

USER MANUAL FRONT END USER

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

MODUL UTAMA - MDR CLASS A

DISEDIAKAN OLEH :



LIST OF CONTENTS

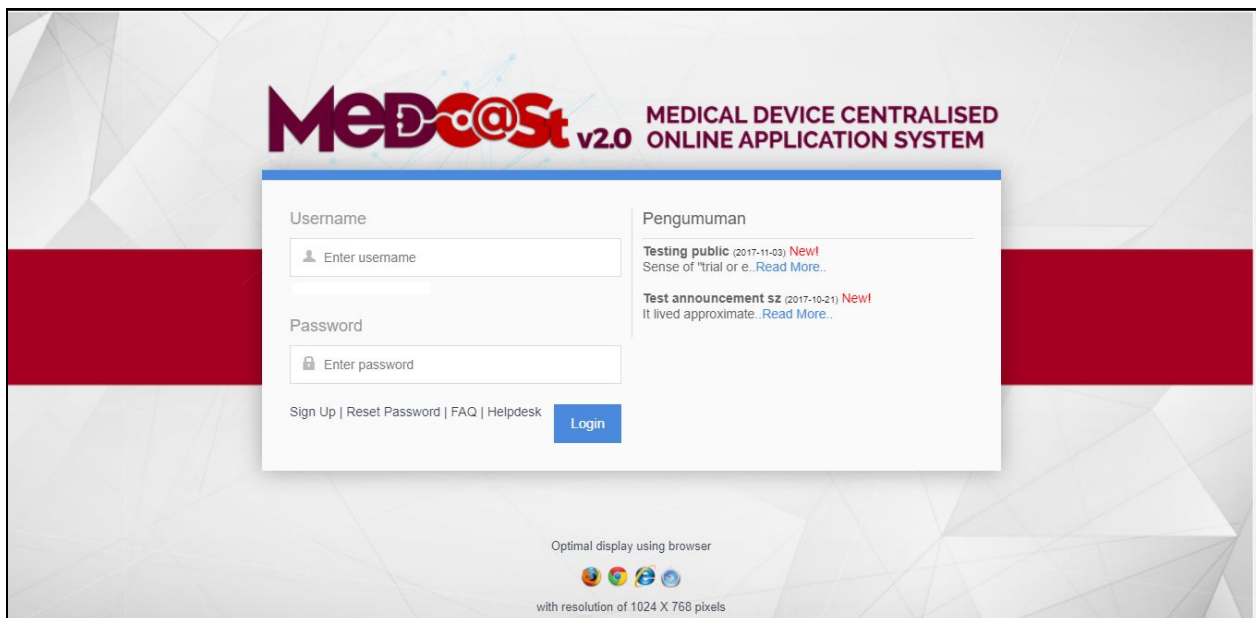
1.0 INTRODUCTION	3
1.1 SIGN UP	4
1.1.1 VERIFIED EMAIL FOR NEW ACCOUNT	5
2.0 CREATE NEW MEDICAL DEVICE REGISTRATION A APPLICATION	9
2.1 CLASSIFICATION FORM	12
2.2 FILL IN THE APPLICATION FORMS	18
2.2.1 SECTION 1 : MEDICAL CLASS CLASSIFICATION	18
2.2.2 SECTION 2 : DETERMINE IF THE PRODUCT A MEDICAL DEVICE	21
2.2.3 SECTION 3 : GENERAL INFORMATION	23
2.2.4 SECTION 4 : MEDICAL DEVICE GROUPING	27
2.2.5 SECTION 5 : ADDITIONAL REQUIREMENTS	39
2.2.6 SECTION 6 : MANUFACTURER INFORMATION	43
2.2.7 SECTION 7 : PRE-MARKET CLEARANCE / PRE-MARKET APPROVAL	47
2.2.8 SECTION 8 : LABELLING	55
2.2.9 SECTION 9 : POST-MARKET SURVEILLANCE AND VIGILANCE	57
2.2.10 SECTION 10 : DECLARATION OF CONFORMITY & ATTESTATION	59
3.0 RE-REGISTRATION APPLICATION	62
4.0 CHANGE OF NOTIFICATION APPLICATION	103
5.0 WITHDRAWAL CERTIFICATE	116
6.0 WITHDRAWAL APPLICATION	119
7.0 CHANGE OF AR	121

1.0 INTRODUCTION

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

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

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



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

1.1 SIGN UP

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

MeDC@St v2.0 MEDICAL DEVICE CENTRALISED ONLINE APPLICATION SYSTEM

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

Address

Reason Create Account In Medcast

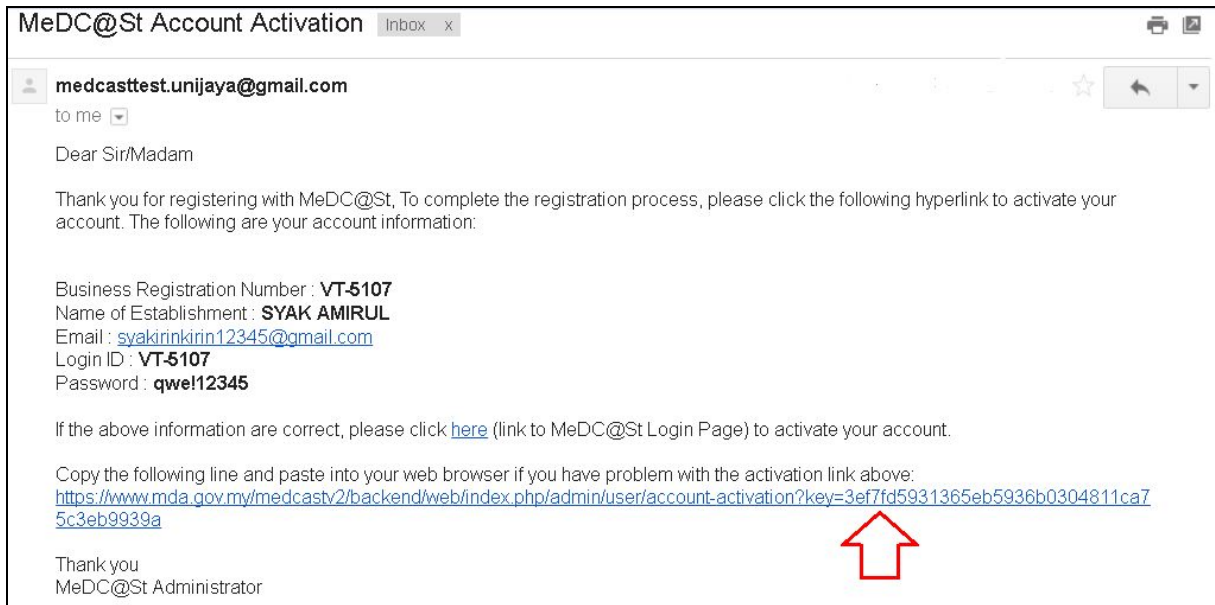
- Establishment Licensing & Medical Device
- CAB Application
- GLPCP Application
- Notification Application

The registration form contains the following fields and buttons:

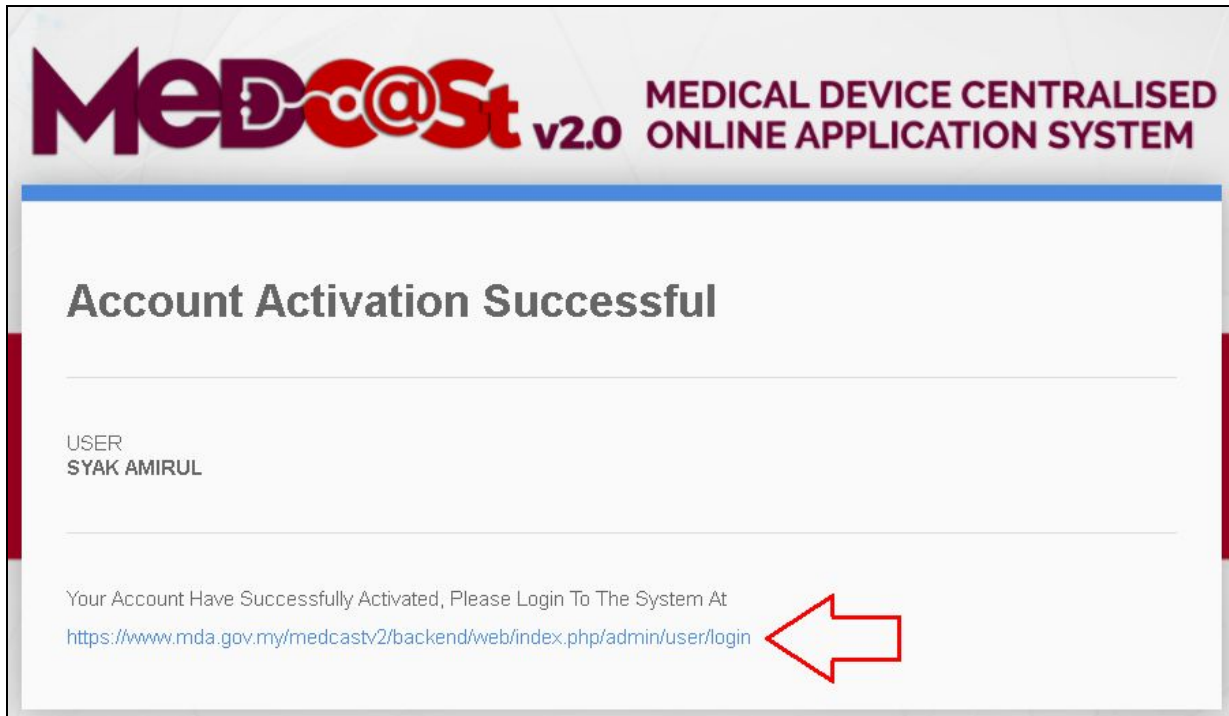
- State: Dropdown menu with "-Select State-" selected.
- City: Dropdown menu with "-Select City-" selected.
- Postcode: Text input field.
- Telephone No: Text input field.
- Fax No: Text input field.
- Password: Text input field.
- Re-Confirm Password: Text input field.
- Buttons: "Cancel" (red) and "Sign Up" (blue).

1.1.1 VERIFIED EMAIL FOR NEW ACCOUNT

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



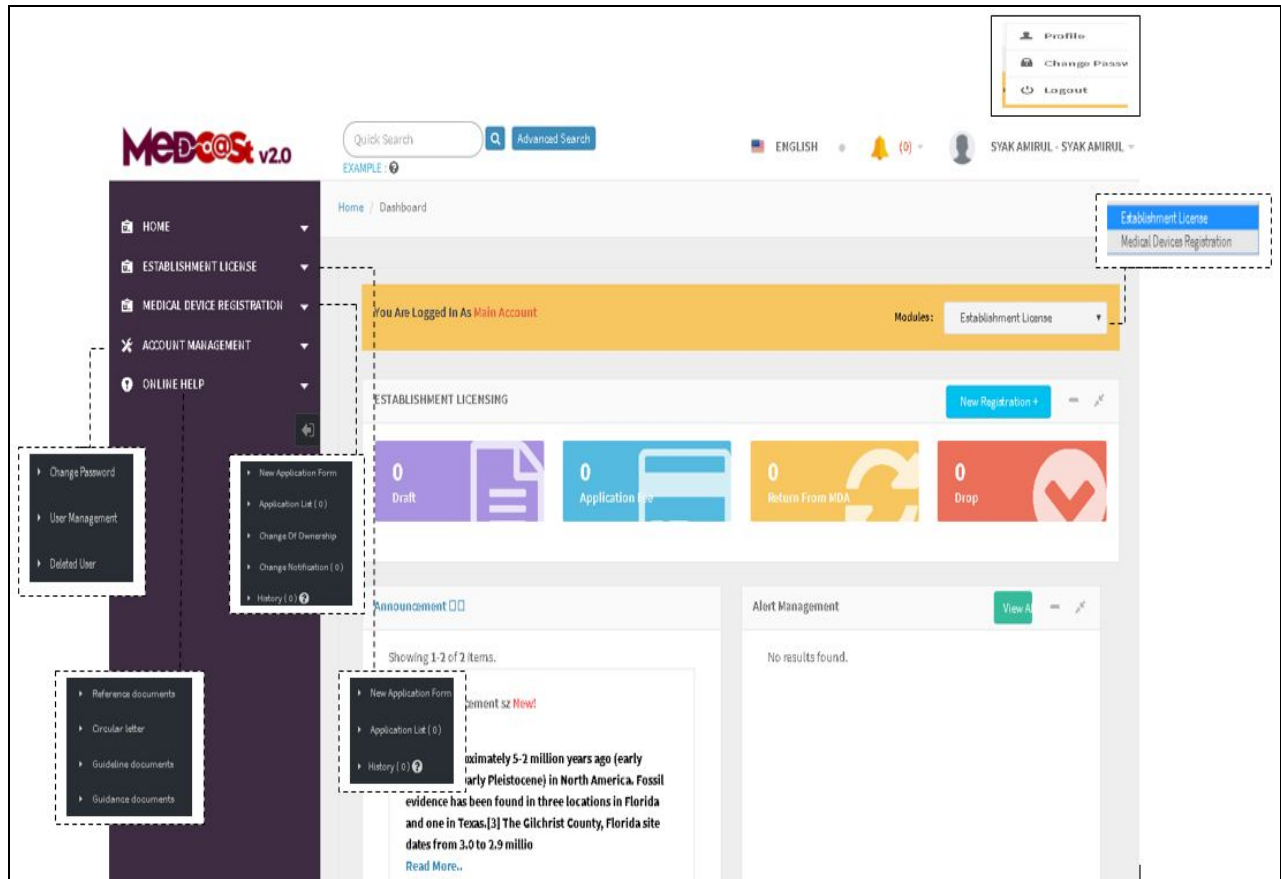
The account activation screen will display. The user must click at the link to login into the account.



The login screen will display.

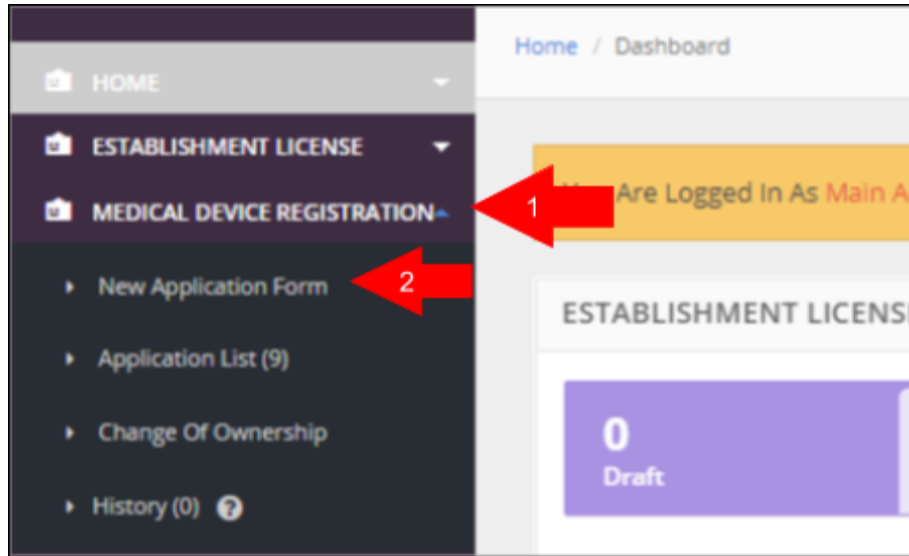


The user login successfully in the system medcast. It show the dashboard of the account.

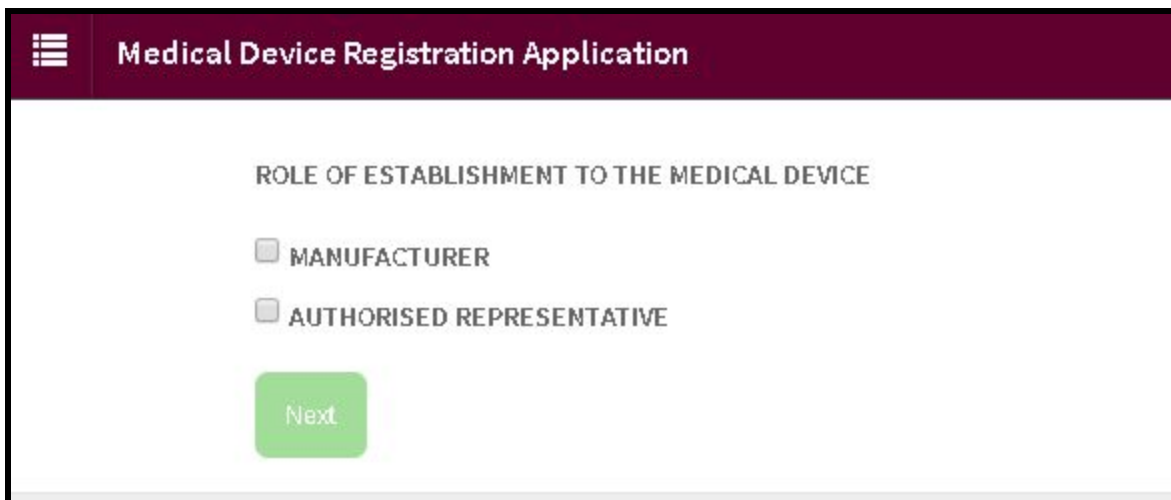


****User must create new establishment license first to create new medical device registration (Refer User Manual EL Front End User)**


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

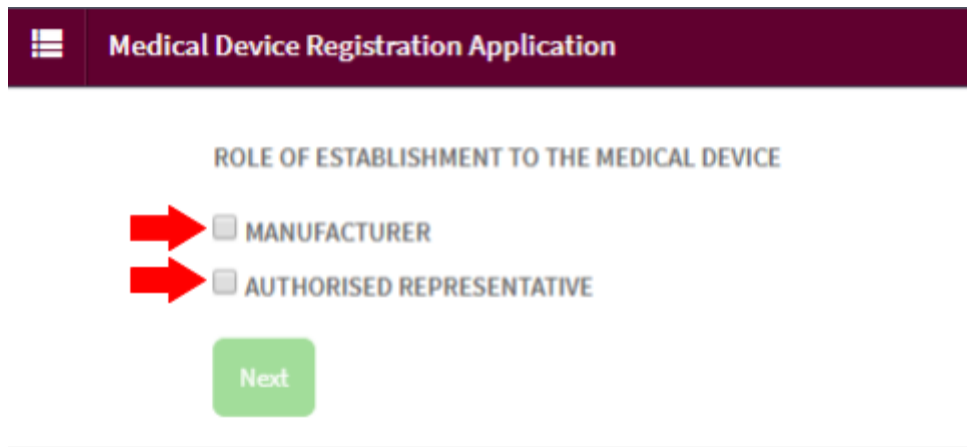


Medical Device Registration Application will display.

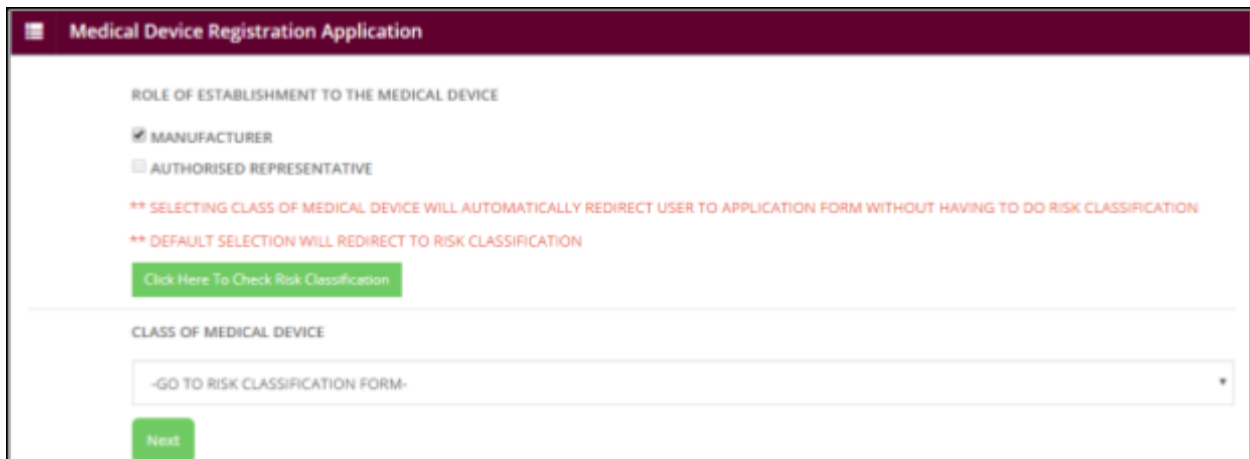


2.0 CREATE NEW MEDICAL DEVICE REGISTRATION A APPLICATION

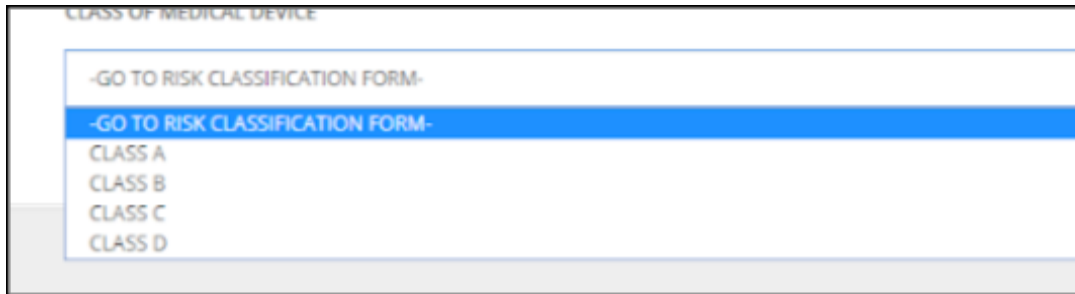
Tick on the checkbox 'MANUFACTURER' or 'AUTHORISED REPRESENTATIVE' to create new application and click on the button  to proceed. User only can make one application at one time. 'Next' button will enable after user tick applications checkbox.




After click  the diagram will show.



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



If the user choose GO TO RISK CLASSIFICATION FORM and click  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 - -

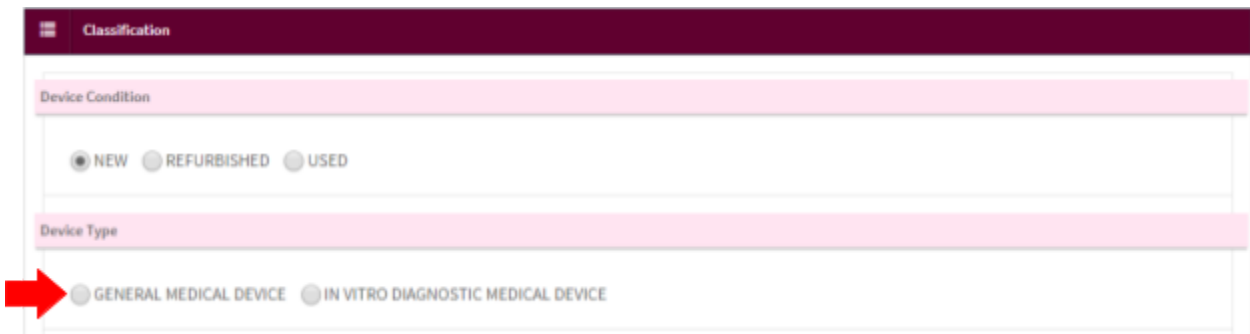
2.1 CLASSIFICATION FORM

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



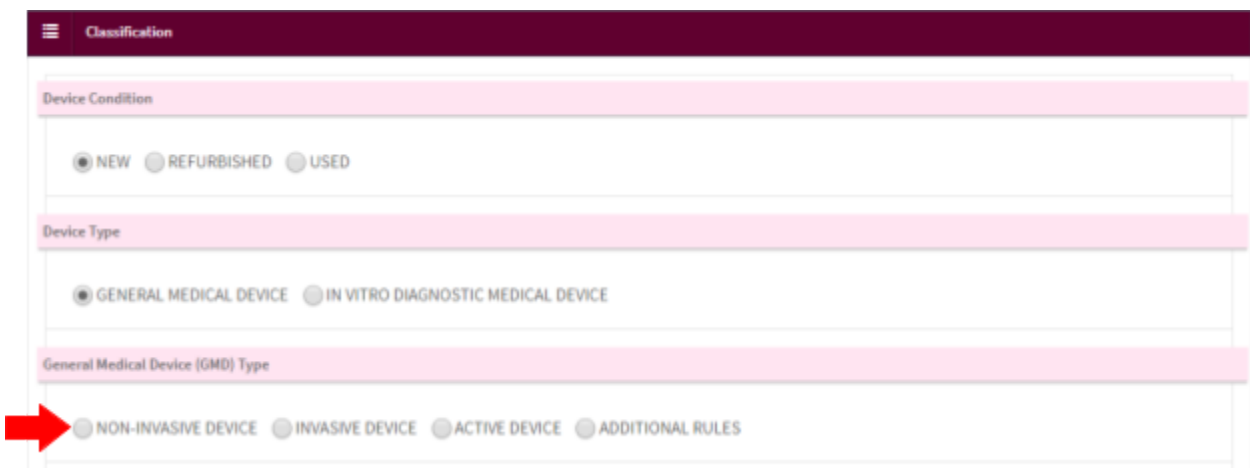
The screenshot shows the 'Classification' form with a dark purple header. Below the header is a pink bar labeled 'Device Condition'. Underneath, there are three radio buttons: 'NEW', 'REFURBISHED', and 'USED'. A red arrow points to the 'NEW' radio button, which is selected.

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 a form titled 'Classification' with several 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' radio button.

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

This screenshot shows the 'Rules 1 Details' section of the form:

- 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.
- Rule 1 Details:** Radio buttons for:
 - MEDICAL DEVICE THAT IS INTENDED TO BE IN CONTACT WITH INJURED SKIN AND INTENDED AS A BARRIER, OR FOR COMPRESSION, OR ABSORPTION OF EXUDATE (selected)
 - INTENDED PRINCIPALLY FOR WOUNDS WHICH BREACH THE DERMIS
 - THE WOUND CAN BE HEAL ONLY THROUGH SECONDARY INTENT
 A red arrow points to the first radio button.

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

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	:	Medical device that is intended to be in contact with injured skin and intended as a barrier, or for compression, or absorption of exudate
Medical Device Risk Class	:	Class A

[Go To Class A Classification](#)

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

Click [Go To Class A Classification](#) to go to next step step.

User tick checkbox at 'Intended Uses' field.

Rule 1 Details

NON-INVASIVE DEVICES WHICH COME INTO CONTACT WITH INJURED SKIN

Intended Uses

Act As A Mechanical Barrier

For Compression Or Maintain Wound Position

For Absorption Of Exudates

Others

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

Rule 1 Details

NON-INVASIVE DEVICES WHICH COME INTO CONTACT WITH INJURED SKIN

Intended Uses

Act As A Mechanical Barrier

For Compression Or Maintain Wound Position

For Absorption Of Exudates

Others

Medical Device Risk And Classification Details

Based On Your Choose, Your Medical Device Risk And Classification Are:-

Medical Device Type	:	NEW
Medical Device Risk Type	:	GENERAL MEDICAL DEVICE (GMD) - NON-INVASIVE DEVICE
Medical Device Rule	:	RULE 1
Medical Device Rule Detail	:	Non-invasive Devices Which Come Into Contact With Injured Skin
Medical Device Intended Uses	:	Act As A Mechanical Barrier
		1. For Compression Or Maintain Wound Position
Medical Device Class	:	Class A

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

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

Intended Uses

Act As A Mechanical Barrier

For Compression Or Maintain Wound Position

For Absorption Of Exudates

Others

Please specify

Medical Device Risk And Classification Details

Based On Your Choose, Your Medical Device Risk And Classification Are:-

Medical Device Type : NEW

Medical Device Risk Type : GENERAL MEDICAL DEVICE (GMD) - NON-INVASIVE DEVICE

Medical Device Rule : RULE 1

Medical Device Rule Detail : Non-invasive Devices Which Come Into Contact With Injured Skin

Medical Device Intended Uses : Act As A Mechanical Barrier

1. Please Specify

Medical Device Class : **Class A**

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

Display after user fill 'Please specify' text box.

Intended Uses

Act As A Mechanical Barrier

For Compression Or Maintain Wound Position

For Absorption Of Exudates

Others

➔ Example Class A

Medical Device Risk And Classification Details

Based On Your Choose, Your Medical Device Risk And Classification Are:-

Medical Device Type : **NEW**

Medical Device Risk Type : **GENERAL MEDICAL DEVICE (GMD) - NON- INVASIVE DEVICE**

Medical Device Rule : **RULE 1**

Medical Device Rule Detail : **Non-invasive Devices Which Come Into Contact With Injured Skin**

Medical Device Intended Uses : **Act As A Mechanical Barrier**

Medical Device Class : **Class A**

Create Application

Class Payment Details

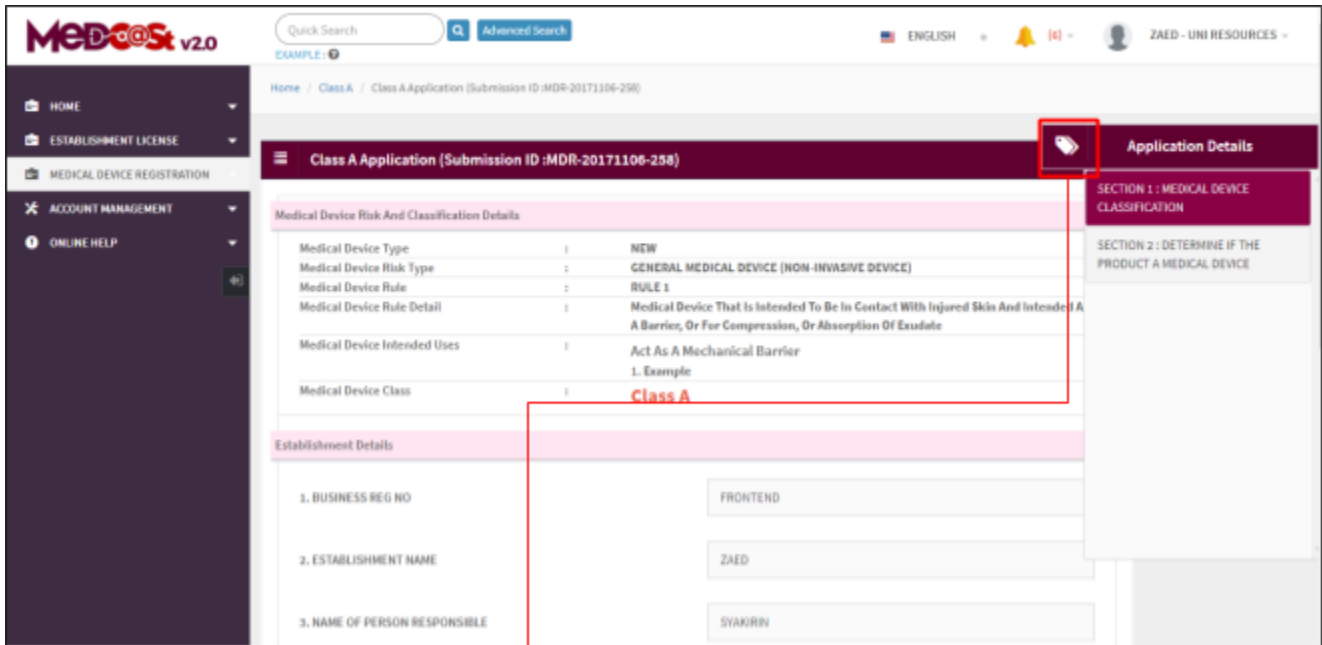
The Medical Device Risk Class Payment Are As Follows:-

CLASS	DEVICE RISK TYPE	FEE TYPE	AMOUNT (RM)
CLASS A	IN-VITRO, GENERAL MEDICAL DEVICE	APPLICATION FEE	100.00

Click Go To Class A Classification to go to next step step.

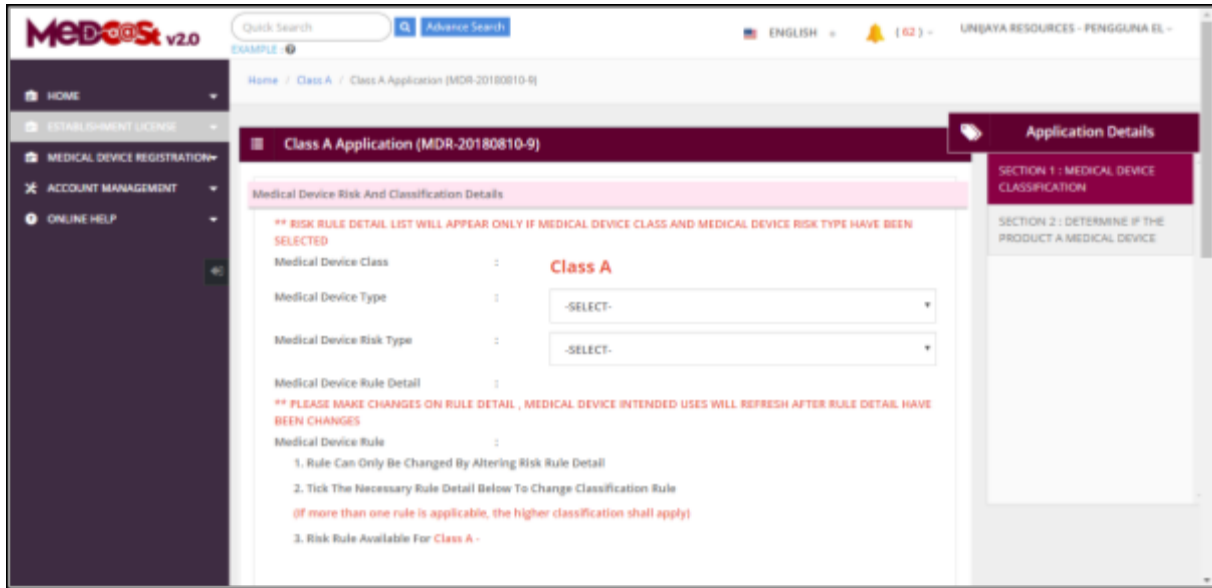
2.2 FILL IN THE APPLICATION FORMS

2.2.1 SECTION 1 : MEDICAL CLASS CLASSIFICATION

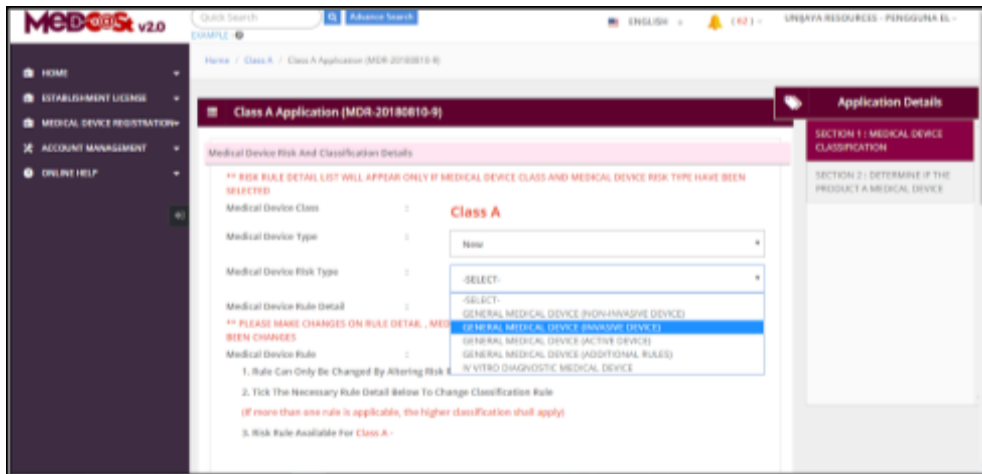


Hide the sidebar for full display

Rules detail will be display



User can choose the Medical Risk Type.



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

Medical Device Risk And Classification Details

Medical Device Class : **Class A**

Medical Device Type : New

Medical Device Risk Type : GENERAL MEDICAL DEVICE (NON-INVASIVE DEVICE)

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 - GENERAL MEDICAL DEVICE (NON-INVASIVE DEVICE)

- RULE 1
- RULE 2
- RULE 4

<input checked="" type="radio"/>	Non-invasive devices which come into contact with injured skin	RULE 1
<input type="radio"/>	Channelling or storing for eventual administration	RULE 2
<input type="radio"/>	Devices that either do not touch the patient or contact the intact skin only	RULE 4

Medical Device Intended Uses

**** NO LIST FOR MEDICAL DEVICE INTENDED USE FOR DEVICE**

Class A - GENERAL MEDICAL DEVICE (NON-INVASIVE DEVICE) -

Choose Rules that appropriate with Risk Rules Available.

<input checked="" type="radio"/>	Non-invasive devices which come into contact with injured skin	RULE 1
<input type="radio"/>	Channelling or storing for eventual administration	RULE 2
<input type="radio"/>	Devices that either do not touch the patient or contact the intact skin only	RULE 4

After that, choose intended uses that appropriate with user.

Medical Device Intended Uses

Non-invasive devices intended for channelling or storing

<input checked="" type="checkbox"/>	Body Liquids or tissue body
<input checked="" type="checkbox"/>	Liquids
<input checked="" type="checkbox"/>	Gases

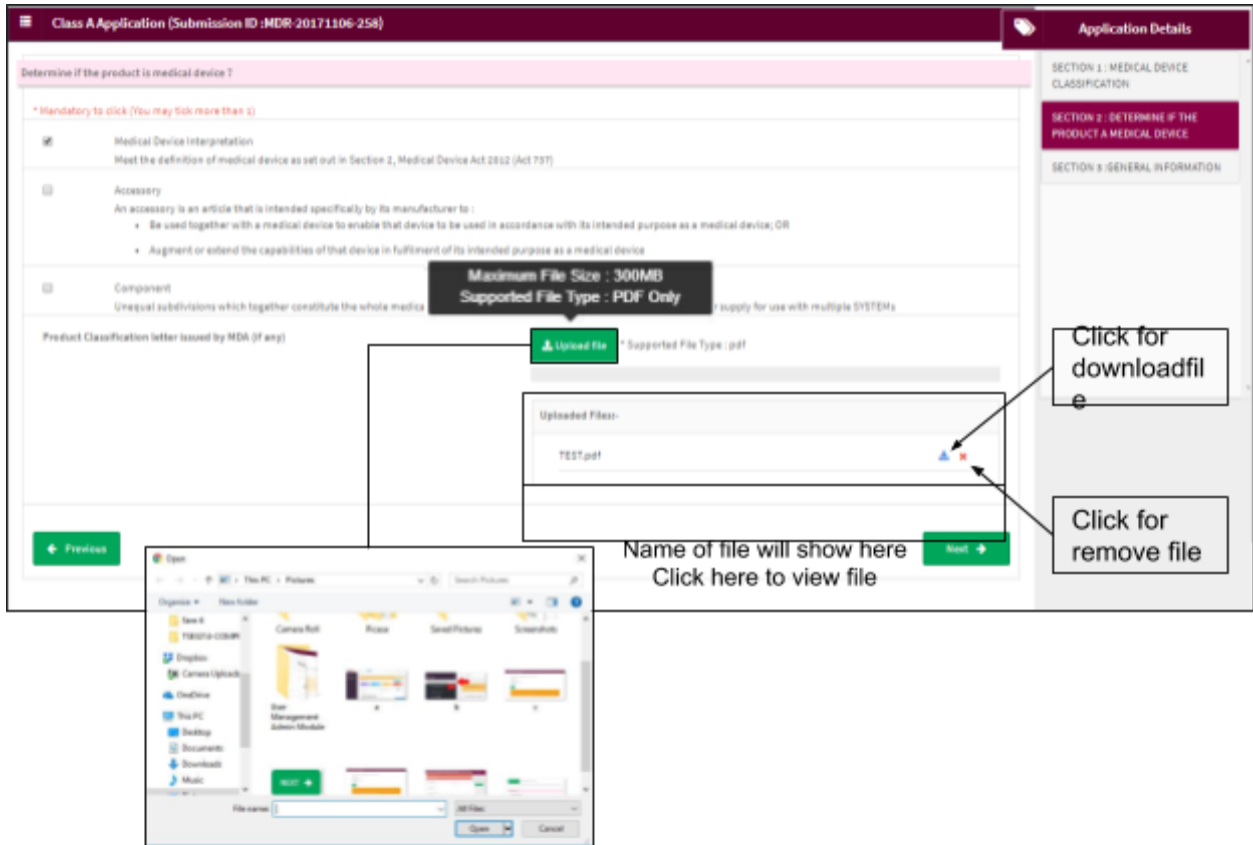
for the purpose of eventual infusion, administration or introduction into the body AND NOT to be connected to an active device in Class B or a higher class

Click  to proceed next step.


2.2.2 SECTION 2 : DETERMINE IF THE PRODUCT A MEDICAL DEVICE


The screenshot displays a web application interface for a 'Class A Application' with Submission ID MDR-20171106-258. The main content area is titled 'Determine if the product is medical device?' and includes a mandatory instruction: '* Mandatory to click (You may tick more than 1)'. A red arrow points to a checkbox labeled 'Medical Device Interpretation', which is currently unchecked. Below this checkbox is the text 'Meet the definition of medical device as set out in Section 2, Medical Device Act 2012 (Act 737)'. A green 'Previous' button is located at the bottom left of the form. On the right side, there is a sidebar titled 'Application Details' containing two sections: 'SECTION 1 : MEDICAL DEVICE CLASSIFICATION' and 'SECTION 2 : DETERMINE IF THE PRODUCT A MEDICAL DEVICE'.


User click a checkbox and automatically other checkboxes will display.



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

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

Click  to go to the next section.

Click  to go to the previous section.

2.2.3 SECTION 3 : GENERAL INFORMATION

‘Next’ button is invisible until user complete this section.

The screenshot displays a web application interface for a 'Class A Application' with Submission ID MDR-20171106-258. The main content area is titled 'Medical Device General Information' and contains three mandatory fields:

- 1. Medical Device Name ***: A text input field with the example text 'eg: ABC® Nitrile Examination Glove, Powdered'.
- 2. Proprietary Name / Brand ***: A text input field with the example text 'eg: Brand ABC'.
- 3. Medical Device Category ***: A dropdown menu currently showing 'Select'. A list of categories is visible below the dropdown, including: ACTIVE IMPLANTABLE DEVICES, ANAESTHETIC AND RESPIRATORY DEVICES, DENTAL DEVICES, ELECTRO MECHANICAL MEDICAL DEVICES, HOSPITAL HARDWARE, IN VITRO DIAGNOSTIC DEVICES, NON-ACTIVE IMPLANTABLE DEVICES, OPHTHALMIC AND OPTICAL DEVICES, REUSABLE DEVICES, SINGLE-USE DEVICES, ASSISTIVE PRODUCTS FOR PERSONS WITH DISABILITY, DIAGNOSTIC AND THERAPEUTIC RADIATION DEVICES, COMPLEMENTARY THERAPY DEVICES, BIOLOGICALLY-DERIVED DEVICES, HEALTHCARE FACILITY PRODUCTS AND ADAPTATIONS, LABORATORY EQUIPMENT, and MEDICAL SOFTWARE.

On the right side, a sidebar titled 'Application Details' shows a navigation menu with three sections: SECTION 1: MEDICAL DEVICE CLASSIFICATION, SECTION 2: DETERMINE IF THE PRODUCT A MEDICAL DEVICE, and SECTION 3: GENERAL INFORMATION (which is currently selected).

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

Class A Application (Submission ID :MDR-20171116-258)

All fields marked with * are mandatory

Hover at ? on field input for help

Medical Device General Information

1. Medical Device Name *

eg: ABC® Nitrile Examination Glove, Powdered

2. Proprietary Name / Brand *

eg: Brand Abc

3. Medical Device Discipline *

Select

4. Medical Device Category *

Select

Application Details

SECTION 1 : MEDICAL DEVICE CLASSIFICATION

SECTION 2 : DETERMINE IF THE PRODUCT A MEDICAL DEVICE

SECTION 3 : GENERAL INFORMATION

Medical Device Discipline *

- Select
- BIOCHEMISTRY
- GENETIC TESTING
- HAEMATOLOGY
- HISTOLOGY/CYTOLOGY
- IMMUNOLOGY
- MICROBIOLOGY

Medical Device Category *

- Select
- HAEMOGLOBIN TESTING
- GENERAL COAGULATION TESTS
- HAEMOSTASIS (COAGULATION)
- OTHER HAEMATOLOGY TESTS
- CYTOKINES (LYMPHOKINES)/ IMMUNOMODULATORS
- IMMUNOHAEMATOLOGY (BLOOD BANK)

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

4. Is The Medical Device Meant For Export Only?
 Yes NO

5. Description Of Medical Device : *
eg: A single-use and non-sterile device made of nitrile. It will have appropriate characteristics (e.g., strength, elasticity), and uniformity of dimensions.

6. Common Intended Use Of Medical Device : *
eg: As a two-way protective barrier of patient/healthcare providers during patient examination/treatment against contaminants.

7. HS Code : *
eg: 4015 1100

8. GMDN Code : *
eg: 56287

9. Unique Device Identifier : *

Application Details

- SECTION 1 : MEDICAL DEVICE CLASSIFICATION
- SECTION 2 : DETERMINE IF THE PRODUCT A MEDICAL DEVICE
- SECTION 3 : GENERAL INFORMATION**

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

10. UMDNS Code : *

IFU / BROCHURE / PRODUCT CATALOGUE (to support the intended use of medical device)

Upload file * Supported File Type : pdf

Uploaded Files:-

Previous **Next**


SECTION 3 : GENERAL INFORMATION


SECTION 4 : MEDICAL DEVICE GROUPING

Open

File name: **Open** **Cancel**

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

Click  to go to the next section.

Click  to go to the previous section.

2.2.4 SECTION 4 : MEDICAL DEVICE GROUPING

The screenshot shows a web application interface for a Class A Application (Submission ID :MDR-20171107-259). The main content area is titled "Medical Device Grouping" and contains a section labeled "Grouping Type For Medical Device". This section lists five radio button options: "Single", "System", "Family", "Family of System", and "Set". Each option is accompanied by a red arrow pointing to its radio button. Below the list is a green "Previous" button with a left-pointing arrow. On the right side, there is a sidebar titled "Application Details" which contains a list of sections: "SECTION 1 : MEDICAL DEVICE CLASSIFICATION", "SECTION 2 : DETERMINE IF THE PRODUCT A MEDICAL DEVICE", "SECTION 3 :GENERAL INFORMATION", and "SECTION 4 : MEDICAL DEVICE GROUPING". The "SECTION 4" item is highlighted in a dark purple color, indicating the current step in the process.

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

i) 'Single' radio button.

Class A Application (Submission ID :MDR-20171107-259)

Medical Device Grouping

Grouping Type For Medical Device

Single

1. Device Identifier :

2. Model :

Application Details

- SECTION 1 : MEDICAL DEVICE CLASSIFICATION
- SECTION 2 : DETERMINE IF THE PRODUCT A MEDICAL DEVICE
- SECTION 3 :GENERAL INFORMATION
- SECTION 4 : MEDICAL DEVICE GROUPING**
- SECTION 5 : ADDITIONAL REQUIREMENTS
- SECTION 6 : MANUFACTURER INFORMATION

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

ii) 'System' radio button.

System

A medical device SYSTEM comprises of a number of constituent components that are :

1. From the same Manufacturer : Yes NO

2. Intended to be used in combination to complete a common intended purpose : Yes NO

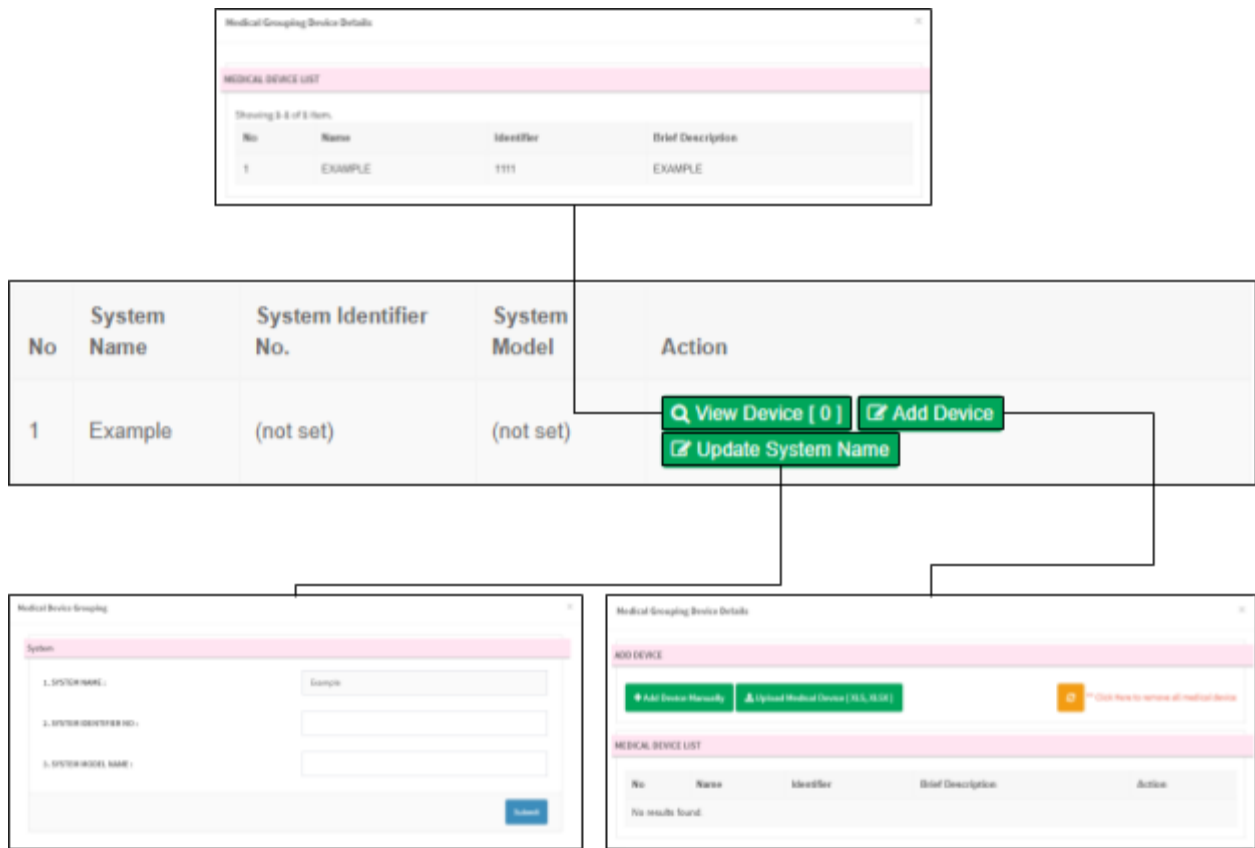
3. Compatible when used as a SYSTEM : Yes NO

4. Sold under a SYSTEM name or the labeling, instruction for use (IFU), brochures or catalogues for each constituent component states that the constituent component is intended for use with the SYSTEM : Yes NO

No	System Name	System Identifier No.	System Model	Action
1	Example	(not set)	(not set)	<input type="button" value="View Device [0]"/> <input type="button" value="Add Device"/> <input type="button" value="Update System Name"/>

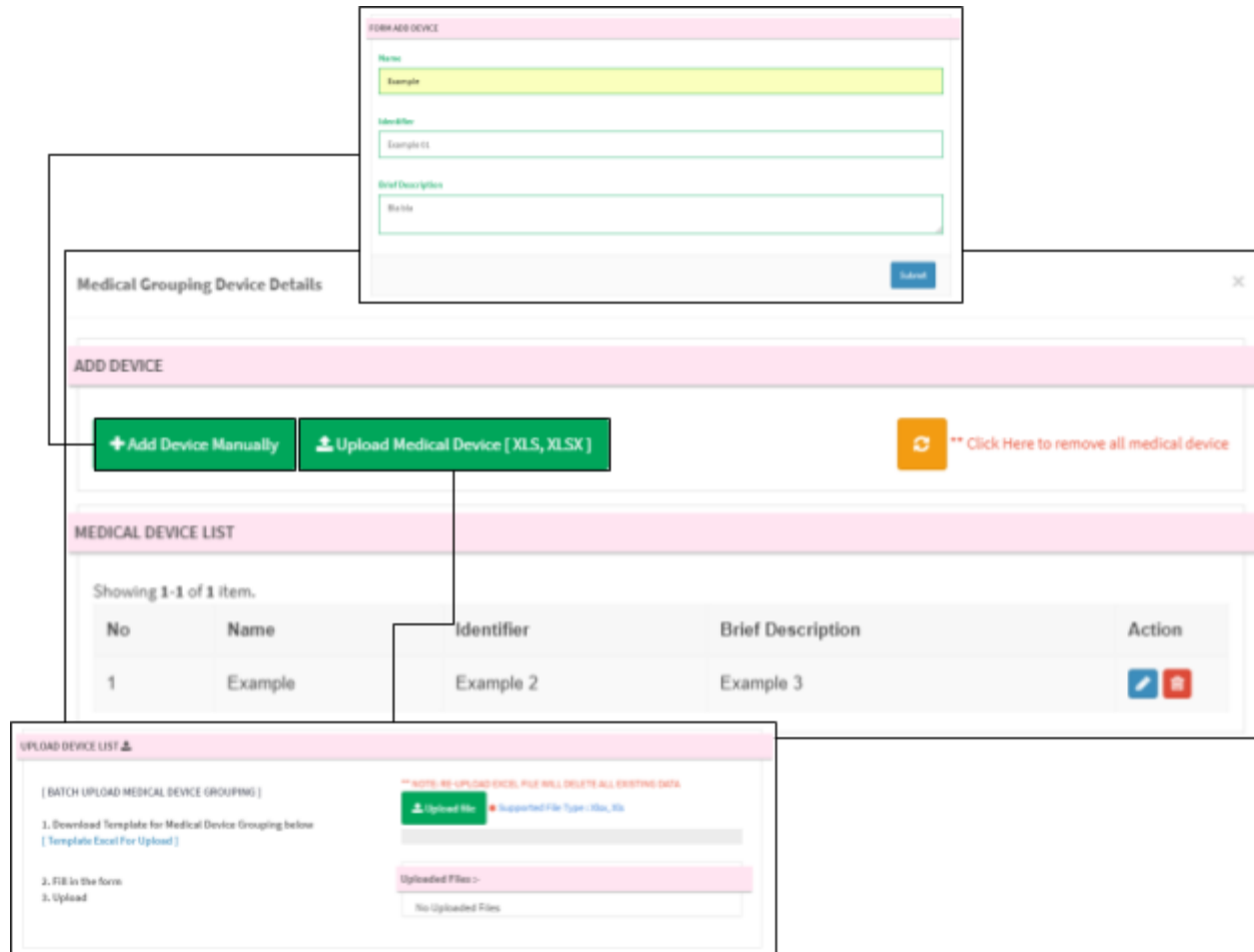
Application Details



- SECTION 1 : MEDICAL DEVICE CLASSIFICATION
- SECTION 2 : DETERMINE IF THE PRODUCT A MEDICAL DEVICE
- SECTION 3 :GENERAL INFORMATION
- SECTION 4 : MEDICAL DEVICE GROUPING**




Click **View Device [0]** to view device list.

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



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

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

 button for user edit device details.

 button for user delete device.

 button for user delete all medical devices.

iii) 'Family' radio button.

Family

A medical device FAMILY is a collection of medical devices and each medical device FAMILY member :

1. Is from the same Manufacturer : Yes No

2. Is of the same risk classification : Yes No

3. Has the same medical device proprietary name : Yes No

4. Has a common intended purpose or an overall intended purpose (This refers to the overall intended purpose of reusable surgical instrument, regardless of location of the body they are used on) : Yes No

5. Has the same design and manufacturing process : Yes No

6. Has variations that are within the scope of the permissible variants : Yes No

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

Application Details

SECTION 1 : MEDICAL DEVICE CLASSIFICATION

SECTION 2 : DETERMINE IF THE PRODUCT A MEDICAL DEVICE

SECTION 3 : GENERAL INFORMATION

SECTION 4 : MEDICAL DEVICE GROUPING

Medical Grouping Device Details

MEDICAL DEVICE LIST

Showing 0 of 0 items.

No	Name of device, subelement components, accessories, reagents and/or articles as per product label	Device Identifier No	Precedence Verdict	Details on Precedence Verdict	Model	Serial Description Of Item
1	Example	xxxx	Example	Example	Example	Example

Medical Device Grouping

Family

1. SYSTEM NAME:

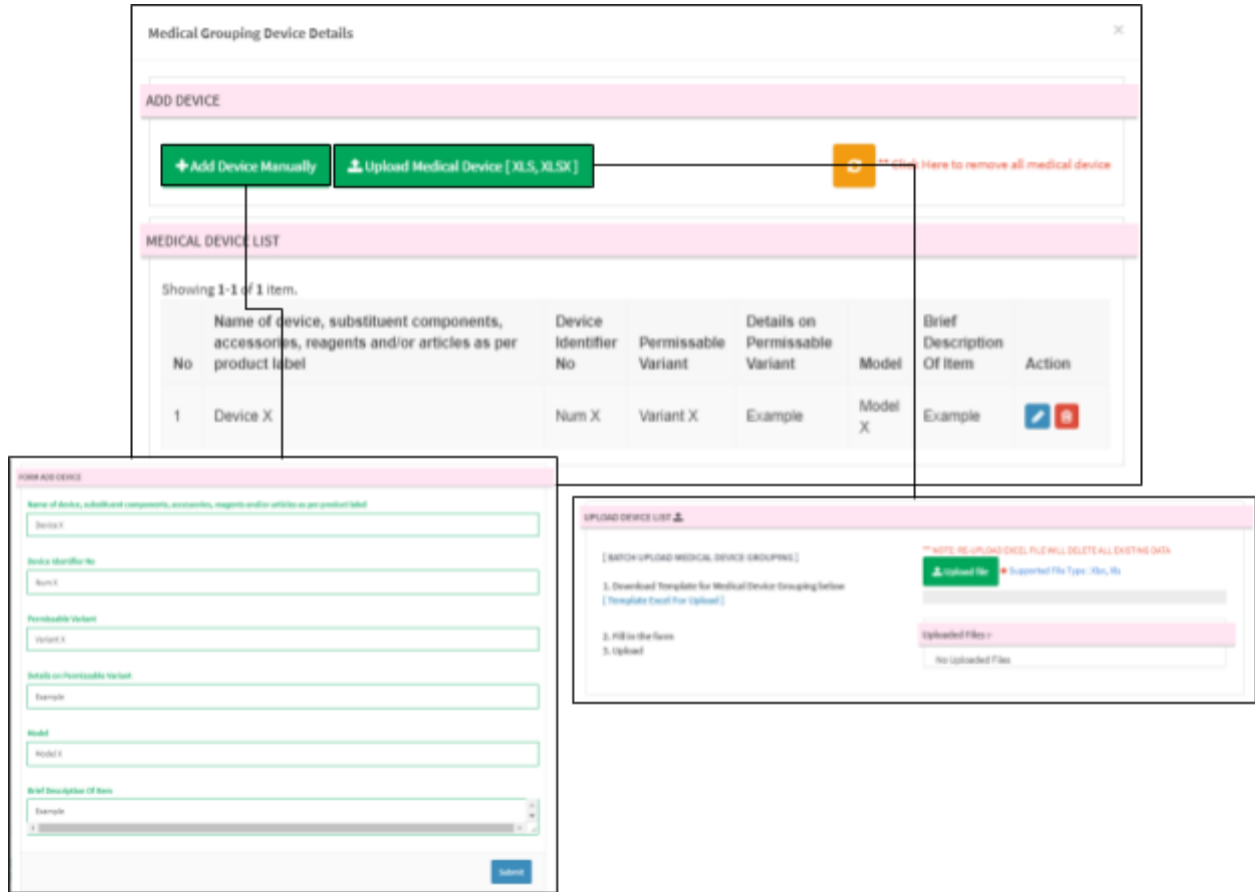
No	Medical Device Name	Action
1	Example	<input type="button" value="View Device [0]"/> <input type="button" value="Add Device"/> <input type="button" value="Update System Name"/>

Medical Grouping Device Details



REFERENCES

MEDICAL DEVICE LIST


No	Name of device, subelement components, accessories, reagents and/or articles as per product label	Device Identifier No	Precedence Verdict	Details on Precedence Verdict	Model	Serial Description Of Item	Action
No results found							



Click  to view device list.

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

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

 button for user edit device details.

 button for user delete device.

 button for user delete all medical devices.

iv) 'Family Of System' radio button.

Family of System

A medical device FAMILY is a collection of medical devices and each medical device FAMILY member :

1. Is from the same Manufacturer : Yes No

2. Is of the same risk classification : Yes No

3. Has the same medical device proprietary name : Yes No

4. Has a common intended purpose or an overall intended purpose (This refers to the overall intended purpose of reusable surgical instrument, regardless of location of the body they are used on) : Yes No

5. Has the same design and manufacturing process : Yes No

6. Has variations that are within the scope of the permissible variants : Yes No

+ Add System Name/Model

No	System Name	System Identifier No.	System Model	Action
1	EXAMPLE	11111	MODEL X	🔍 View Device [0] ➕ Add Device ✎ Update System Name 🗑 Delete

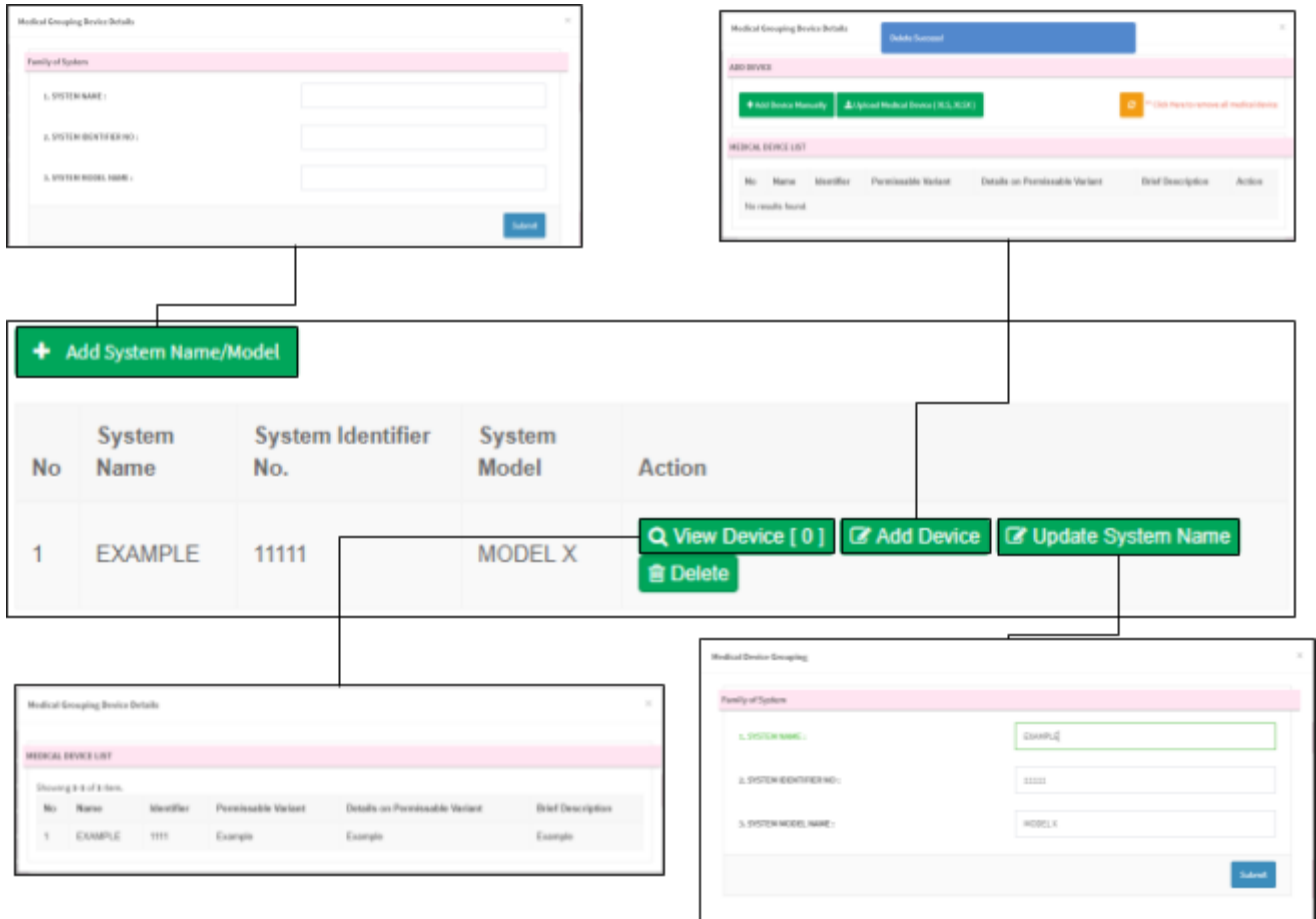
Application Details

SECTION 1 : MEDICAL DEVICE CLASSIFICATION

SECTION 2 : DETERMINE IF THE PRODUCT A MEDICAL DEVICE

SECTION 3 :GENERAL INFORMATION

SECTION 4 : MEDICAL DEVICE GROUPING



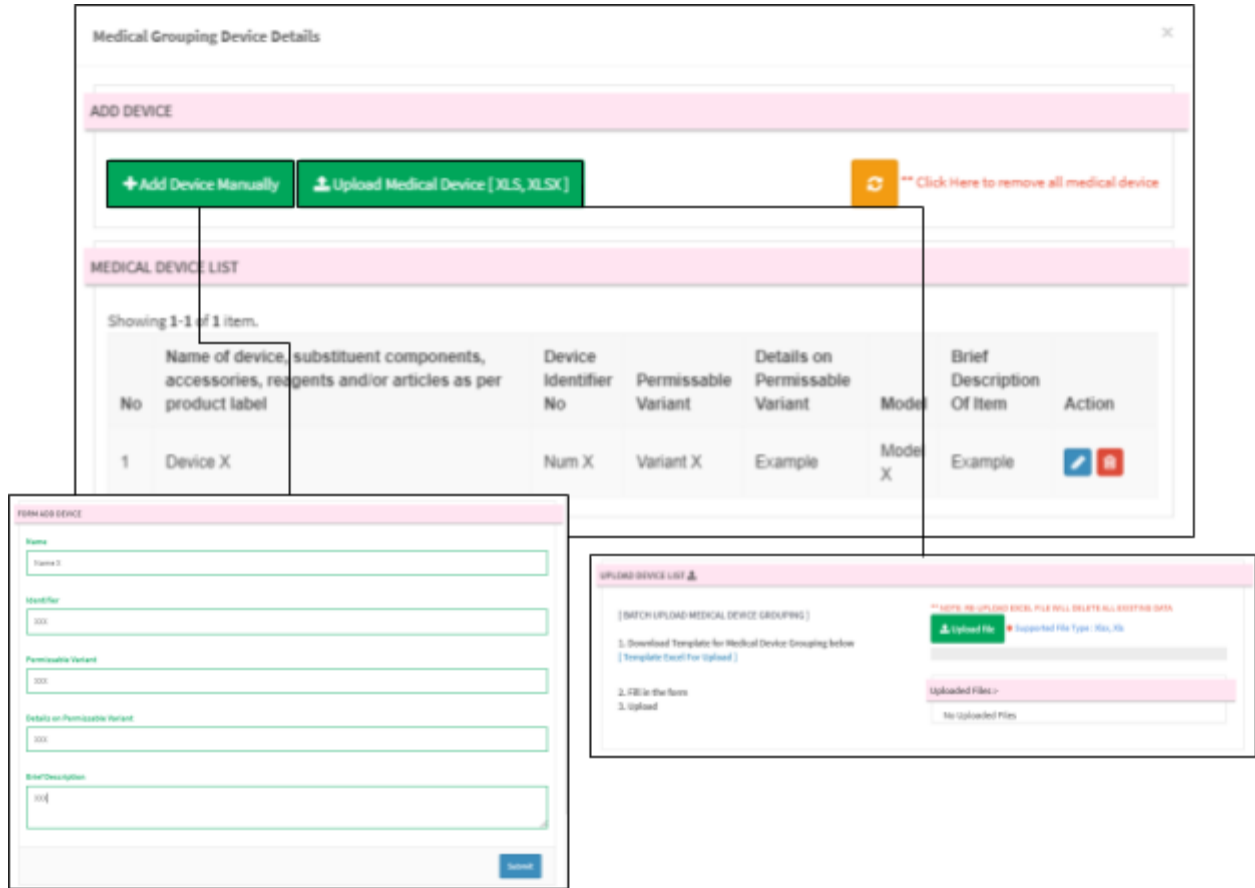
Click **+ Add System Name/Model** to add system name or model.



Click **View Device [0]** to view device list.

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


Click **Submit** to confirm update.

Click **Delete** to delete device.



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

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

 button for user edit device details.

 button for user delete device.



button for user delete all medical devices.

v) 'Set' radio button.

Set

A medical device SET is a collection of two or more medical devices, assembled together as one package by a manufacturer. The medical device SET has the following:

1. A single proprietary SET name : Yes No
2. A common intended use : Yes No
3. Classification allocated to the set is at the level of the highest classified device within the set : Yes No

No	SET Name as Per Product Label	SET Identifier No.	Action
1	Medical device x	(not set)	View Device [0] Add Device Update System Name

Application Details

SECTION 1 : MEDICAL DEVICE CLASSIFICATION

SECTION 2 : DETERMINE IF THE PRODUCT A MEDICAL DEVICE

SECTION 3 : GENERAL INFORMATION

SECTION 4 : MEDICAL DEVICE GROUPING

Medical Grouping Device Details

MEDICAL DEVICE LIST

Showing 1 of 1 item.

No	Name	Identifier	Brief Description
1	EXAMPLE	1111	Example

Medical Grouping Device Details

ADD DEVICE

[Add Device Manually](#)
[Upload Medical Device \(MSL, MSU\)](#)
 Click here to remove all medical device

MEDICAL DEVICE LIST

No	Name	Identifier	Brief Description	Action
No results found				

No	SET Name as Per Product Label	SET Identifier No.	Action
1	Medical device x	(not set)	View Device [0] Add Device Update System Name

Medical Device Grouping



Set

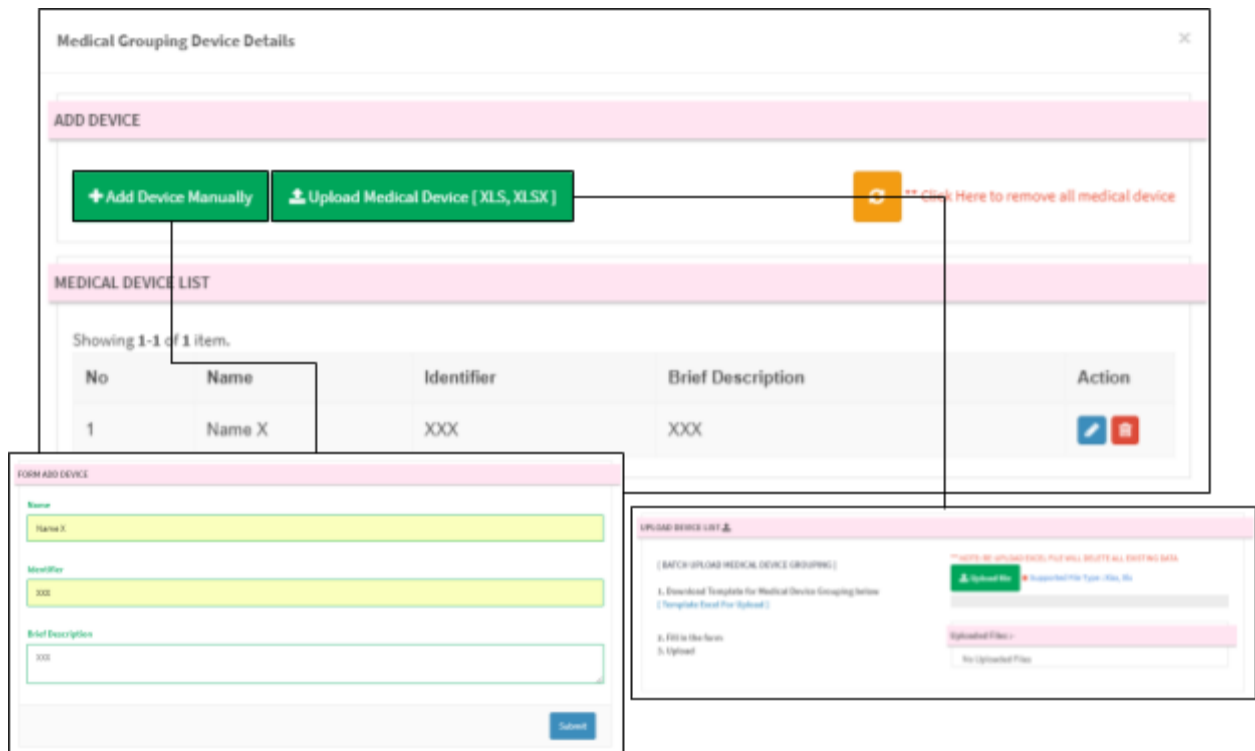
1. SET NAME AS PER PRODUCT LABEL:



2. SET IDENTIFIER NO.:



[Submit](#)


Click [View Device \[0 \]](#) to view device list.

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




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


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

 button for user edit device details.


 button for user delete device.

 button for user delete all medical devices.

Click  to go to the next section.

Click  to go to the previous section.

2.2.5 SECTION 5 : ADDITIONAL REQUIREMENTS

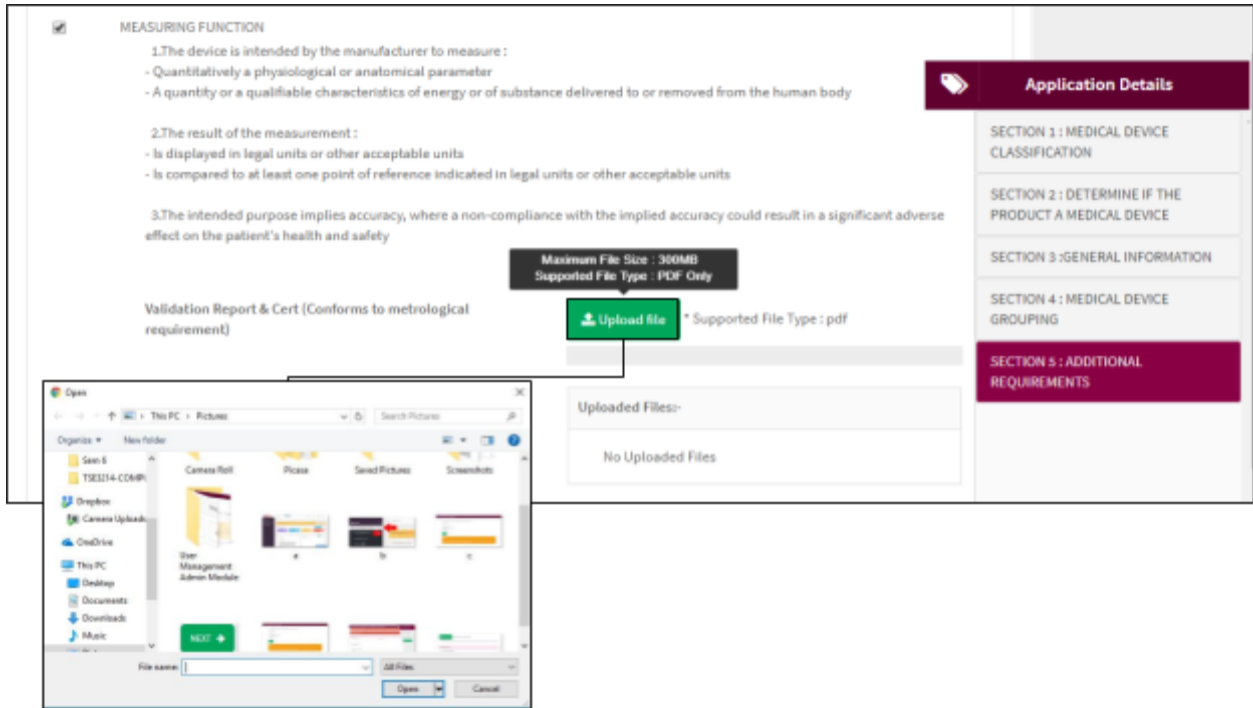


Class A Application (Submission ID :MDR-20171107-259)		Application Details
Additional Requirement		SECTION 1 : MEDICAL DEVICE CLASSIFICATION
<input type="checkbox"/> MEASURING FUNCTION		SECTION 2 : DETERMINE IF THE PRODUCT A MEDICAL DEVICE
<input type="checkbox"/> SUPPLIED STERILE		SECTION 3 :GENERAL INFORMATION
<input type="checkbox"/> OTHERS		SECTION 4 : MEDICAL DEVICE GROUPING
<input type="checkbox"/> ACTIVE		SECTION 5 : ADDITIONAL REQUIREMENTS
<input type="checkbox"/> CONTAIN ANIMAL, HUMAN, MICROBIAL, RECOMBINANT ORIGIN (IVD)		SECTION 6 : MANUFACTURER INFORMATION

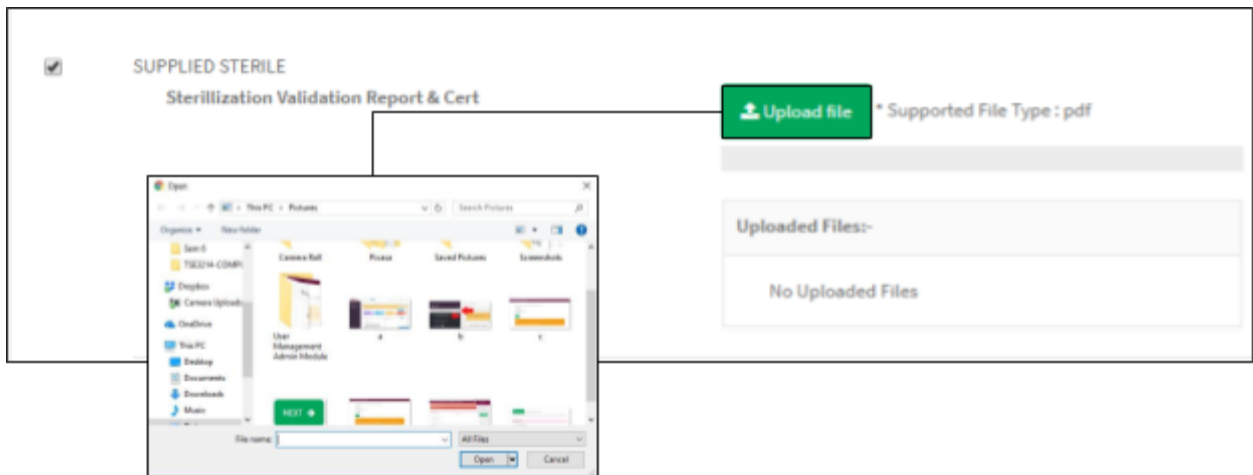
User tick checkbox in red circle (**if necessary**) and user can tick more than one checkbox. If

not, user click  to go to next section.

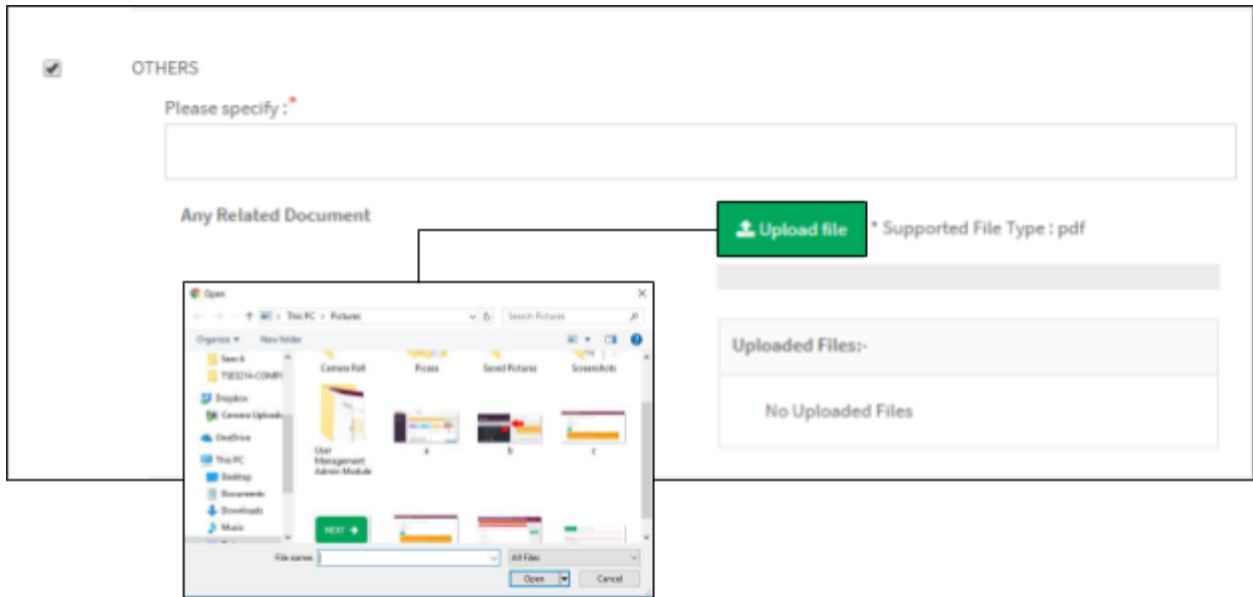
If user tick any checkboxes above, user has to complete that field before user go to the next section.

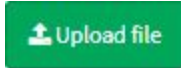


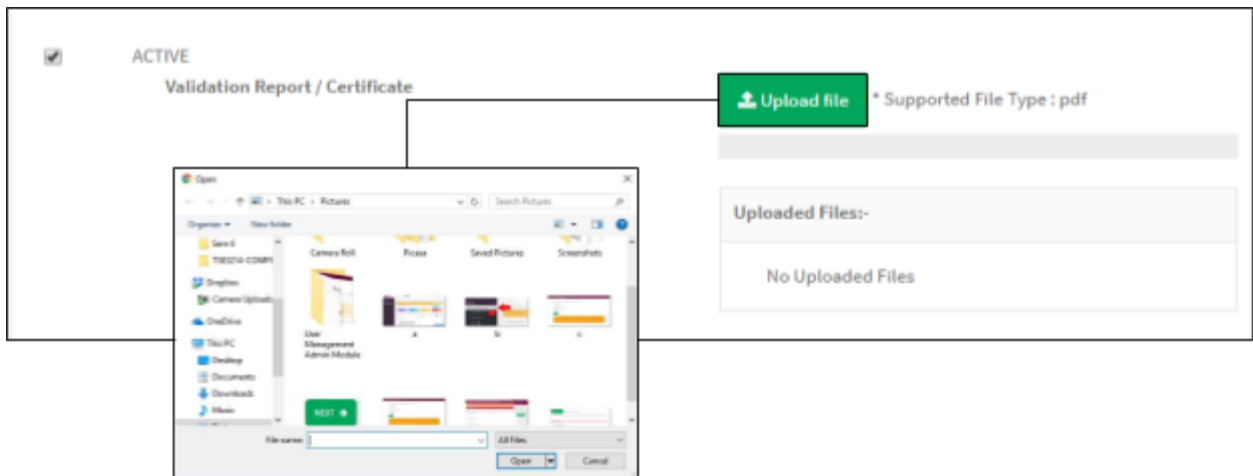
User click  to upload file. **The file must be pdf format and size not more than 300 MB.**



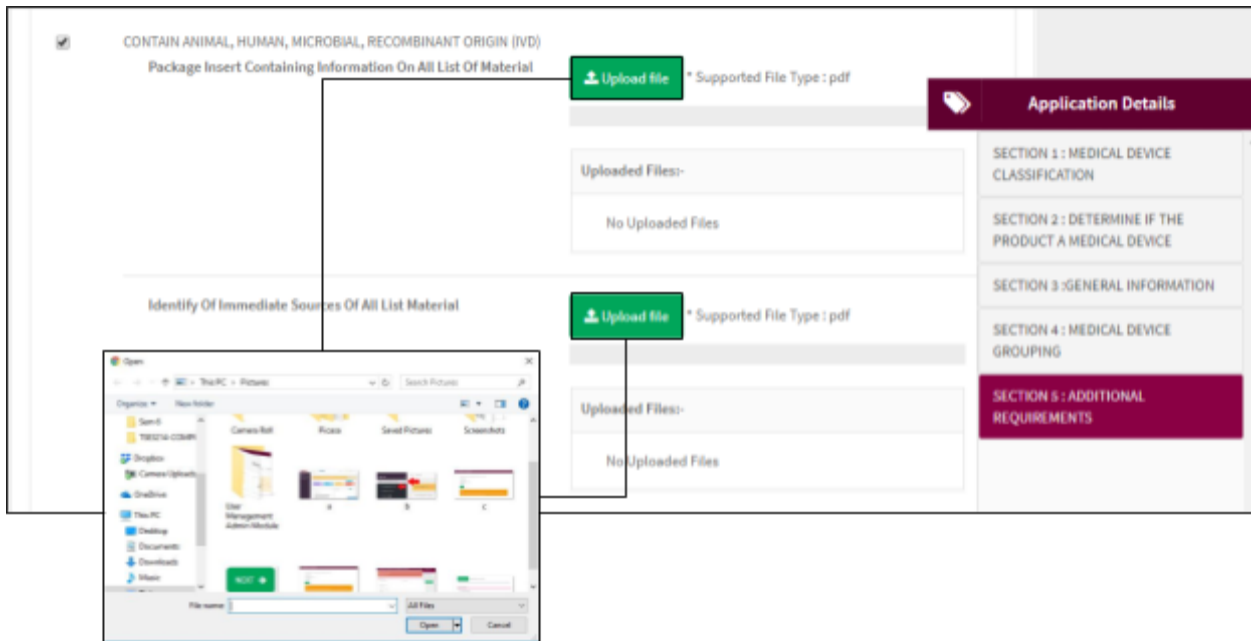
User click  to upload file. **The file must be pdf format and size not more than 300 MB.**




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




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



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

Click  to go to the next section.

Click  to go to the previous section.

2.2.6 SECTION 6 : MANUFACTURER INFORMATION

Diagram below show section 6 for Manufacturer.

‘Next’ button is invisible until user complete this section.

The screenshot displays a web application interface for a Class A Application (Submission ID: MDR-20171107-259). The main form is divided into several sections:

- Manufacturer Information:** Contains fields for Name of Manufacturer (19), Manufacturer Registration No (MDA/CAB-019), Name of Registered Manufacturer Auditor (MOHAMAD SAHAFIE BIN ZAINAL), and Certificate Expiry Date (2019-11-21).
- Quality Management System Information:** Includes a field for Quality Management System Certificate and an 'Uploaded Files' section with two 'TEST.pdf' files.
- List Of Manufacturing Site:** A table with columns: No, Name Of Manufacturing Site, Address Of Manufacturing Site, Post Code/Zip Code, Manufacturing Site Upload File, and Action. It currently shows 'No results found'.

A modal window titled 'Manufacturing Site Information' is open, showing a form with three text input fields: '1. Name Of Manufacturing Site', '2. Address Of Manufacturing Site', and '3. Post Code/Zip Code'. A 'Submit' button is located at the bottom right of the modal.

On the right side, there is a sidebar titled 'Application Details' with a list of sections: SECTION 1: MEDICAL DEVICE CLASSIFICATION, SECTION 2: DETERMINE IF THE PRODUCT A MEDICAL DEVICE, SECTION 3: GENERAL INFORMATION, SECTION 4: MEDICAL DEVICE GROUPING, SECTION 5: ADDITIONAL REQUIREMENTS, and SECTION 6: MANUFACTURER INFORMATION (which is highlighted in red).

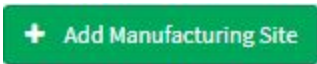

User click  to add new data. User has to fill all the text box then click . New data will display in 'List Of Manufacturing Site' table.

Diagram below show section 6 for Authorised Representative.
'Next' button is invisible until user complete this section.

The screenshot displays a web application interface for a 'Class A Application' (Submission ID: MDR-20171116-256). The main content area is titled 'Manufacturer Information' and contains four numbered fields:

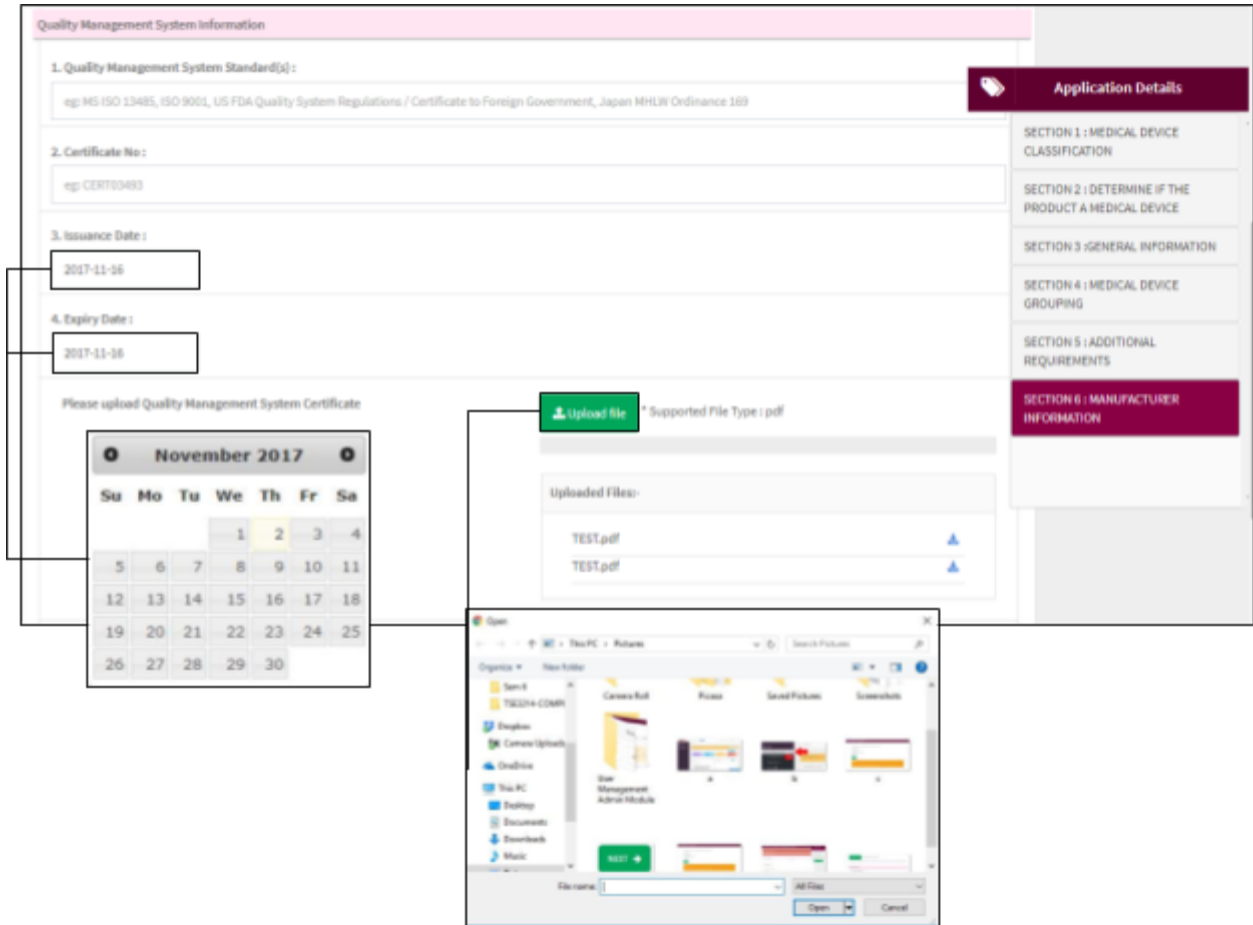
- 1. Name Of Legal Manufacturer : (Text input with example: eg: Medical Assistant System)
- 2. Address Of Legal Manufacturer : (Text input with example: eg: Jalan Ampang)
- 3. Post Code/zip Code : (Text input with example: eg: 53300)
- 4. Country : (Drop-down menu with placeholder: Select Country)


On the right side, there is a sidebar titled 'Application Details' with a list of sections:

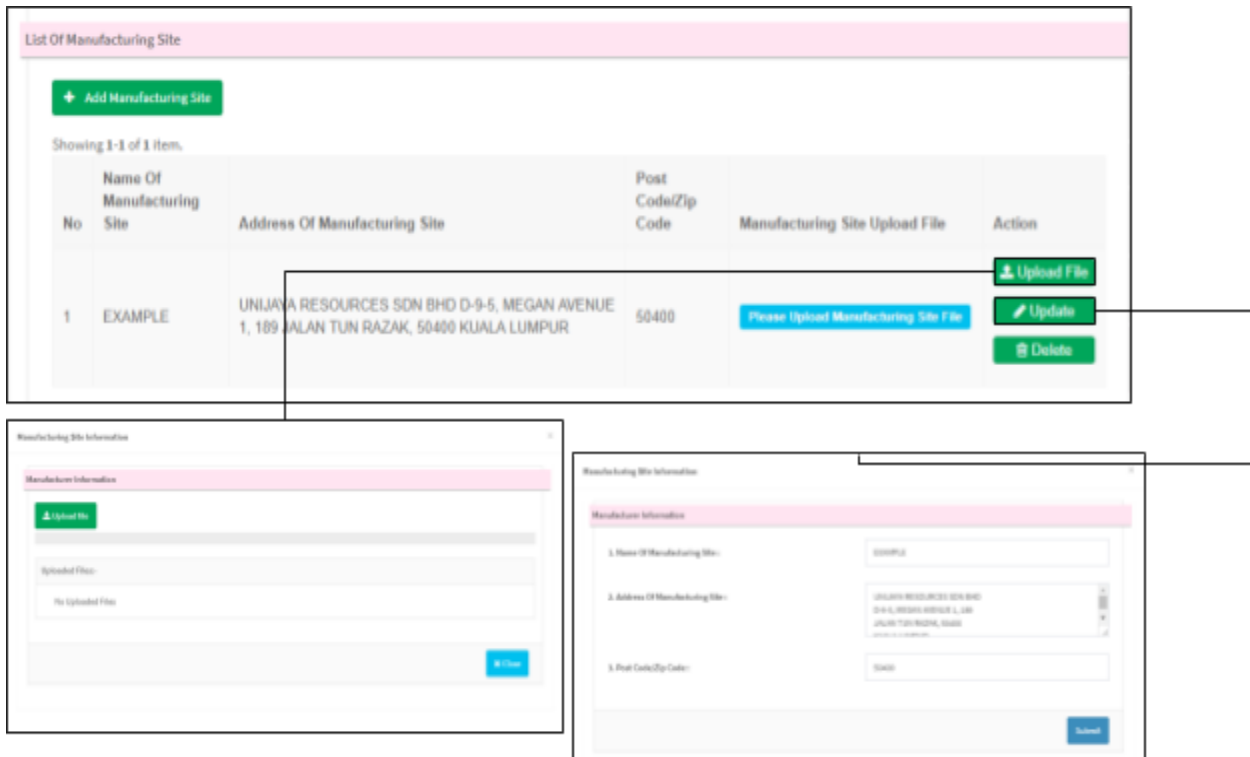
- SECTION 1: MEDICAL DEVICE CLASSIFICATION
- SECTION 2: DETERMINE IF THE PRODUCT A MEDICAL DEVICE
- SECTION 3: GENERAL INFORMATION
- SECTION 4: MEDICAL DEVICE GROUPING
- SECTION 5: ADDITIONAL REQUIREMENTS
- SECTION 6: MANUFACTURER INFORMATION** (highlighted in dark red)

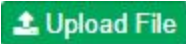

Below the main form, a separate window shows the expanded 'Select Country' drop-down menu, listing various countries including Afghanistan, Albania, Algeria, Andorra, Angola, Anguilla, Antarctica, Antigua and Barbuda, Argentina, Armenia, Aruba, Australia, Austria, Azerbaijan, Bahamas, Bahrain, Bangladesh, Barbados, and Belarus.





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



.User fill all text boxes and then user select date in 'Issuance Date' and 'Expiry Date' calendar text box or user can write the date using **YYYY-MM-DD** format. Click at  to upload file. **The file must be pdf format and size not more than 300 MB.(If necessary)**





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

No	Name Of Manufacturing Site	Address Of Manufacturing Site	Post Code/Zip Code	Manufacturing Site Upload File	Action
1	EXAMPLE	UNIJAYA RESOURCES SDN BHD D-9-5, MEGAN AVENUE 1, 189 JALAN TUN RAZAK, 50400 KUALA LUMPUR	50400	TEST.pdf 	  

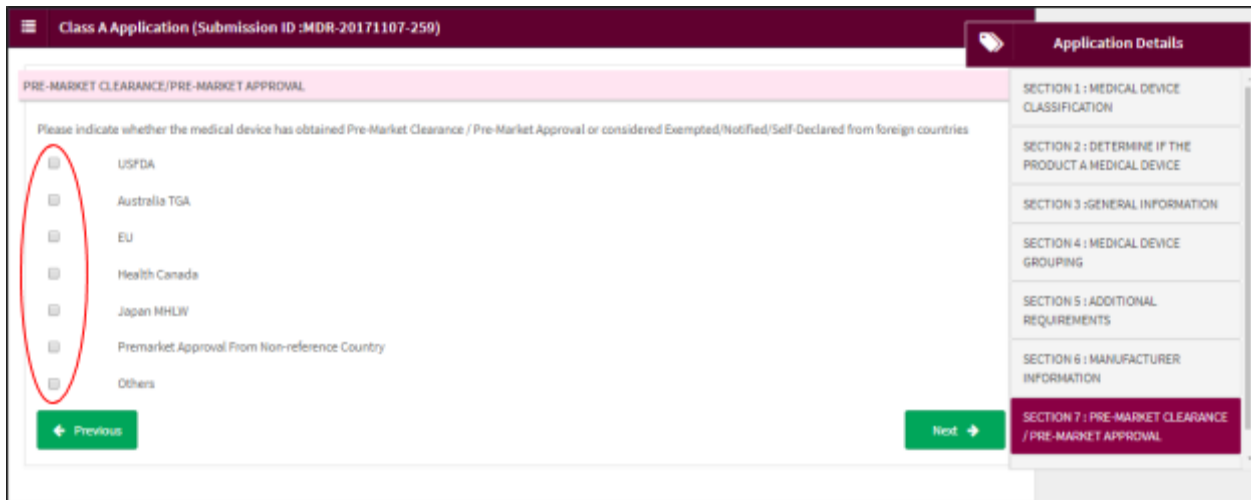
Click  to update the data.

Click  to delete the data.

Click  to go to the next section.

Click  to go to the previous section.

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



Class A Application (Submission ID :MDR-20171107-259)

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

- USAFDA
- Australia TGA
- EU
- Health Canada
- Japan MHLW
- Premarket Approval From Non-reference Country
- Others

Application Details

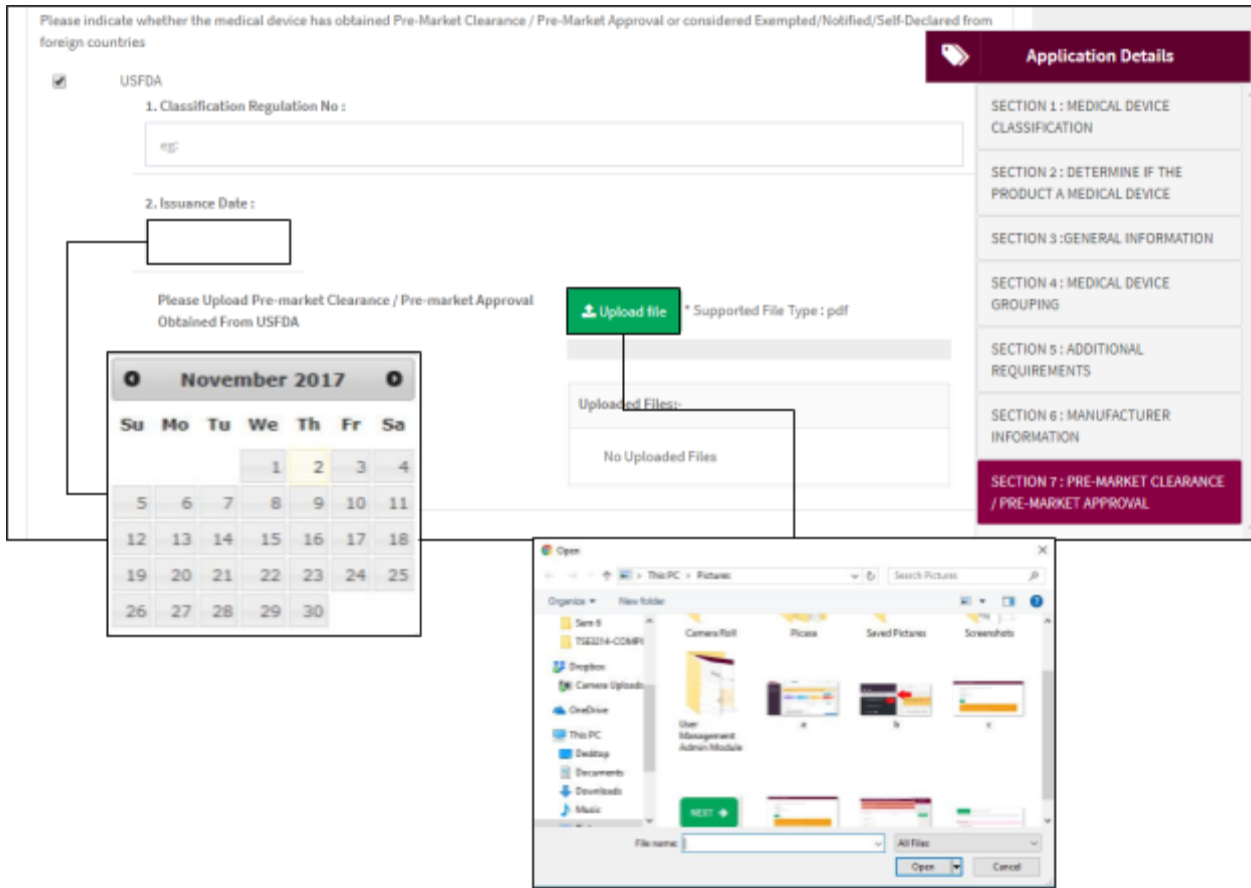
- SECTION 1 : MEDICAL DEVICE CLASSIFICATION
- SECTION 2 : DETERMINE IF THE PRODUCT A MEDICAL DEVICE
- SECTION 3 :GENERAL INFORMATION
- SECTION 4 : MEDICAL DEVICE GROUPING
- SECTION 5 :ADDITIONAL REQUIREMENTS
- SECTION 6 : MANUFACTURER INFORMATION
- SECTION 7 : PRE-MARKET CLEARANCE / PRE-MARKET APPROVAL

User tick checkbox in red circle (**if necessary**) and user can tick more than one checkbox. If

not, user click  to skip this section.

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

i) 'USFDA' checkbox.

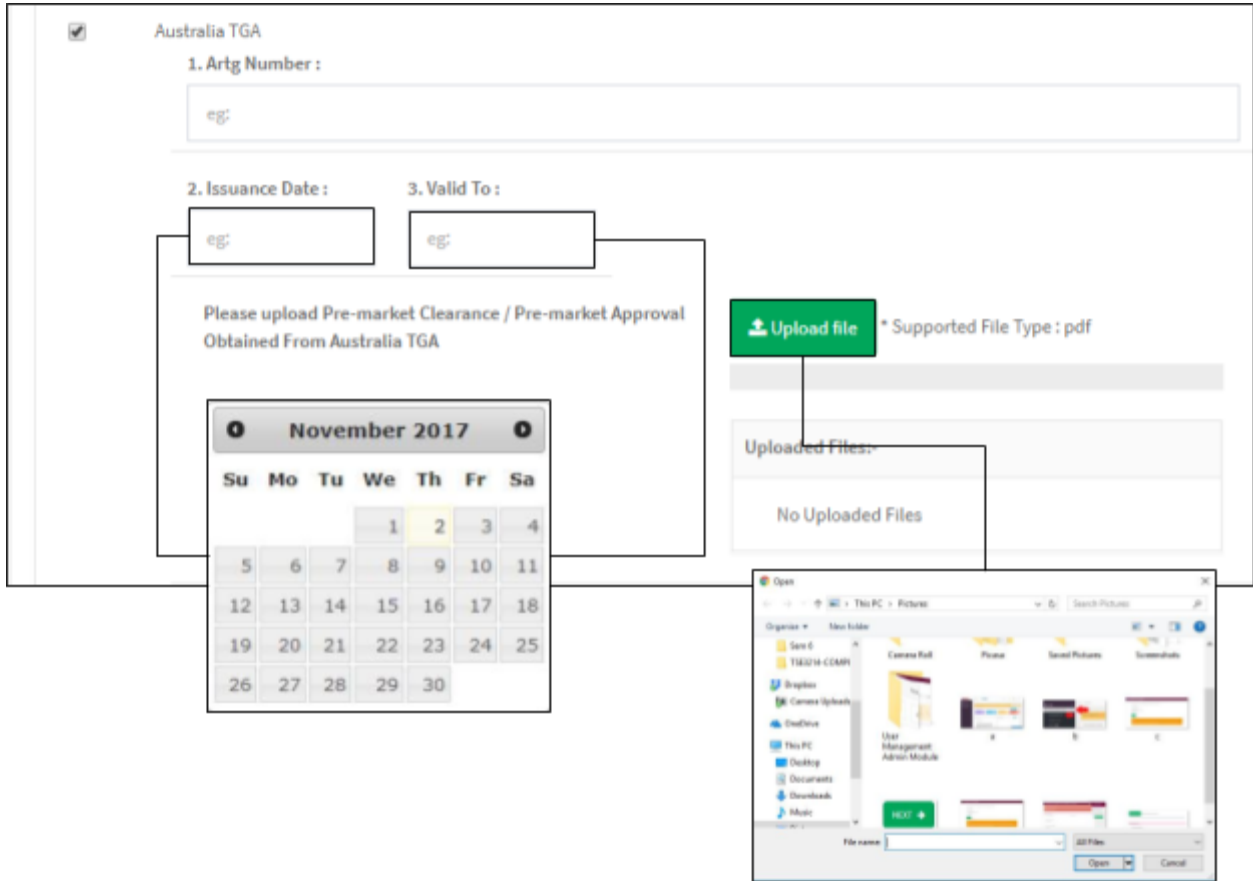


User fill 'Classification Regulation No' text box.

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

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

ii) 'Australia TGA' checkbox.

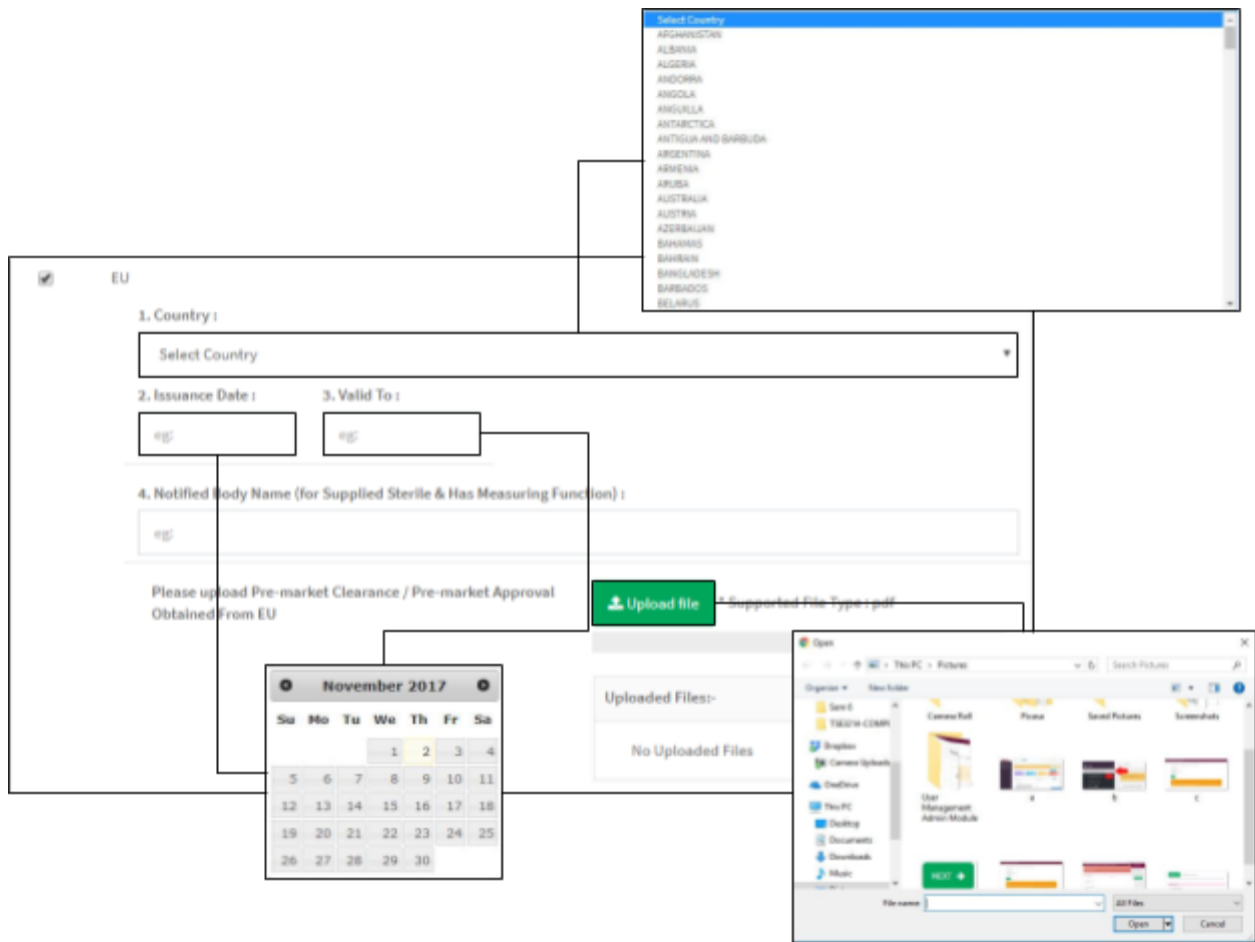


User fill ' Artg Number' textbox.

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

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

iii) 'EU' checkbox.



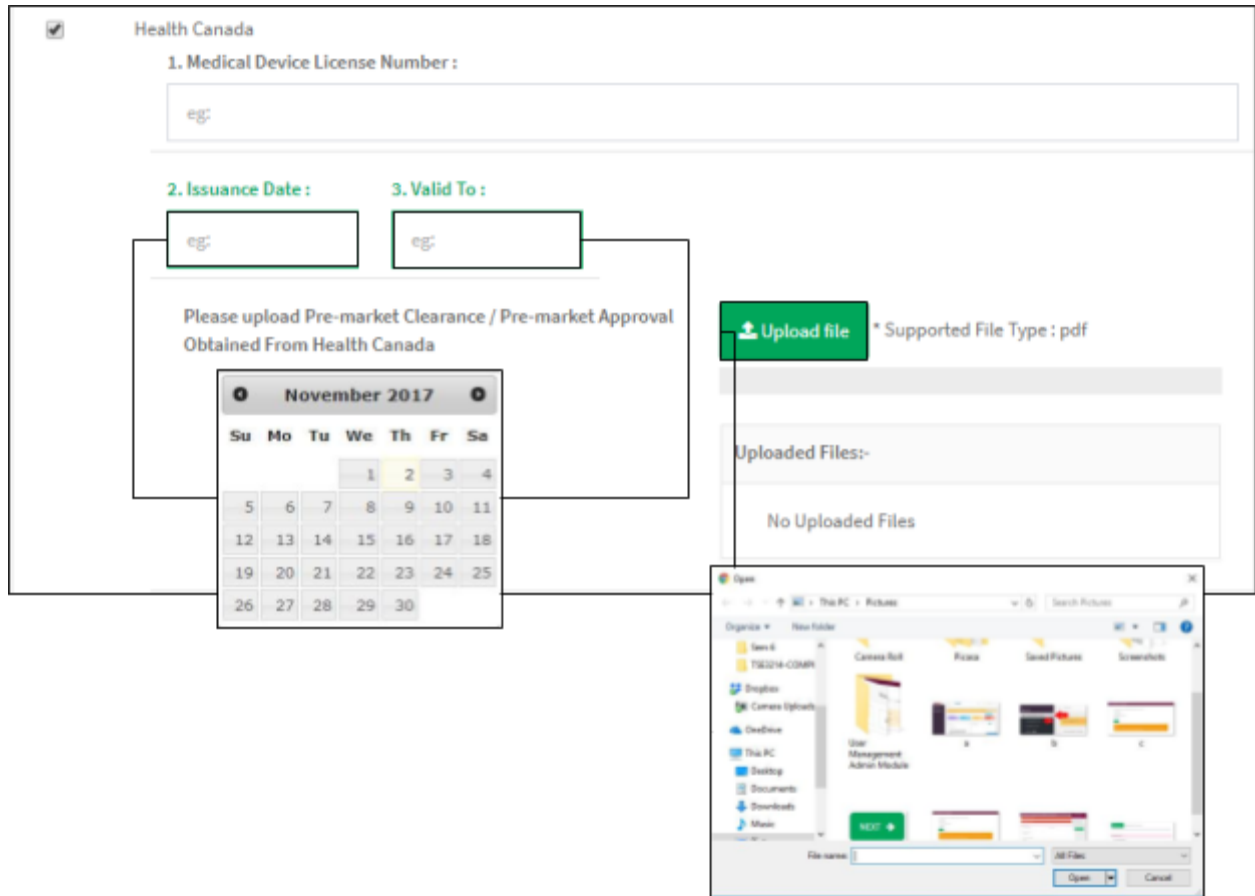
User select from 'Country' dropdown text box.

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

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


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

iv) 'Health Canada' checkbox.

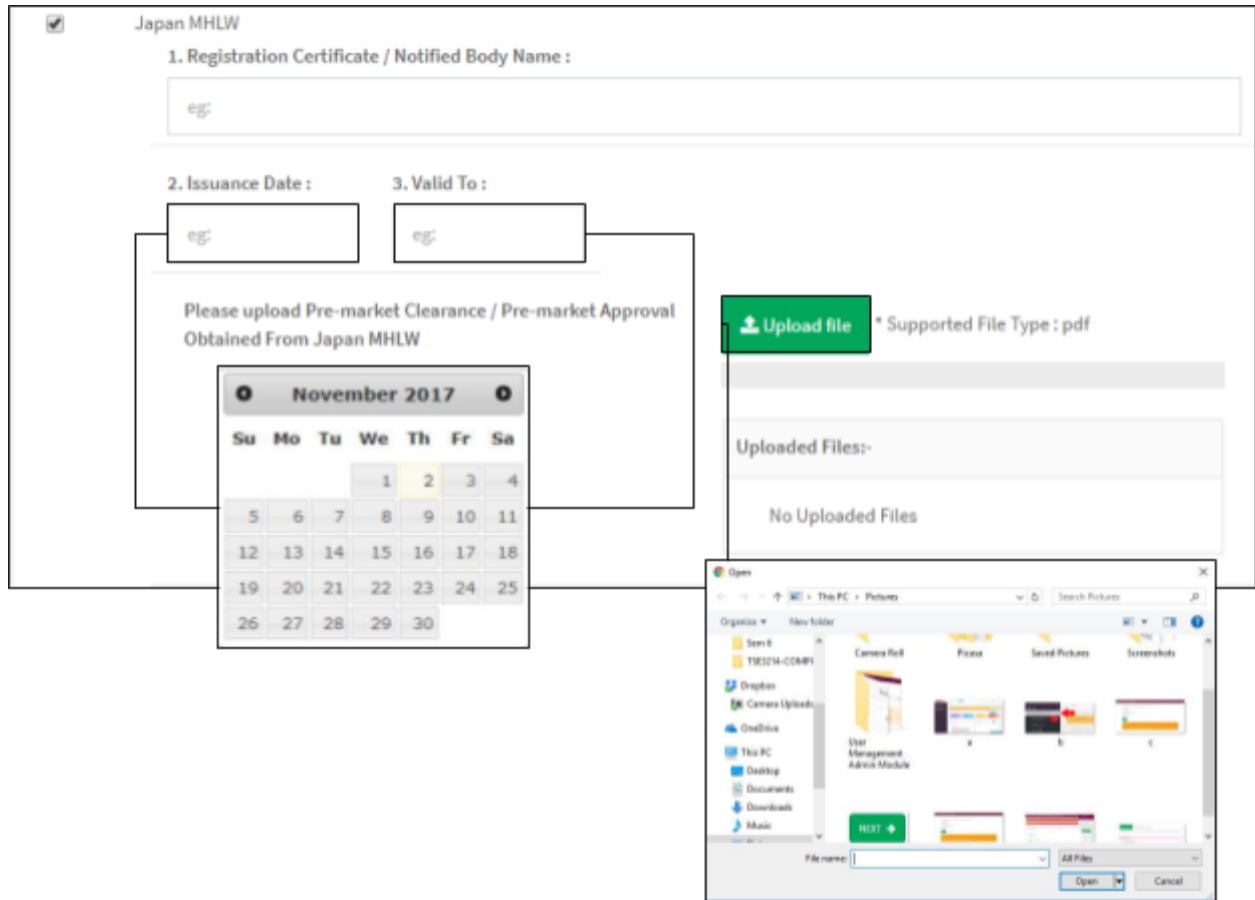


User fill 'Medical Device License Number' text box.

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


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

v) 'Japan MHLW' checkbox.

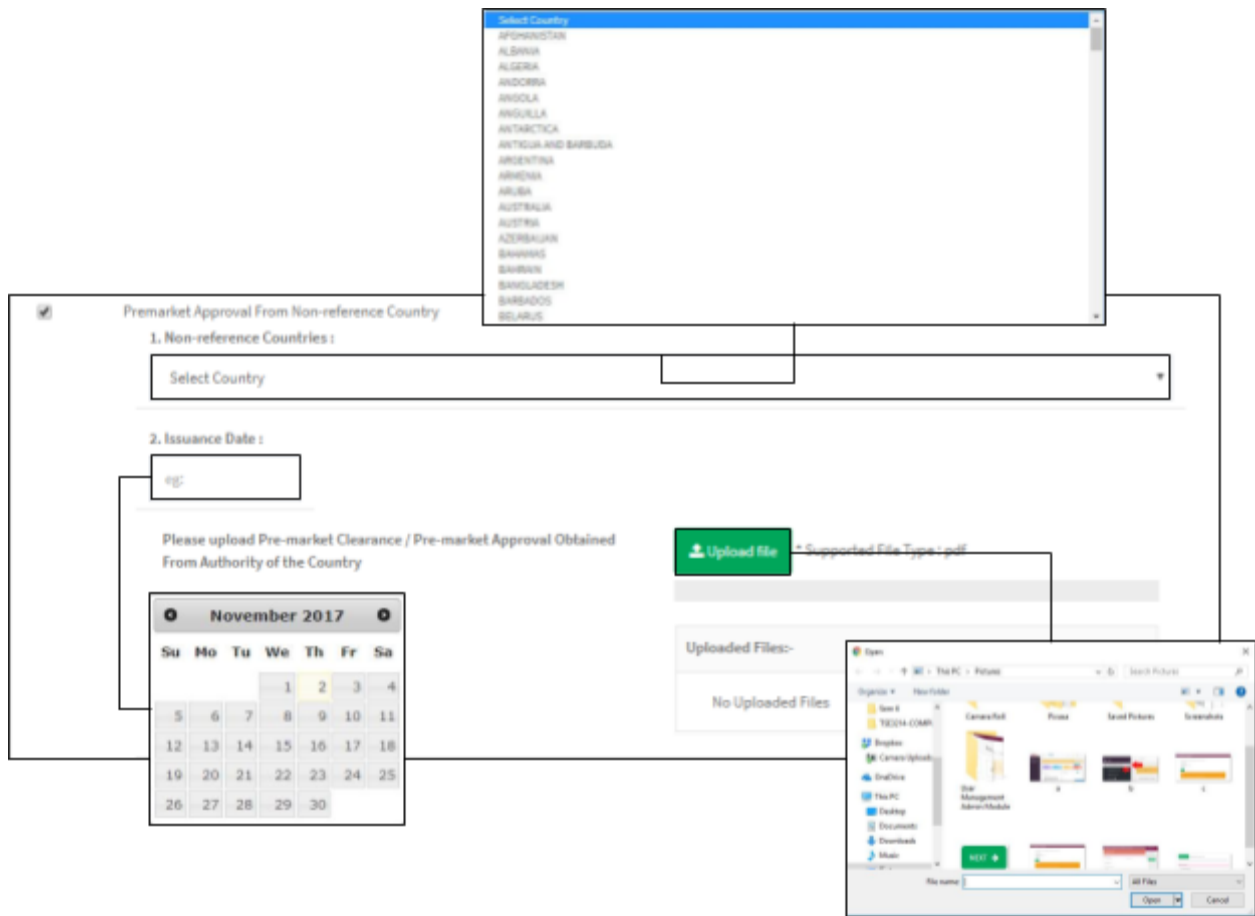


User fill 'Registration Certificate / Notified Body Name' text box.

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

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

vi) 'Pre-market Approval From Non-reference Country' checkbox.



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

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


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


vii) 'Others' checkbox.



The screenshot shows a form with a checked checkbox labeled 'Others'. Below the checkbox is a text box with the label '1. Please Specify :'. The text box is empty and has a thin border.

User has to fill 'Please Specify' text box.

Click  to go to the next section.

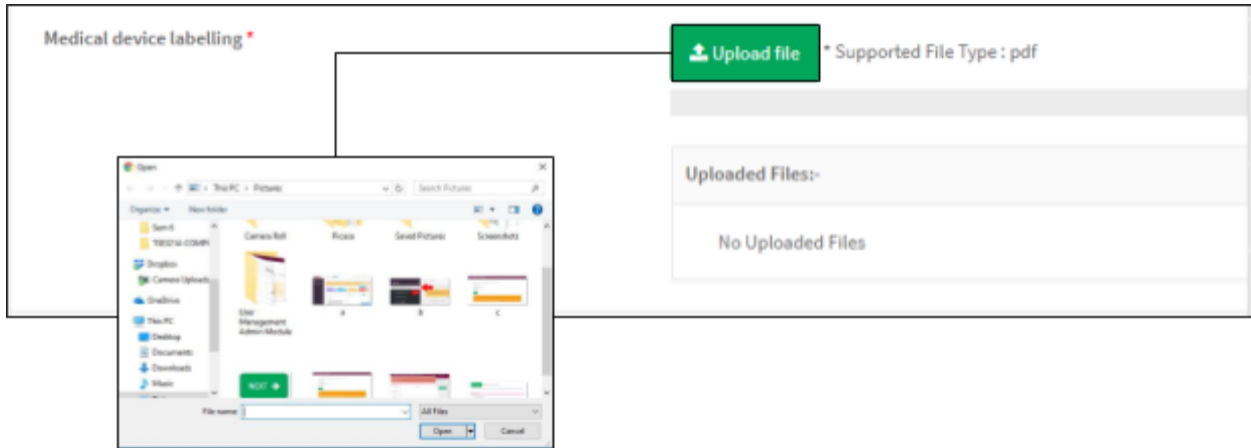
Click  to go to the previous section.

2.2.8 SECTION 8 : LABELLING

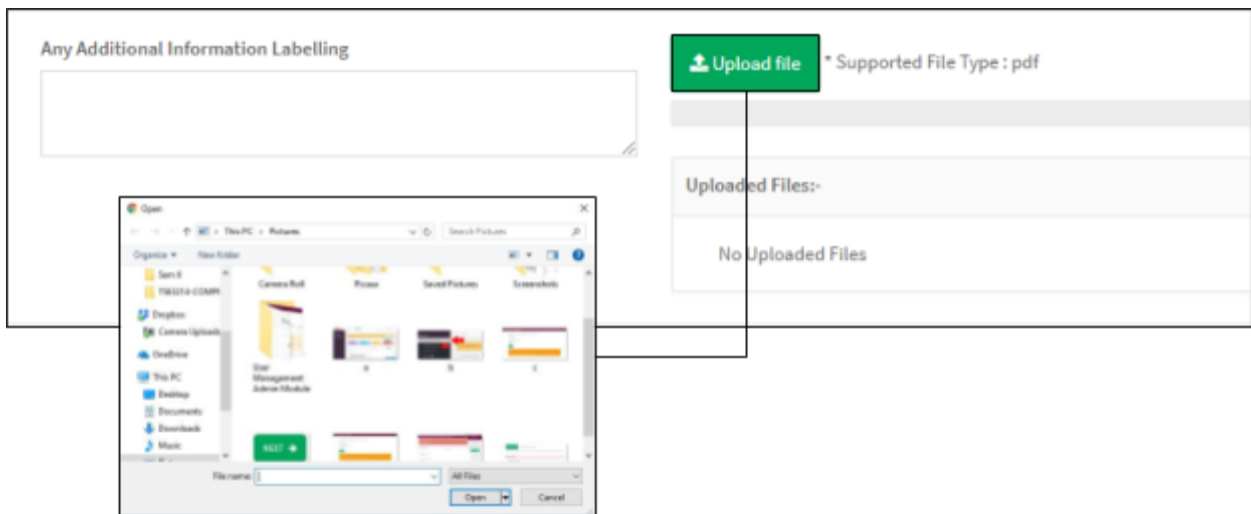
Diagram below show section 8 page.

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

The screenshot displays the MeDC@St v2.0 web application interface. The top navigation bar includes the logo, search options, language selection (ENGLISH), a notification bell with a count of 2, and a user profile for 'Example E1 name - MOHD FARIQ'. A dark sidebar on the left contains menu items: HOME, ESTABLISHMENT LICENSE, MEDICAL DEVICE REGISTRATION, ACCOUNT MANAGEMENT, and ONLINE HELP. The main content area is titled 'Class A Application (Submission ID :MDR-20171114-254)'. It features a red banner with the text 'All fields marked with * are mandatory' and a tooltip that says 'Hover at [icon] on field input for help'. The 'LABELLING (Must comply with Labeling Requirements as set out in Medical Device Regulations 2012.)' section contains two uploadable fields. The first is 'Medical device labelling *' with an 'Upload file' button (Supported File Type : pdf) and an 'Uploaded Files-' area showing 'No Uploaded Files'. The second is 'Any Additional Information Labelling' with another 'Upload file' button and an 'Uploaded Files-' area showing 'No Uploaded Files'. A green 'Previous' button is located at the bottom left of the form. On the right, an 'Application Details' sidebar lists sections 2 through 8, with 'SECTION 8 : LABELLING' highlighted in a dark purple bar.





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



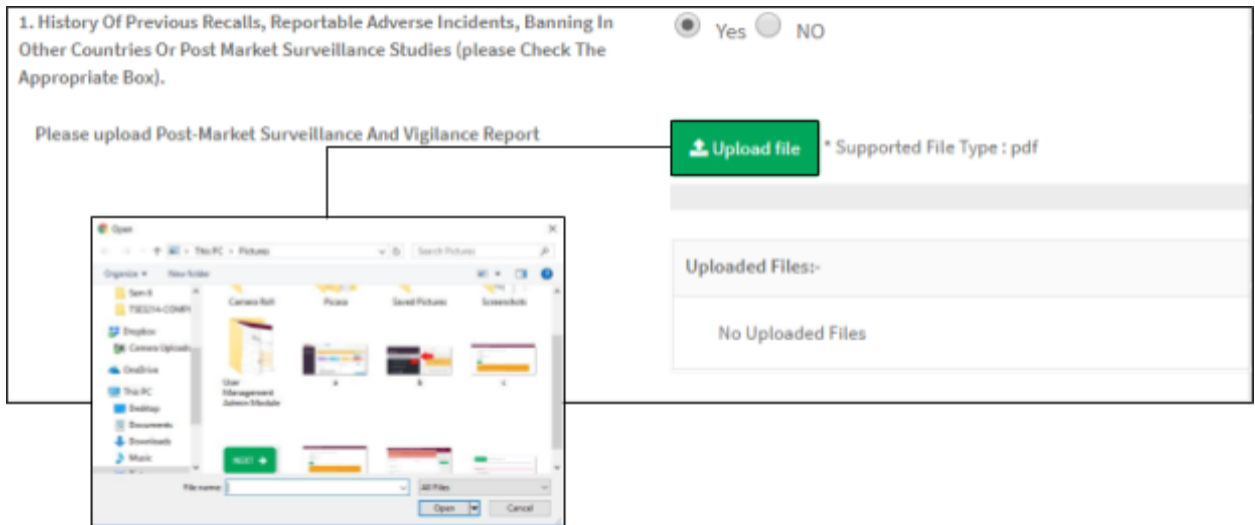
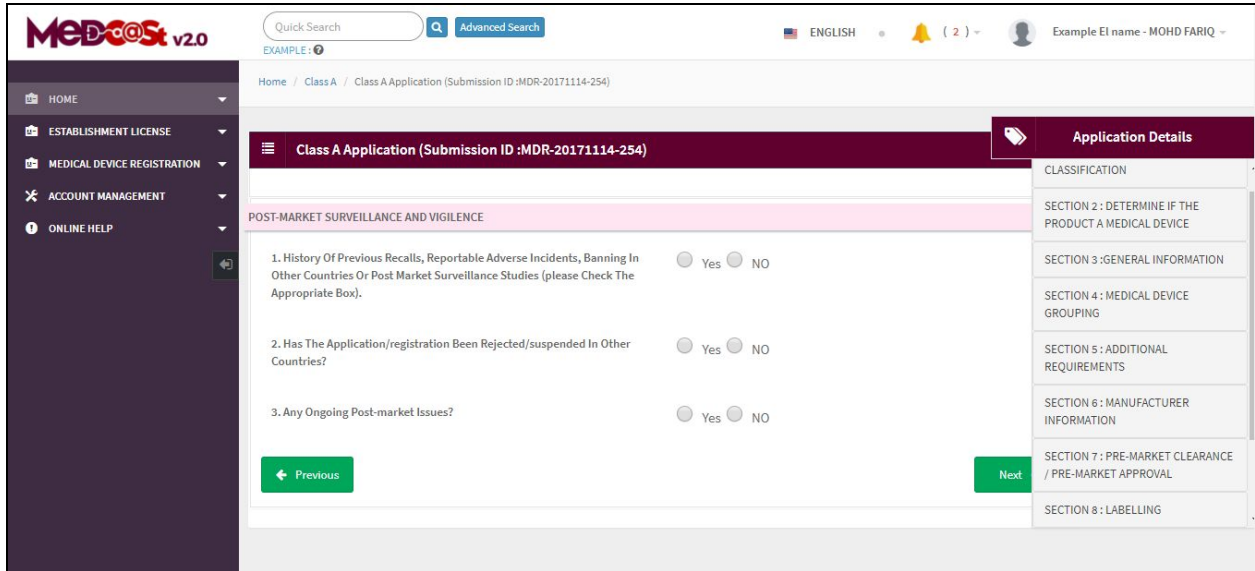
User fill 'Any Additional Information Labelling' text box. **(If necessary)**

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

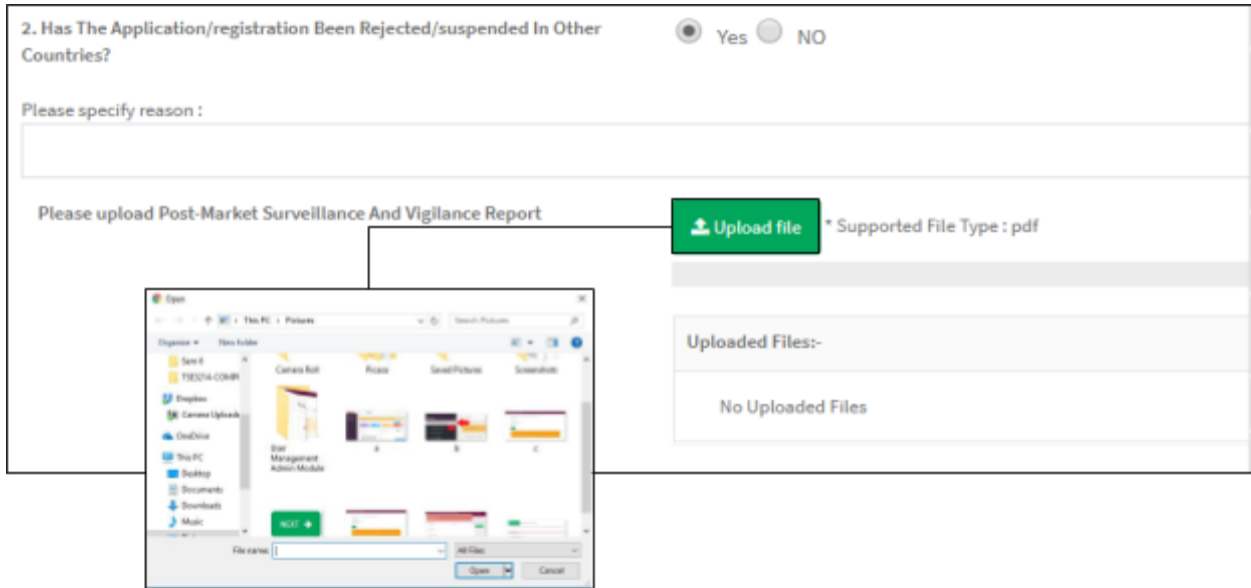
Click  to go to the next section.


Click  to go to the previous section.

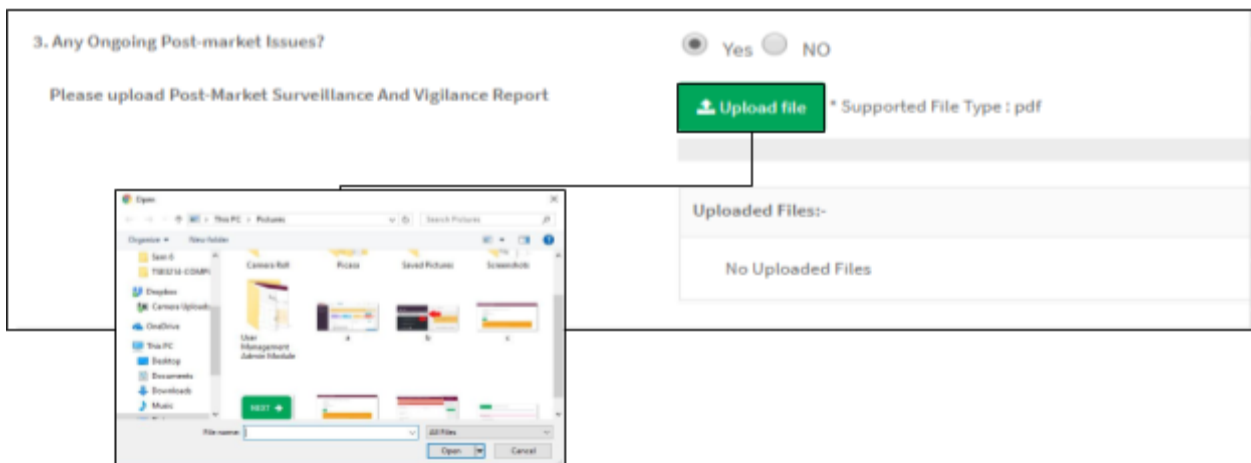
2.2.9 SECTION 9 : POST-MARKET SURVEILLANCE AND VIGILANCE




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




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



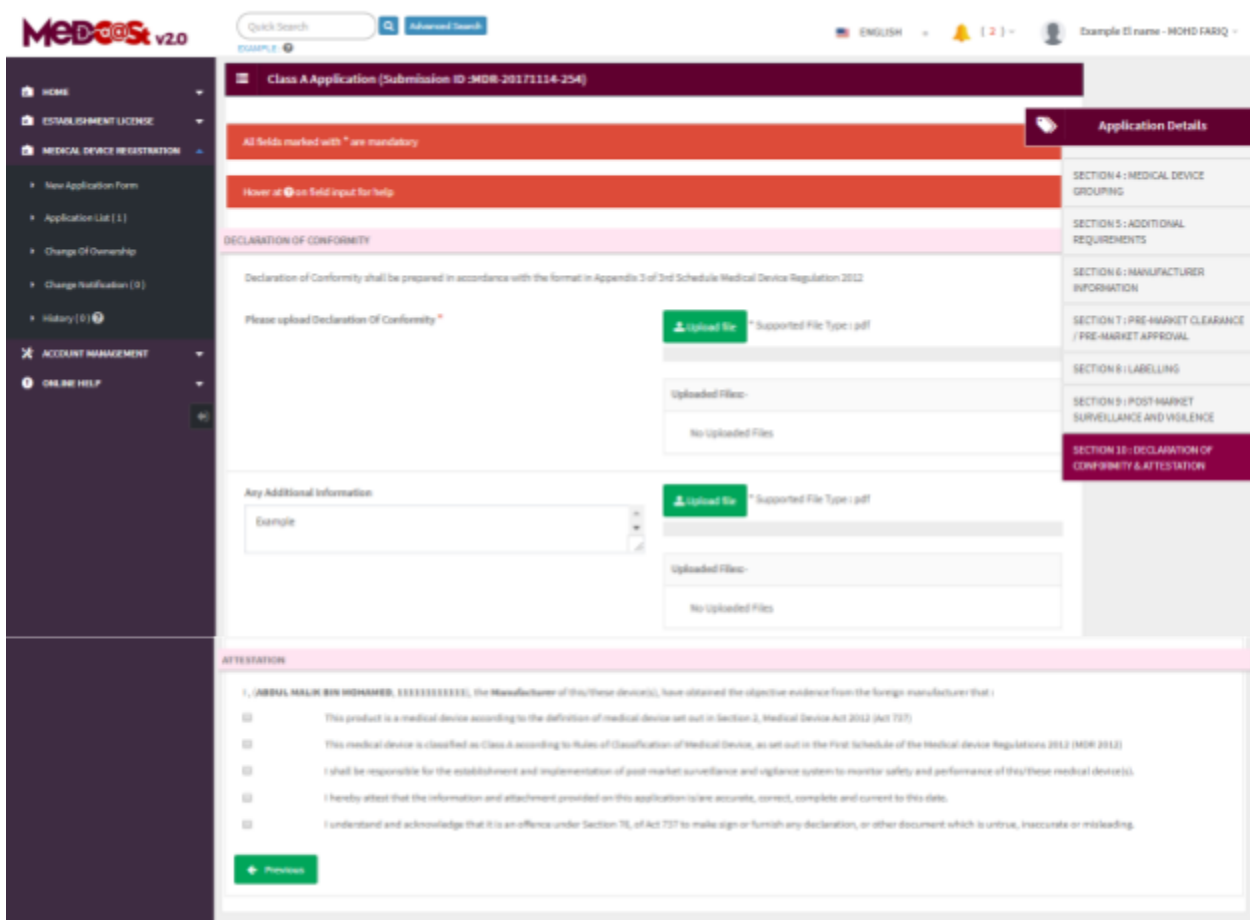
If user tick 'Yes', user has to upload file. Click  to upload file. **The file must be pdf format and size not more than 300 MB.**

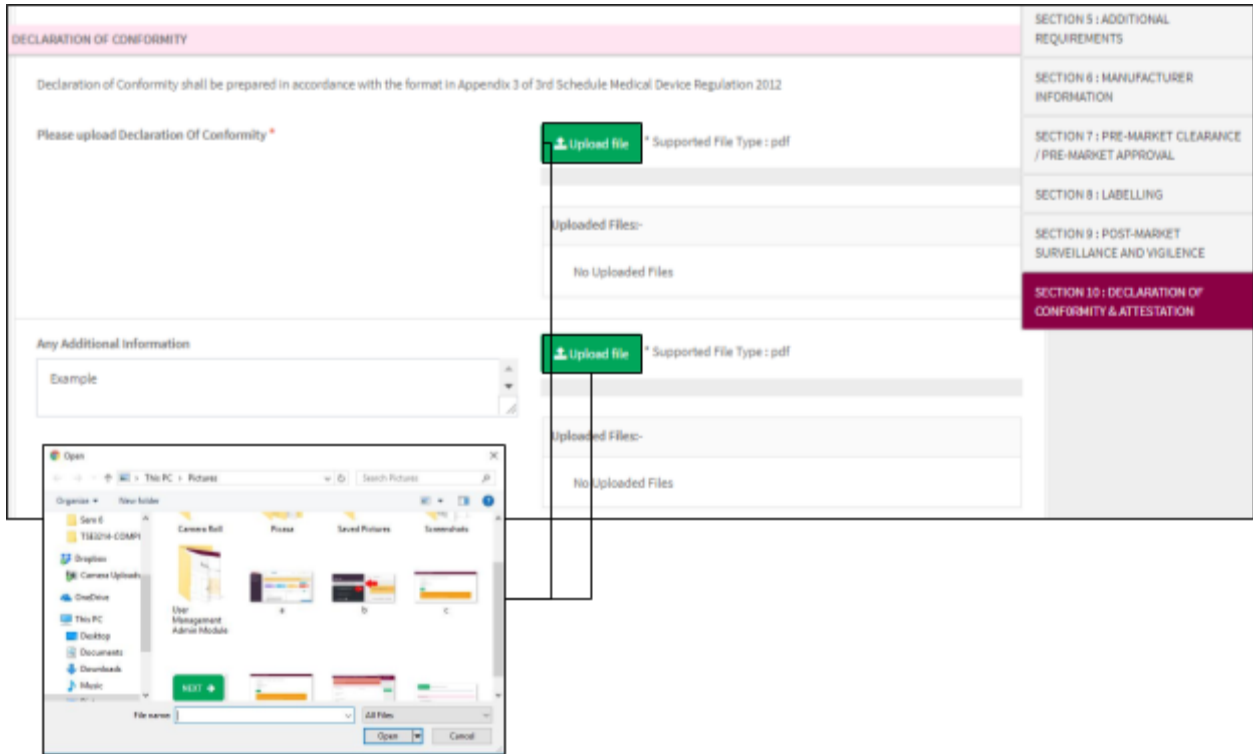
Click  to go to the next section.

Click  to go to the previous section.


2.2.10 SECTION 10 : DECLARATION OF CONFORMITY & ATTESTATION

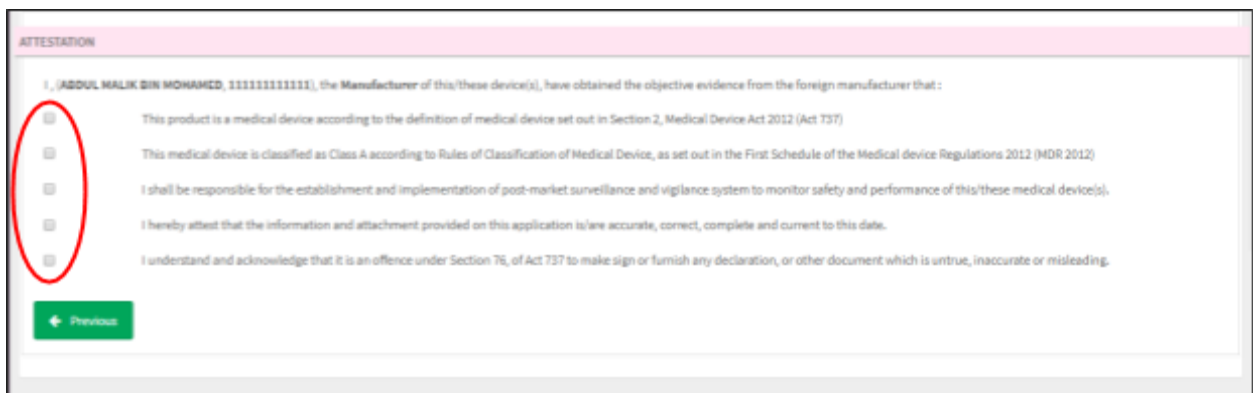
'Preview & Submit' button is invisible until user complete this section.






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

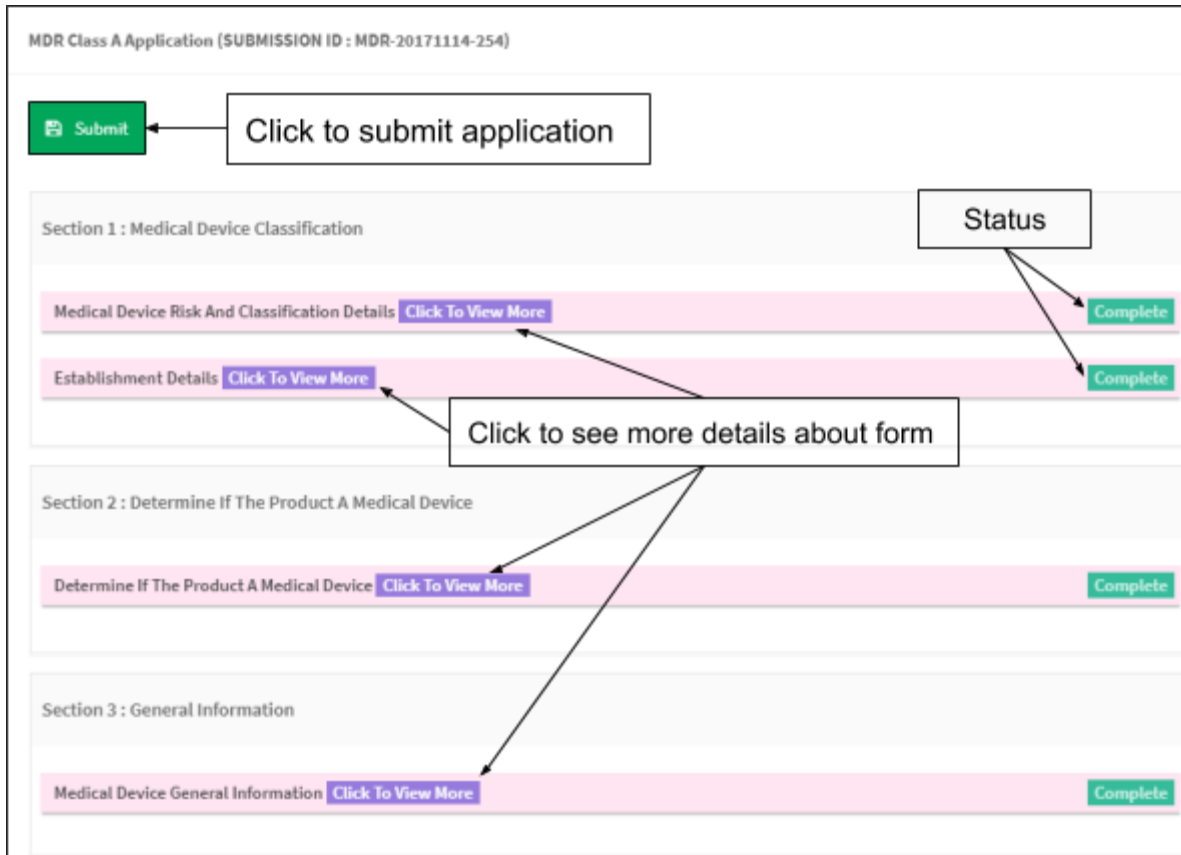
User click  to upload file. **The file must be pdf format and size not more than 300 MB.**


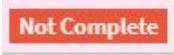


User has to tick all the checkbox before user can submit application.

 PREVIEW & SUBMIT

User click  to preview before submit application.

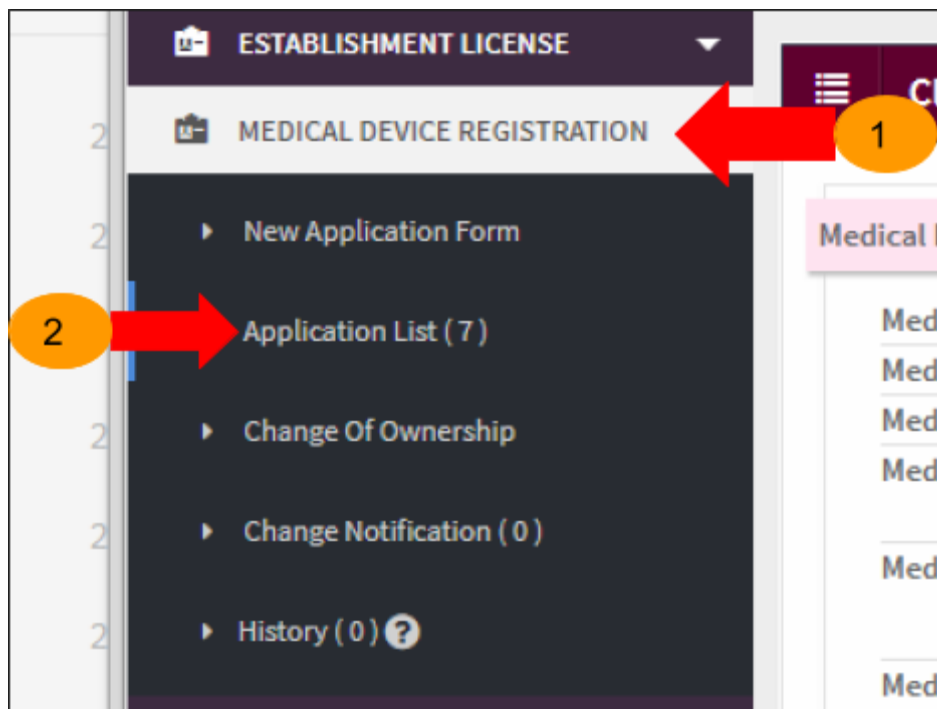



Submission only can do if all form status is . If status , user has to complete the form.


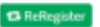
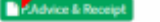
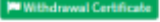

Then, click  to submit application.

3.0 RE-REGISTRATION APPLICATION

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



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

6	MDR-20171121-262	NEW REGISTRATION	21-11-2017	MANUFACTURER	CLOVIE	A	GENERAL MEDICAL DEVICE (GMD)	COMPLETE	    
---	------------------	------------------	------------	--------------	--------	---	------------------------------	----------	---

Establishment Details	
1. BUSINESS REG NO	BAIMDR
2. ESTABLISHMENT NAME	BAIZURA SYAIFULLAH
3. NAME OF PERSON RESPONSIBLE	HUSSAIN BIN ABDULLAH
4. ADDRESS	BANGUNAN DARUZZAKAH, LORONG HAJI HUSSEIN 2, CHOW KIT
5. EMAIL	cc@gmail.com
6. TELEPHONE NO	603-12323412
7. NAME OF CONTACT PERSON	HUSSAIN BIN ABDULLAH
8. ESTABLISHMENT LICENSING STATUS	COMPLETE

Application Details

[VIEW PREVIOUS APPLICATION](#)

SECTION 1 : MEDICAL DEVICE CLASSIFICATION

SECTION 2 : DETERMINE IF THE PRODUCT A MEDICAL DEVICE


SECTION 3 : GENERAL INFORMATION

SECTION 4 : MEDICAL DEVICE GROUPING

SECTION 5 : ADDITIONAL REQUIREMENTS

SECTION 6 : MANUFACTURER INFORMATION

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

User unable to edit this section, this section only display for user. User click  to go to the next step.

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

Class A Application [Submission ID :MDR-20171206-283]

Determine if the product is medical device ?

* Mandatory to click (You may tick more than 1)

Medical Device Interpretation
Meet the definition of medical device as set out in Section 2, Medical Device Act 2012 (Act 737)

Accessory
An accessory is an article that is intended specifically by its manufacturer to :
▪ Be used together with a medical device to enable that device to be used in accordance with its intended purpose as a medical device; OR
▪ Augment or extend the capabilities of that device in fulfillment of its intended purpose as a medical device

Component
Unequal subdivisions which together constitute the whole medical device to achieve the latter intended purpose; AND meant for supply for use with multiple SYSTEMS

Product Classification letter issued by MDA (if any)

Upload file * Supported File Type : pdf

Uploaded Files:-
API_EN.pdf

User click  to go to the next step.

User click  to go to the previous form.

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

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

☰ Class A Application (Submission ID :MDR-20171206-283)

All fields marked with * are mandatory

Hover at ⓘ on field input for help

Medical Device General Information

1. Medical Device Name * ⓘ
eg: ABC® Nitrile Examination Glove, Powdered

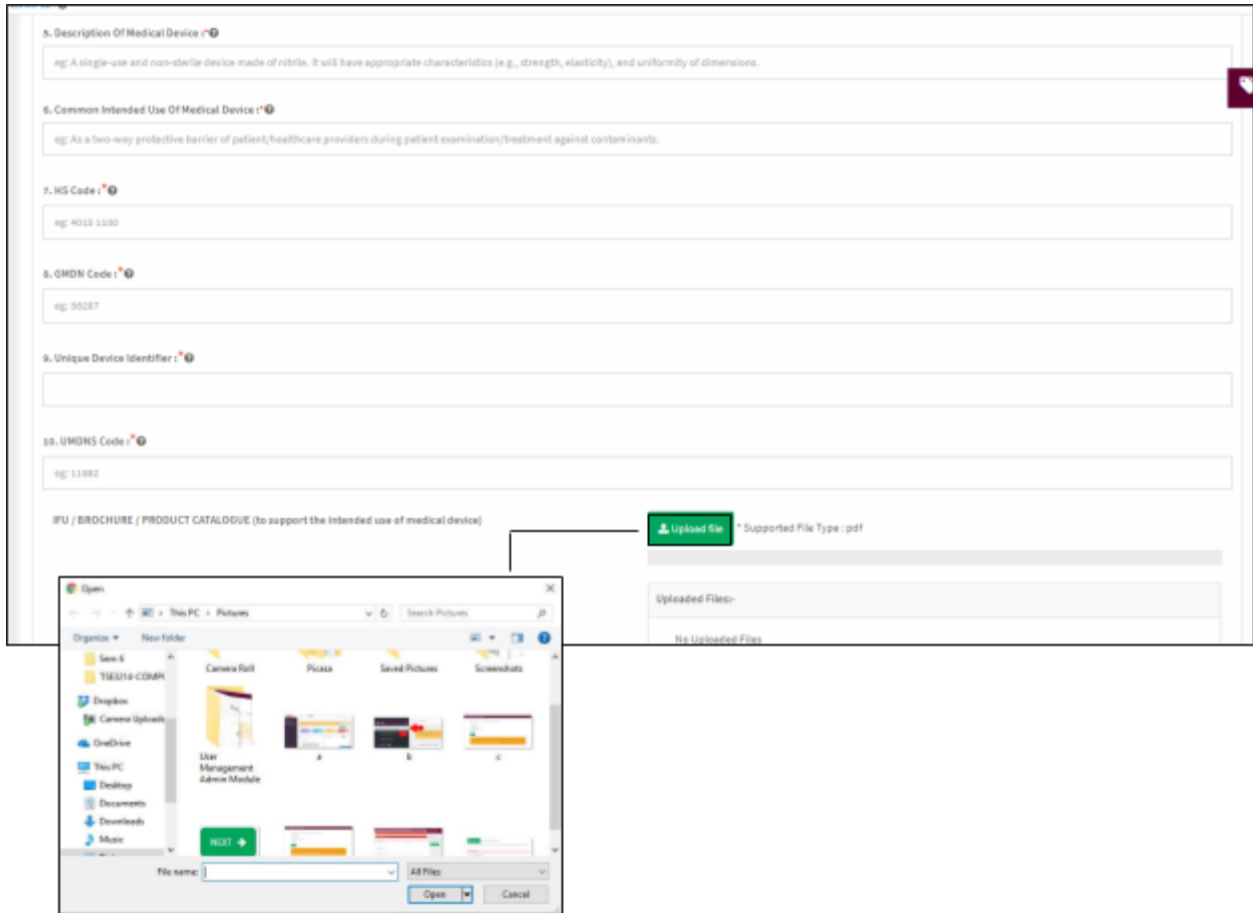
2. Proprietary Name / Brand *
eg: Brand Abc


3. Medical Device Category : *
Select

4. Is The Medical Device Meant For Export Only?
 Yes NO

Select

- ACTIVE IMPLANTABLE DEVICES
- ANAESTHETIC AND RESPIRATORY DEVICES
- DENTAL DEVICES
- ELECTRO MECHANICAL MEDICAL DEVICES
- HOSPITAL HARDWARE
- IN-VITRO DIAGNOSTIC DEVICES
- NON-ACTIVE IMPLANTABLE DEVICES
- OPHTHALMIC AND OPTICAL DEVICES
- REUSABLE DEVICES
- SINGLE-USE DEVICES
- ASSISTIVE PRODUCTS FOR PERSONS WITH DISABILITY
- DIAGNOSTIC AND THERAPEUTIC RADIATION DEVICES
- COMPLEMENTARY THERAPY DEVICES
- BIOLOGICALLY-DERIVED DEVICES
- HEALTHCARE FACILITY PRODUCTS AND ADAPTATIONS
- LABORATORY EQUIPMENT
- MEDICAL SOFTWARE



Click  to upload file. **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.

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

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

The screenshot displays the 'Medical Device Grouping' section of a 'Class A Application (Submission ID :MDR-20171107-259)'. The page is divided into two main areas: the main content area and a sidebar titled 'Application Details'.

Main Content Area:

- Section: **Medical Device Grouping**
- Section Header: **Grouping Type For Medical Device**
- Options (radio buttons):
 - Single
 - System
 - Family
 - Family of System
 - Set
- Navigation: A green button labeled 'Previous' with a left-pointing arrow.

Application Details Sidebar:

- SECTION 1 : MEDICAL DEVICE CLASSIFICATION
- SECTION 2 : DETERMINE IF THE PRODUCT A MEDICAL DEVICE
- SECTION 3 :GENERAL INFORMATION
- SECTION 4 : MEDICAL DEVICE GROUPING (highlighted in dark purple)

Five red arrows point to the radio buttons for 'Single', 'System', 'Family', 'Family of System', and 'Set'.

i) 'Single' radio button.

The screenshot shows a web application interface for 'Class A Application (Submission ID :MDR-20171107-259)'. The main content area is titled 'Medical Device Grouping' and contains a section for 'Grouping Type For Medical Device'. Under this section, the 'Single' radio button is selected. Below the radio button, there are two text input fields: '1. Device Identifier :' with a placeholder 'eg: #IVD-Medical-Brand-A' and '2. Model :' with a placeholder 'eg: #IVD-Medical-Model-A'. To the right of the main form is a sidebar titled 'Application Details' containing a list of sections: SECTION 1 : MEDICAL DEVICE CLASSIFICATION, SECTION 2 : DETERMINE IF THE PRODUCT A MEDICAL DEVICE, SECTION 3 :GENERAL INFORMATION, SECTION 4 : MEDICAL DEVICE GROUPING (highlighted in maroon), SECTION 5 : ADDITIONAL REQUIREMENTS, and SECTION 6 : MANUFACTURER INFORMATION.

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

ii) 'System' radio button.

System

A medical device SYSTEM comprises of a number of constituent components that are:

1. From the same Manufacturer : Yes NO
2. Intended to be used in combination to complete a common intended purpose : Yes NO
3. Compatible when used as a SYSTEM : Yes NO
4. Sold under a SYSTEM name or the labeling, instruction for use (IFU), brochures or catalogues for each constituent component states that the constituent component is intended for use with the SYSTEM : Yes NO

No	System Name	System Identifier No.	System Model	Action
1	Example	(not set)	(not set)	View Device [0] Add Device Update System Name

Application Details

SECTION 1 : MEDICAL DEVICE CLASSIFICATION

SECTION 2 : DETERMINE IF THE PRODUCT A MEDICAL DEVICE

SECTION 3 : GENERAL INFORMATION

SECTION 4 : MEDICAL DEVICE GROUPING

Medical Grouping Device Details

MEDICAL DEVICE LIST

Showing 1 of 1 items.

No	Name	Identifier	Brief Description
1	EXAMPLE	TTTT	EXAMPLE

No	System Name	System Identifier No.	System Model	Action
1	Example	(not set)	(not set)	View Device [0] Add Device Update System Name

Medical Device Grouping

System

1. DEVICE NAME:

2. SYSTEM IDENTIFIER NO.:

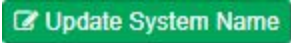

3. SYSTEM MODEL:

Medical Grouping Device Details

MEDICAL DEVICE LIST

No results found

Click [View Device \[0 \]](#) to view device list.



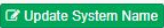
Click  to update [System Identifier No.] and [System Model] then click  to confirm update.

iii) 'Family' radio button

Family

A medical device FAMILY is a collection of medical devices and each medical device FAMILY member :

1. Is from the same Manufacturer : Yes No
2. Is of the same risk classification : Yes No
3. Has the same medical device proprietary name : Yes No
4. Has a common intended purpose or an overall intended purpose (This refers to the overall intended purpose of reusable surgical instrument, regardless of location of the body they are used on) : Yes No
5. Has the same design and manufacturing process : Yes No
6. Has variations that are within the scope of the permissible variants : Yes No

No	Medical Device Name	Action
1	Example	  

Application Details

SECTION 1 : MEDICAL DEVICE CLASSIFICATION

SECTION 2 : DETERMINE IF THE PRODUCT A MEDICAL DEVICE

SECTION 3 : GENERAL INFORMATION

SECTION 4 : MEDICAL DEVICE GROUPING

Medical Grouping Device Details

MEDICAL DEVICE LIST

Showing 1 of 1 item.

No.	Name of device, substantial components, accessories, reagents and/or articles as per product label	Device Identifier No.	Parent/Child Status	Details on Parent/Child Status	Model	Final Description/CI Item
1	Example	10110	Example	Example	Example	Example

Medical Device Grouping

Family

1. SYSTEM NAME:

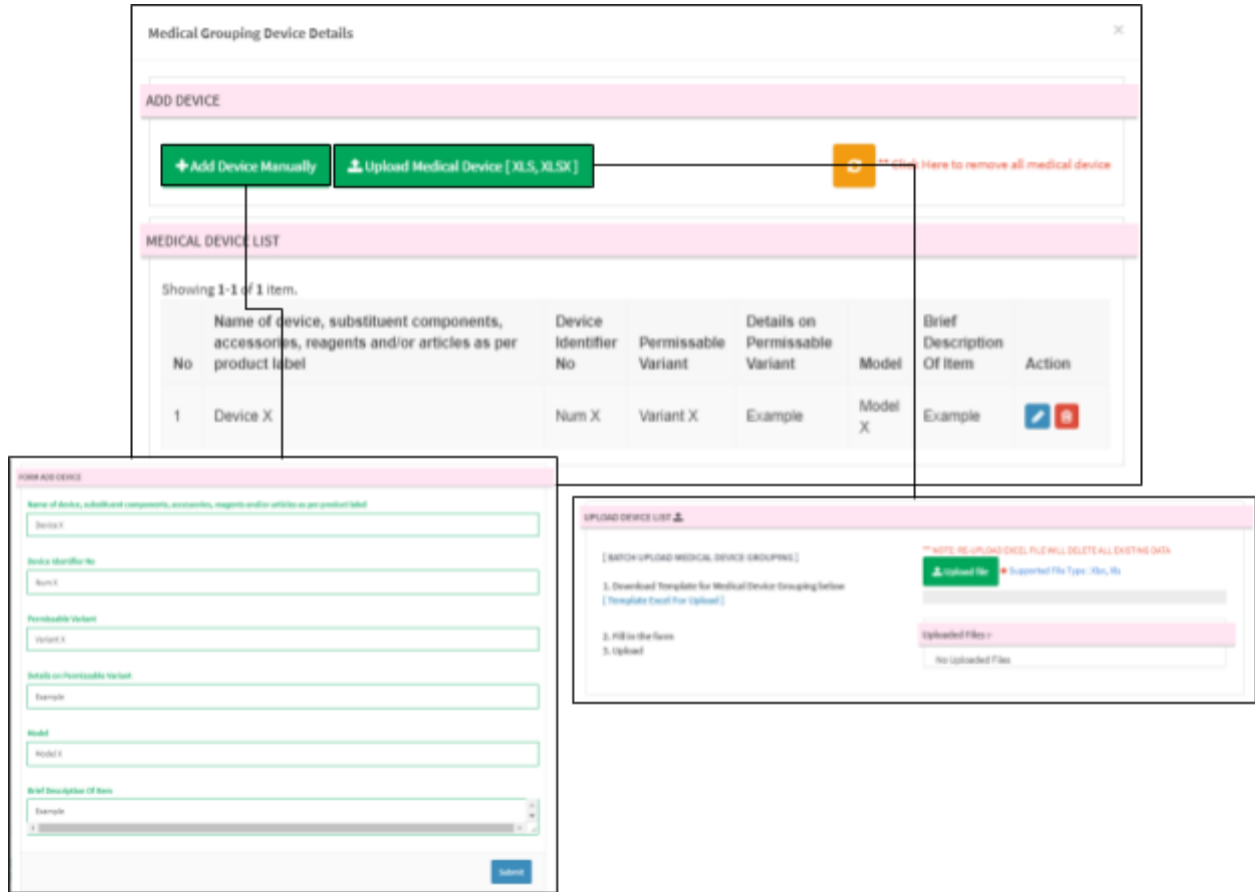
No	Medical Device Name	Action
1	Example	<input type="button" value="View Device [0]"/> <input type="button" value="Add Device"/> <input type="button" value="Update System Name"/>

Medical Grouping Device Details



ADD DEVICE

MEDICAL DEVICE LIST


No.	Name of device, substantial components, accessories, reagents and/or articles as per product label	Device Identifier No.	Parent/Child Status	Details on Parent/Child Status	Model	Final Description/CI Item	Action
No results found.							



Click  to view device list.

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

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

 button for user edit device details.



button for user delete device.



button for user delete all medical devices.

iv) 'Family Of System' radio button.

Family of System

A medical device FAMILY is a collection of medical devices and each medical device FAMILY member :

1. Is from the same Manufacturer : Yes No
2. Is of the same risk classification : Yes No
3. Has the same medical device proprietary name : Yes No
4. Has a common intended purpose or an overall intended purpose (This refers to the overall intended purpose of reusable surgical instrument, regardless of location of the body they are used on) : Yes No
5. Has the same design and manufacturing process : Yes No
6. Has variations that are within the scope of the permissible variants : Yes No

+ Add System Name/Model

No	System Name	System Identifier No.	System Model	Action
1	EXAMPLE	11111	MODEL X	View Device [0] Add Device Update System Name Delete

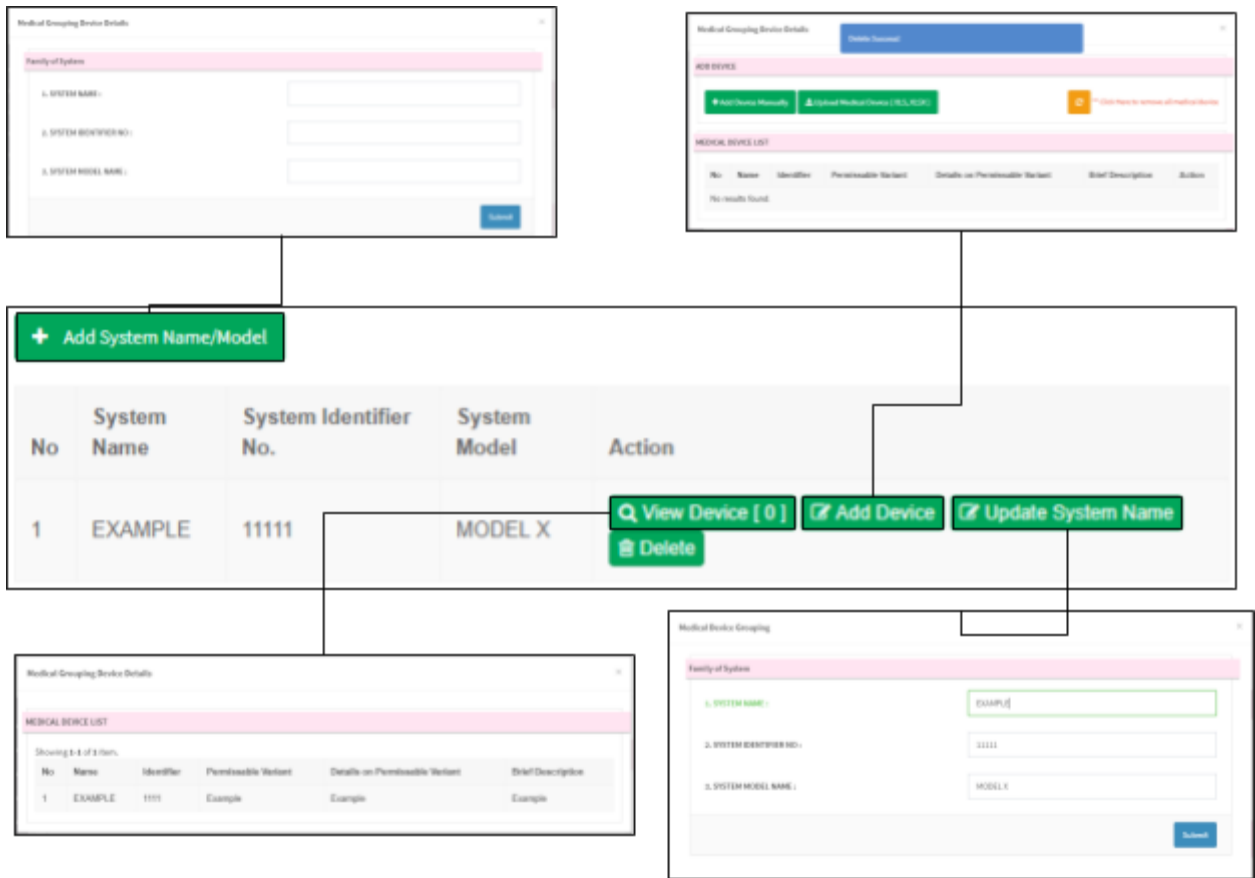
Application Details

SECTION 1 : MEDICAL DEVICE CLASSIFICATION

SECTION 2 : DETERMINE IF THE PRODUCT A MEDICAL DEVICE

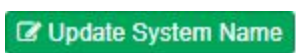
SECTION 3 : GENERAL INFORMATION

SECTION 4 : MEDICAL DEVICE GROUPING



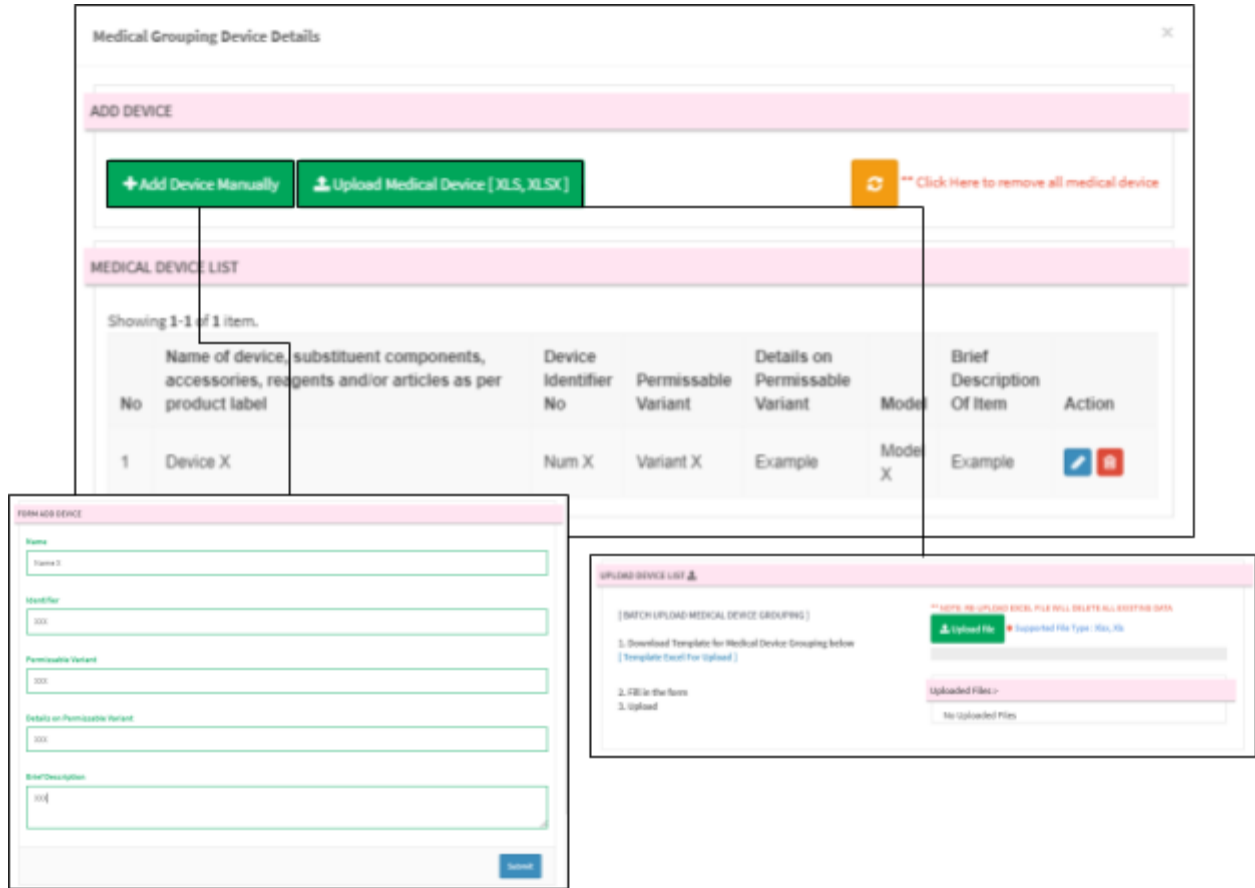
Click  to add system name or model.



Click  to view device list.

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


Click  to confirm update.

Click  to delete device.



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

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

 button for user edit device details.

 button for user delete device.



button for user delete all medical devices.

v) 'Set' radio button.

Set

A medical device SET is a collection of two or more medical devices, assembled together as one package by a manufacturer. The medical device SET has the following:

1. A single proprietary SET name : Yes No
2. A common intended use : Yes No
3. Classification allocated to the set is at the level of the highest classified device within the set : Yes No

No	SET Name as Per Product Label	SET Identifier No.	Action
1	Medical device x	(not set)	View Device [0] Add Device Update System Name

Application Details

SECTION 1 : MEDICAL DEVICE CLASSIFICATION

SECTION 2 : DETERMINE IF THE PRODUCT A MEDICAL DEVICE

SECTION 3 : GENERAL INFORMATION

SECTION 4 : MEDICAL DEVICE GROUPING

Medical Grouping Device Details

MEDICAL DEVICE LIST

Showing 1 of 1 item.

No	Name	Identifier	Brief Description
1	EXAMPLE	1111	Example

Medical Grouping Device Details

ADD DEVICE

[Add Device Manually](#)
[Upload Medical Device \(MSL, MSU\)](#)
 Click here to remove all medical device

MEDICAL DEVICE LIST

No	Name	Identifier	Brief Description	Action
No results found				

No	SET Name as Per Product Label	SET Identifier No.	Action
1	Medical device x	(not set)	View Device [0] Add Device Update System Name



Medical Device Grouping

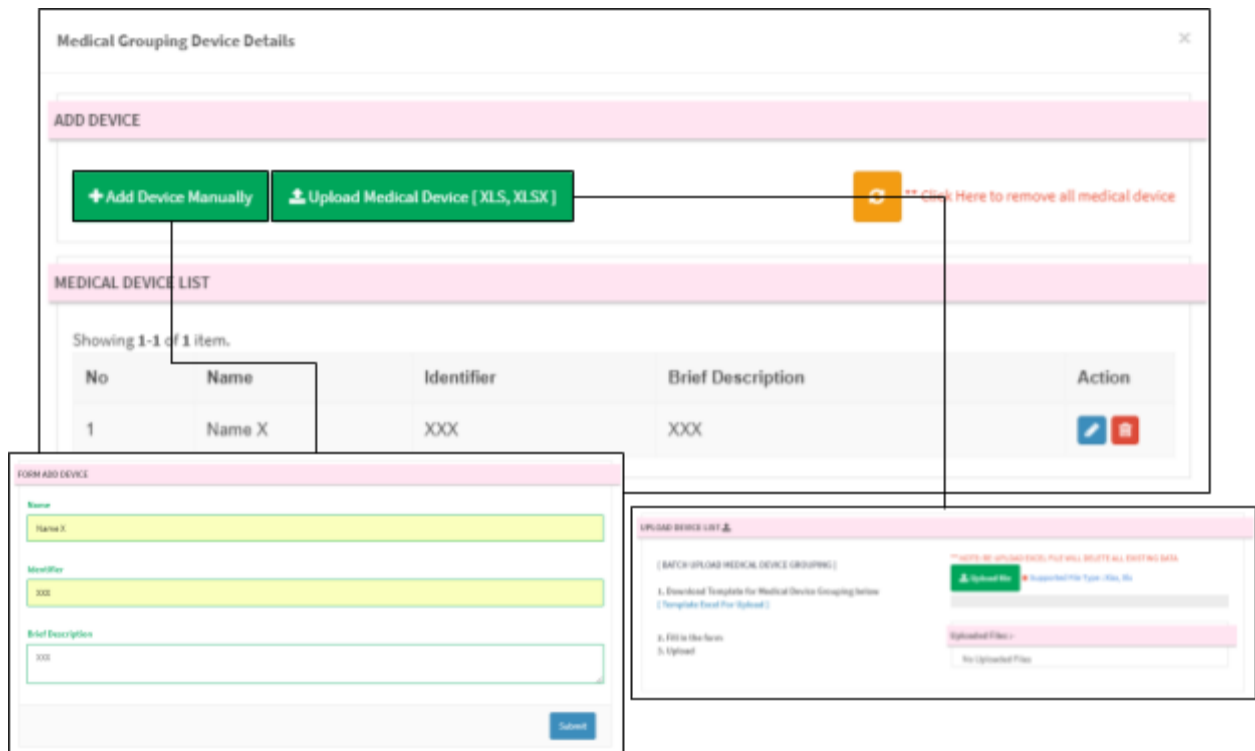
Set



1. SET NAME AS PER PRODUCT LABEL:

2. SET IDENTIFIER NO.:


Click [View Device \[0 \]](#) to view device list.

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




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


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

 button for user edit device details.

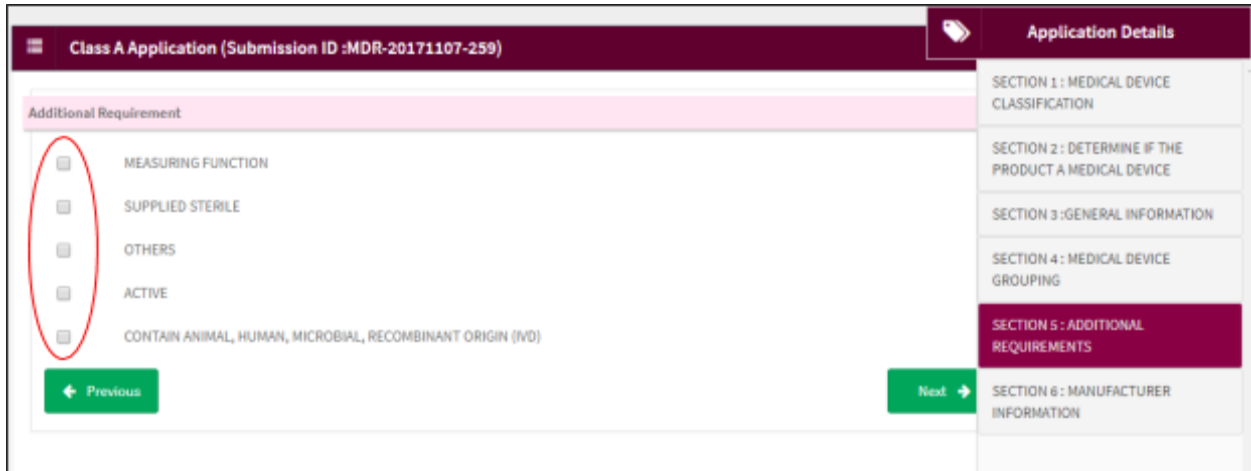
 button for user delete device.

 button for user delete all medical devices.

Click  to go to the next section.

Click  to go to the previous section.

The diagram below show SECTION 5 : ADDITIONAL REQUIREMENT

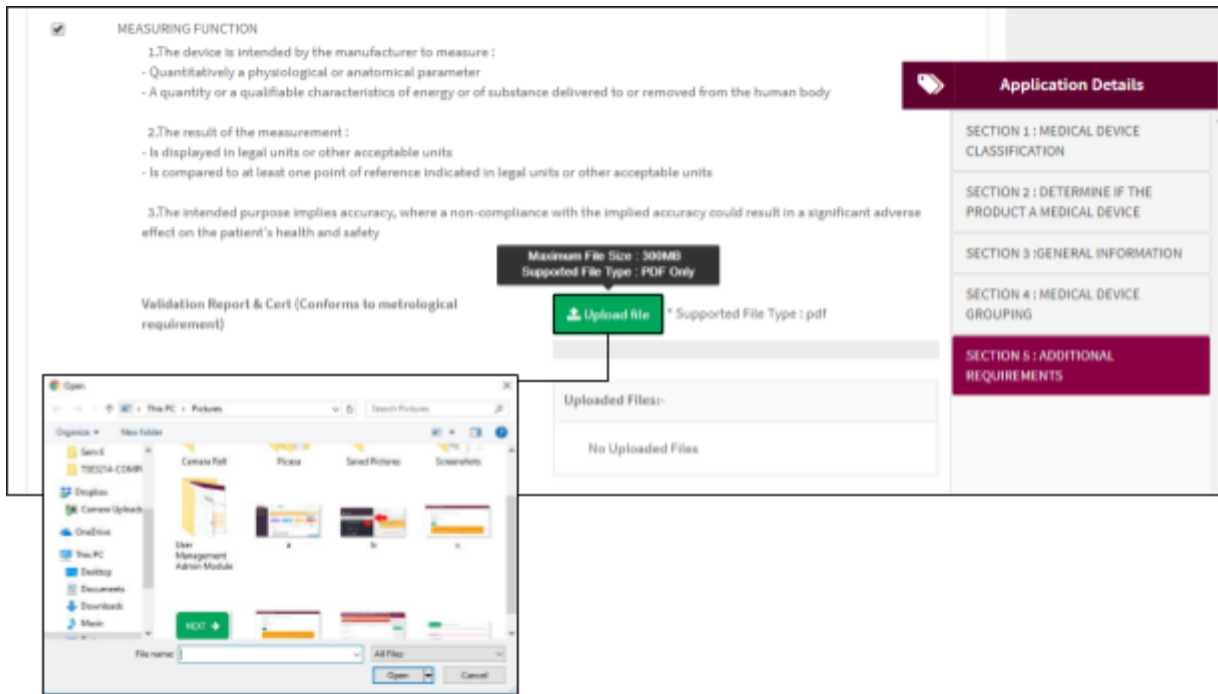



The screenshot displays the 'Class A Application' interface. The main content area is titled 'Additional Requirement' and lists five options, each with a checkbox. The first three checkboxes are circled in red. The options are: MEASURING FUNCTION, SUPPLIED STERILE, OTHERS, ACTIVE, and CONTAIN ANIMAL, HUMAN, MICROBIAL, RECOMBINANT ORIGIN (IVO). Below the list are 'Previous' and 'Next' navigation buttons. On the right, the 'Application Details' sidebar shows a list of sections, with 'SECTION 5: ADDITIONAL REQUIREMENTS' highlighted in red.

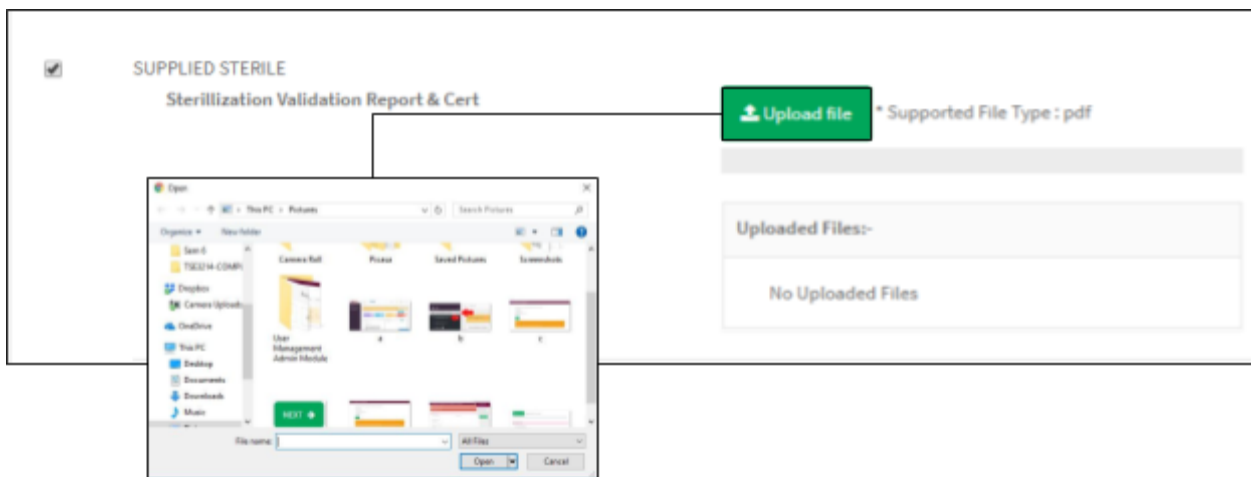
User tick checkbox in red circle (**if necessary**) and user can tick more than one checkbox. If


not, user click  to go to next section.

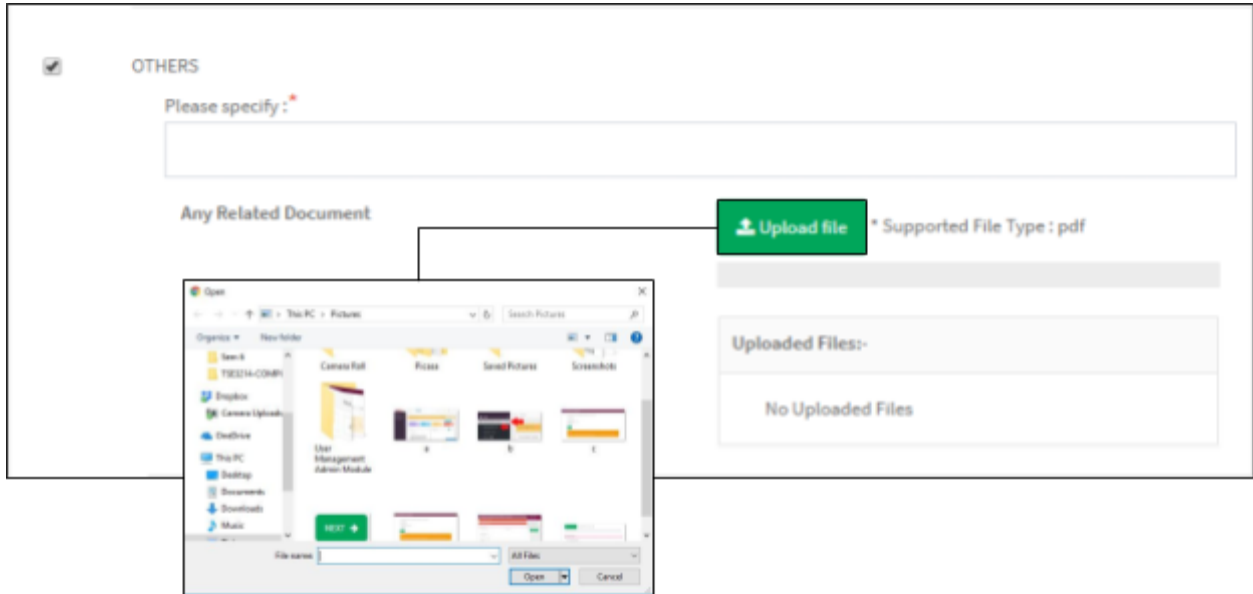
If user tick any checkboxes above, user has to complete that field before user go to the next section.




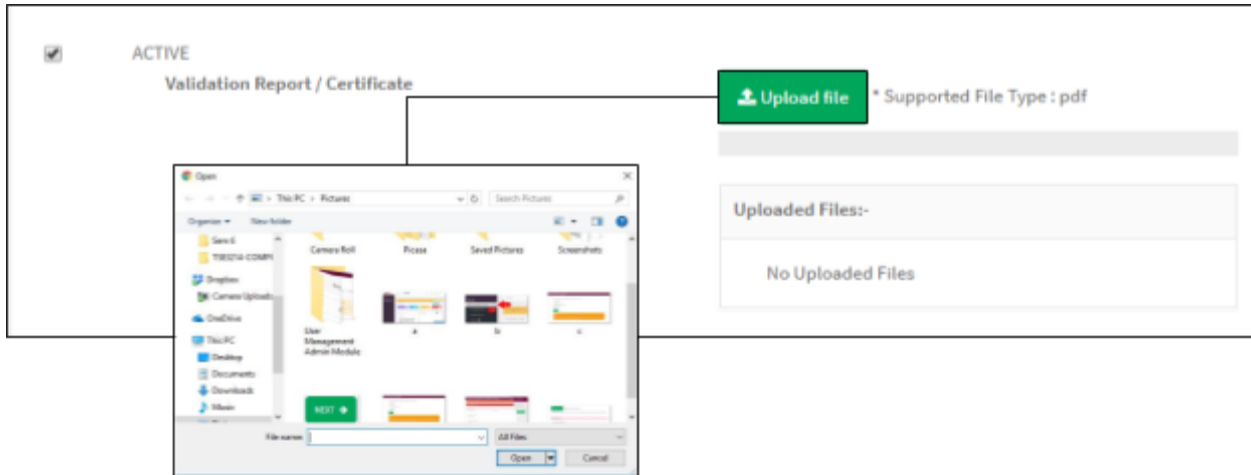
User click  to upload file. **The file must be pdf format and size not more than 300 MB.**



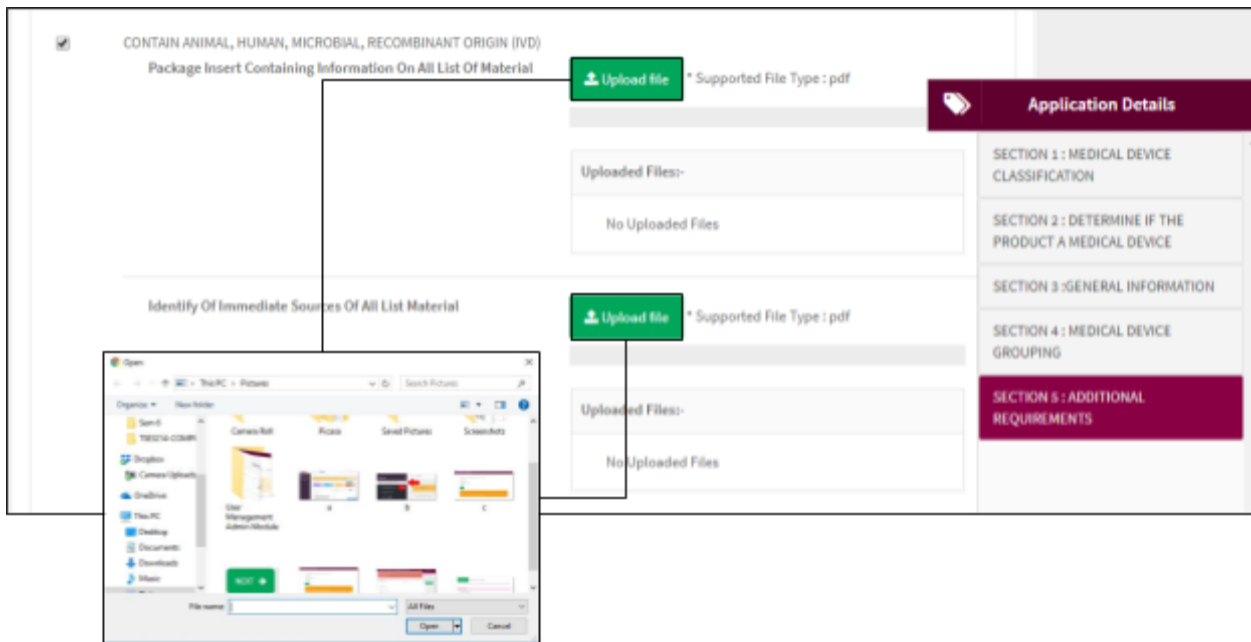
User click  to upload file. **The file must be pdf format and size not more than 300 MB.**




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




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



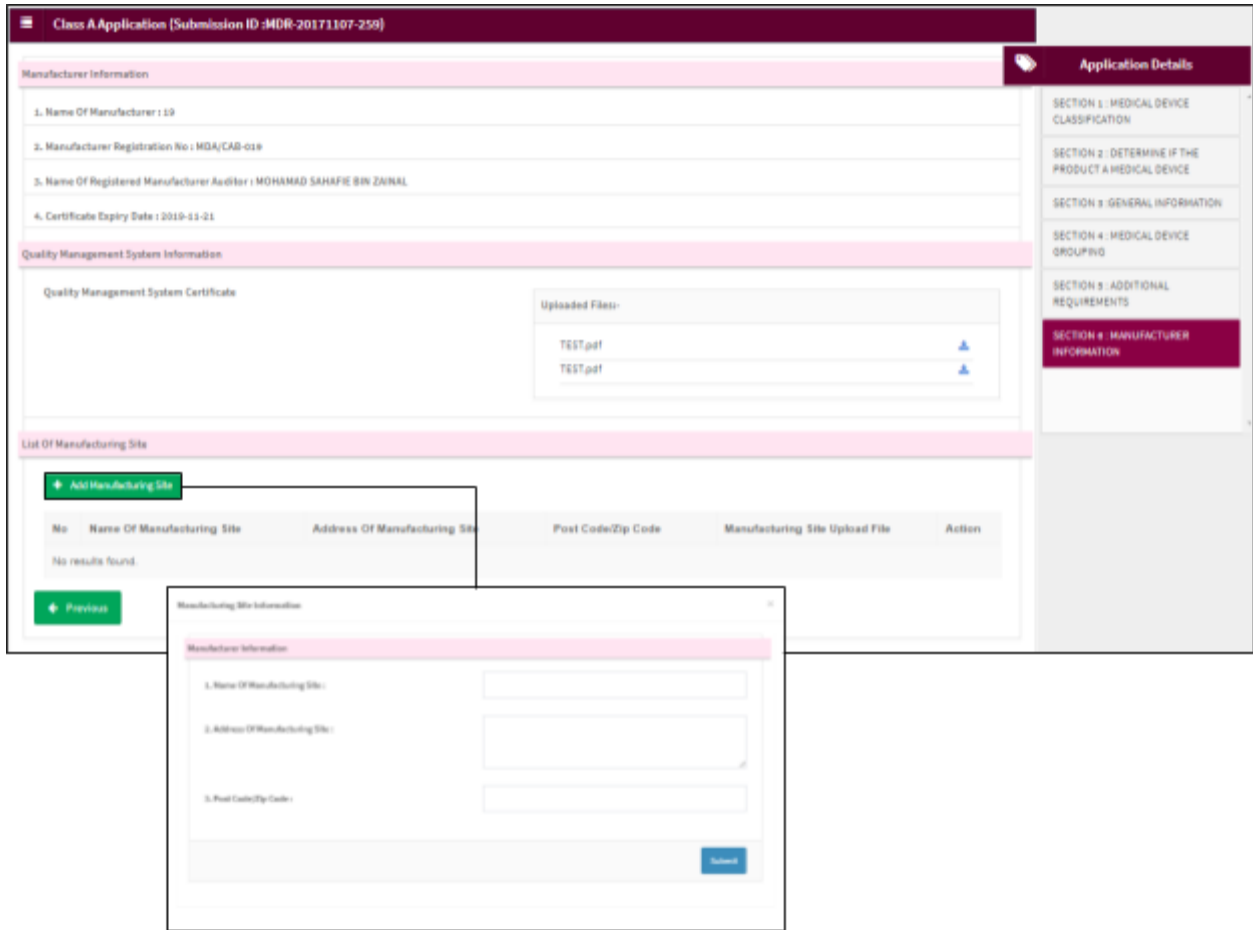
User click  to upload file. **The file must be pdf format and size not more than 300 MB.**

Click  to go to the next section.

Click  to go to the previous section.

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

Diagram below show section 6 for Manufacturer.



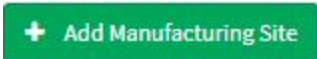

User click  to add new data. User has to fill all the text box then click . New data will display in 'List Of Manufacturing Site' table.

Diagram below show section 6 for Authorised Representative.
'Next' button is invisible until user complete this section.

The screenshot displays a web application interface for a Class A Application. The top header shows the submission ID: MDR-20171116-256. Below the header, there are two red informational banners: "All fields marked with * are mandatory" and "Hover at [help icon] on field input for help".

The main form area is titled "Manufacturer Information" and contains four numbered text input fields:

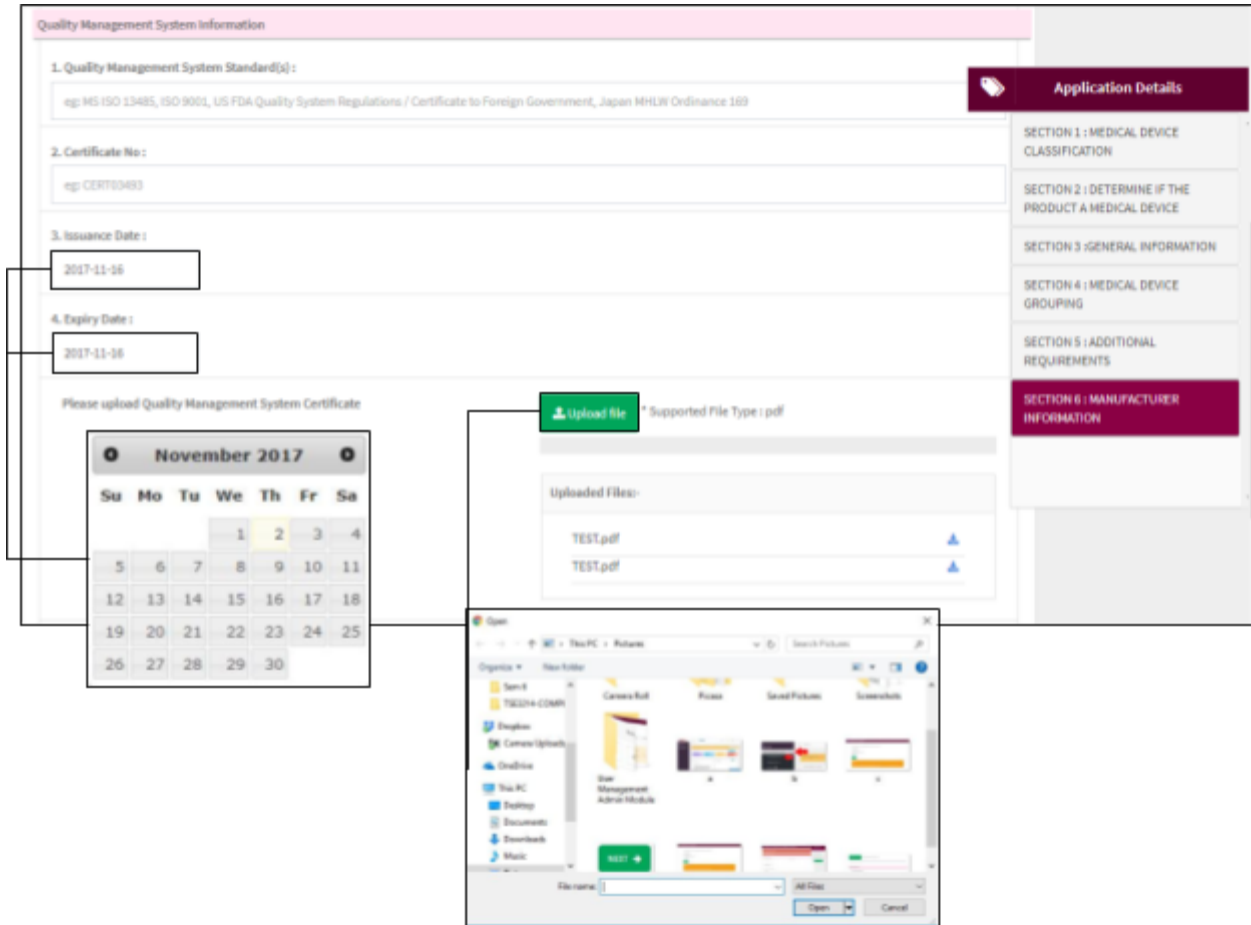
- 1. Name Of Legal Manufacturer : (example: Medical Assistant System)
- 2. Address Of Legal Manufacturer : (example: Jalan Ampang)
- 3. Post Code/zip Code : (example: 53300)
- 4. Country : (dropdown menu)


To the right of the form is a vertical sidebar titled "Application Details" with a list of sections:

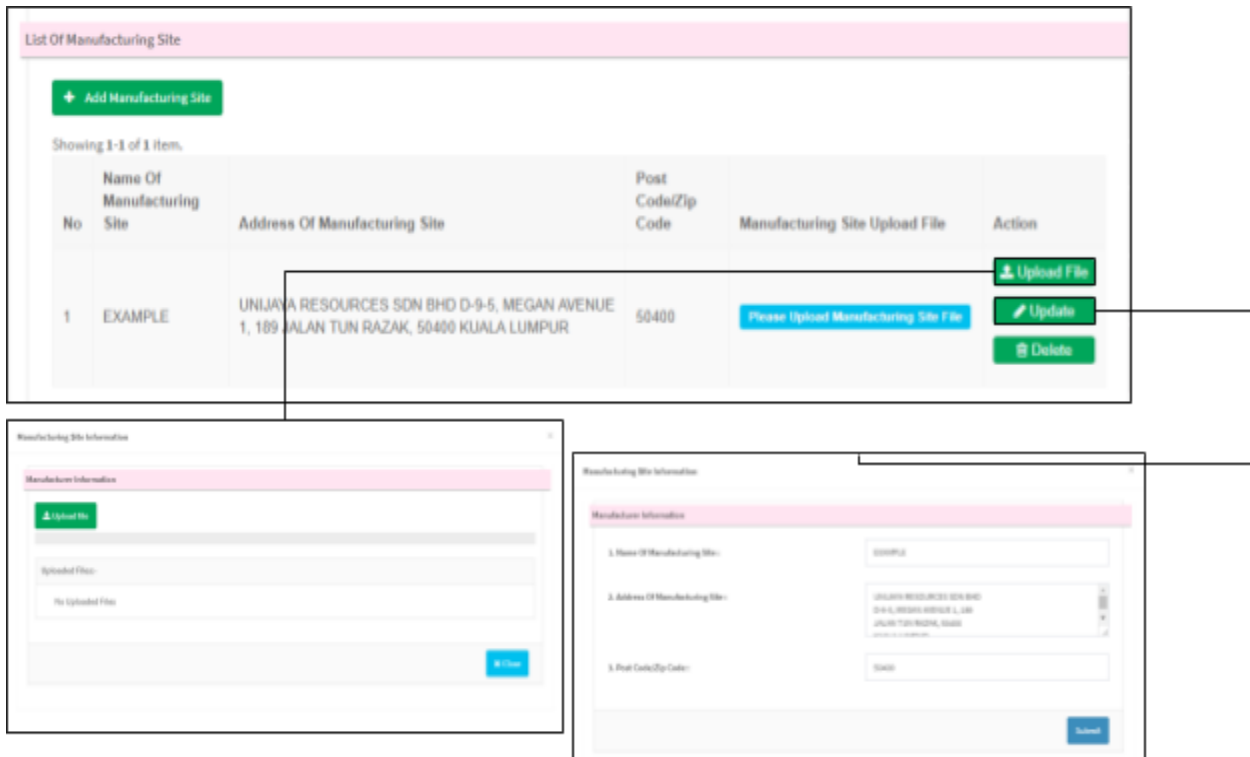
- SECTION 1 : MEDICAL DEVICE CLASSIFICATION
- SECTION 2 : DETERMINE IF THE PRODUCT A MEDICAL DEVICE
- SECTION 3 : GENERAL INFORMATION
- SECTION 4 : MEDICAL DEVICE GROUPING
- SECTION 5 : ADDITIONAL REQUIREMENTS
- SECTION 6 : MANUFACTURER INFORMATION (highlighted in dark red)

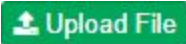

The "Country" dropdown menu is expanded, showing a list of countries including: AFGHANISTAN, ALBANIA, ALGERIA, ANDORRA, ANGOLA, ANGUILLA, ANTARCTICA, ANTIGUA AND BARBUDA, ARGENTINA, ARMENIA, ARUBA, AUSTRALIA, AUSTRIA, AZERBAIJAN, BAHAMAS, BAHRAIN, BANGLADESH, BARBADOS, and BELARUS.





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



.User fill all text boxes and then user select date in 'Issuance Date' and 'Expiry Date' calendar text box or user can write the date using **YYYY-MM-DD** format. Click at  to upload file. **The file must be pdf format and size not more than 300 MB.(If necessary)**





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

No	Name Of Manufacturing Site	Address Of Manufacturing Site	Post Code/Zip Code	Manufacturing Site Upload File	Action
1	EXAMPLE	UNIJAYA RESOURCES SDN BHD D-9-5, MEGAN AVENUE 1, 189 JALAN TUN RAZAK, 50400 KUALA LUMPUR	50400	TEST.pdf 	  

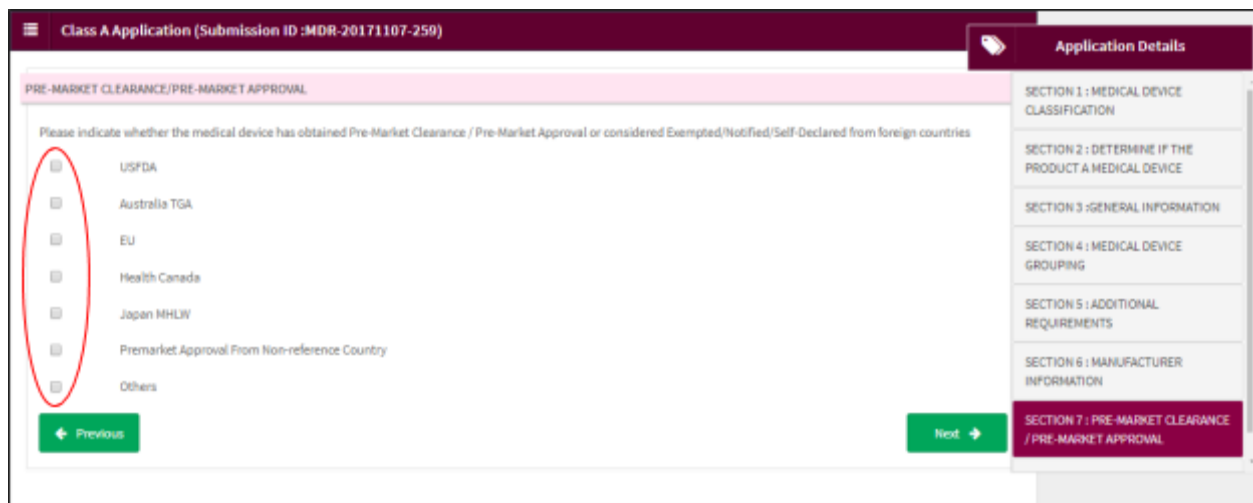
Click  to update the data.

Click  to delete the data.

Click  to go to the next section.

Click  to go to the previous section.

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

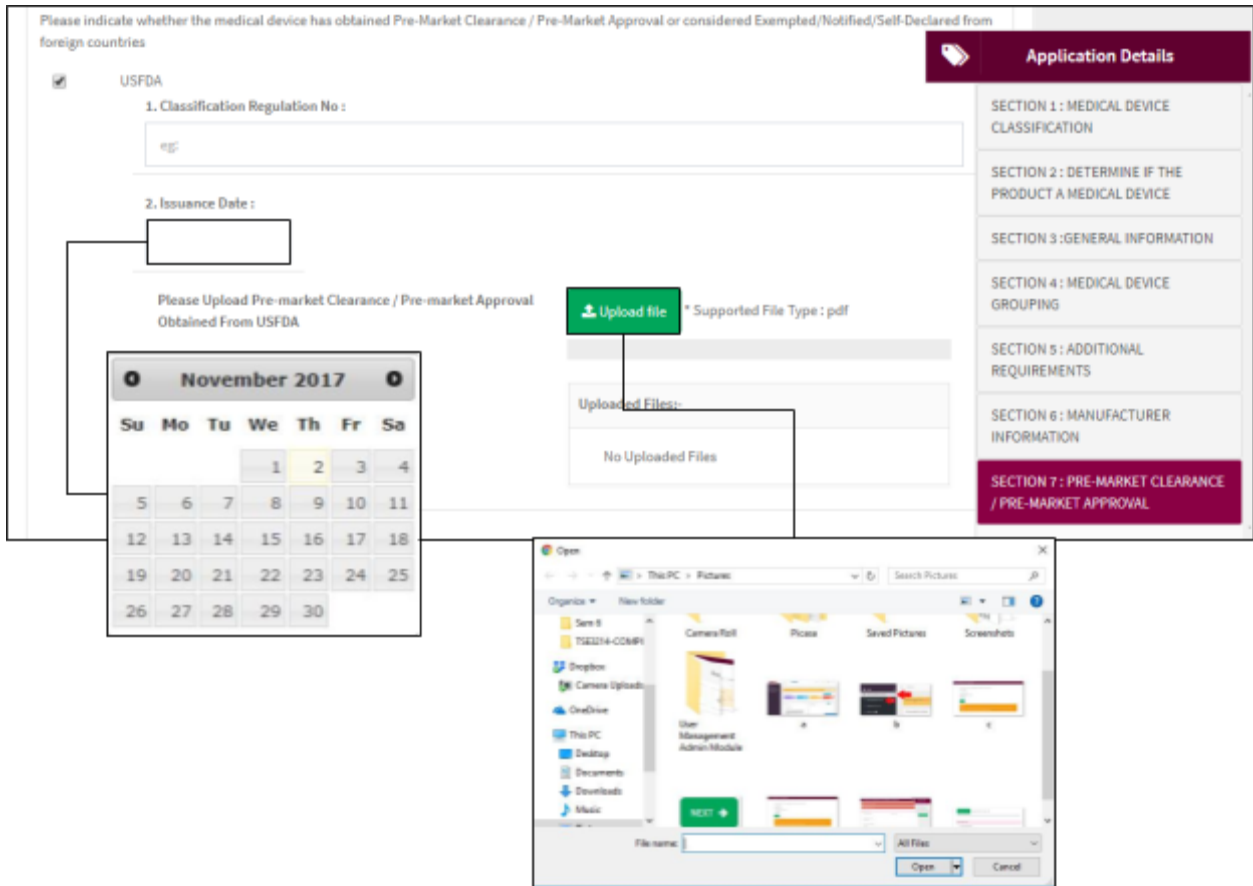


User tick checkbox in red circle (if necessary) and user can tick more than one checkbox. If

not, user click  to skip this section.

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

i) 'USFDA' checkbox.

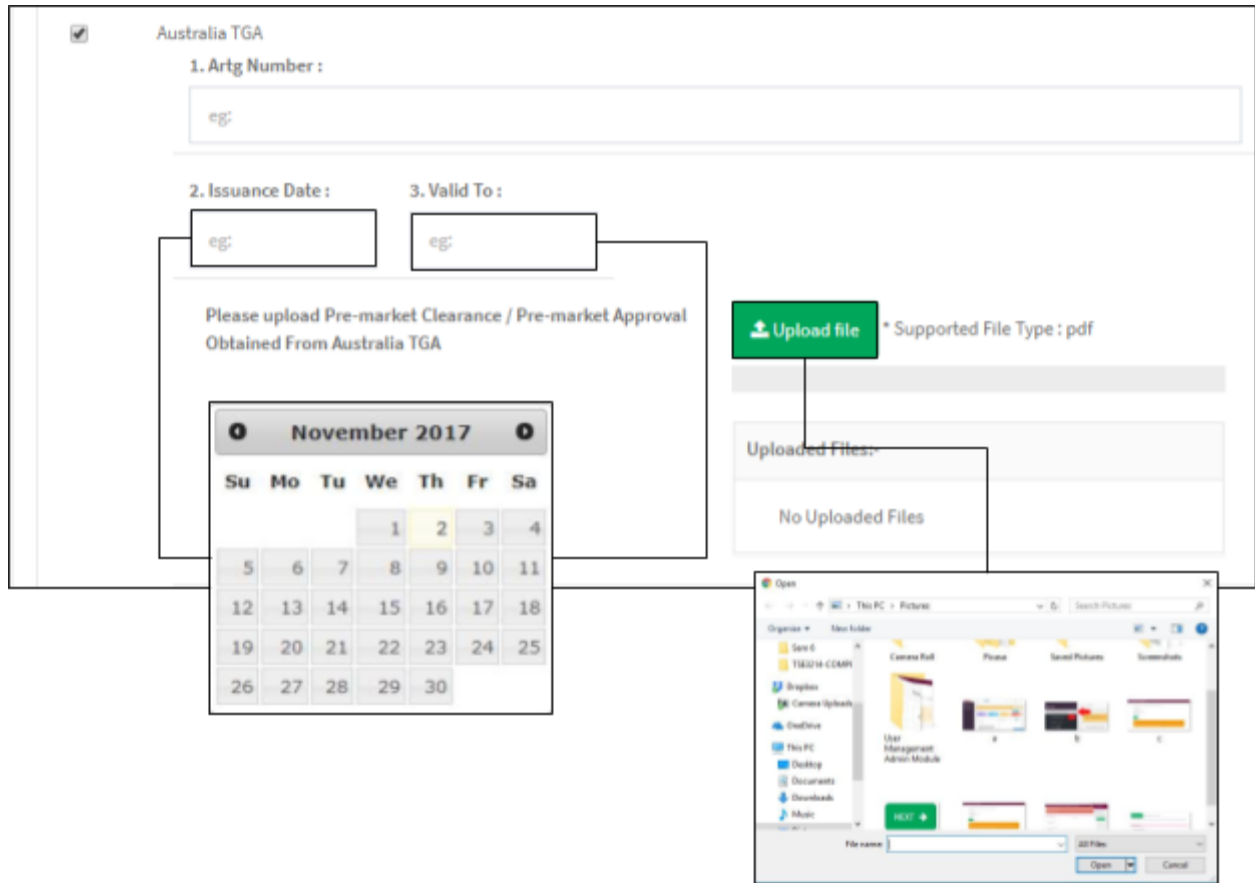


User fill 'Classification Regulation No' text box.

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

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

ii) 'Australia TGA' checkbox.

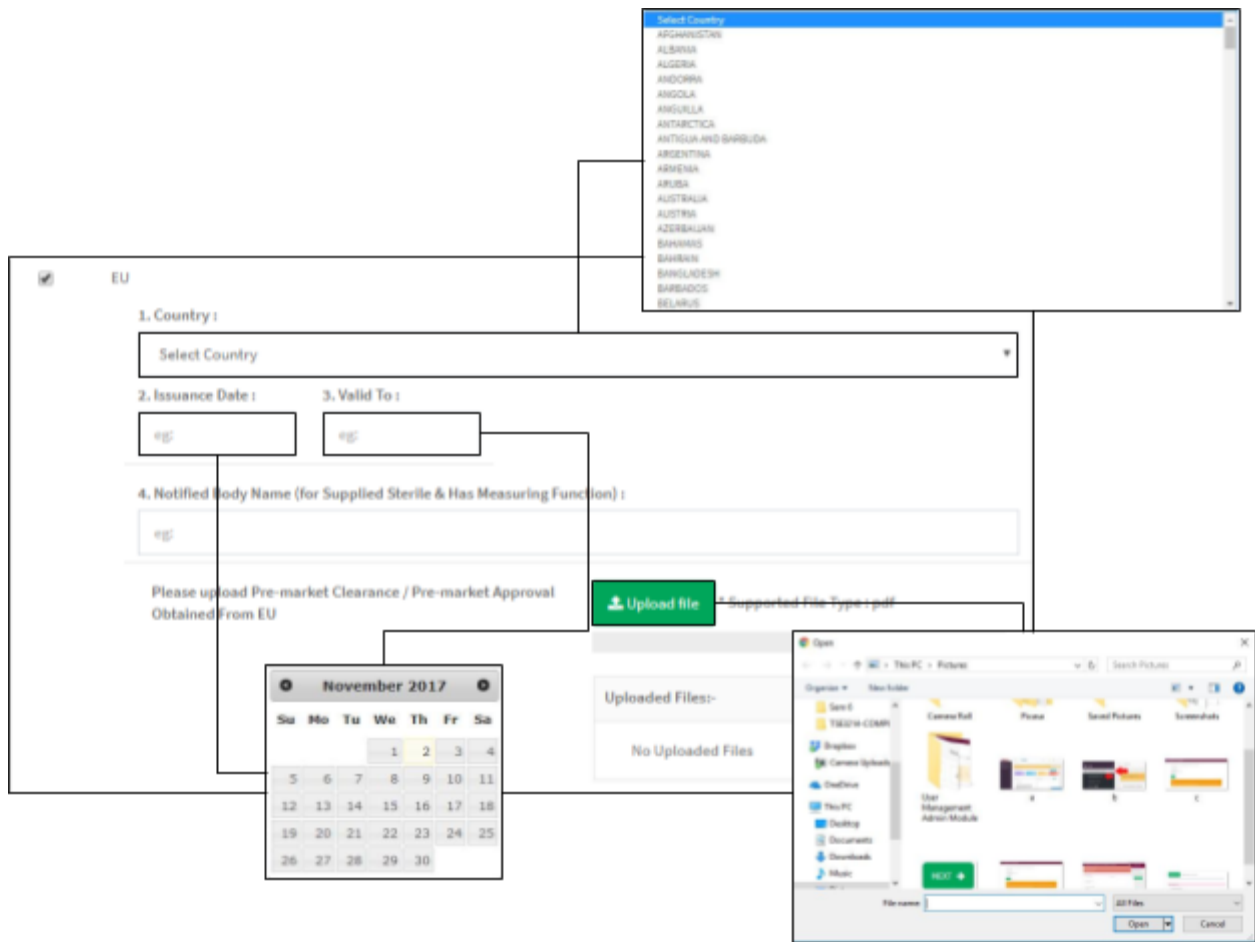


User fill ' Artg Number' textbox.

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

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

iii) 'EU' checkbox.



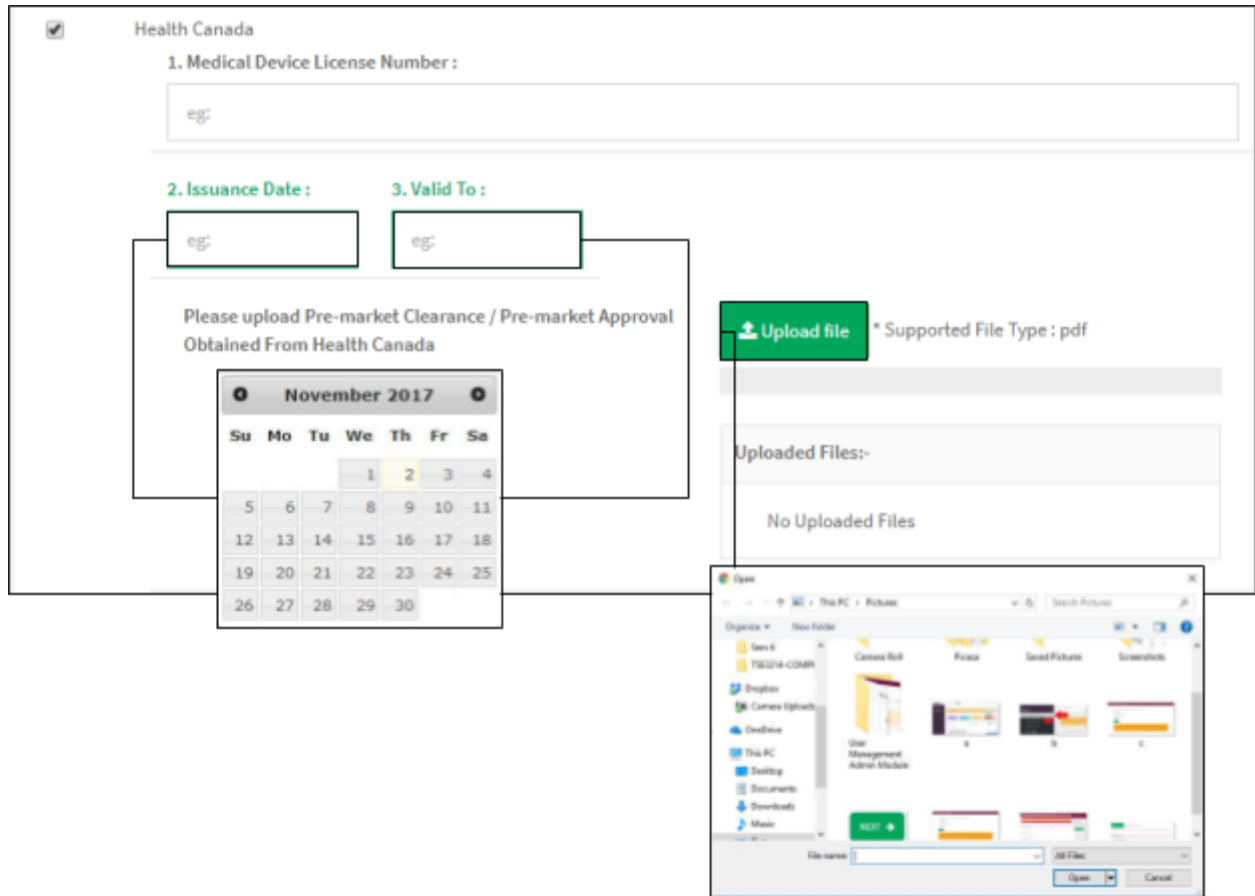
User select from 'Country' dropdown text box.

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

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


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

iv) 'Health Canada' checkbox.

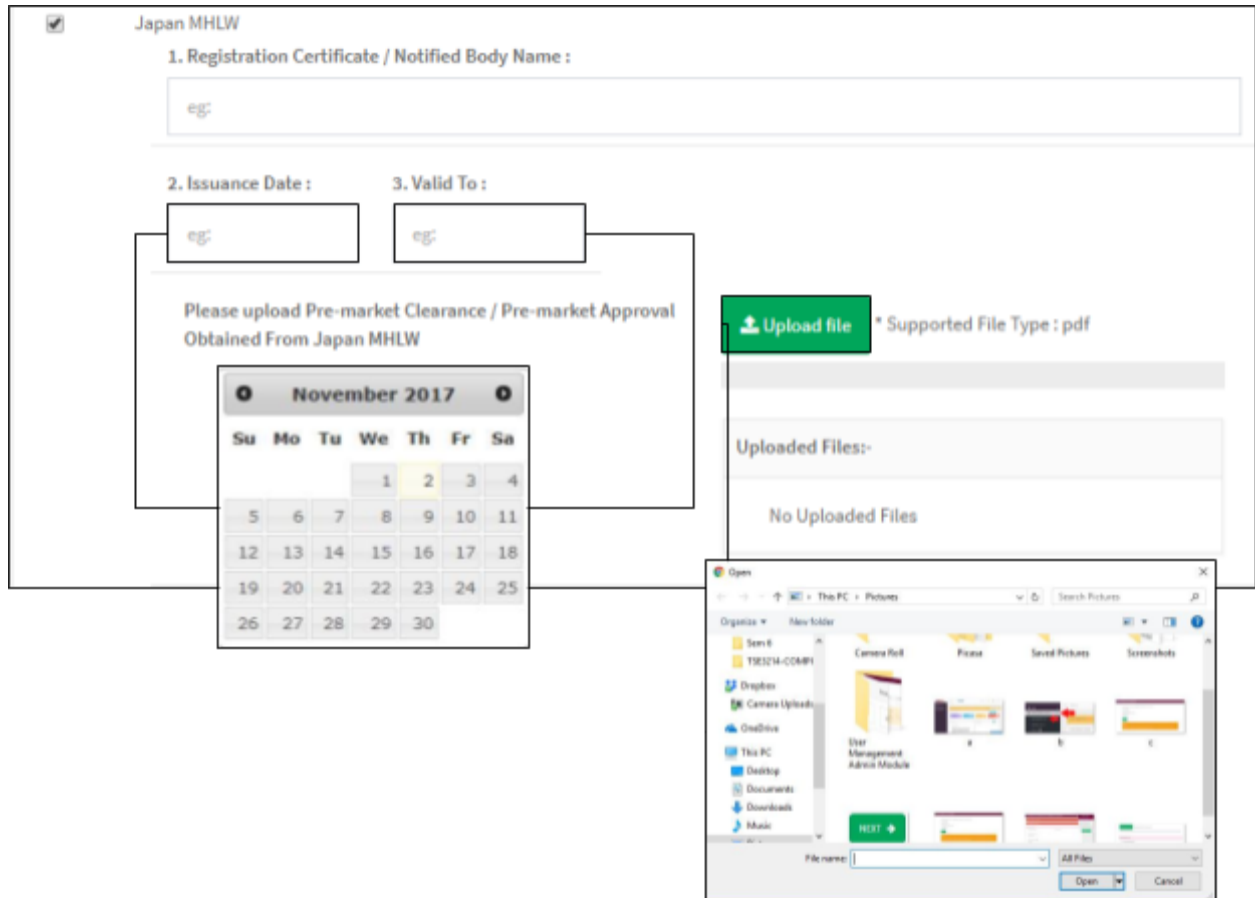


User fill 'Medical Device License Number' text box.

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

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

v) 'Japan MHLW' checkbox.

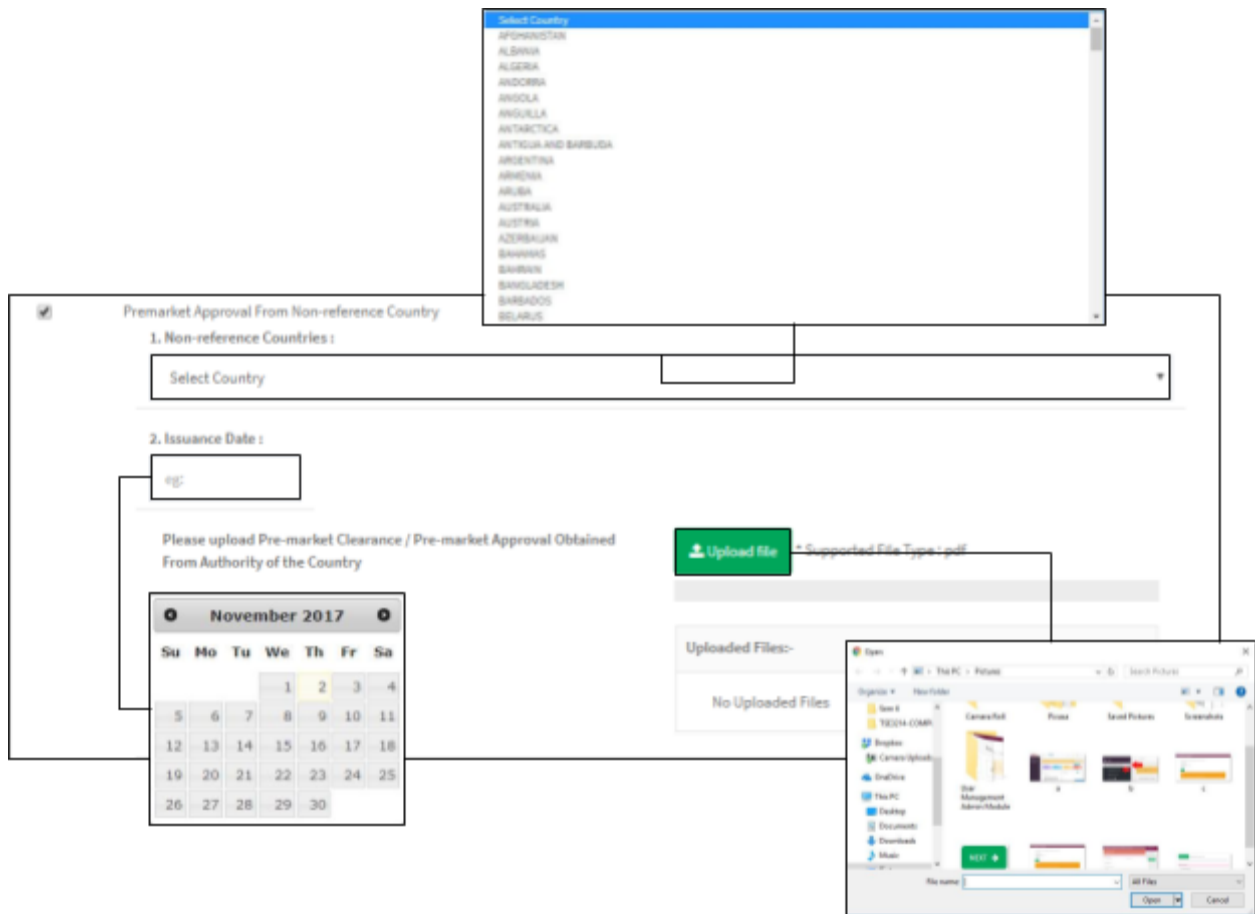


User fill 'Registration Certificate / Notified Body Name' text box.

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

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

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



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

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


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


vii) 'Others' checkbox.



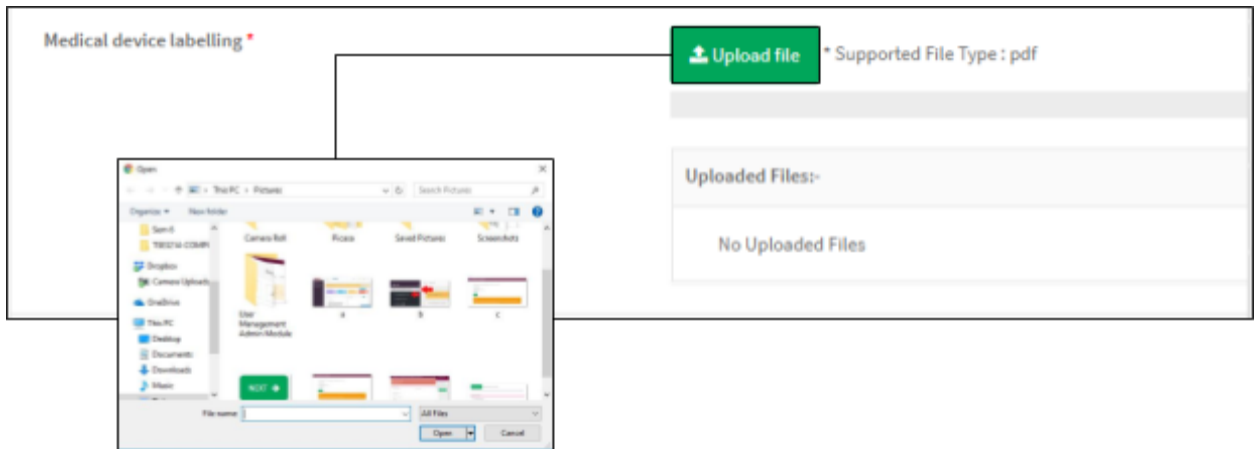
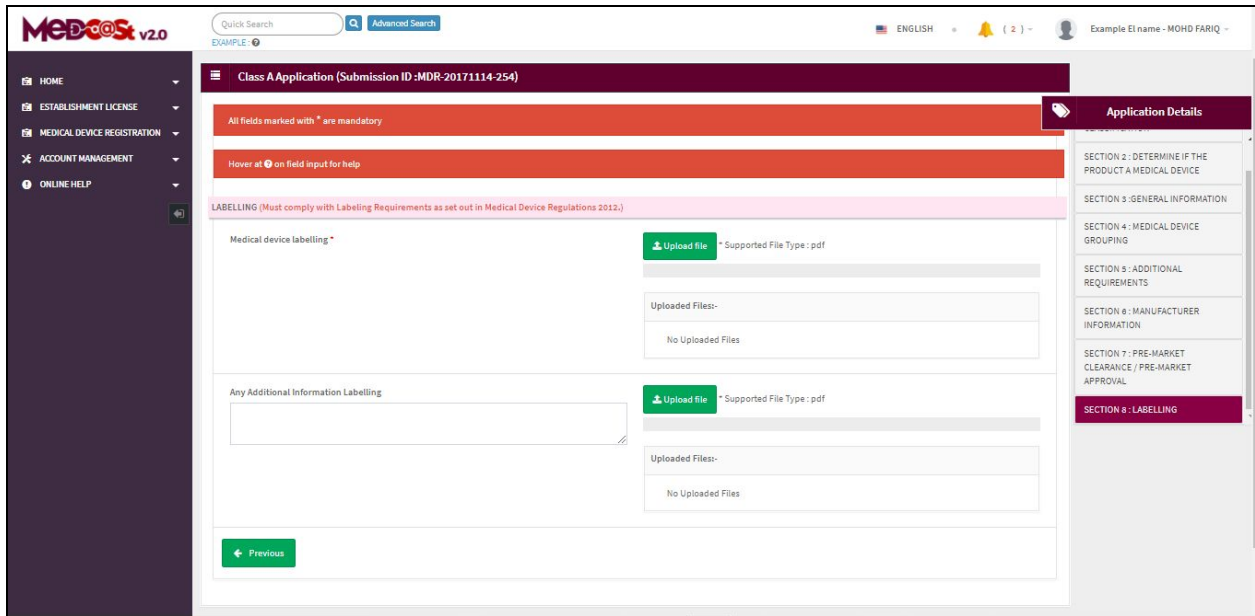
The screenshot shows a form with a checked checkbox labeled 'Others'. Below the checkbox is a text box with the label '1. Please Specify :'. The text box is empty and has a thin border.


User has to fill 'Please Specify' text box.

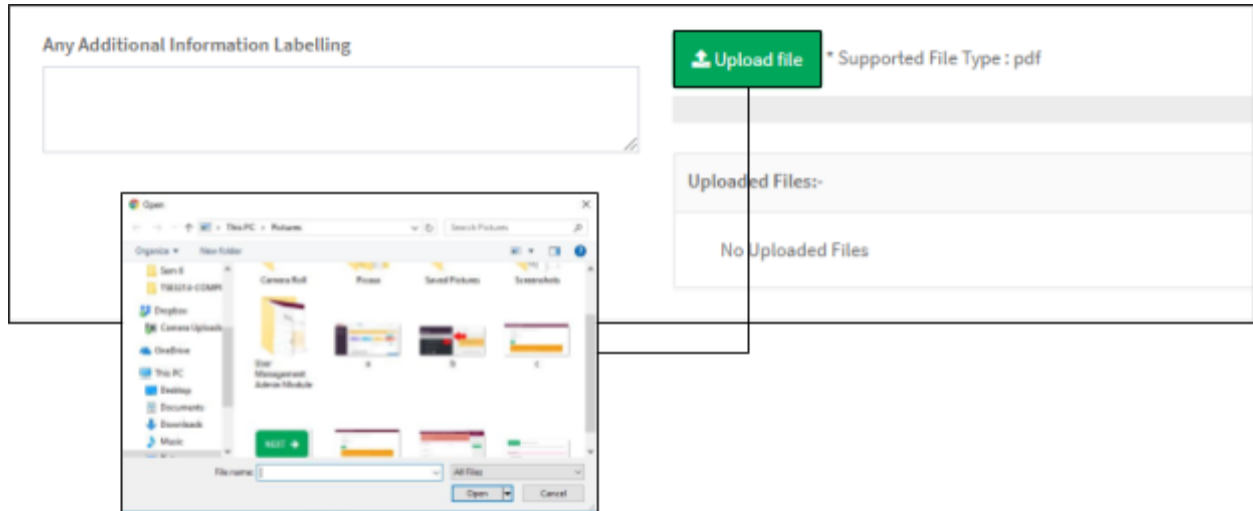
Click  to go to the next section.

Click  to go to the previous section.

Next, user will go to SECTION 8 : LABELLING page





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



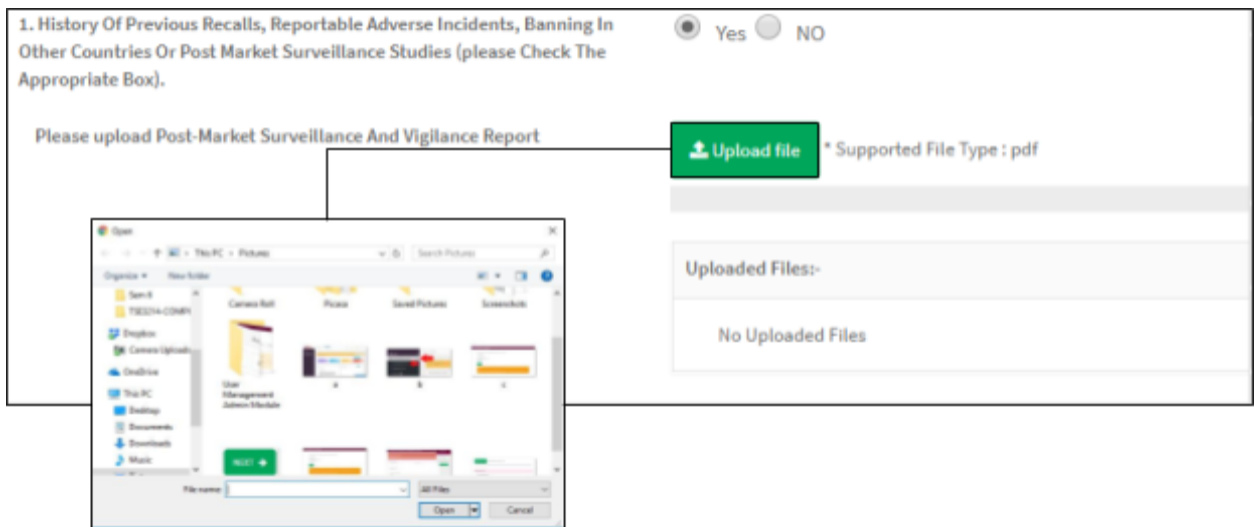
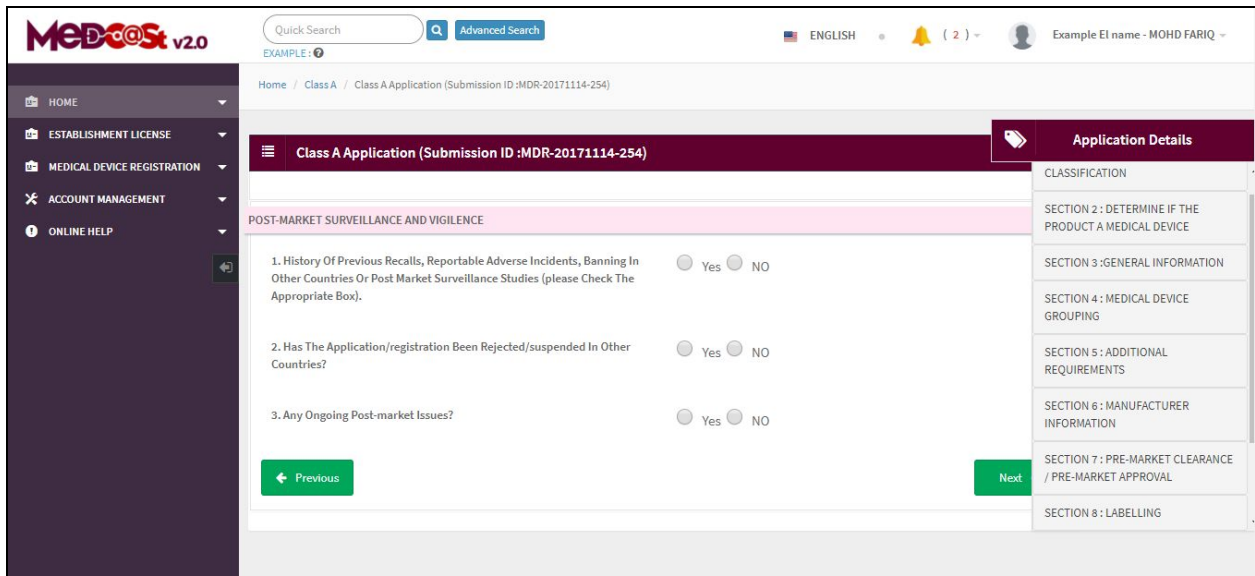
User fill 'Any Additional Information Labelling' text box. **(If necessary)**


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

Click  to go to the next section.

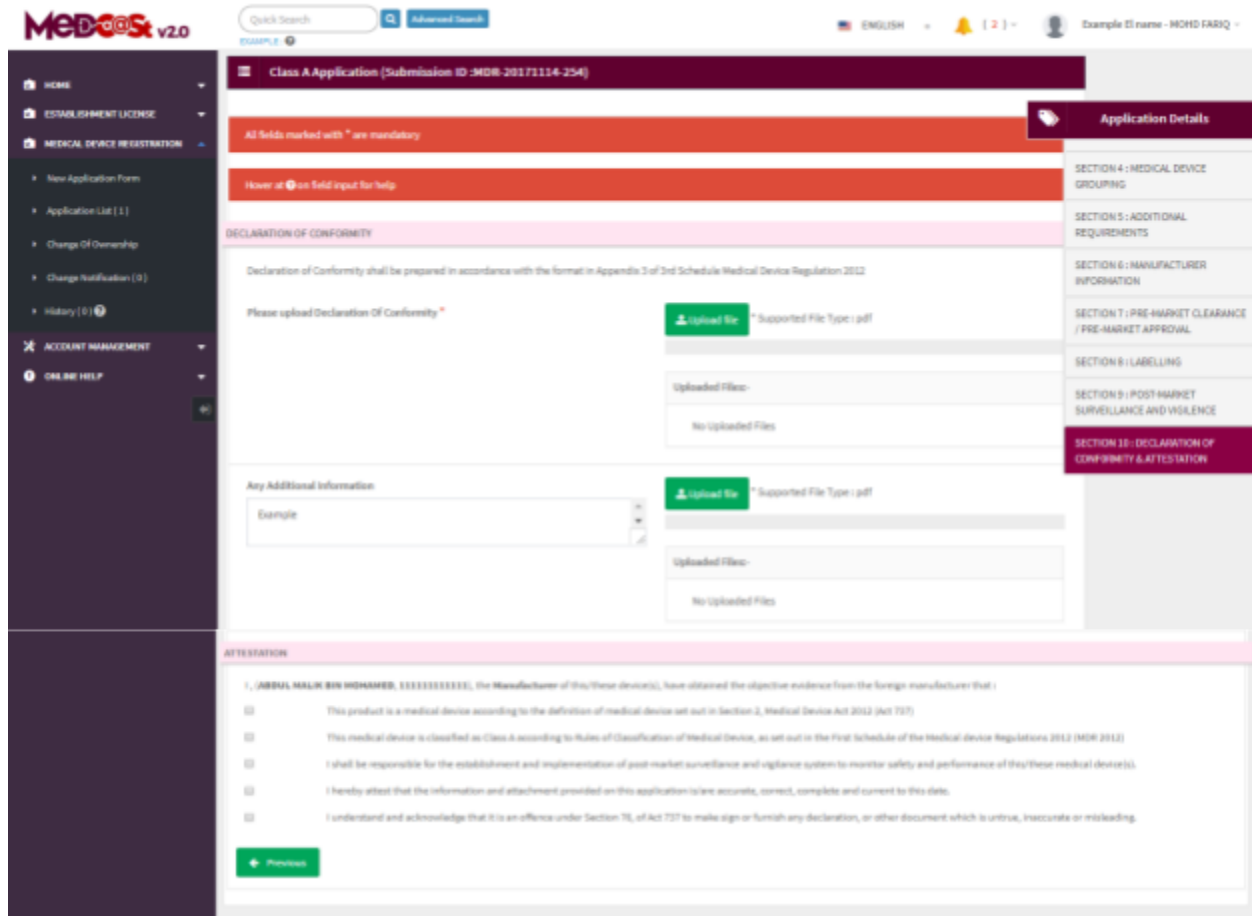
Click  to go to the previous section.

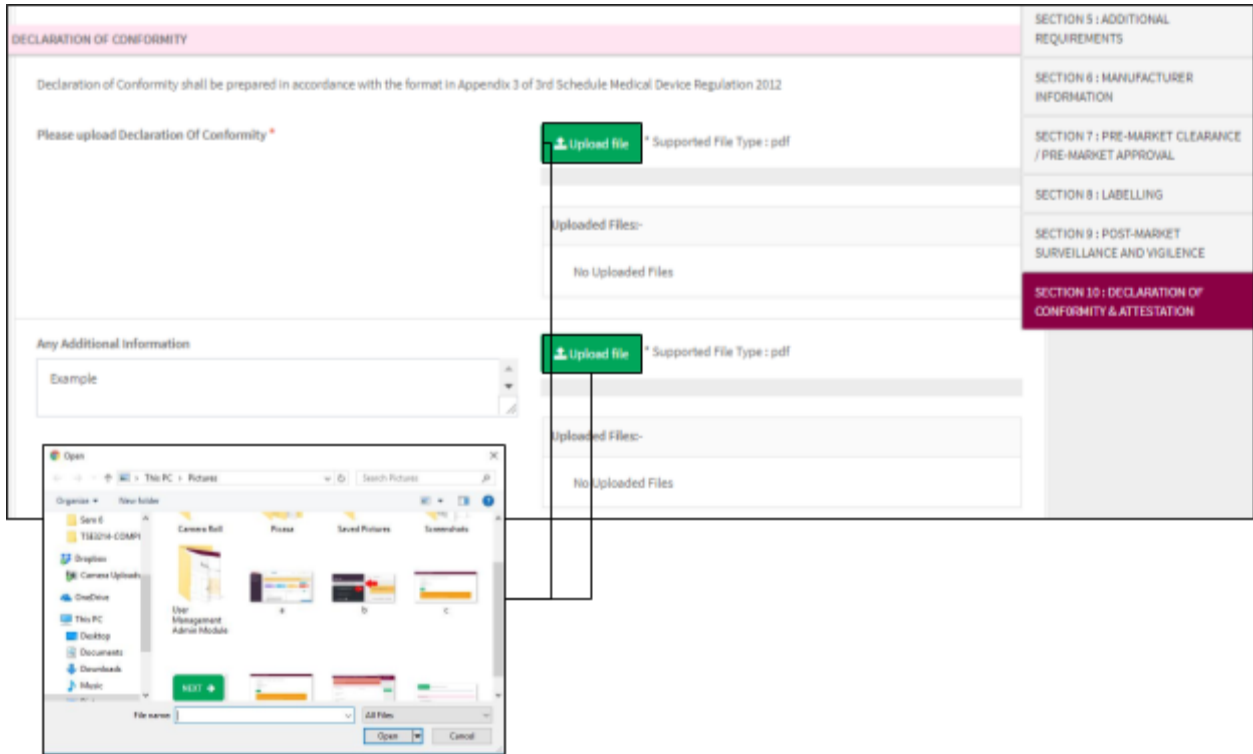
The diagram below show SECTION 9 : POST -MARKET SURVEILLANCE AND VIGILENCE




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

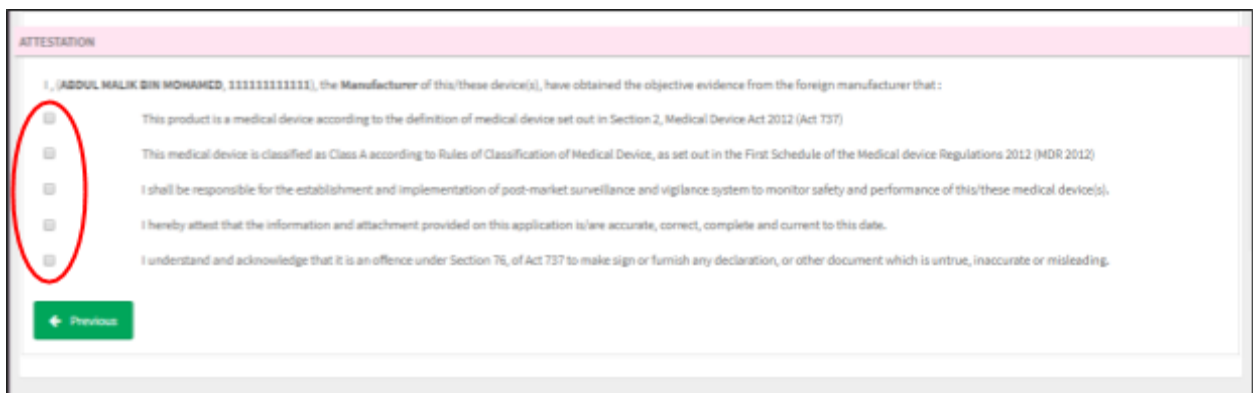
Next, user will go to SECTION 10 : DECLARATION OF CONFORMITY & ATTESTATION page.






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

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

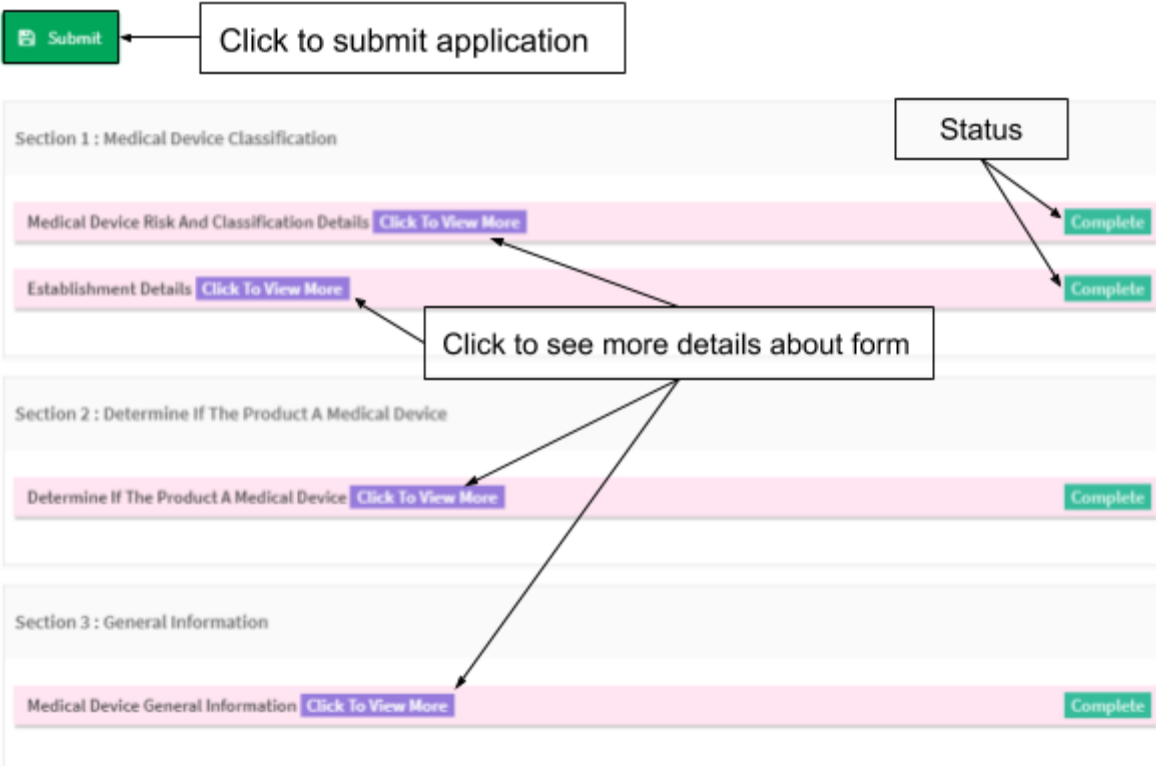


User has to tick all the checkbox before user can submit application.

 PREVIEW & SUBMIT

User click  to preview before submit application.

MDR Class A Application (SUBMISSION ID : MDR-20171114-254)





The screenshot shows a web application interface for an MDR Class A Application. At the top left, there is a green 'Submit' button with a document icon. A callout box labeled 'Click to submit application' points to this button. Below the button, the form is organized into sections:

- Section 1 : Medical Device Classification**
 - Medical Device Risk And Classification Details: [Click To View More](#) (with a 'Complete' status indicator)
 - Establishment Details: [Click To View More](#) (with a 'Complete' status indicator)
- Section 2 : Determine If The Product A Medical Device**
 - Determine If The Product A Medical Device: [Click To View More](#) (with a 'Complete' status indicator)
- Section 3 : General Information**
 - Medical Device General Information: [Click To View More](#) (with a 'Complete' status indicator)

A central callout box labeled 'Click to see more details about form' has arrows pointing to each of the 'Click To View More' links. A 'Status' label at the top right has arrows pointing to the 'Complete' status indicators for the first two items in Section 1.

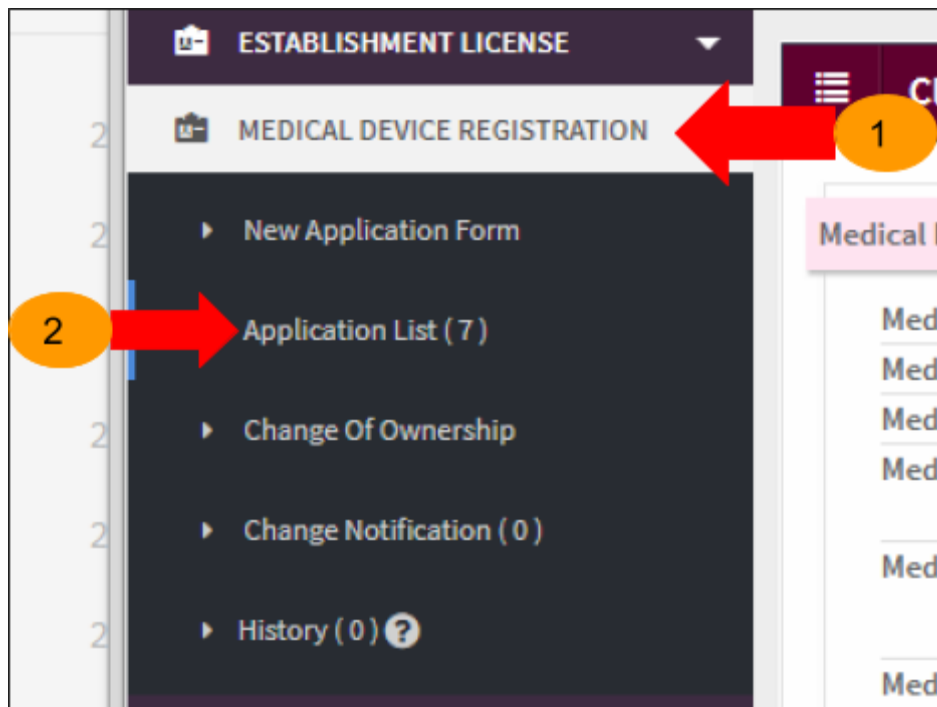
has

Submission only can do if all form status is . If status , user has to complete the form.

Then, click  to submit application.

4.0 CHANGE OF NOTIFICATION APPLICATION

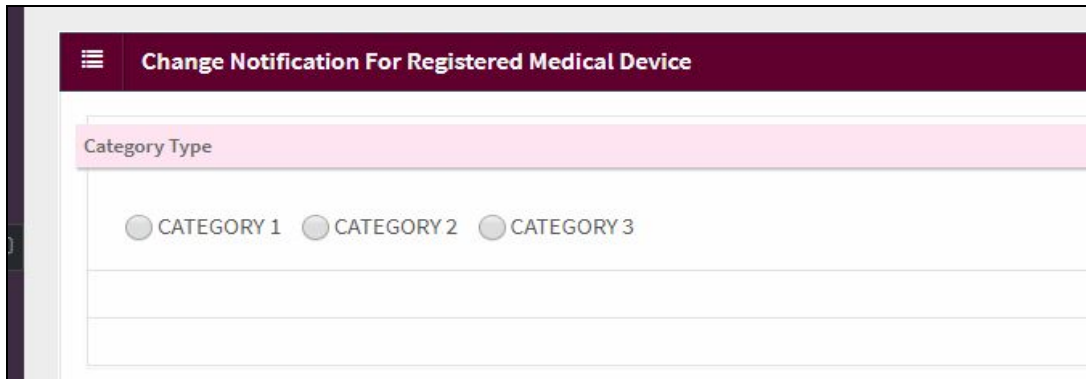
User go to *Application List* page to change of notification application.



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

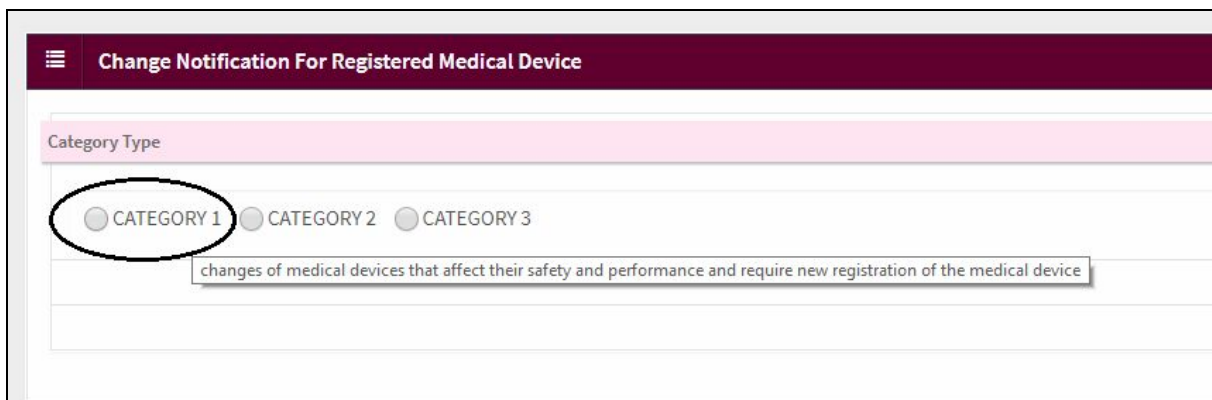
6	MDR-20171121-262	NEW REGISTRATION	21-11-2017	MANUFACTURER	CLOWIE	A	GENERAL MEDICAL DEVICE (GMD)	COMPLETE	<div style="display: flex; flex-direction: column; gap: 5px;"> Withdraw Application View ReRegister PA Advice & Receipt Withdrawal Certificate + Change Of Notification </div>
---	------------------	--	------------	--------------	--------	---	------------------------------	----------	--

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



The screenshot shows a web interface for creating a change notification. At the top, there is a dark red header with a hamburger menu icon and the text "Change Notification For Registered Medical Device". Below the header is a light pink section titled "Category Type". Underneath, there are three radio button options: "CATEGORY 1", "CATEGORY 2", and "CATEGORY 3".

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



This screenshot is similar to the previous one, but it shows a tooltip for the "CATEGORY 1" radio button. The radio button is circled in black, and a white tooltip box with a grey border appears below it, containing the text: "changes of medical devices that affect their safety and performance and require new registration of the medical device".

The user can select more than one type of changes.

Category Type

CATEGORY 1 CATEGORY 2 CATEGORY 3

[SELECT TYPE OF CHANGES]

Change in manufacturing facility, process and quality management system (QMS)

All changes to certificates for manufacturing and sterilisation facilities

Documentation Requirements	Provided?		Upload document (applicable field)
	Yes	No	
Valid certificate and report.	<input type="radio"/>	<input checked="" type="radio"/>	Please provide justification if no is selected

Unless the change only—

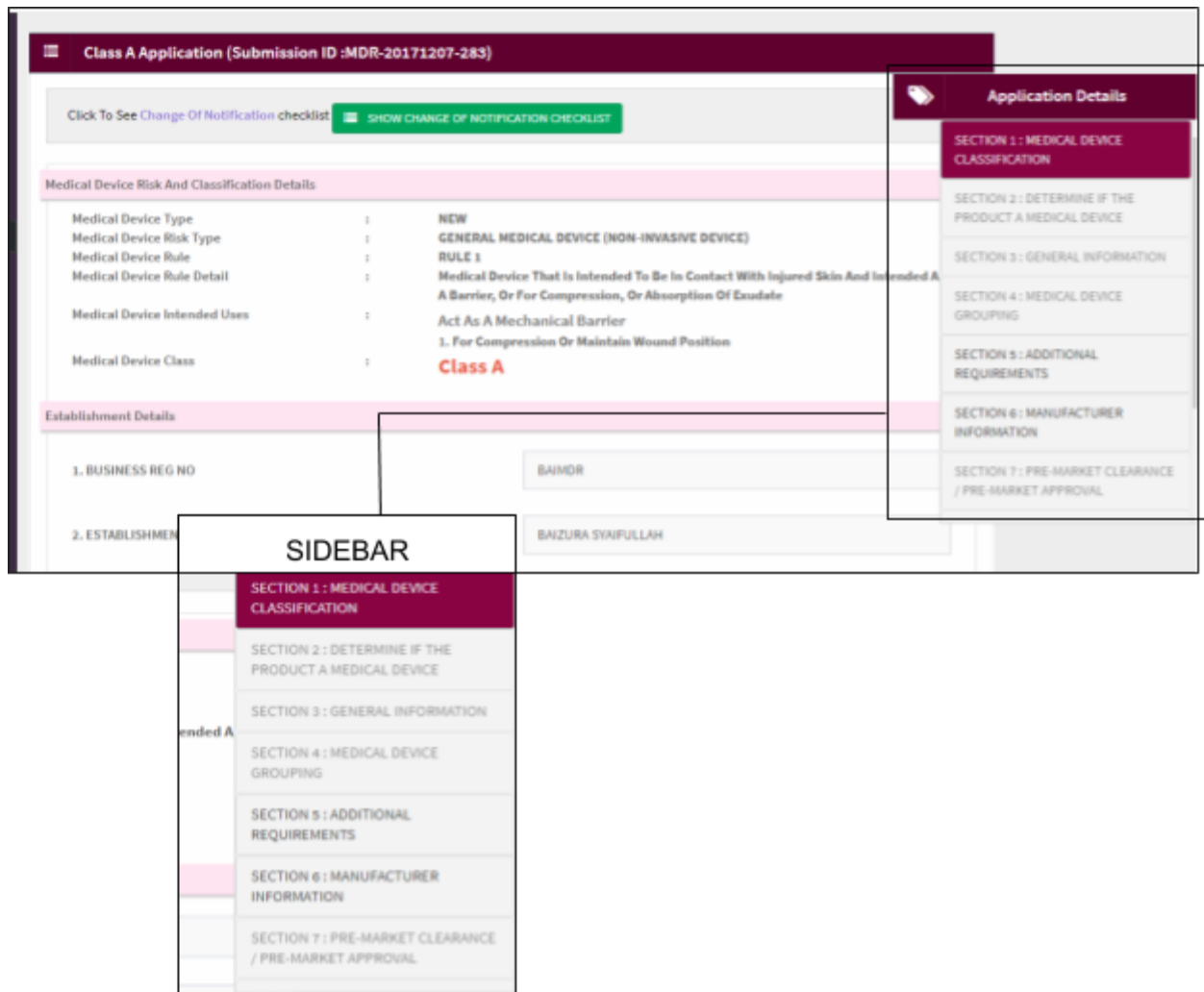
i) Involves an update of certificate QMS validity date only
 OR
 ii) Involves an update of QMS

Documentation Requirements	Provided?		Upload document (applicable field)
	Yes	No	
Valid QMS certificate	<input type="radio"/>	<input checked="" type="radio"/>	Please provide justification if no is selected

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

PROCEED TO REGISTRATION APPLICATION CHANGE OF NOTIFICATION

Then, click to proceed the registration of the change of notification application.



To edit a certain section, the user can click [Next](#) to go to the editable section or click the sidebar to go directly to the editable section.

The diagram below show SECTION 5 : ADDITIONAL REQUIREMENT that need to be change. User can tick checkbox other than previous in other to make a change and user can tick more



than one checkbox. If not, user click to go to next section.

Click To See [Change Of Notification checklist](#)
SHOW CHANGE OF NOTIFICATION CHECKLIST

Additional Requirement

MEASURING FUNCTION
 1.The device is intended by the manufacturer to measure :
 - Quantitatively a physiological or anatomical parameter
 - A quantity or a qualifiable characteristics of energy or of substance delivered to or removed from the human body

 2.The result of the measurement :
 - Is displayed in legal units or other acceptable units
 - Is compared to at least one point of reference indicated in legal units or other acceptable units

 3.The intended purpose implies accuracy, where a non-compliance with the implied accuracy could result in a significant adverse effect on the patient's health and safety

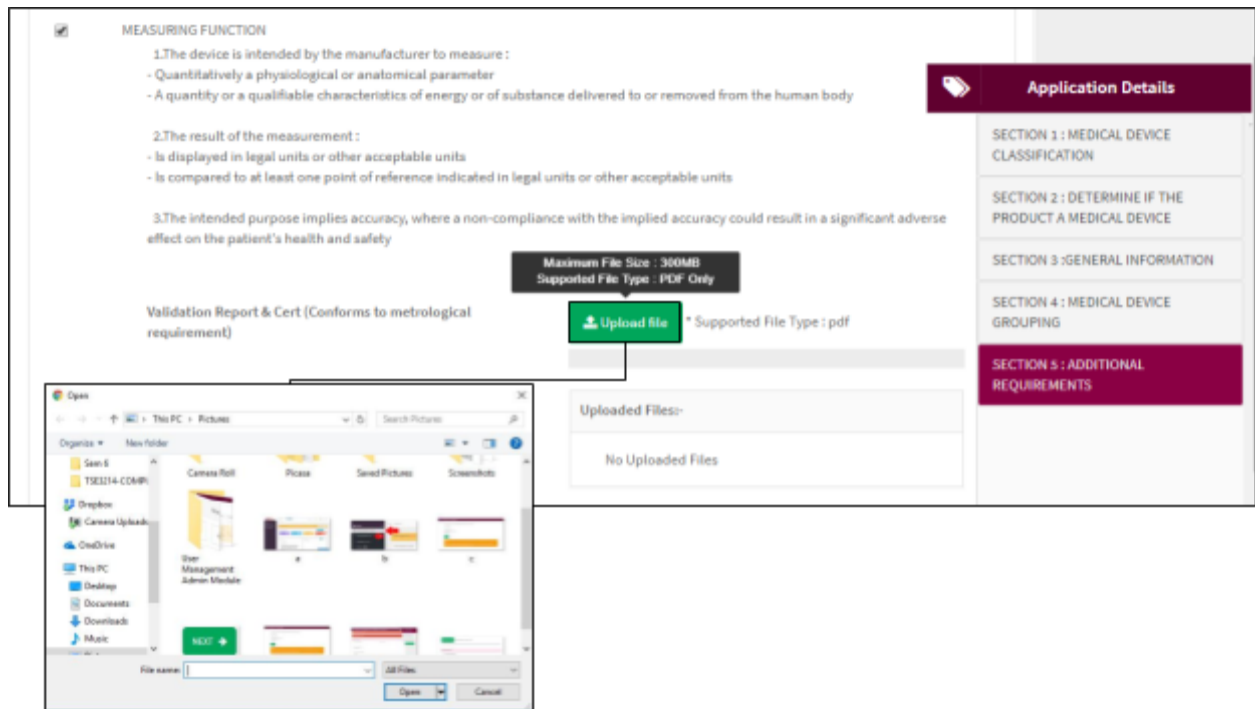
 Validation Report & Cert (Conforms to metrological requirement)

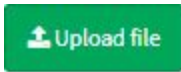
Upload file * Supported File Type : pdf

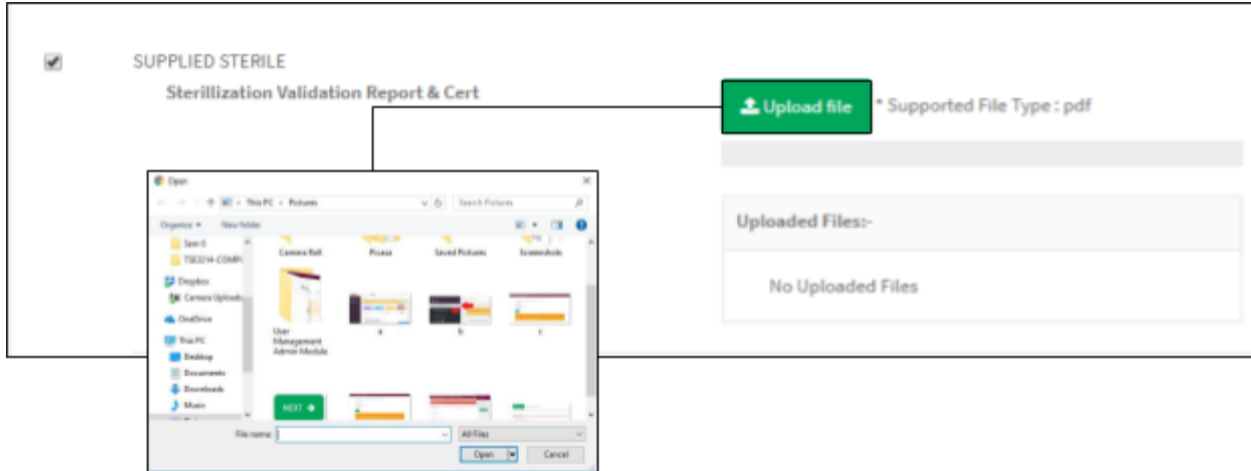
Uploaded Files:-


150537297259ba2b2c300cc5.41407858.pdf
📄 ✖

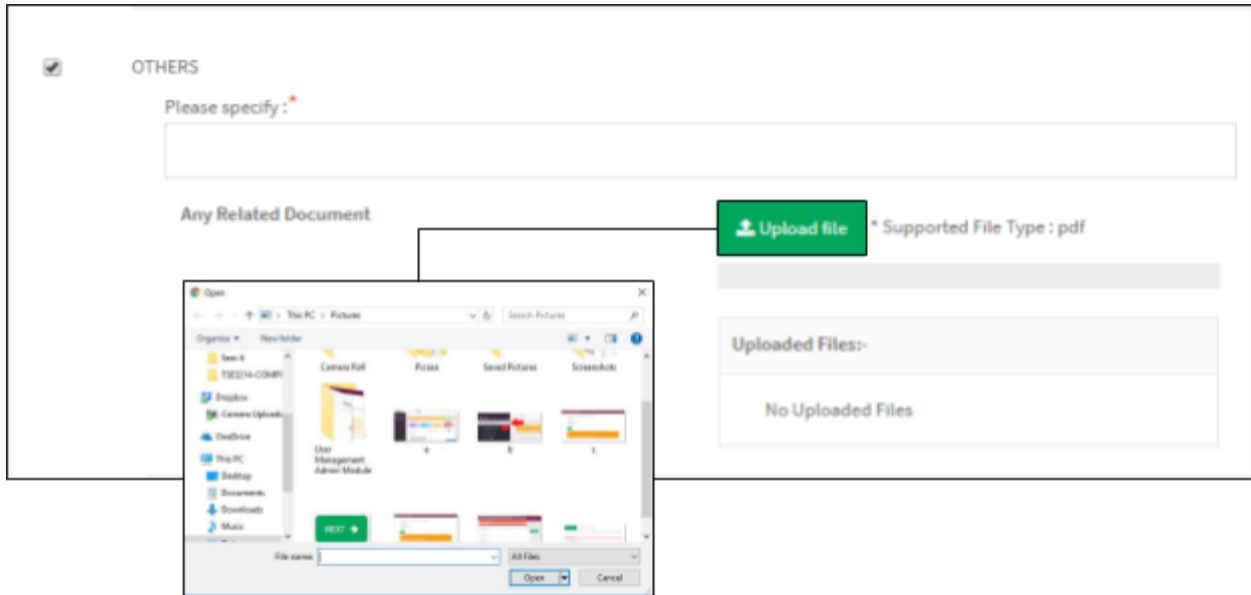
SUPPLIED STERILE
 OTHERS
 ACTIVE
 CONTAIN ANIMAL, HUMAN, MICROBIAL, RECOMBINANT ORIGIN (IVD)




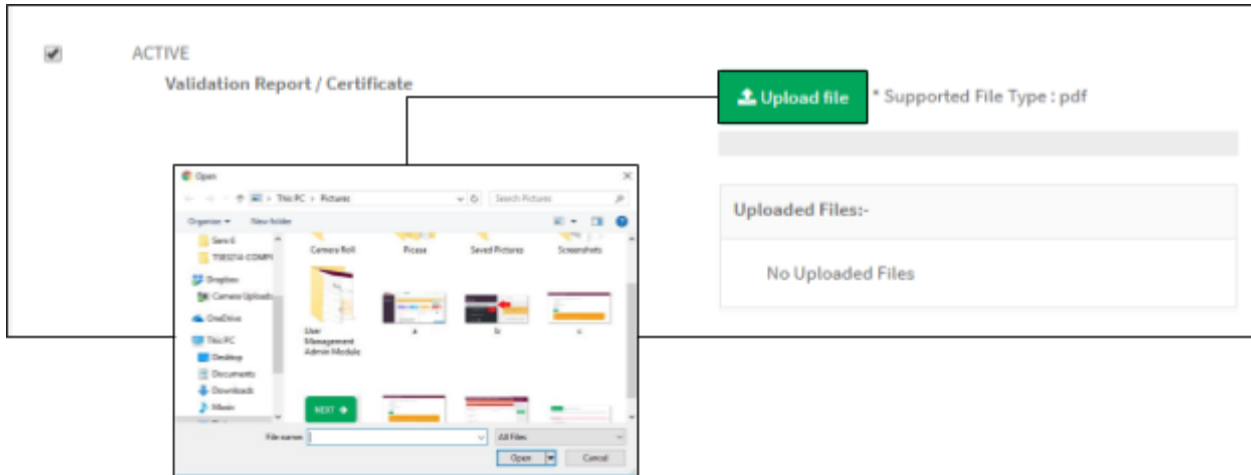
User click  to change the old upload file to the new upload file. **The file must be pdf format and size not more than 300 MB.**



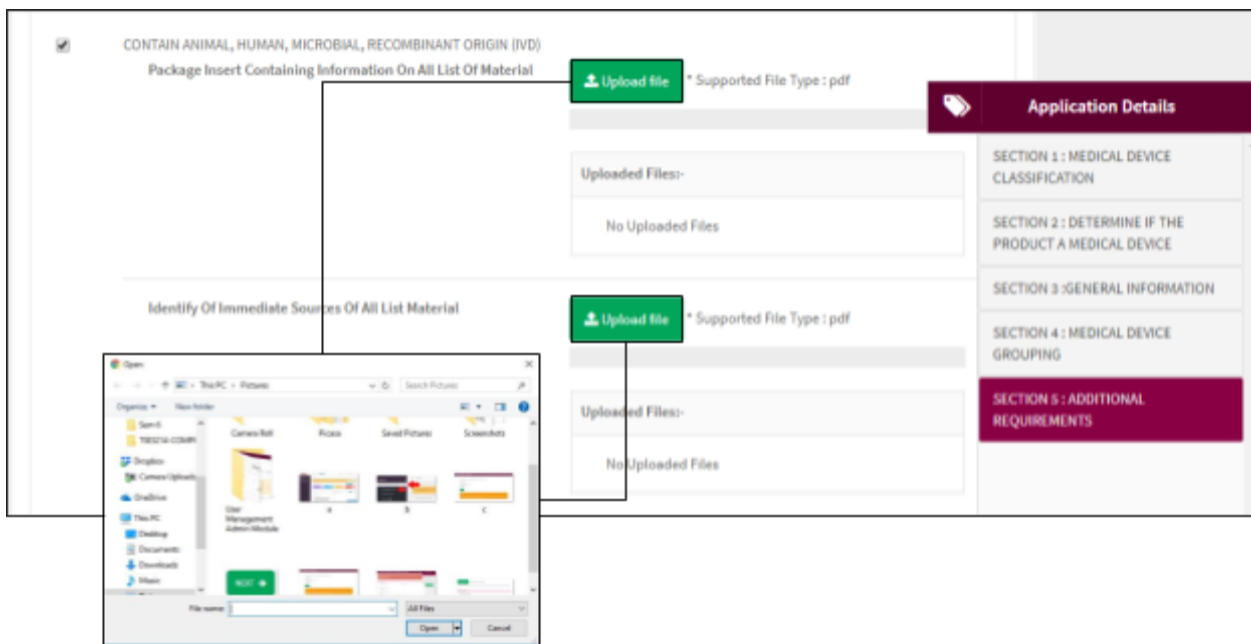
User click  to upload file. **The file must be pdf format and size not more than 300 MB.**

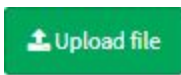


User has fill 'Please specify' text box first then click  to upload file. **The file must be pdf format and size not more than 300 MB.**




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



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

The user can click  to go to the editable section

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

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

The screenshot displays the 'Manufacturer Information' section with the following details:

- 1. Name Of Manufacturer : II
- 2. Manufacturer Registration No : FFRICAB
- 3. Name Of Registered Manufacturer Auditor : SHB HAN ENBU HAMBAL
- 4. Certificate Expiry Date : 2020-12-31

The 'Quality Management System Information' section shows a 'Quality Management System Certificate' field and an 'Uploaded Files' list containing:

- IKLAL_MDU_2017.PDF
- A737-Q4LPDF

The 'List Of Manufacturing Site' table is shown with one entry:

Name Of Manufacturing Site	Address Of Manufacturing Site	Post Code/Zip Code	Manufacturing Site Upload File	Action
M33-EN	LOT M 12, MEZZANINE CENTRE, AMPANG POINT, SHOPPING CENTRE, JALAN MAMANDA 3,	54300	15057297295a26a390a0541407058.pdf	Upload File Update Details

The 'Add Manufacturing Site' form contains the following fields:

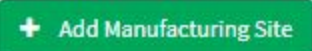


- 1. Name Of Manufacturing Site:
- 2. Address Of Manufacturing Site:
- 3. Post Code/Zip Code:


A 'Submit' button is located at the bottom right of the form.

The 'Update Manufacturing Site' form contains the following fields:

- 1. Name Of Manufacturing Site: M33EN
- 2. Address Of Manufacturing Site: LOT M 12, MEZZANINE CENTRE, AMPANG POINT, SHOPPING CENTRE, JALAN MAMANDA 3,
- 3. Post Code/Zip Code: 54300

A 'Submit' button is located at the bottom right of the form.

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

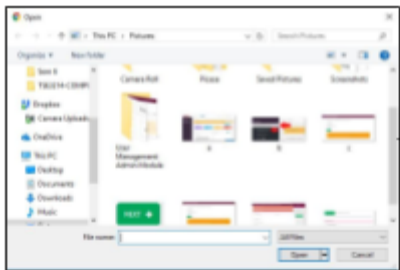
User click  to change the old upload file or to new upload files.

List Of Manufacturing Site

[+ Add Manufacturing Site](#)

Showing 1-1 of 1 items.

No	Name Of Manufacturing Site	Address Of Manufacturing Site	Post Code/Zip Code	Manufacturing Site Upload File	Action
1	M33H0N	LOT M 12, MEZZANINE CENTRE, AMPANG POINT, SHOPPING CENTRE, JALAN MAMANDA 3,	54300	150637297259ba2b2c300cc5 41407658.pdf	+ Add Manufacturing Site Update Delete



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

ATTESTATION

I, (ABDUL MALIK BIN MOHAMED, 111111111111), the Manufacturer of this/these device(s), have obtained the objective evidence from the foreign manufacturer that:

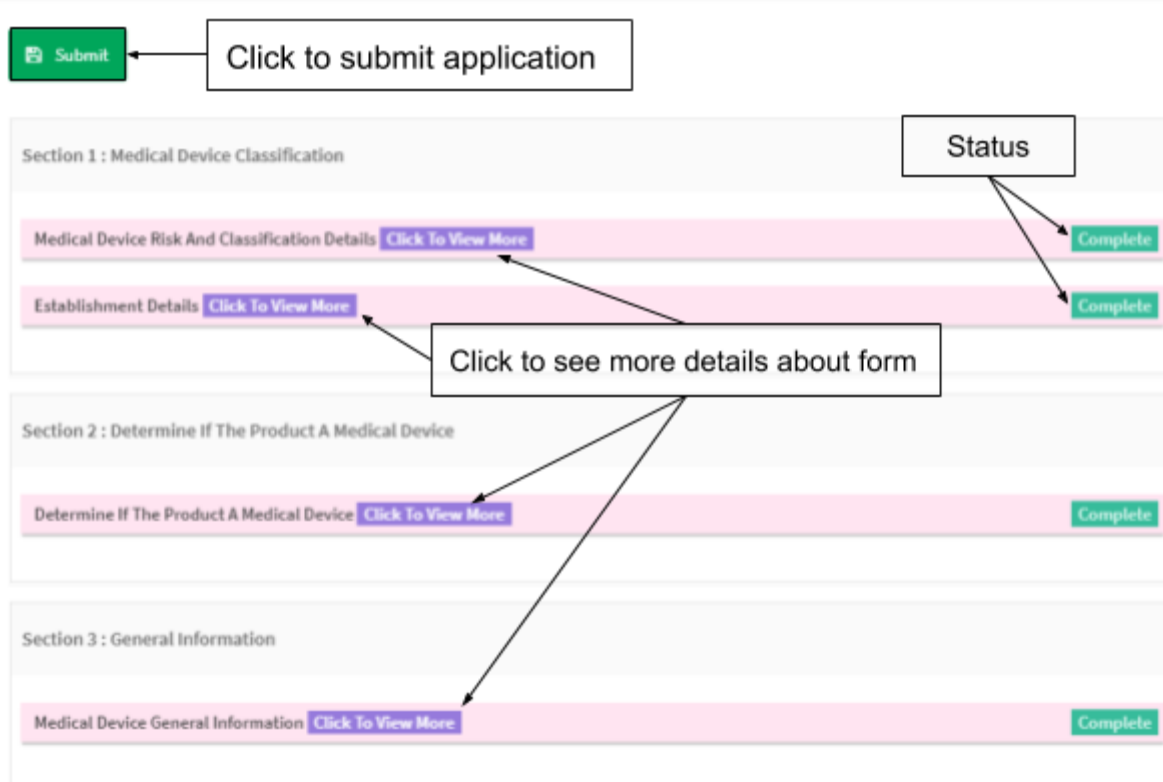
- This product is a medical device according to the definition of medical device set out in Section 2, Medical Device Act 2012 (Act 737)
- This medical device is classified as Class A according to Rules of Classification of Medical Device, as set out in the First Schedule of the Medical device Regulations 2012 (MDR 2012)
- 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](#)

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

User click  to preview before submit application.

MDR Class A Application (SUBMISSION ID : MDR-20171114-254)

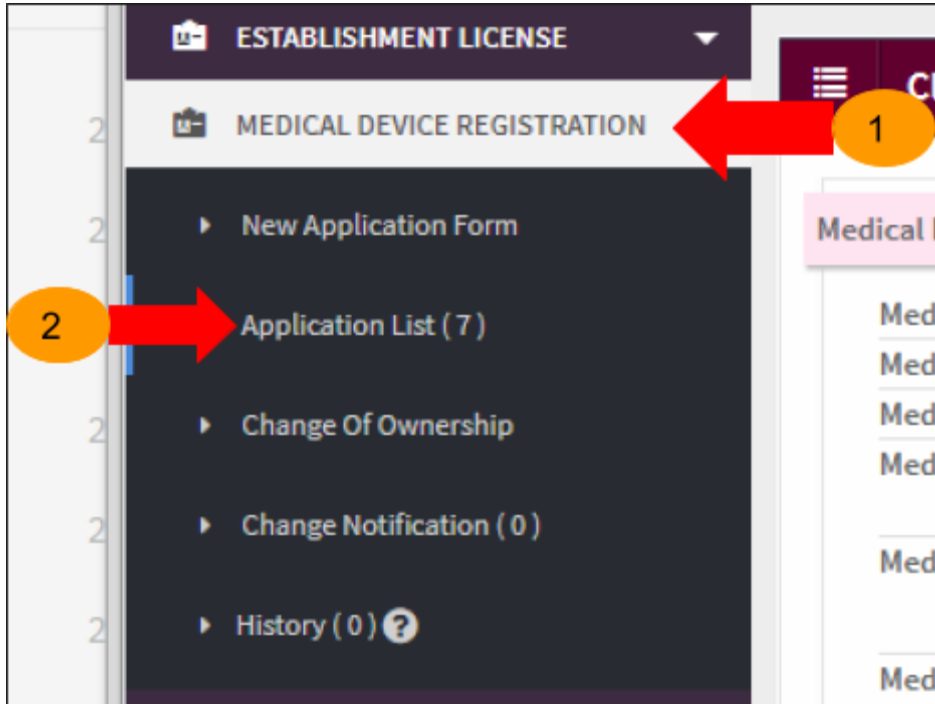


Submission only can do if all form status is **Complete** . If status **Not Complete** , user has to complete the form.

Then, click **Submit** to submit application.

5.0 WITHDRAWAL CERTIFICATE

User go to *Application List* page to withdrawal certificate



The diagram below show *Application List* page. Click [Withdrawal Certificate](#) to withdrawal certificate.

MDR- 20171121- 262	NEW REGISTRATION	21-11-2017	MANUFACTURER	CLOWIE	A	GENERAL MEDICAL DEVICE (GMD)	COMPLETE	Withdrawal Application
								View ReRegister P.Advice & Receipt Withdrawal Certificate Change Of Notification

Medical Device Registration Application

Withdrawal Certificate - [MDR-20171121-262](#)

Medical Device Registration No : MDR-20171121-262

Medical Device Name : CLOVIE

Proprietary Name/Brand : BRAND K

Model : FAMILY OF SYSTEM

Description Of Medical Device


MEDICAL PURPOSE

Intended Use Of Medical Device

MEDICAL PURPOSE

Upload official letter for medical device registration application withdrawal

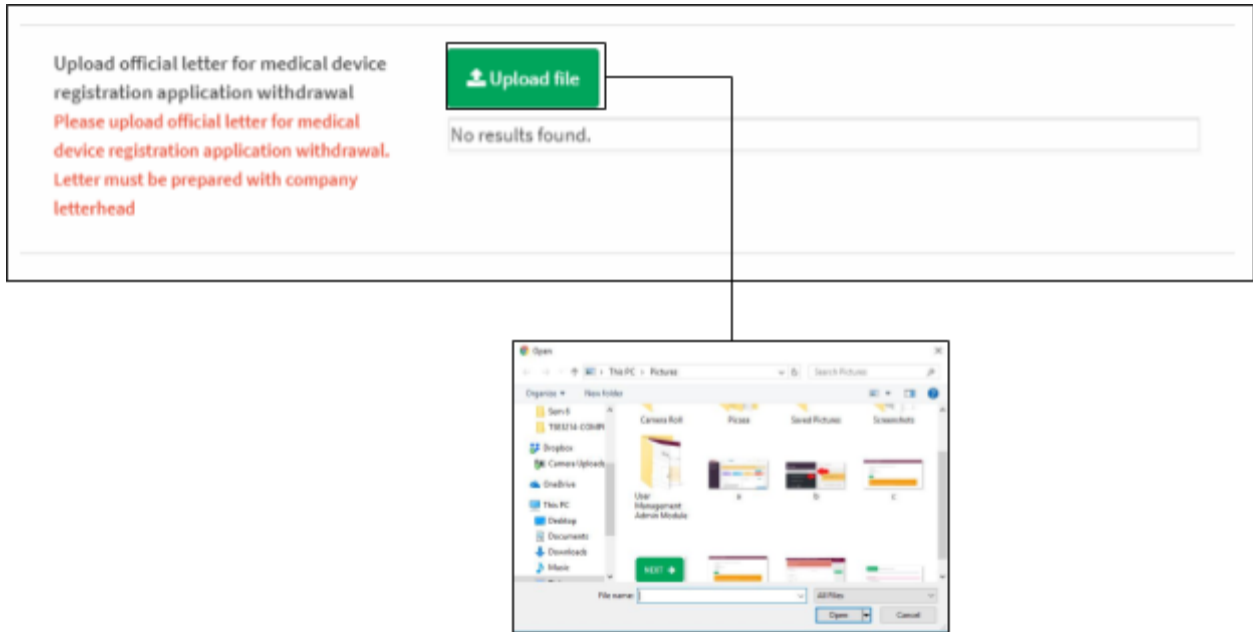
Please upload official letter for medical device registration application withdrawal. Letter must be prepared with company letterhead

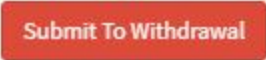
 Upload file

No results found.

User must upload file to proceed withdrawal application

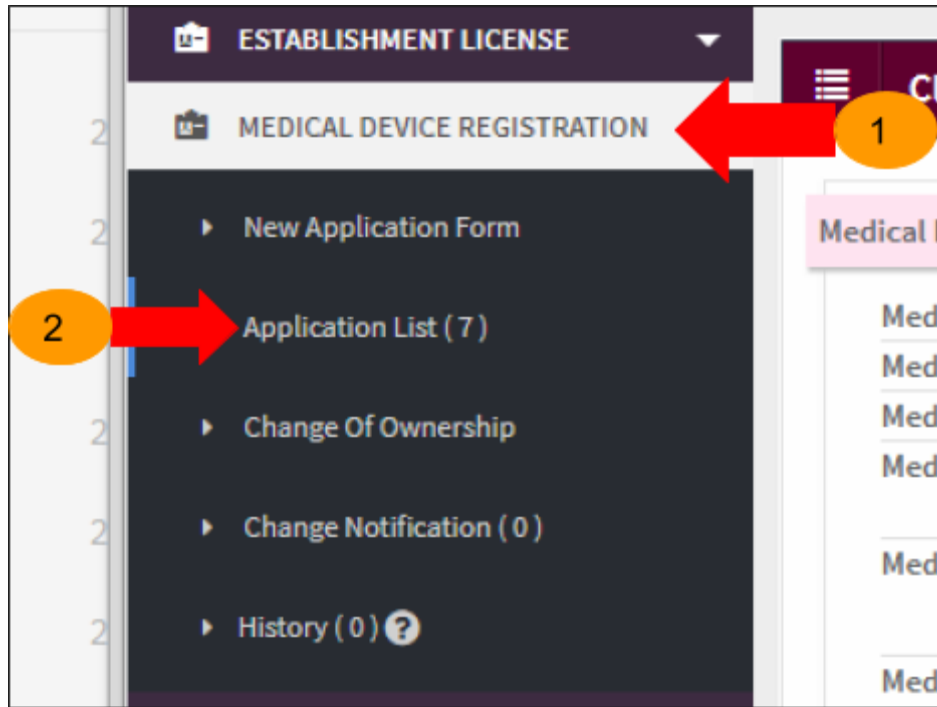
User click  to upload file. **The file must be pdf format and size not more than 300 MB.**



Then, click  to submit withdrawal certificate application.

6.0 WITHDRAWAL APPLICATION

User go to *Application List* page to withdrawal application



The diagram below show *Application List* page. Click [Withdrawal Application](#) to withdrawal application.

MDR-20171215-312	NEW REGISTRATION	15-12-2017	AUTHORISED REPRESENTATIVE	AQUITO MENDICINE	A	GENERAL MEDICAL DEVICE (GMD)	APPLICATION FEE (UNPAID)	View Payment PAdvice & Receipt 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



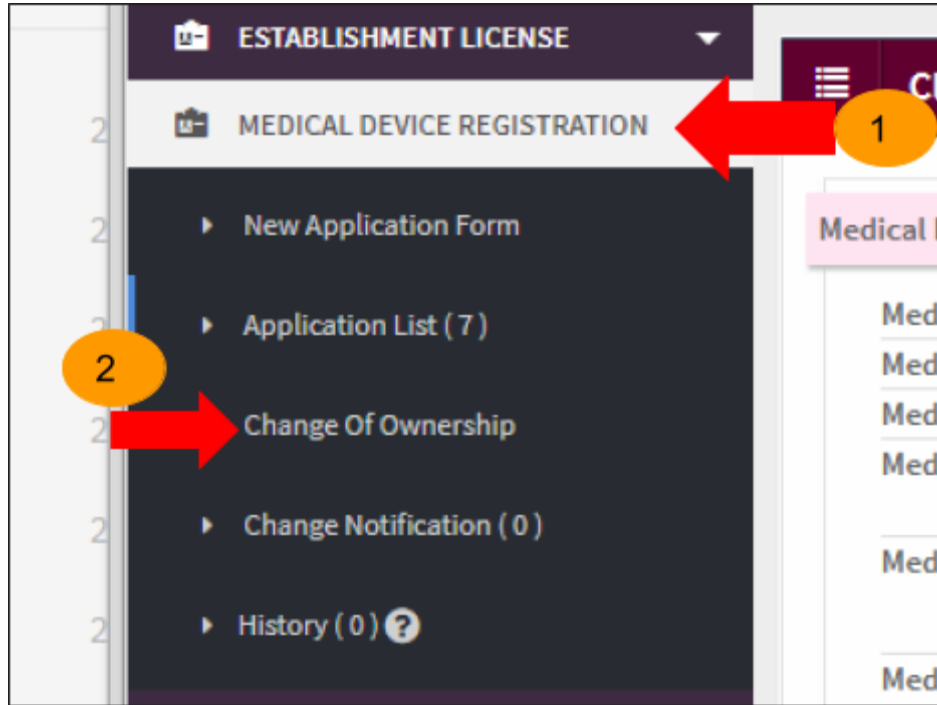
to submit.

Withdrawal Application - MDR-20171215-312

Medical Device Registration No	: MDR-20171215-312
Medical Device Name	: AQUITO MENDICINE
Proprietary Name/Brand	: BRAND A
Model	: SINGLE
Description Of Medical Device	<input type="text" value="Example"/>
Intended Use Of Medical Device	<input type="text" value="Example"/>
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	 <input type="text" value="No results found."/>

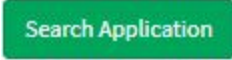
7.0 CHANGE OF AR

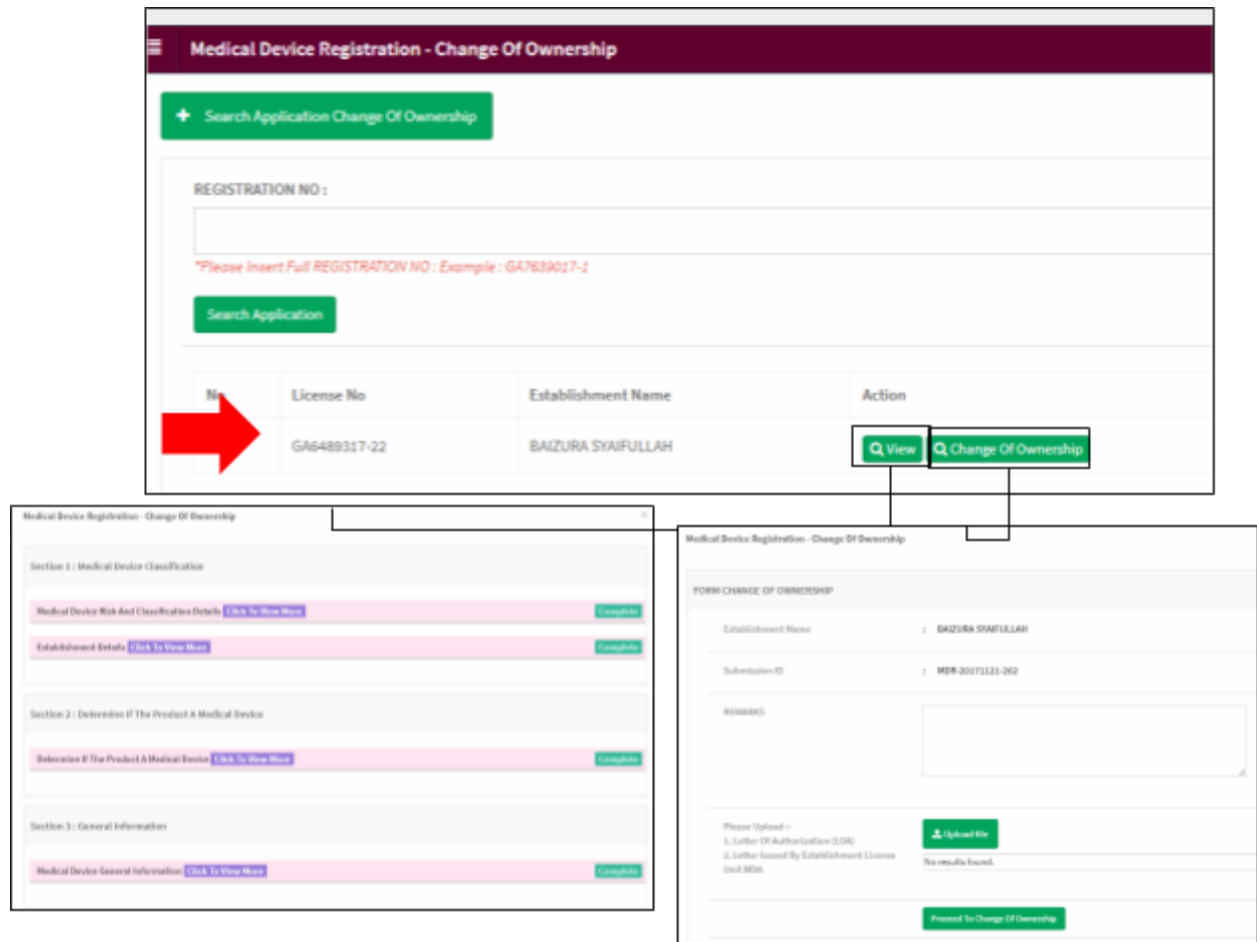
User go to *Change of Ownership* page to change of AR


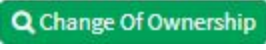




The diagram below show *Change of Ownership* page.

A screenshot of a web application page titled 'Change Of Ownership'. At the top left, there is a green button with a plus sign and the text 'Search Application Change Of Ownership'. Below this is a search form with a label 'REGISTRATION NO:' and a text input field. A red error message below the input field reads: '*Please Insert Full REGISTRATION NO: Example : GA7639017-J'. Below the input field is a green button labeled 'Search Application'. At the bottom of the page, there is a table with four columns: 'No', 'License No', 'Establishment Name', and 'Action'. The table is currently empty.

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



- 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



No results found.

