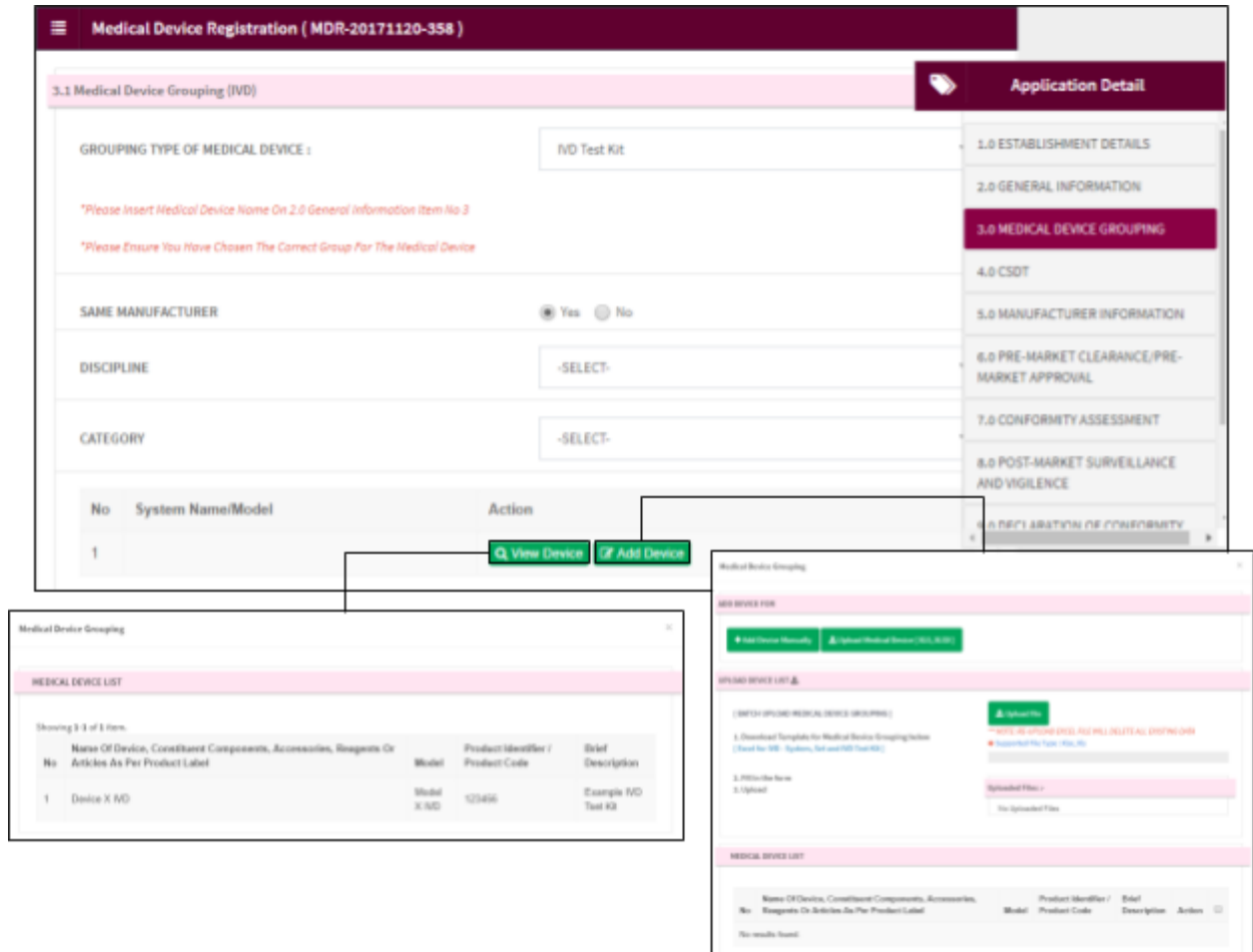


- Click  to add new device.
- Click  to view device.

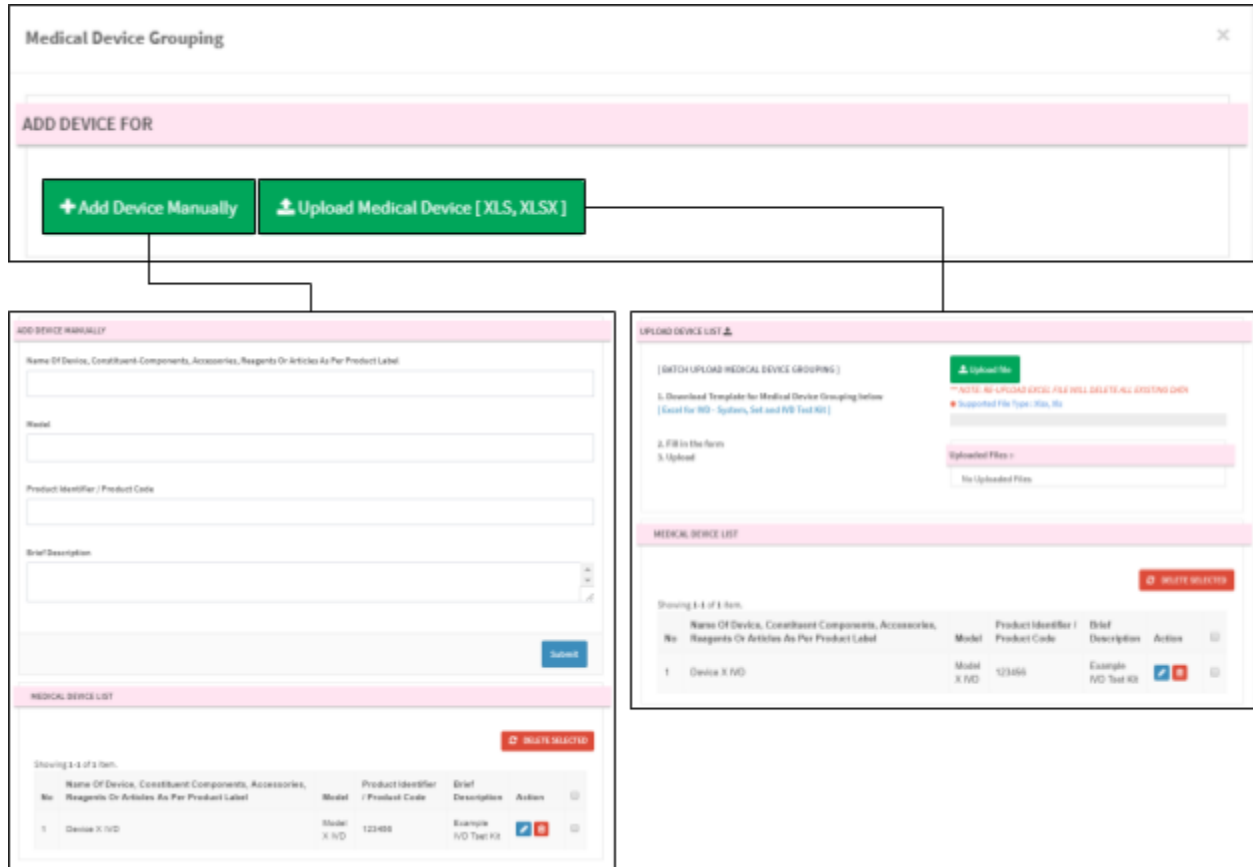











- User click  , then user have to fill the form and click  to add device.
- User click  , user have to upload file. User click  to upload excel file. **The file must be xlsx or xls format.**
-  button for user edit device details.
-  button for user delete device.
-  button to delete selected data in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

v) IVD Test Kit

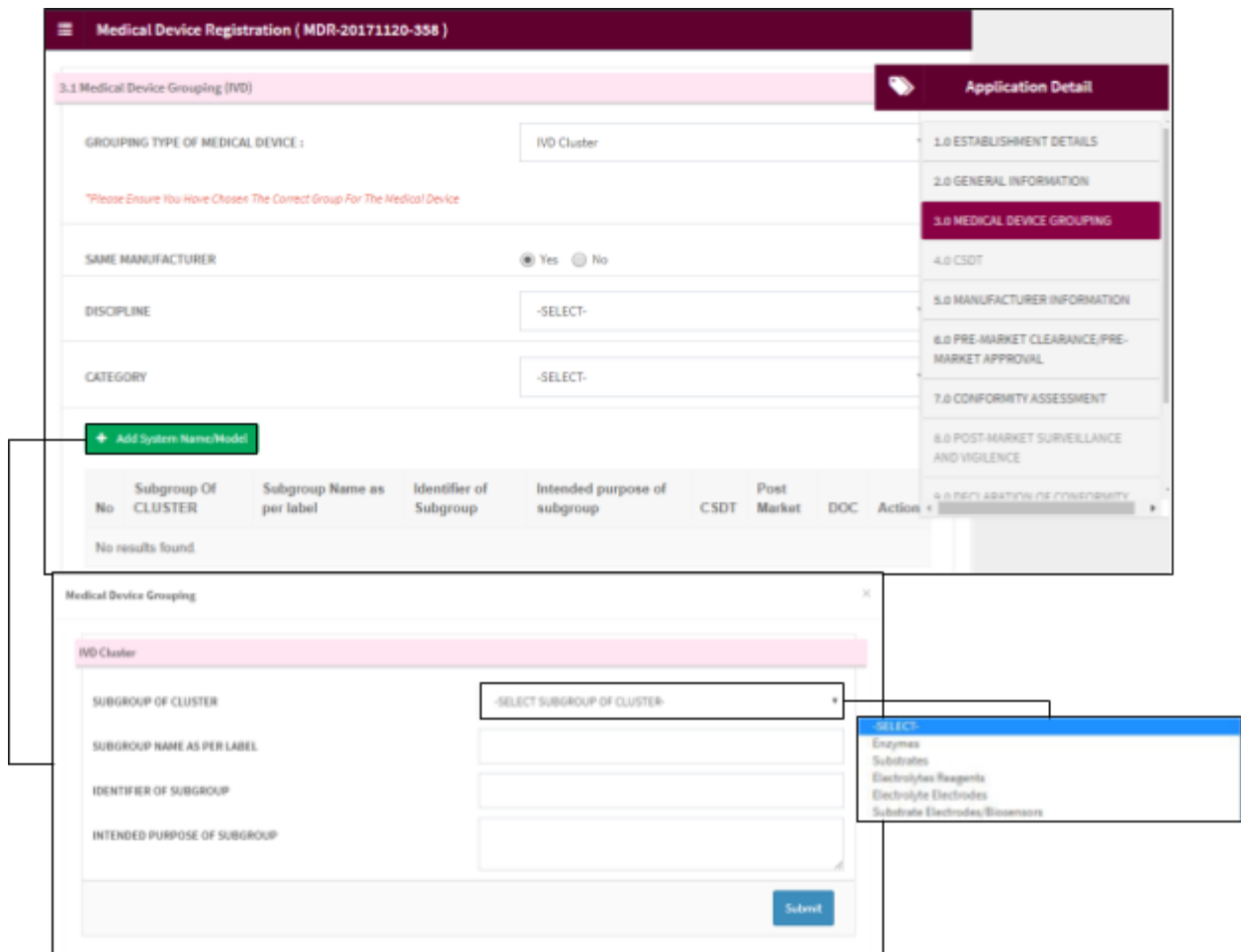


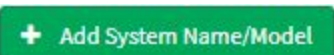

- Click  to add new device.
- Click  to view device.



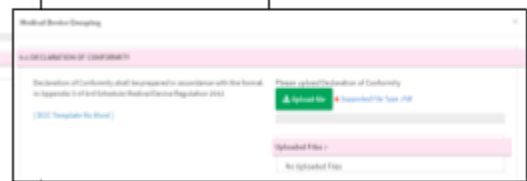
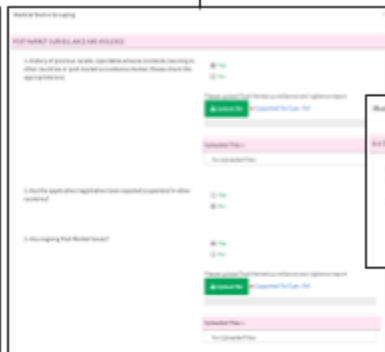
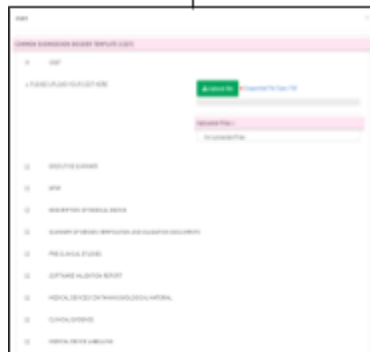
- User click  , then user have to fill the form and click  to add device.
- User click  , user have to upload file. User click  to upload excel file. **The file must be xlsx or xls format.**
-  button for user edit device details.
-  button for user delete device.
-  button to delete selected data in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

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 Grouping

IVD Cluster

SUBGROUP OF CLUSTER:

SUBGROUP NAME AS PER LABEL:

IDENTIFIER OF SUBGROUP:

INTENDED PURPOSE OF SUBGROUP:

Medical Device Grouping

ADD DEVICE

UPLOAD MEDICAL DEVICE LIST

[INFO] PLEASE UPLOAD MEDICAL DEVICE GROUPING

1. Download template for Medical Device Grouping below.
 [Request for Template](#)

2. Fill in the form

3. Upload

MEDICAL DEVICE LIST



No	Name of Reagent/ Article/ Calibrator/ Control/ Analyzer (in the subgroup) as per Label	Device Type (Reagent/ Article/ Calibrator/ Control/ Analyzer/ Others)	Identifier of Reagent or Article	Brief Description of Reagent or Article (include the permissible variants together for Family)	Action
No records found.					

Medical Device Grouping

MEDICAL DEVICE LIST

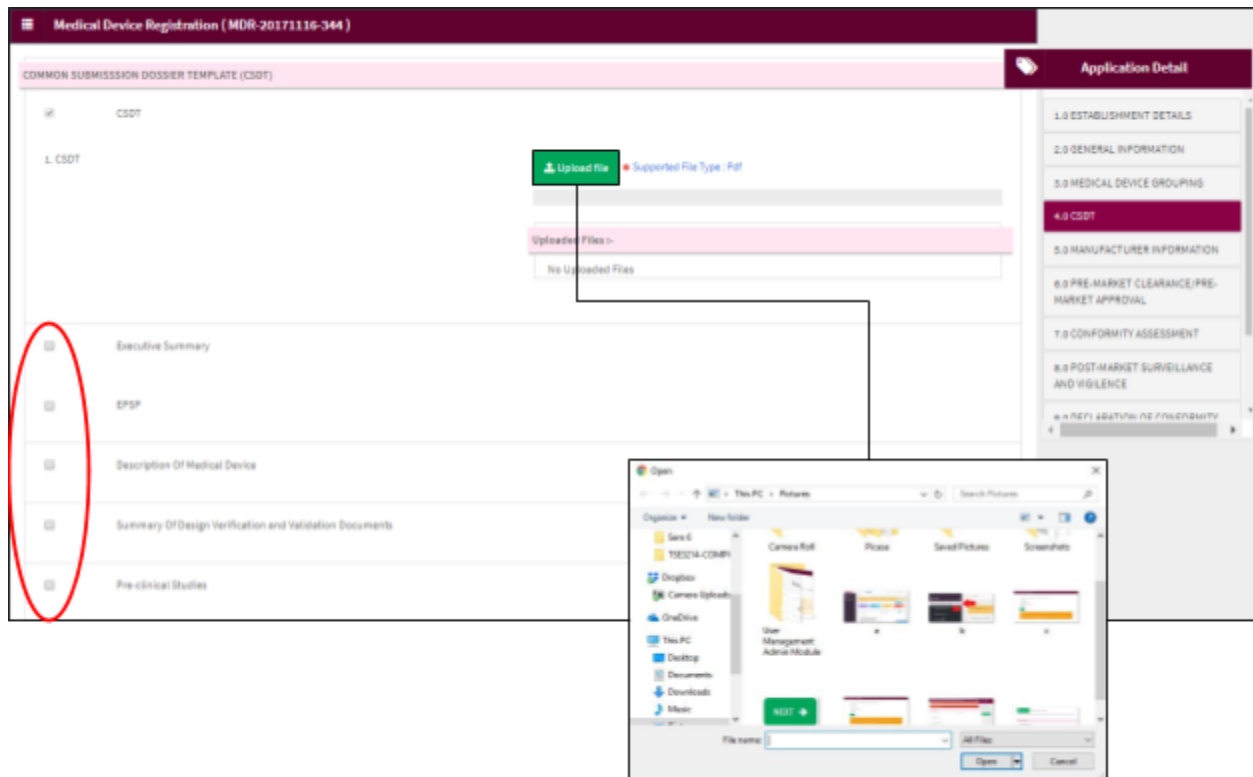
Showing 3 - 1 of 1 item.

No	Name of Reagent/ Article/ Calibrator/ Control/ Analyzer (in the subgroup) as per Label	Device Type (Reagent/ Article/ Calibrator/ Control/ Analyzer/ Others)	Identifier of Reagent or Article	Brief Description of Reagent or Article (include the permissible variants together for Family)
1	Name X	Device Type X	123456	XXXX

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



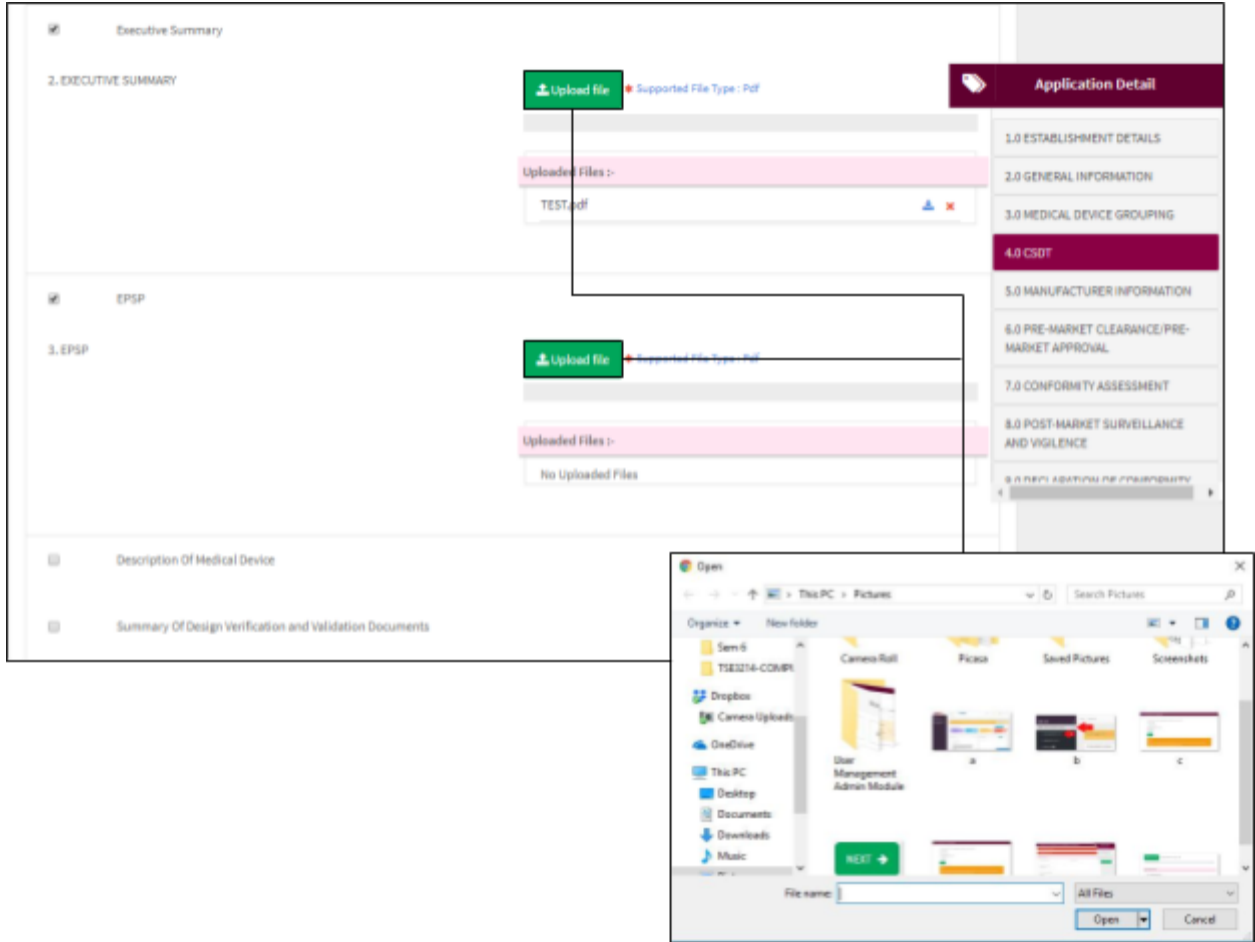
<input type="checkbox"/>	Software Validation Report
<input type="checkbox"/>	Medical Devices Containing Biological Material
<input type="checkbox"/>	Clinical Evidence
<input type="checkbox"/>	Medical Device Labelling
<input type="checkbox"/>	Risk Analysis
<input type="checkbox"/>	Manufacturer Information
<input type="checkbox"/>	Use Of Existing Bibliography
<input type="checkbox"/>	MISC



Previous Next

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



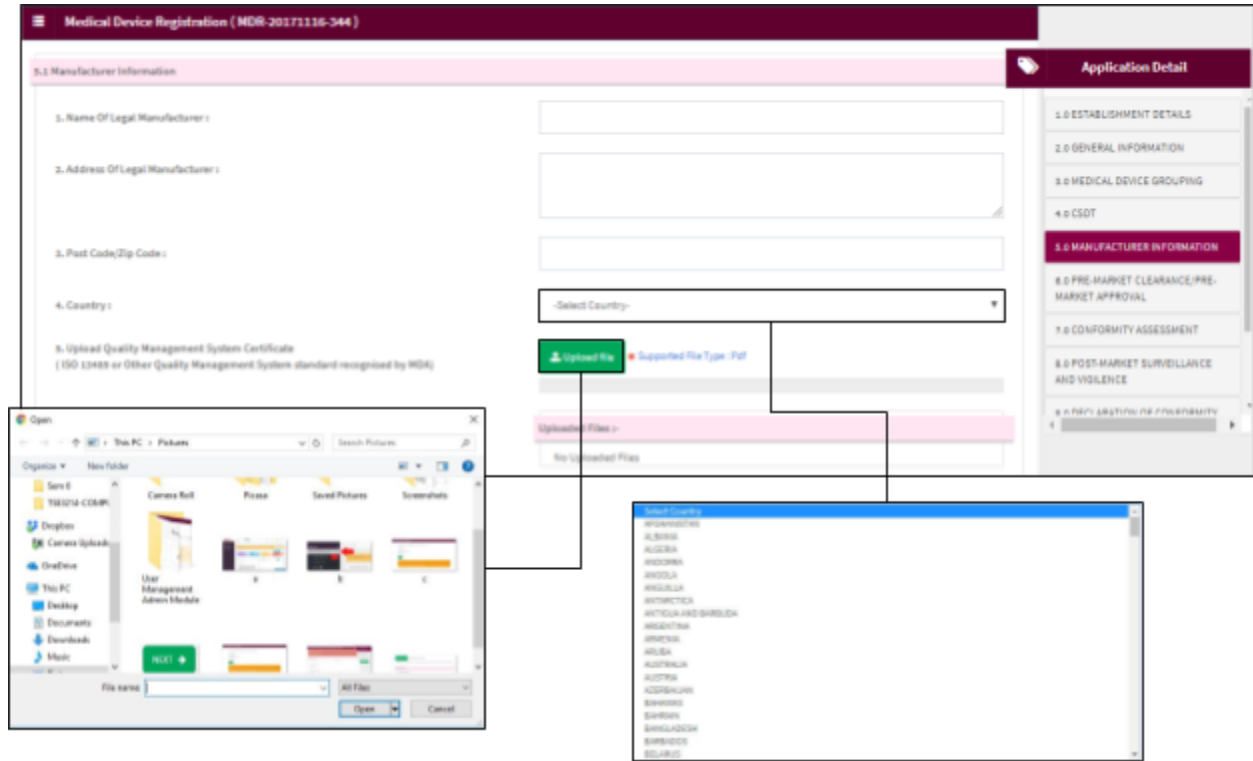
to upload file. **The file must be pdf format and size not more than 300 MB.**




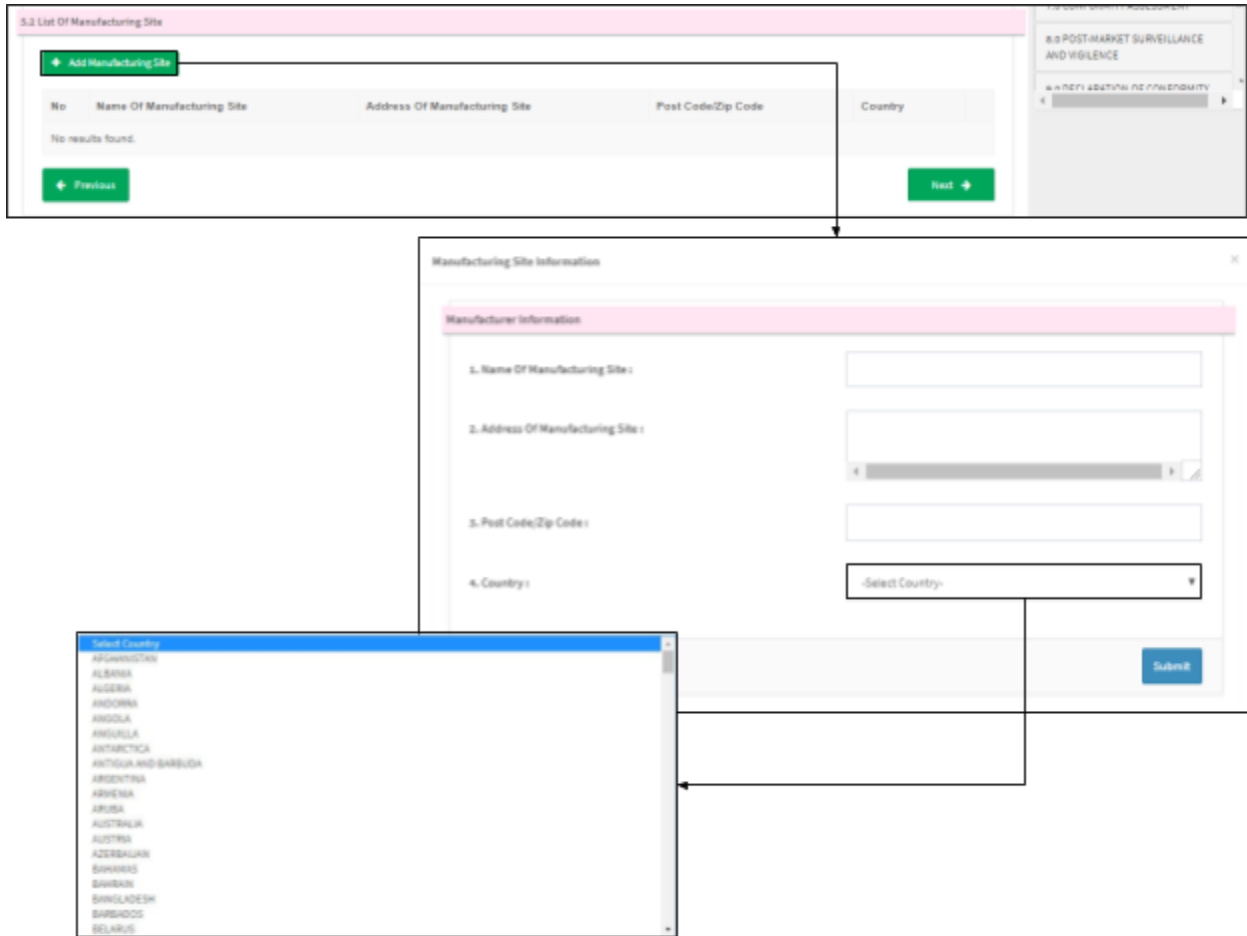
- Click  to go to the next section.
- Click  to go to the previous section.

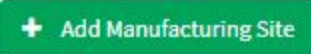

2.2.5 5.0 MANUFACTURER INFORMATION

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  .

No	Name Of Manufacturing Site	Address Of Manufacturing Site	Post Code/Zip Code	Country	
1	DEVICE X	KUALA LUMPUR	50100	MALAYSIA	 

Manufacturing Site Information


Manufacturer Information

1. Name Of Manufacturing Site :

2. Address Of Manufacturing Site :

3. Post Code/Zip Code :

4. Country :

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

2.2.6 6.0 PRE-MARKET CLEARANCE/ PRE-MARKET APPROVAL

Medical Device Registration (MDR-20171116-344)

6.1 PRE-MARKET CLEARANCE/PRE-MARKET APPROVAL

Please indicate whether the medical device has obtained Pre-Market Clearance / Pre-Market Approval or considered Exempted/Notified/Self-Declared from foreign countries

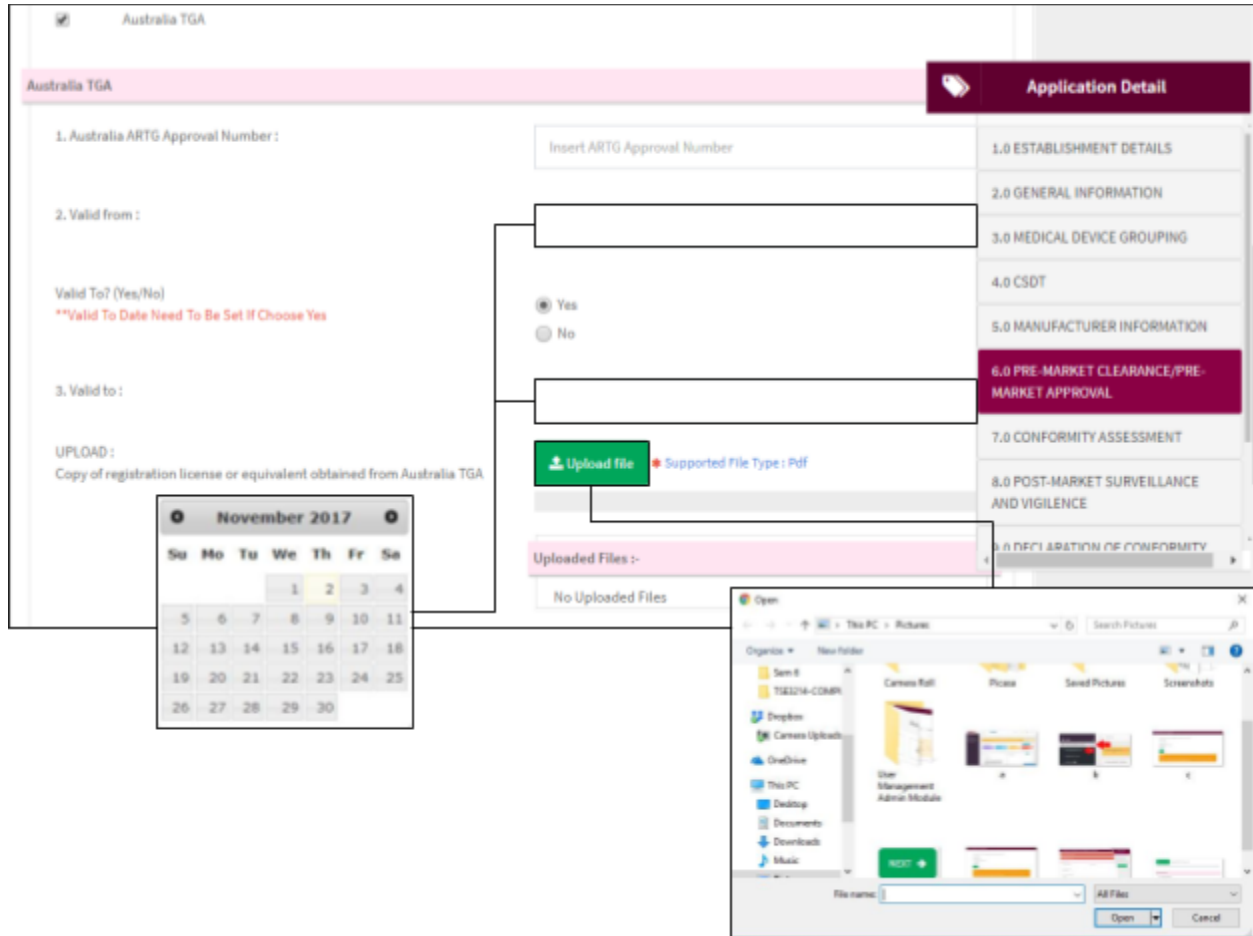
<input type="checkbox"/>	USFDA
<input type="checkbox"/>	Australia TGA
<input type="checkbox"/>	EU
<input type="checkbox"/>	Health Canada
<input type="checkbox"/>	Japan MHLW
<input type="checkbox"/>	Other


Application Detail

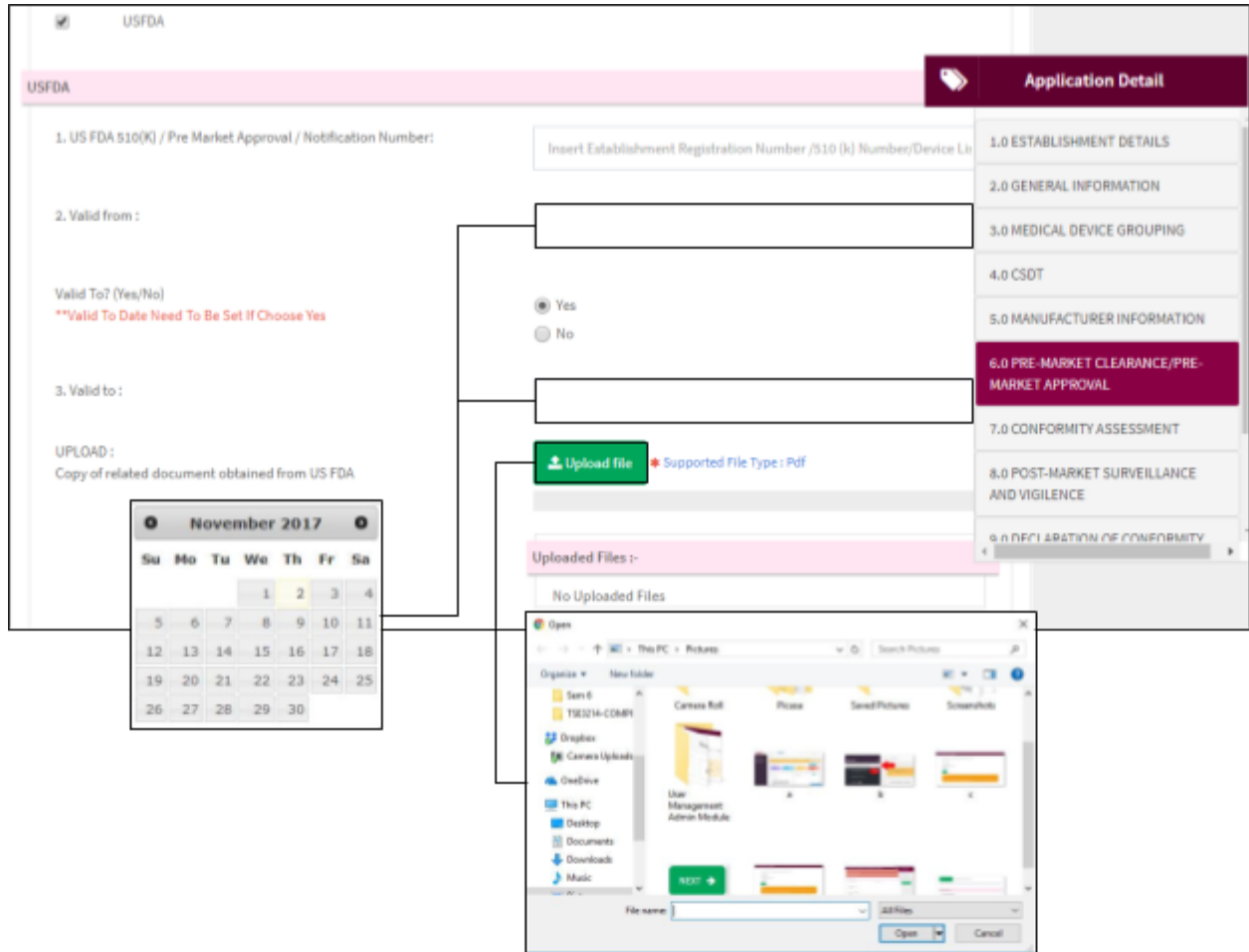
- 1.0 ESTABLISHMENT DETAILS
- 2.0 GENERAL INFORMATION
- 3.0 MEDICAL DEVICE GROUPING
- 4.0 CSDT
- 5.0 MANUFACTURER INFORMATION
- 6.0 PRE-MARKET CLEARANCE/PRE-MARKET APPROVAL**
- 7.0 CONFORMITY ASSESSMENT
- 8.0 POST-MARKET SURVEILLANCE AND VIGILANCE
- 9.0 RECALL AND CORRECTIVE ACTION

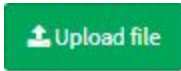
← Previous Next →

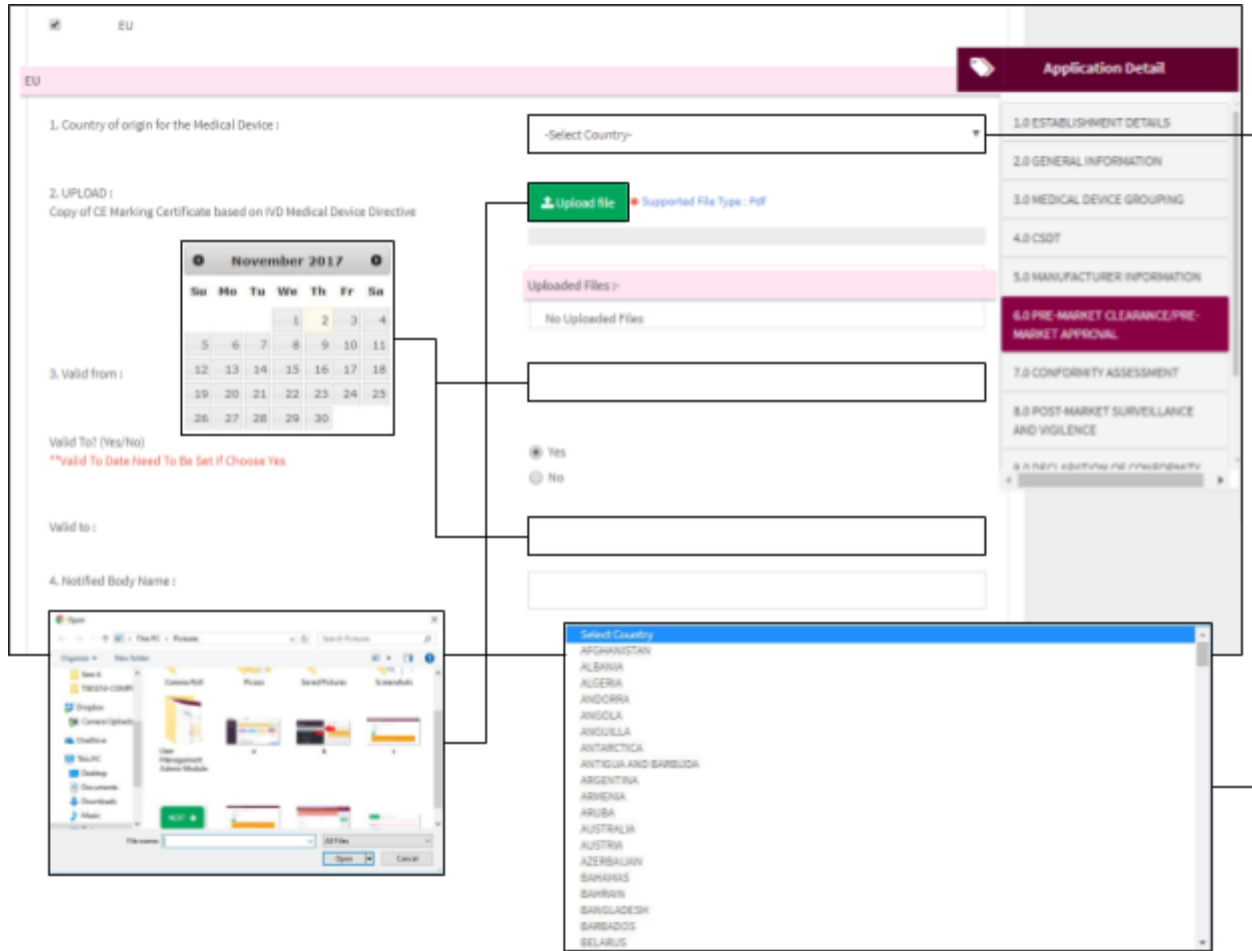
User tick any check box above. **(If necessary)**




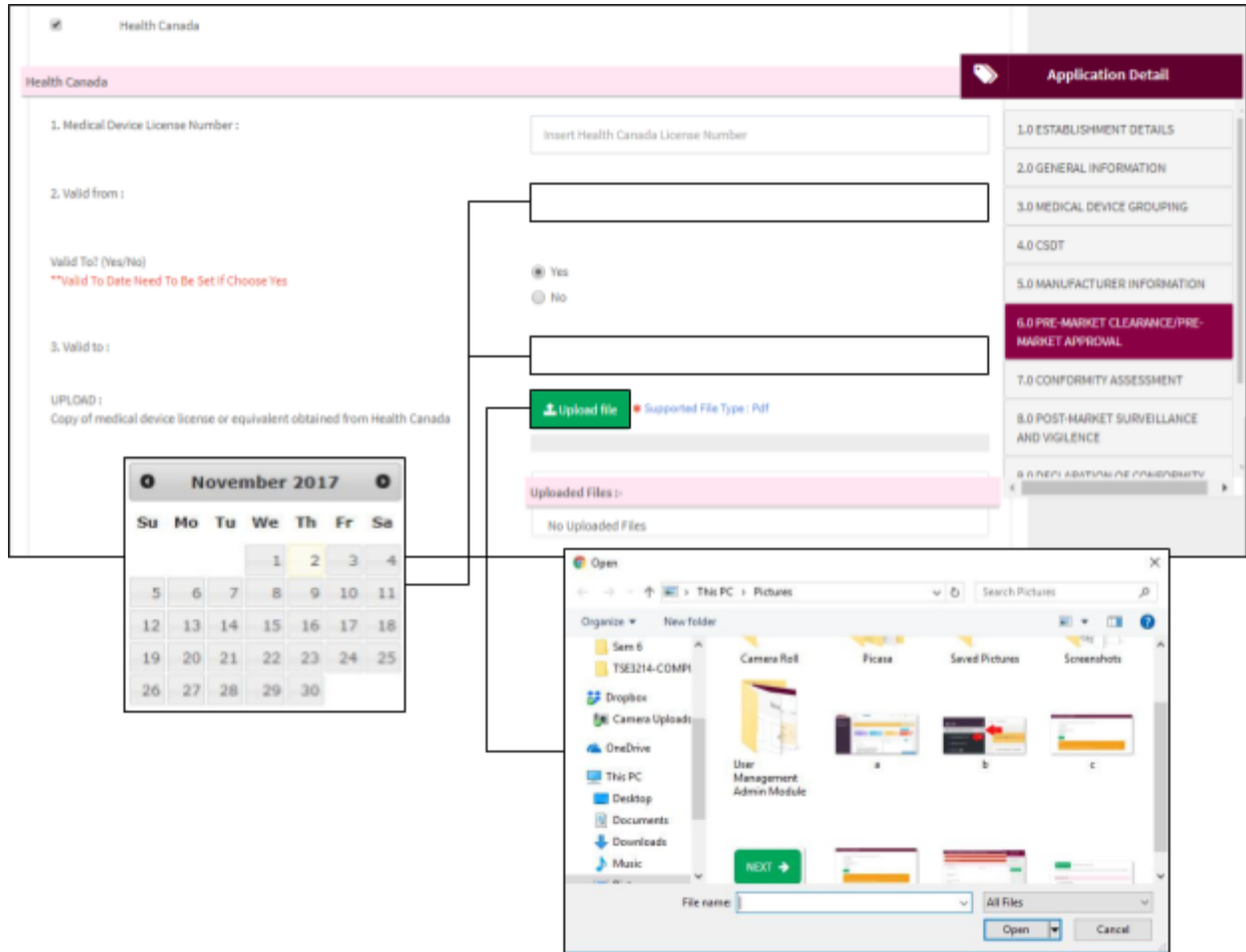
User fill the field then click  to upload file. **The file must be pdf format and size not more than 300 MB.**



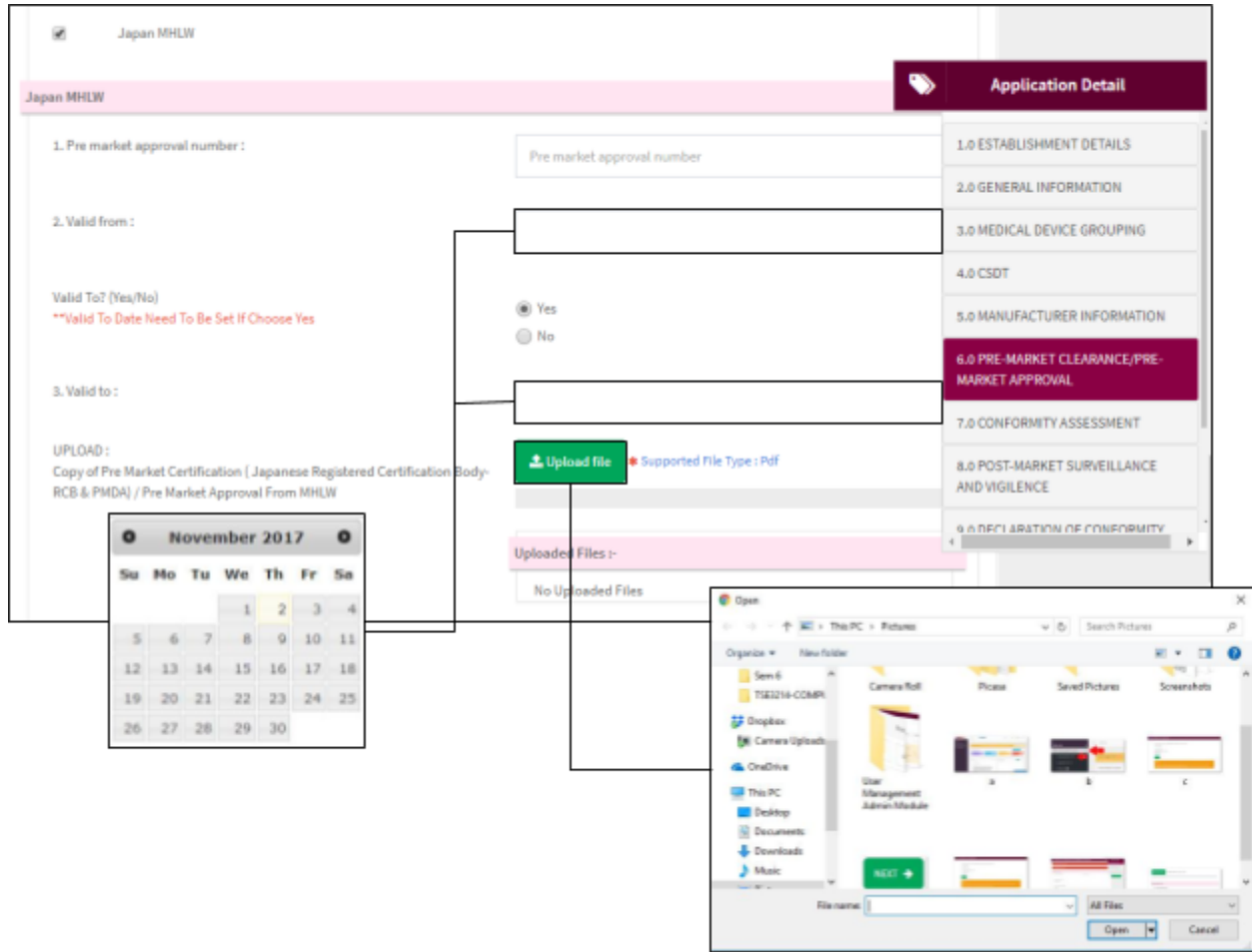
User fill the field then click  to upload file. **The file must be pdf format and size not more than 300 MB.**




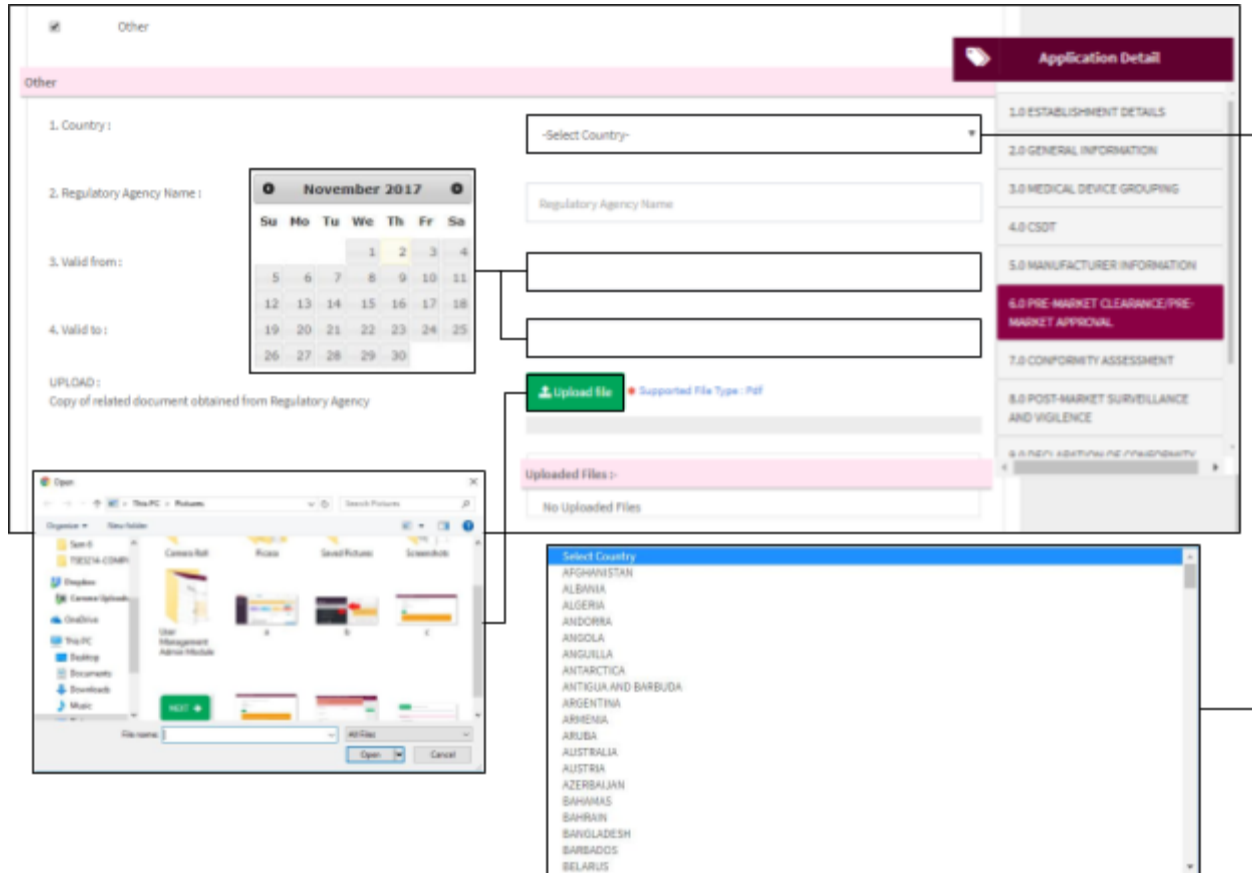
User fill the field then click  to upload file. **The file must be pdf format and size not more than 300 MB.**

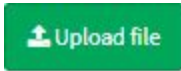


User fill the field then click  to upload file. **The file must be pdf format and size not more than 300 MB.**



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

The screenshot displays the '7.1 Conformity Assessment' section of the application. It features a sidebar on the right with a menu where '7.0 CONFORMITY ASSESSMENT' is selected. The main form area contains the following elements:

- 1. Name of CAB :** A dropdown menu currently showing '-SELECT NAME CAB-'. A callout box below it lists options: ABCD-123, NAZIRAH, TEST CAB, NURUL NAZIRAH, NURAFIABOLAH, NAZIRAH NASIR, and CAB USER.
- 2. CAB Registration No. :** A text input field containing 'ABC SON BHD'.
- 3. Conformity Assessment Certificate : Valid From** and **4. Conformity Assessment Certificate : Valid To**: Two empty text input fields.
- 5. Please upload the CAB certificate and CAB Report**: An 'Upload file' button with a green arrow icon. Below it, a note states 'Supported File Type : Pdf'. An 'Uploaded Files :-' section shows 'No Uploaded File'.
- Navigation:** 'Previous' and 'Next' buttons are located at the bottom left and right of the form, respectively.
- Calendar:** A calendar widget for November 2017 is visible on the right side of the form.
- File Explorer:** An 'Open' dialog box is open, showing the 'Pictures' folder with various image files.

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 VIGILANCE

User have to complete the field.

Medical Device Registration (MDR-20171116-344)

Application Detail

1.0 ESTABLISHMENT DETAILS
 2.0 GENERAL INFORMATION
 3.0 MEDICAL DEVICE GROUPING
 4.0 CSDT
 5.0 MANUFACTURER INFORMATION
 6.0 PRE-MARKET CLEARANCE/PRE-MARKET APPROVAL
 7.0 CONFORMITY ASSESSMENT
8.0 POST-MARKET SURVEILLANCE AND VIGILANCE
 9.0 DECLARATION OF CONFORMITY

8.1 POST-MARKET SURVEILLANCE AND VIGILANCE

1. History of previous recalls, reportable adverse incidents, banning in other countries or post market surveillance studies (Please check the appropriate box) Yes No

2. Has the application/registration been rejected/suspended in other countries? Yes No

3. Any ongoing Post-Market Issues? Yes No

← Previous Next →

1. History of previous recalls, reportable adverse incidents, banning in other countries or post market surveillance studies (Please check the appropriate box) Yes No

Please upload Post-Market surveillance and vigilance report


Supported File Type : Pdf

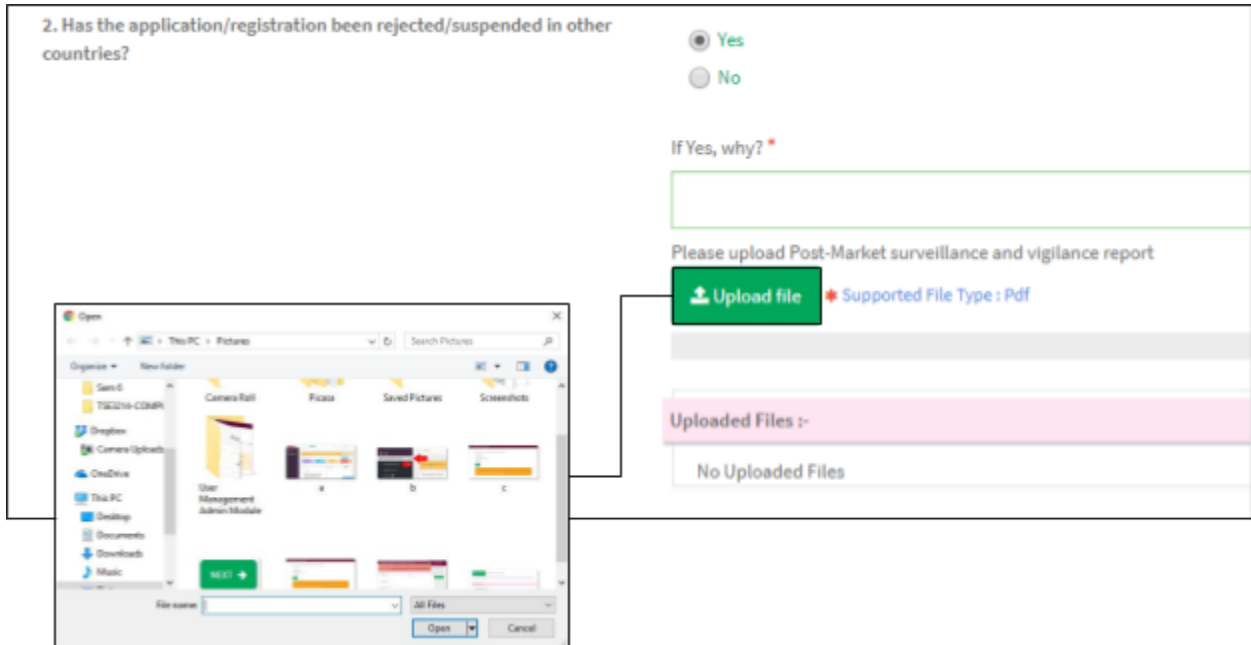
Uploaded Files :-
 No Uploaded Files


File Explorer (Pictures):

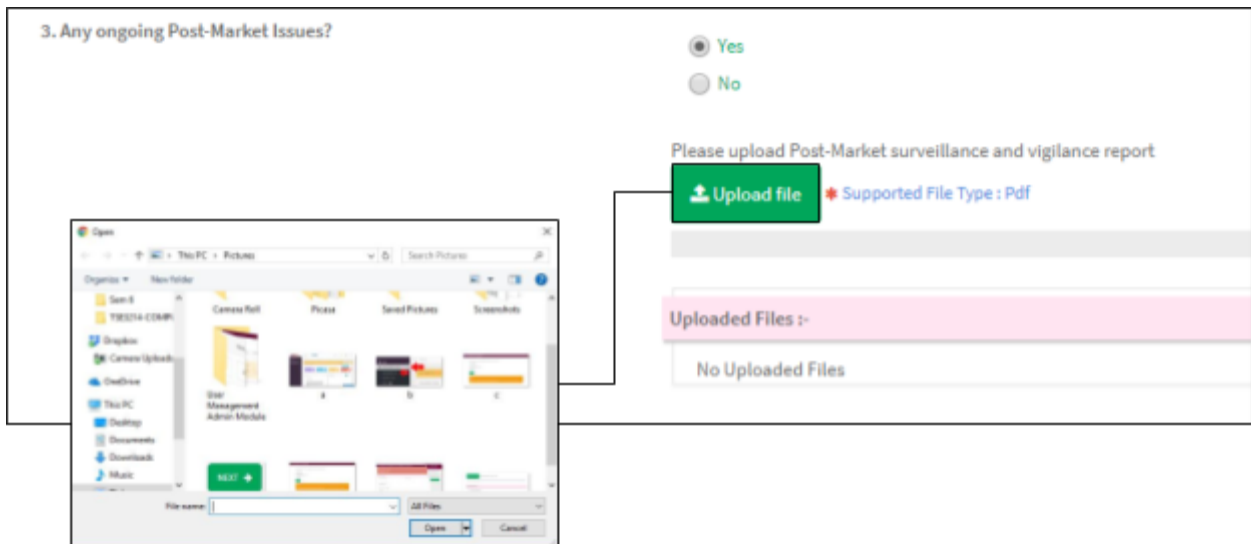
- Sam 6
- TSE2014-COMPL
- Camera Roll
- Picasa
- Saved Pictures
- Screenshots
- Desktop
- Camera Uploads
- CloudDrive
- This PC
- Documents
- Downloads
- Music
- User Management Admin Module


Filename: All Files

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.**

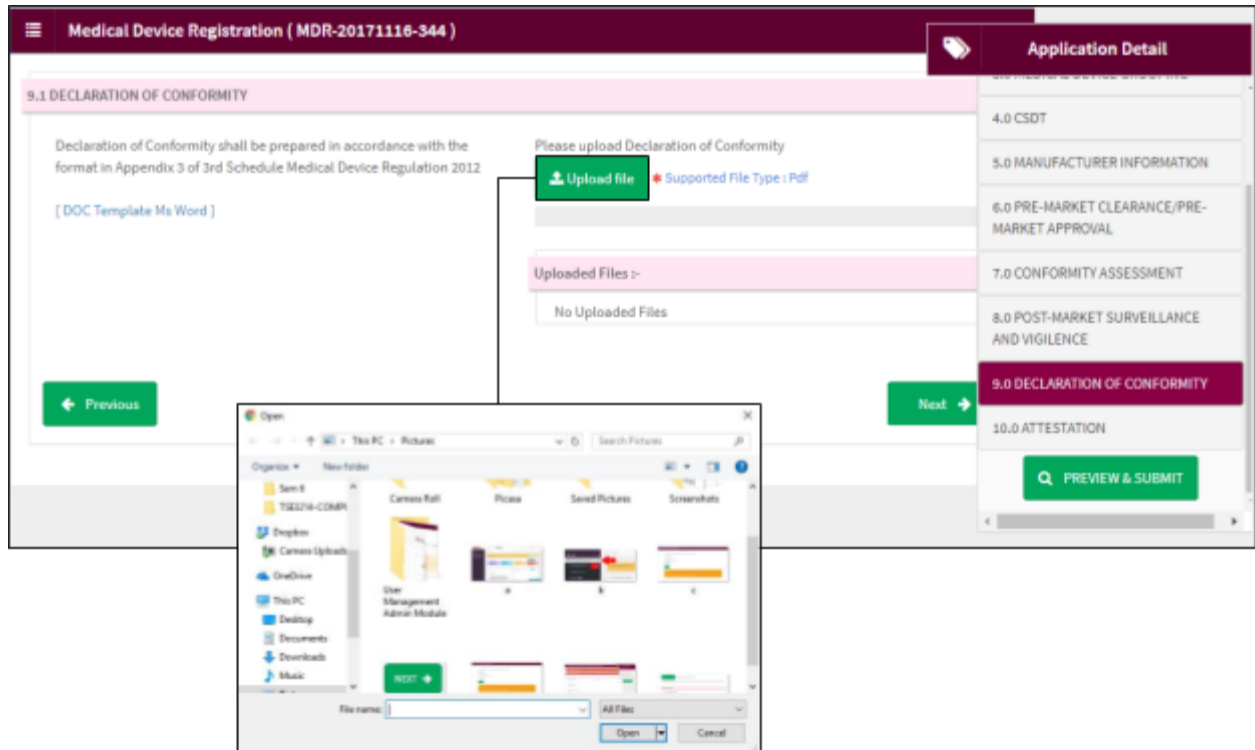


If user tick 'Yes', user have to upload file. Click  to upload file. **The file must be pdf format and size not more than 300 MB.**



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

Medical Device Registration (MDR-20171116-344)

10.1 ATTESTATION

I, _____ the Manufacturer/Authorized Representative of this/these device(s), hereby declare that:

- This product is a medical device according to the definition of medical device set out in Section 2, Medical Device Act 2012 (Act 737)
- I shall be responsible for the establishment and implementation of post-market surveillance and vigilance system to monitor safety and performance of this/these medical device(s).
- I hereby attest that the information and attachment provided on this application is/are accurate, correct, complete and current to this date.
- I understand and acknowledge that it is an offence under Section 76, of Act 737 to make sign or furnish any declaration, or other document which is untrue, inaccurate or misleading.

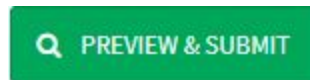
[← Previous](#) [PREVIEW & SUBMIT](#)

Application Detail

- 4.0 CSDT
- 5.0 MANUFACTURER INFORMATION
- 6.0 PRE-MARKET CLEARANCE/PRE-MARKET APPROVAL
- 7.0 CONFORMITY ASSESSMENT
- 8.0 POST-MARKET SURVEILLANCE AND VIGILANCE
- 9.0 DECLARATION OF CONFORMITY
- 10.0 ATTESTATION**

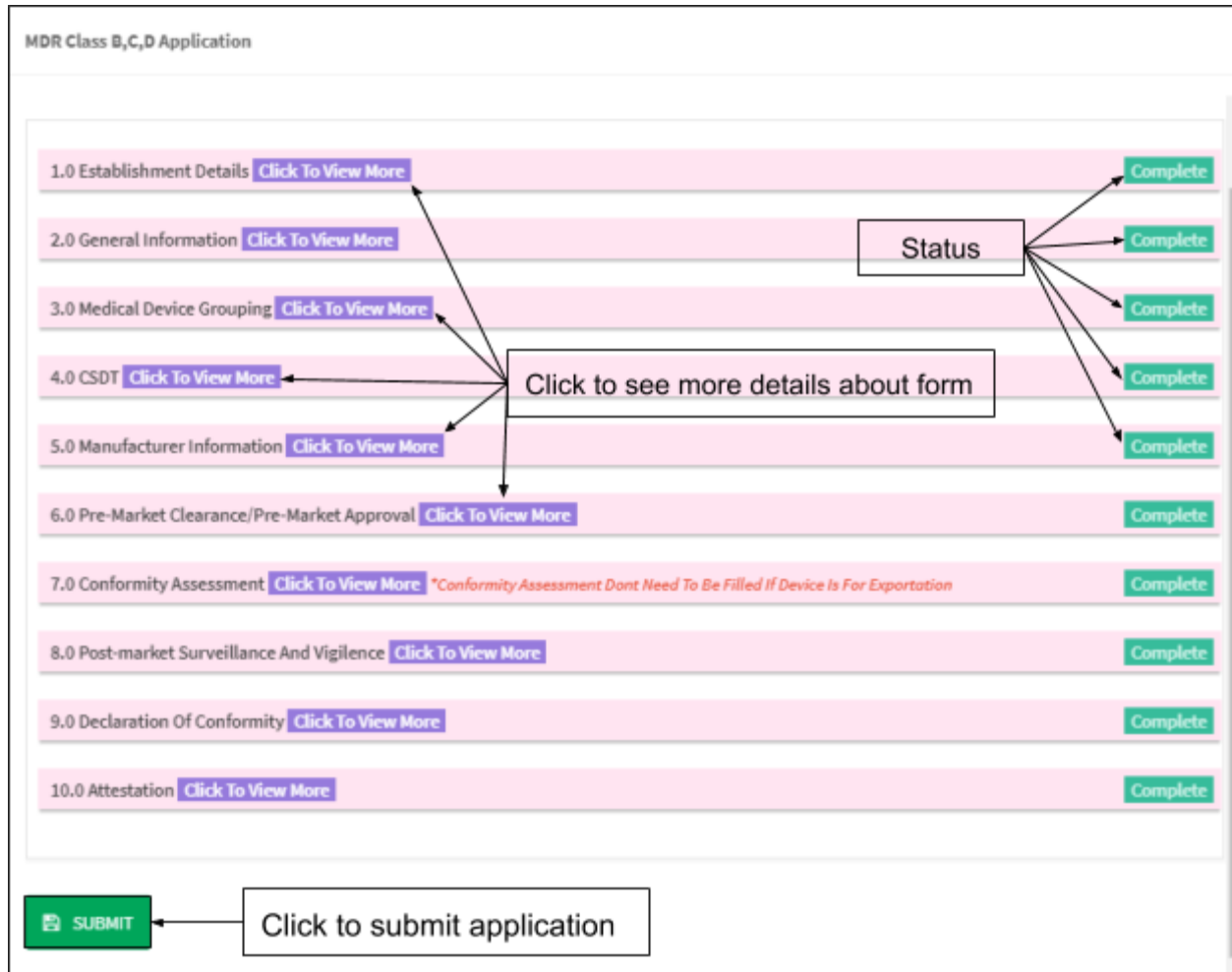
[PREVIEW & SUBMIT](#)

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



to preview before submit application.

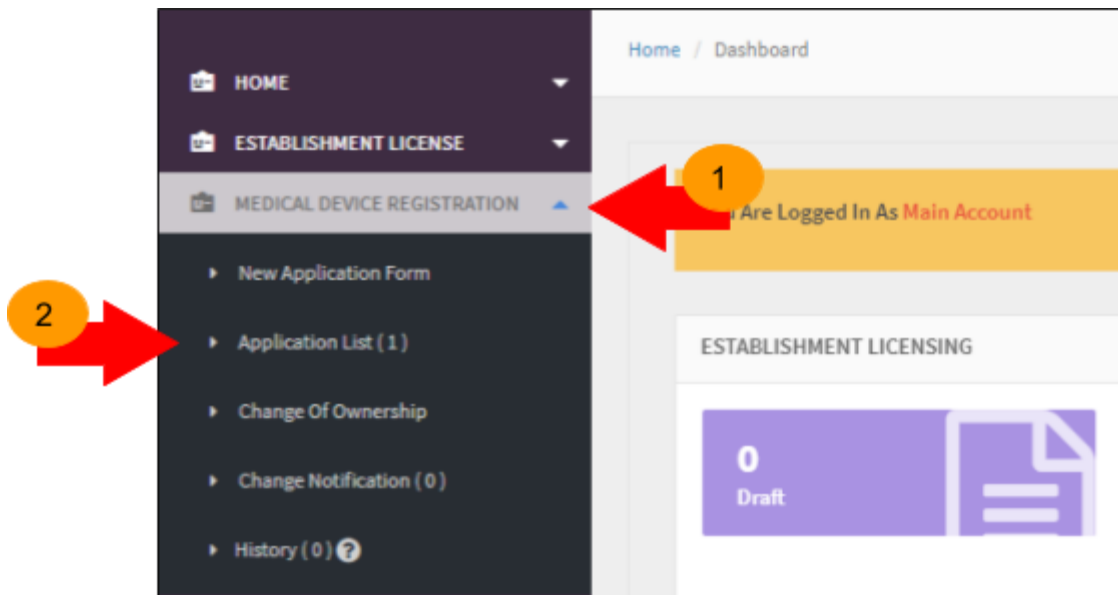
The diagram below will appear after user click [PREVIEW AND SUBMIT] button.



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.

No	Submission ID	Application Type	Date Of Submission	Role Of Establishment	Device Name	Device Class	Device Risk Type	Form Status	Action
1	MDR-20171116-344	NEW REGISTRATION	09-12-2017	MANUFACTURER	DEVICE YVD	B	GENERAL MEDICAL DEVICE (GMD)	COMPLETE	View ReRegister P.Advice & Receipt Withdrawal Certificate Change Notification



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.

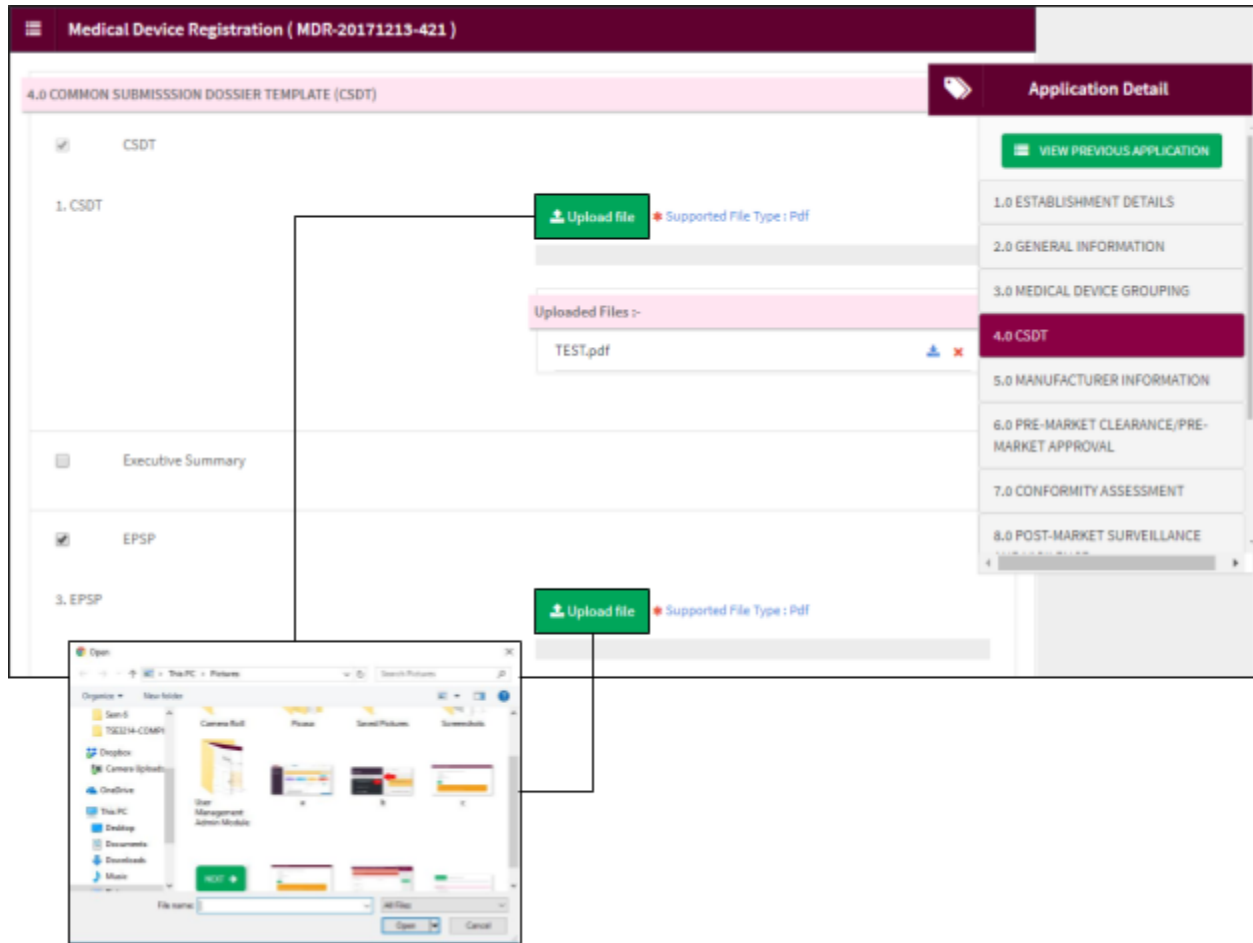
Step	Link	Status
1.0 Establishment Details	Click To View More	Complete
2.0 General Information	Click To View More	Complete
3.0 Medical Device Grouping	Click To View More	Complete
4.0 CSDT	Click To View More	Complete
5.0 Manufacturer Information	Click To View More	Complete
6.0 Pre-Market Clearance/Pre-Market Approval	Click To View More	Complete
7.0 Conformity Assessment	Click To View More	Complete
8.0 Post-Market Surveillance And Vigilance	Click To View More	Complete
9.0 Declaration Of Conformity	Click To View More	Complete
10.0 Withdrawal	Click To View More	Complete

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

The screenshot displays the 'Medical Device Registration (MDR-20171213-421)' interface. The main content area is titled '3.1 Medical Device Grouping (GMD)'. It contains two input fields: 'GROUPING TYPE OF MEDICAL DEVICE' with the value 'Single', and 'DEVICE IDENTIFIER' with the value 'MEDICAL BRAND Y'. A red warning message below the first field reads: '*Please Ensure You Have Chosen The Correct Group For The Medical Device'. At the bottom of the form are two green buttons: 'Previous' with a left arrow and 'Next' with a right arrow. On the right side, there is a vertical sidebar titled 'Application Detail' containing a list of steps: 1.0 ESTABLISHMENT DETAILS, 2.0 GENERAL INFORMATION, 3.0 MEDICAL DEVICE GROUPING (highlighted in dark red), 4.0 CSOT, 5.0 MANUFACTURER INFORMATION, 6.0 PRE-MARKET CLEARANCE/PRE-MARKET APPROVAL, 7.0 CONFORMITY ASSESSMENT, and 8.0 POST-MARKET SURVEILLANCE. A 'VIEW PREVIOUS APPLICATION' button is located at the top of this sidebar.

User click  to go to the next step. User click  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 (*).


The screenshot displays the 'Medical Device Registration (MDR-20171213-421)' interface. The main section is titled '5.1 Manufacturer Information' and contains the following fields:

- 1. Name Of Legal Manufacturer : XXX
- 2. Address Of Legal Manufacturer : XXX
- 3. Post Code/Zip Code : XXX
- 4. Country : BELARUS
- 5. Upload Quality Management System Certificate (ISO 13485 or Other Quality Management System standard recognised by MDA)

An 'Upload file' button is present, with a note 'Supported File Type : Pdf'. Below it, the 'Uploaded Files' section shows a file named 'TEST.pdf'. A sidebar on the right, titled 'Application Detail', lists steps from 1.0 to 8.0, with '5.0 MANUFACTURER INFORMATION' highlighted in red. A 'VIEW PREVIOUS APPLICATION' button is also visible.

An inset window shows a file explorer with the following contents:

- File name: TEST.pdf
- File type: All Files
- Buttons: Open, Cancel

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 (*).

The screenshot shows the 'Medical Device Registration (MDR-20171213-421)' interface. The main section is titled '6.1 PRE-MARKET CLEARANCE/PRE-MARKET APPROVAL'. It contains a checkbox for 'USFDA' which is checked. Below this, there are three numbered fields: '1. US FDA 510(K) / Pre Market Approval / Notification Number:' with the value 'MV2', '2. Valid from:' with the value '01-11-2017', and '3. Valid to:' with the value '19-12-2017'. A radio button for 'Valid To? (Yes/No)' is set to 'Yes', with a red note below it: '**Valid To Date Need To Be Set If Choose Yes'. On the right, a sidebar titled 'Application Detail' lists steps from 1.0 to 8.0, with step 6.0 'PRE-MARKET CLEARANCE/PRE-MARKET APPROVAL' highlighted in red. A 'VIEW PREVIOUS APPLICATION' button is also visible.

User click

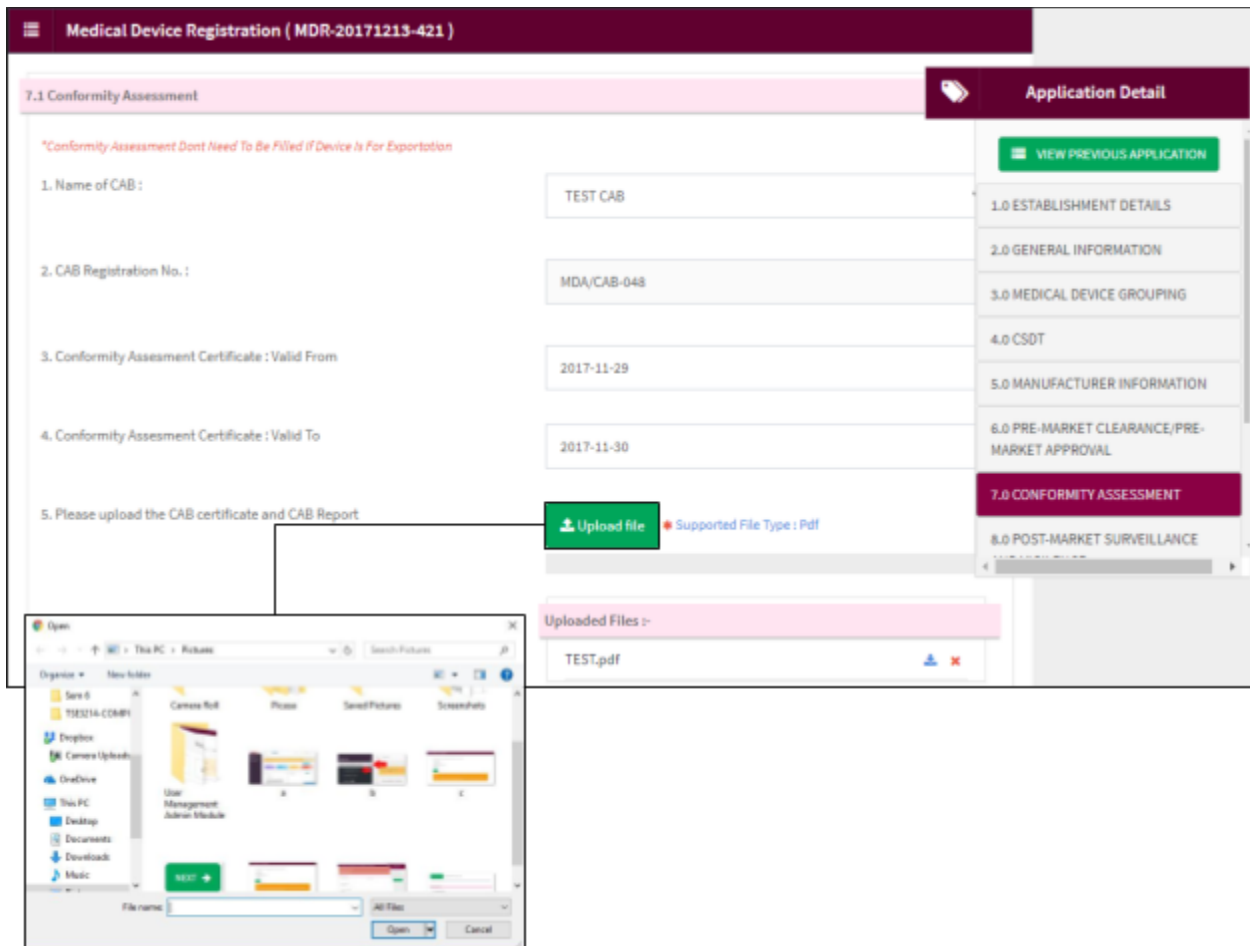



to go to the next step. User click




to go to the previous form.

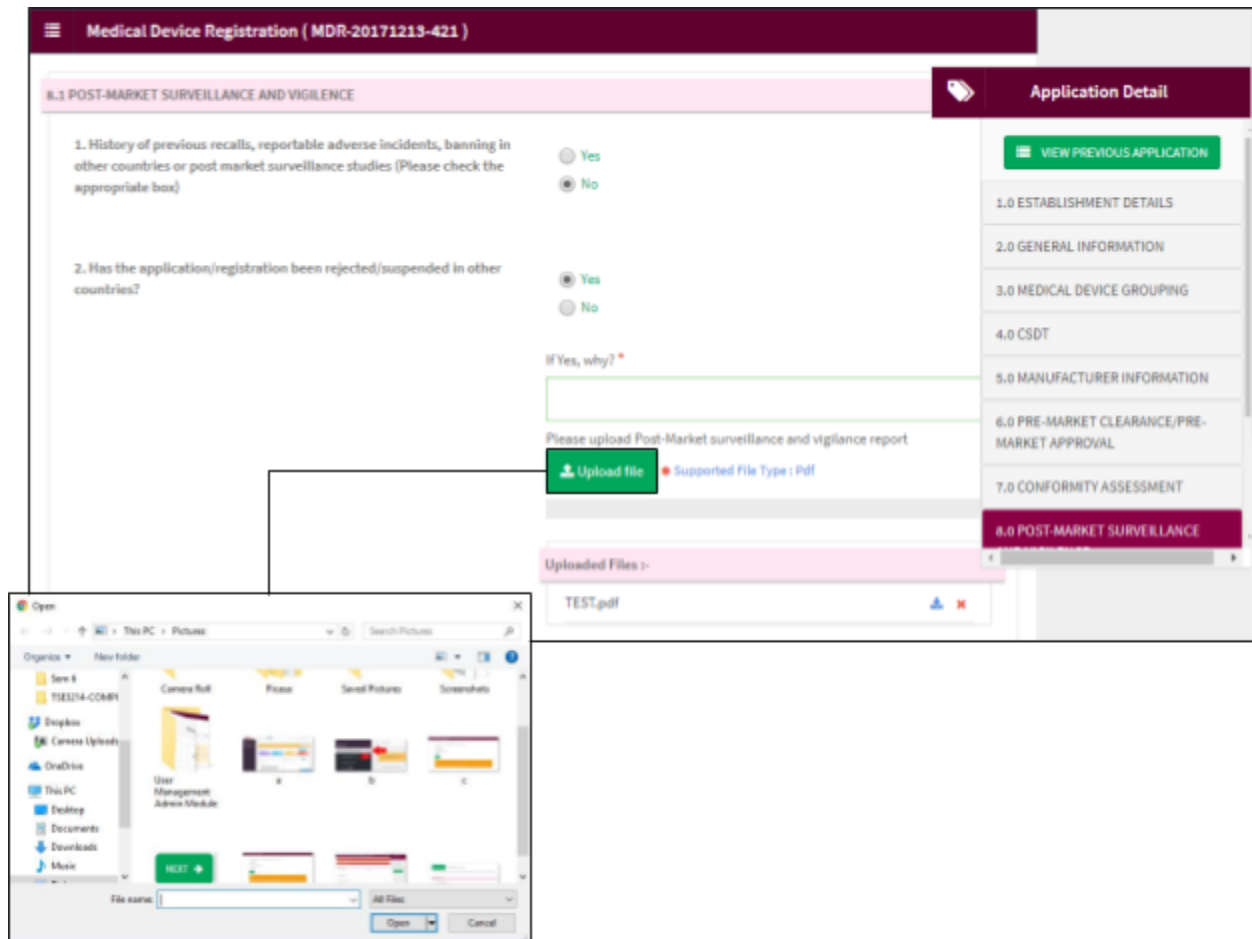
The diagram below show 6.0 PRE-MARKET CLEARANCE/PRE-MARKET APPROVAL form. User have to complete all fields with (*).





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.

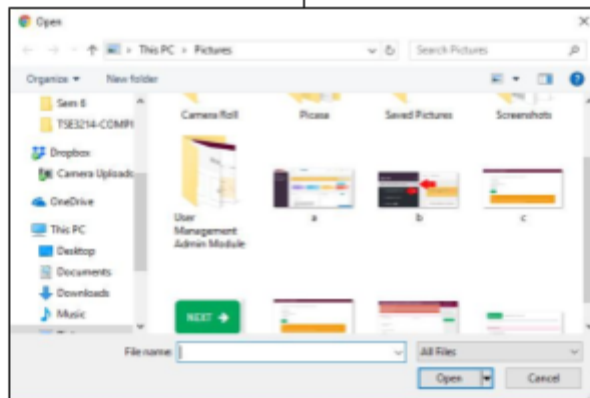
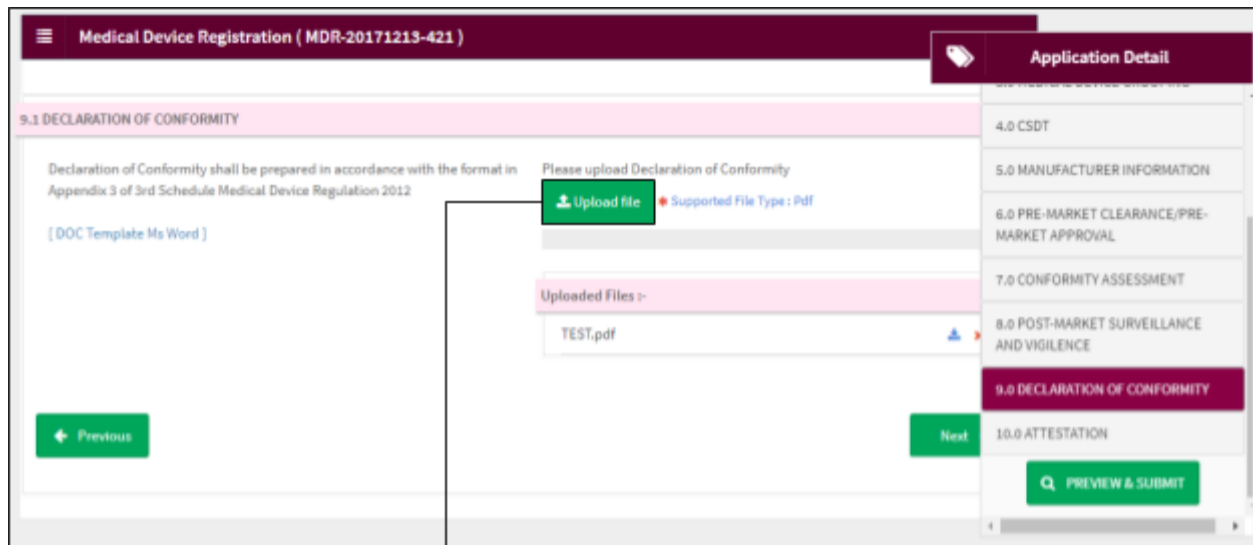
The diagram below show SURVEILLANCE AND VIGILANCE form. User have to complete all fields with (*).





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.**

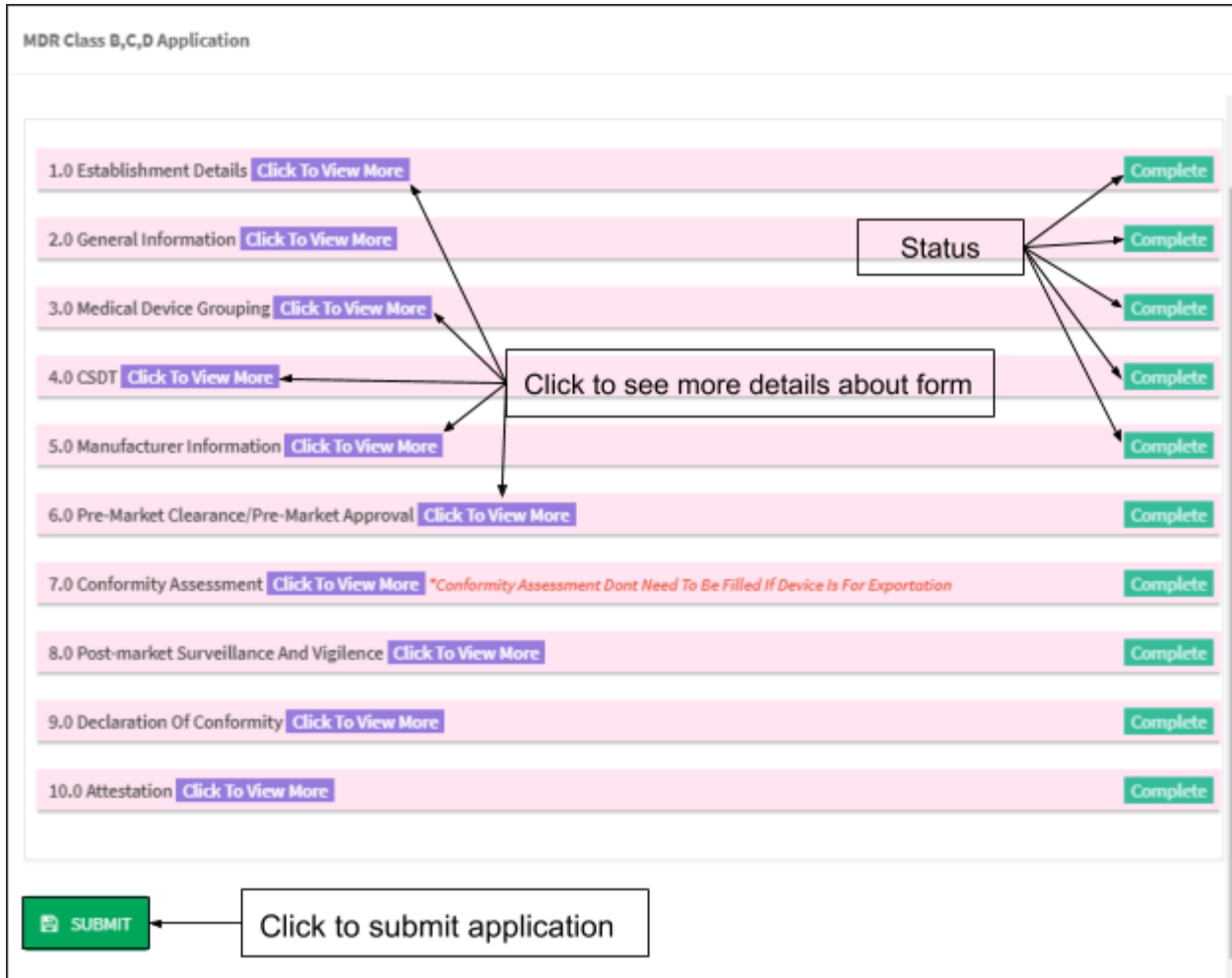
User click  to go to the next step. User click  to go to the previous form.

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



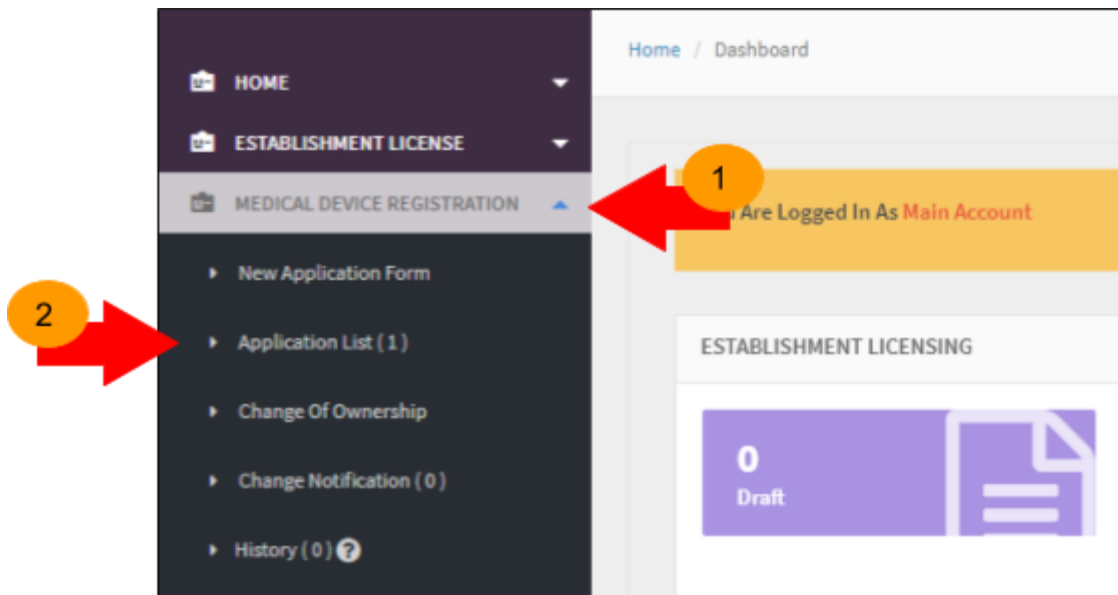
to preview before submit application.



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.

Medical Device Registration

[FILTER APPLICATION](#)

Showing 1-1 of 1 item.

No	Submission ID	Application Type	Date Of Submission	Role Of Establishment	Device Name	Device Class	Device Risk Type	Form Status	Action
1	MDR-20171116-344	NEW REGISTRATION	09-12-2017	MANUFACTURER	DEVICE Y IVD	B	GENERAL MEDICAL DEVICE (GMD)	COMPLETE	View ReRegister PAdvice & Receipt Withdrawal Certificate Change Notification

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

The screenshot shows a web interface with a dark purple header containing a menu icon and the text "Change Notification For Registered Medical Device". Below the header is a light pink section titled "Category Type". Inside this section, there are three radio button options: "CATEGORY 1", "CATEGORY 2", and "CATEGORY 3". The "CATEGORY 1" radio button is currently selected.

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

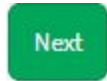
This screenshot shows the same web interface as the previous one, but with more content. The "CATEGORY 1" radio button is selected. Below the category options is a section titled "[SELECT TYPE OF CHANGES]" with a list of seven checkboxes, each followed by a description of a change type. The first checkbox is selected. At the bottom of this section, there is a green "PROCEED" button.

- Change to the intended purpose and/or indication of use of a registered medical device;
- Change to the risk classification of a registered medical device;
- Change to software that affect safety and performance of the registered medical device;
- Addition of variant(s) not considered a permissible variant according to the rules of grouping in Second Schedule of MDR2012 and MDA/GD-05 Product Grouping First Edition October 2013;
- Change to the type, concentration or drug specifications (DS) of medicinal substance in a medical device that incorporates a medicinal product as an ancillary role; and
- Addition of medical devices with device proprietary names different from the registered devices, into a device listing.
- Unless the devices with different proprietary names qualify to be listed together under one listing based on MDA guidance documents on grouping criteria for medical devices registration.

Category 1 change of medical devices that affect their safety and performance and require new registration of the medical device. Registration holders are required to apply new registration according to Act 737 and Medical Device Registration 2012.

PROCEED

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



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

A screenshot of a web application interface. At the top, there is a dark purple header bar with a white hamburger menu icon on the left and the text "Medical Device Registration Application" in white. Below the header, the main content area is white. It features the heading "ROLE OF ESTABLISHMENT TO THE MEDICAL DEVICE" in a light grey font. Underneath, there are two radio button options: "MANUFACTURER" and "AUTHORISED REPRESENTATIVE". Each option has a red arrow pointing to its respective radio button. At the bottom of the form, there is a green "Next" button.

❖ 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.**

The screenshot shows a web interface titled "Change Notification For Registered Medical Device". Under the "Category Type" section, three radio buttons are present: "CATEGORY 1", "CATEGORY 2" (which is selected), and "CATEGORY 3". Below this, a section titled "[SELECT TYPE OF CHANGES]" contains five checkboxes, all of which are currently unchecked:

- Change in manufacturing facility, process and quality management system (QMS)
- Changes in design or specifications of a registered medical device
- Changes to materials in a general medical device
- Changes to materials in an in-vitro diagnostic (IVD) medical device
- Changes to labelling of medical devices
- Changes to registered medical devices registration information

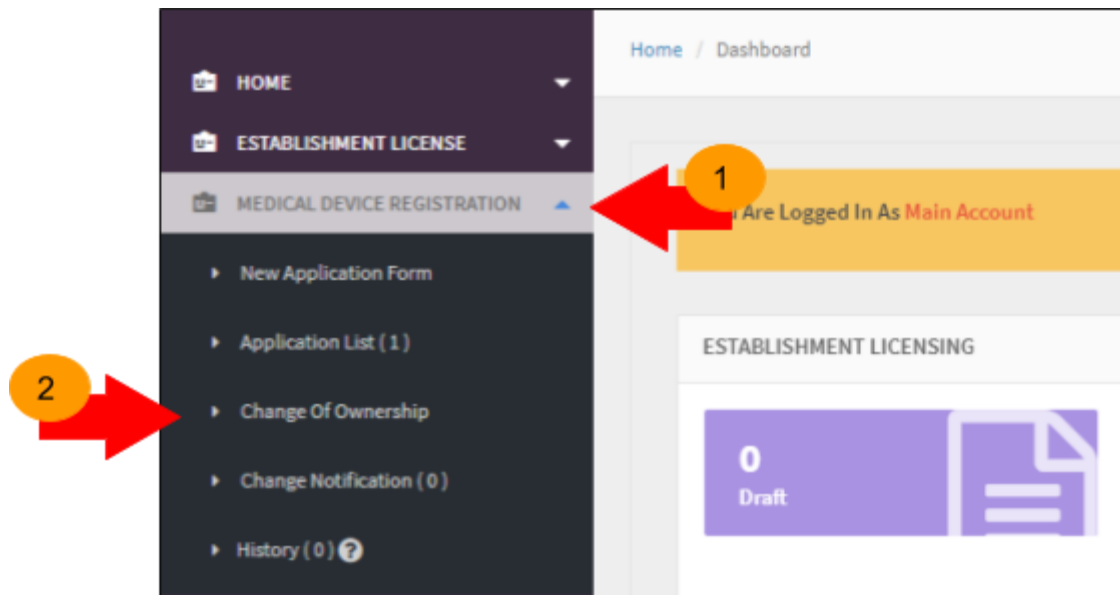
- 3) Category 3, changes may be implemented immediately upon receipt of the acknowledgment from the Authority.**

The screenshot shows the same web interface as above, but with "CATEGORY 3" selected. The "[SELECT TYPE OF CHANGES]" section now shows four checkboxes, with the second one checked:

- Change in manufacturing facility, process and quality management system (QMS)
- Changes in design or specifications of a registered medical device
- Changes to labelling of medical devices
- Changes to registered medical devices registration information


5.0 CHANGE OF OWNERSHIP

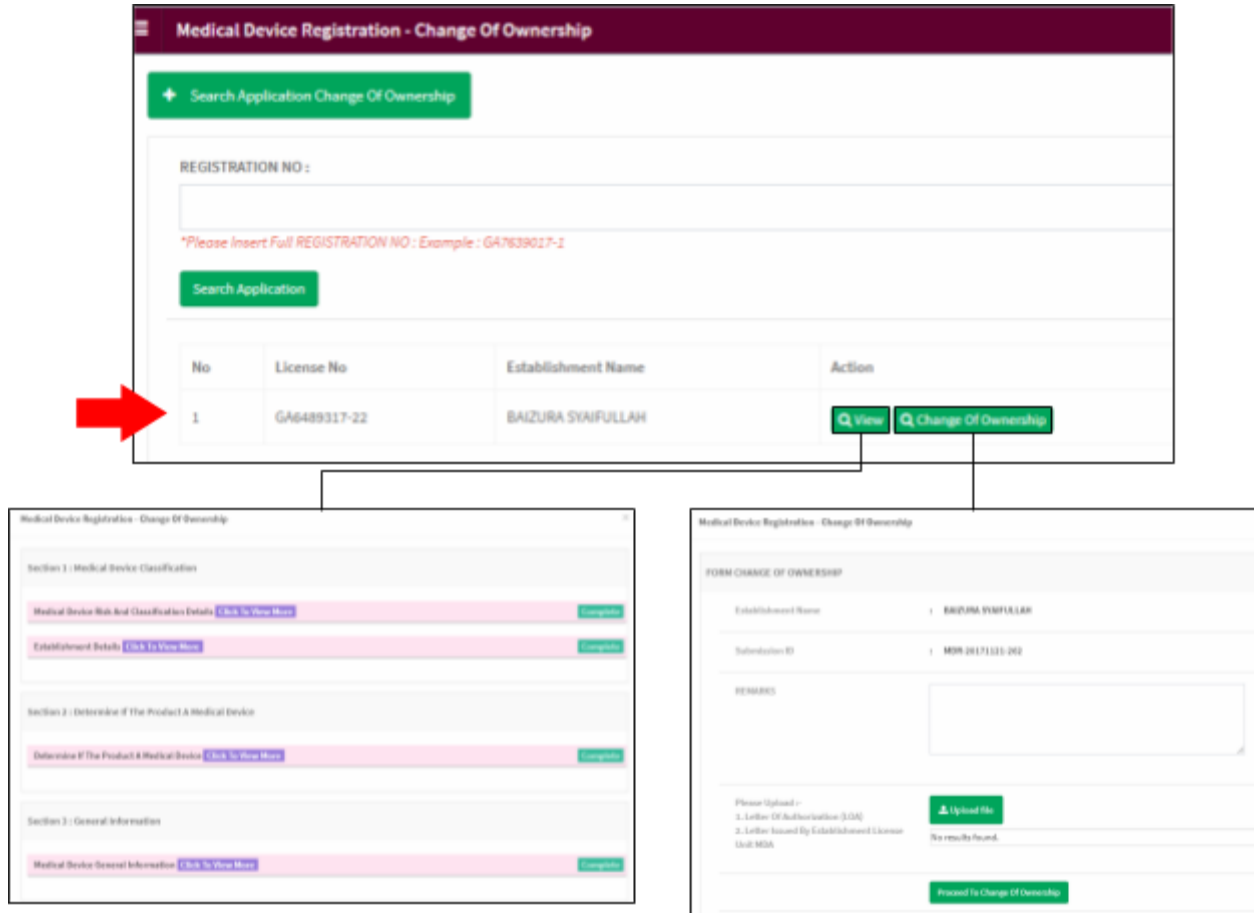
Click on the 'MEDICAL DEVICE REGISTRATION' at the left menu sidebar and click at the 'Change Of Ownership' to create new form.



The diagram below show *Change of Ownership* page.

The screenshot shows a web interface for 'Medical Device Registration - Change Of Ownership'. At the top, there is a green button labeled 'Search Application Change Of Ownership'. Below this, a search form is displayed with the label 'REGISTRATION NO:' and an empty input field. A red asterisk note below the input field reads: '*Please insert Full REGISTRATION NO : Example : GA7639027-1'. A green 'Search Application' button is positioned below the input field. At the bottom of the form, a table is visible with the following columns: 'No', 'License No', 'Establishment Name', and 'Action'.

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





Medical Device Registration - Change Of Ownership

Search Application Change Of Ownership

REGISTRATION NO :



*Please Insert Full REGISTRATION NO : Example : GA7639017-1



Search Application

No	License No	Establishment Name	Action
1	GA6489317-22	BAIZURA SYAIFULLAH	 



Medical Device Registration - Change Of Ownership

Section 1 : Medical Device Classification



Medical Device Risk And Classification Details  

Establishment Details  

Section 2 : Determine if The Product A Medical Device

Determine if The Product A Medical Device  

Section 3 : General Information

Medical Device General Information  

Medical Device Registration - Change Of Ownership

FORM CHANGE OF OWNERSHIP


Establishment Name : BAIZURA SYAIFULLAH

Submission ID : MDR 20171111-202


REMARKS


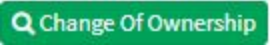
Please Upload :

1. Letter Of Authorization (LOA)
 2. Letter Issued By Establishment License
 Unit MDA



No results found.



- Click  to view the application.
- Click  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.

Medical Device Registration - Change Of Ownership

FORM CHANGE OF OWNERSHIP

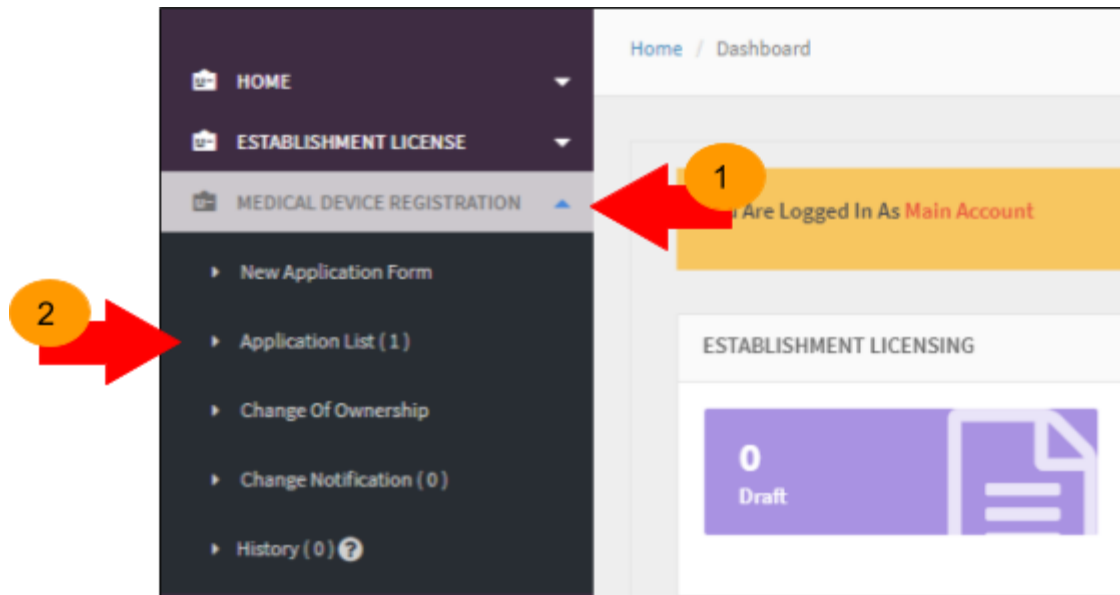
Establishment Name	: BAIZURA SYAIFULLAH
Submission ID	: MDR-20171121-262
REMARKS	<div style="border: 1px solid #ccc; padding: 5px; min-height: 40px;">Example</div>


Please Upload :- 1. Letter Of Authorization (LOA) 2. Letter Issued By Establishment License Unit MDA	<div style="border: 1px solid #ccc; padding: 5px; text-align: center;"> </div> <div style="border: 1px solid #ccc; padding: 5px; margin-top: 5px;">No results found.</div>
---	--

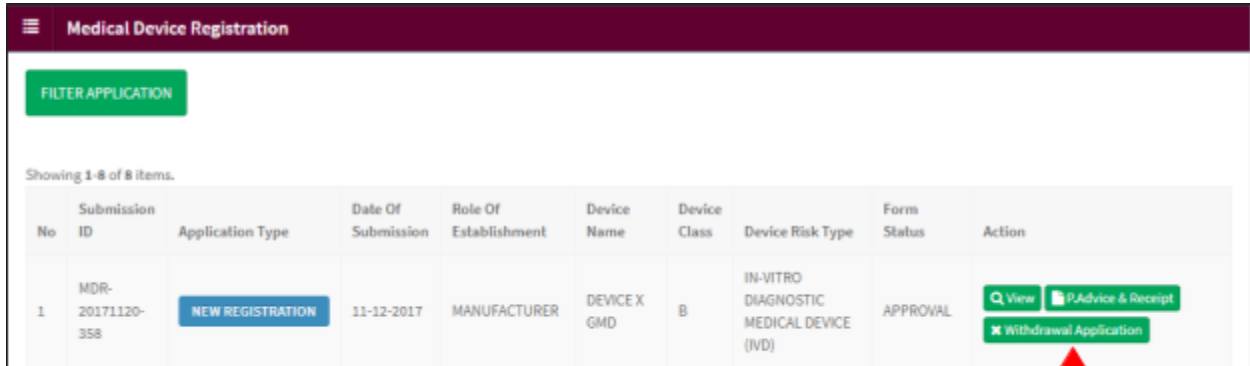
Proceed To Change Of Ownership




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  to withdrawal application.



No	Submission ID	Application Type	Date Of Submission	Role Of Establishment	Device Name	Device Class	Device Risk Type	Form Status	Action
1	MDR-20171120-358	NEW REGISTRATION	11-12-2017	MANUFACTURER	DEVICE X GMD	B	IN-VITRO DIAGNOSTIC MEDICAL DEVICE (IVD)	APPROVAL	  

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.

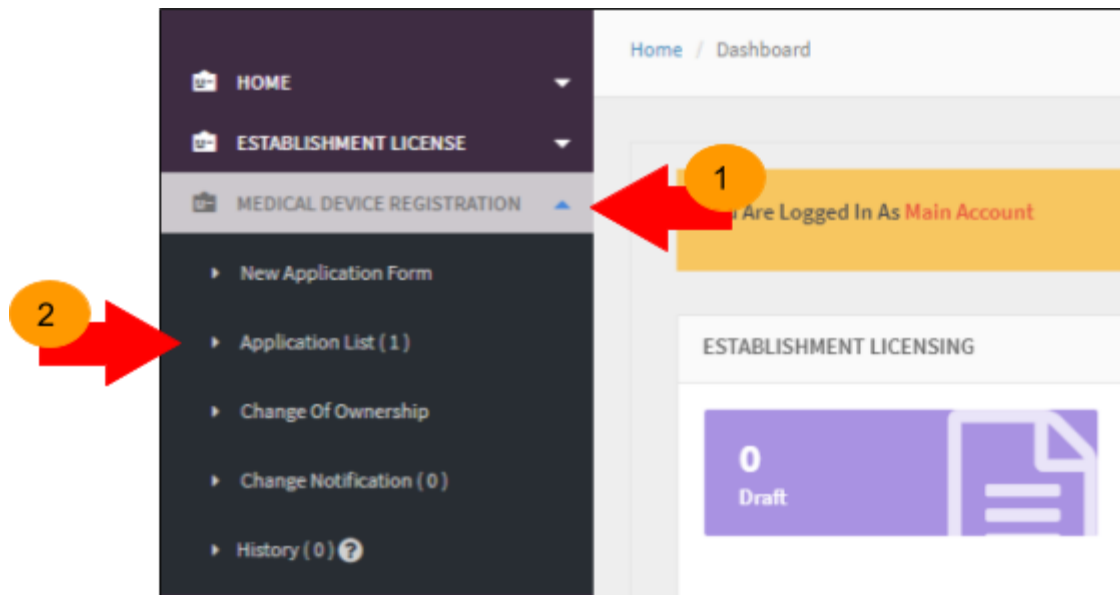
The screenshot shows a web application window titled "Medical Device Registration Application". The main content area is titled "Withdrawal Application - MDR-20171120-356". It contains a form with the following fields:


- Medical Device Registration No: MDR-20171120-356
- Medical Device Name: DEVICE C
- Proprietary Name/Brand: NAME C
- Model: SYSTEM
- Description Of Medical Device: A text area containing the word "Example".
- Intended Use Of Medical Device: A text area containing the word "Example".

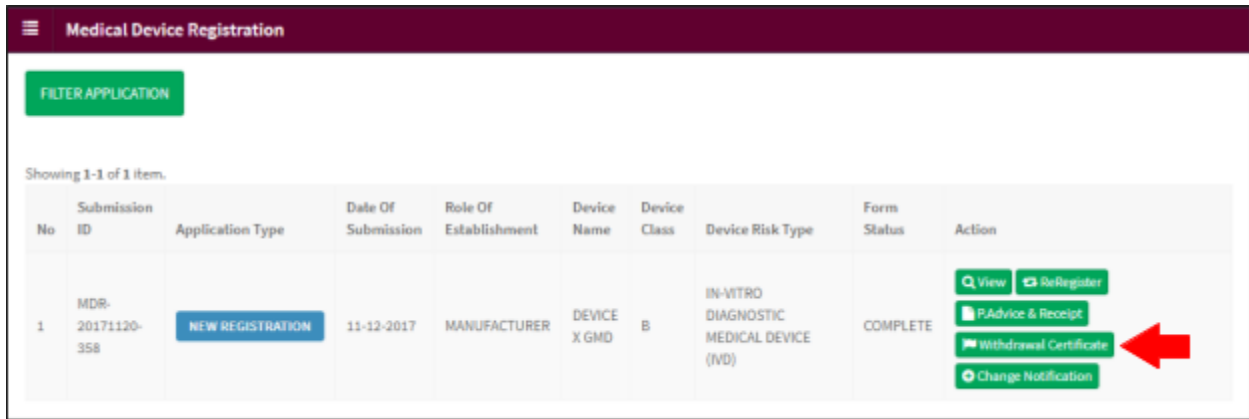
Below the text areas, there is a section for uploading an official letter. It includes a green "Upload file" button, a search bar containing "No results found.", and a red "Submit To Withdrawal" button at the bottom right. Red text instructions state: "Upload official letter for medical device registration application withdrawal. Please upload official letter for medical device registration application withdrawal. Letter must be prepared with company letterhead".

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  to withdrawal application.




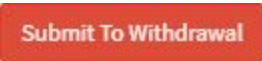
Medical Device Registration

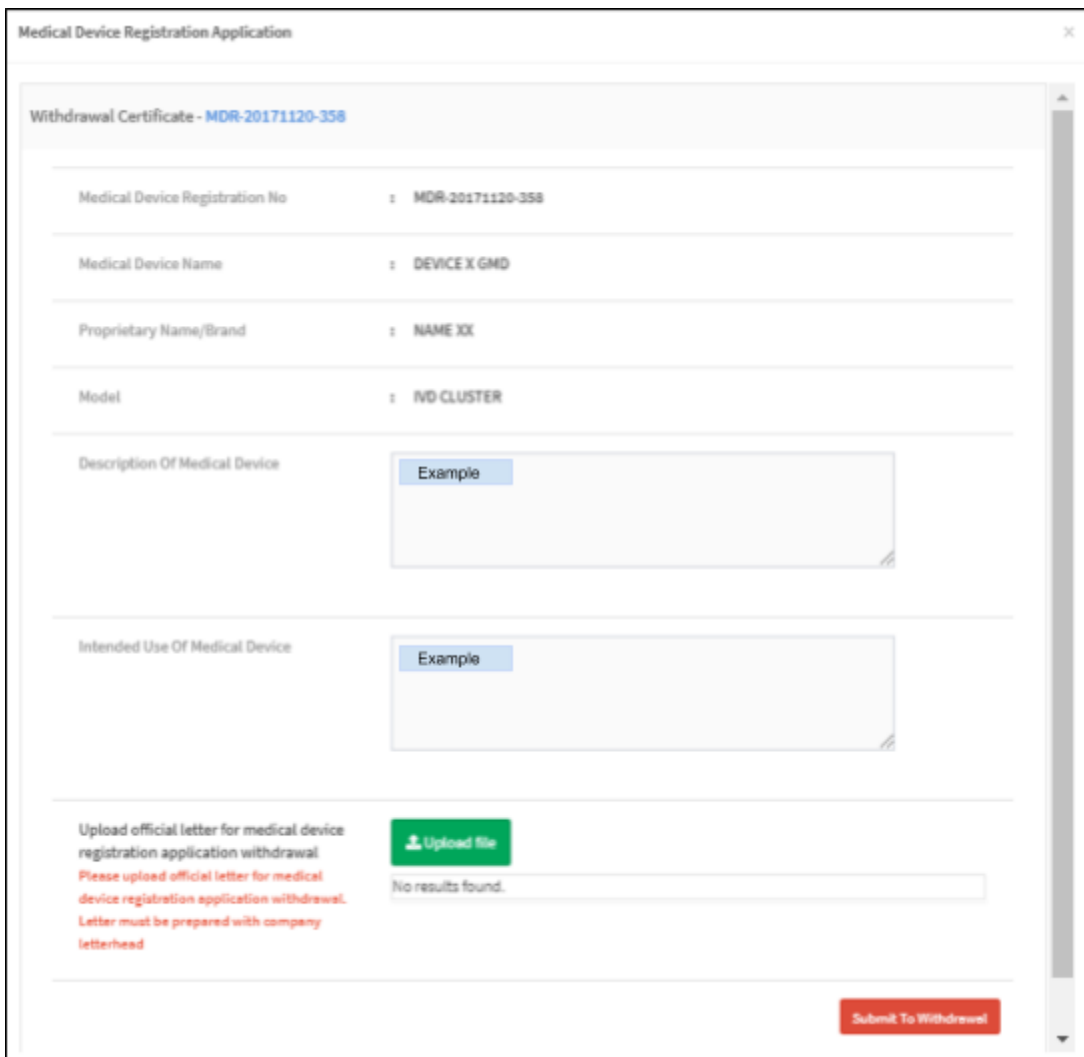
FILTER APPLICATION

Showing 1-1 of 1 item.

No	Submission ID	Application Type	Date Of Submission	Role Of Establishment	Device Name	Device Class	Device Risk Type	Form Status	Action
1	MDR-20171120-358	NEW REGISTRATION	11-12-2017	MANUFACTURER	DEVICE X GMD	B	IN-VITRO DIAGNOSTIC MEDICAL DEVICE (ID)	COMPLETE	View ReRegister P.Advice & Receipt Withdrawal Certificate Change Notification

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

 to submit.



The screenshot shows a web application window titled "Medical Device Registration Application" with a close button (X) in the top right corner. The main content area is titled "Withdrawal Certificate - MDR-20171120-358". Below the title, there is a form with several fields:

- Medical Device Registration No**: MDR-20171120-358
- Medical Device Name**: DEVICE X GMD
- Proprietary Name/Brand**: NAME XX
- Model**: MD CLUSTER
- Description Of Medical Device**: A text area containing the word "Example".
- Intended Use Of Medical Device**: A text area containing the word "Example".
- Upload official letter for medical device registration application withdrawal**: A section with a green "Upload file" button and a text input field containing "No results found." Below this, there is red text: "Please upload official letter for medical device registration application withdrawal. Letter must be prepared with company letterhead".

At the bottom right of the form, there is a red button labeled "Submit To Withdrawal".