

USER MANUAL FRONT END USER

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

**MODUL UTAMA - CHANGE NOTIFICATION CLASS
B, C, D**

DISEDIAKAN OLEH :



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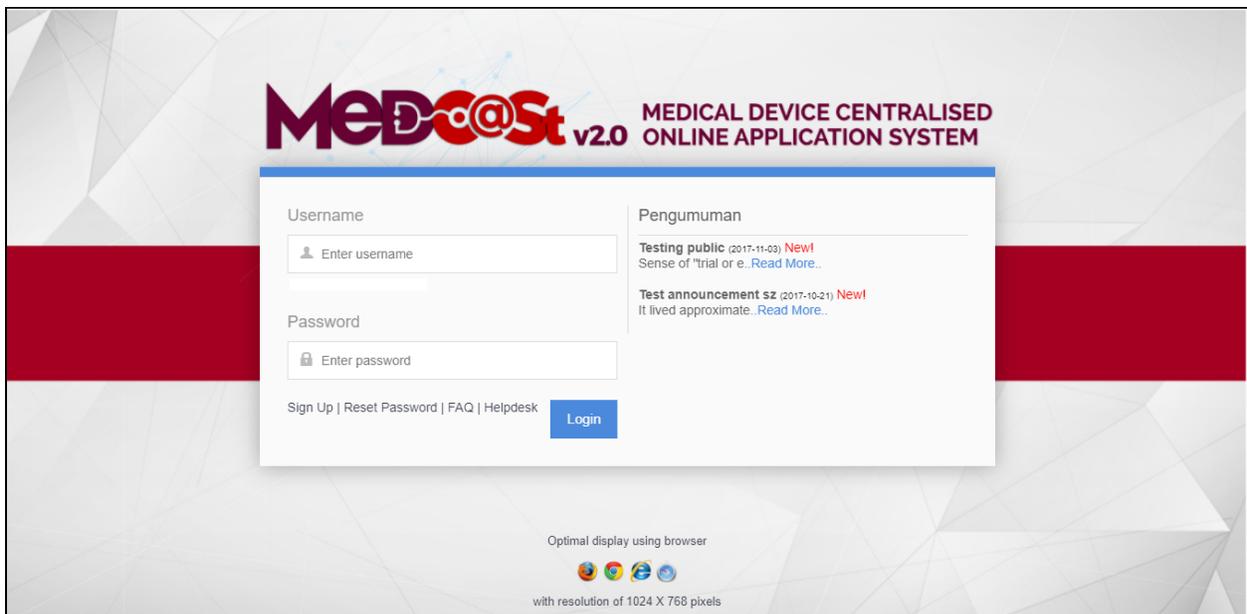
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1.0 INTRODUCTION

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

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

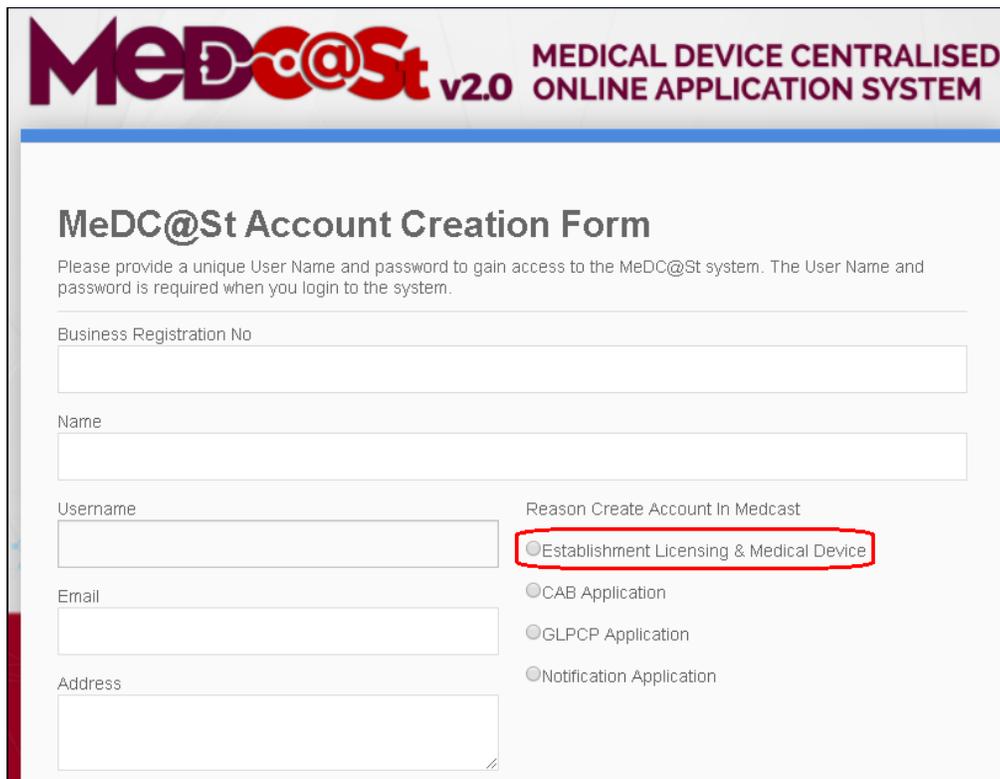
The screen below shows the expected webpage after the address has been keyed in.



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

1.1 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

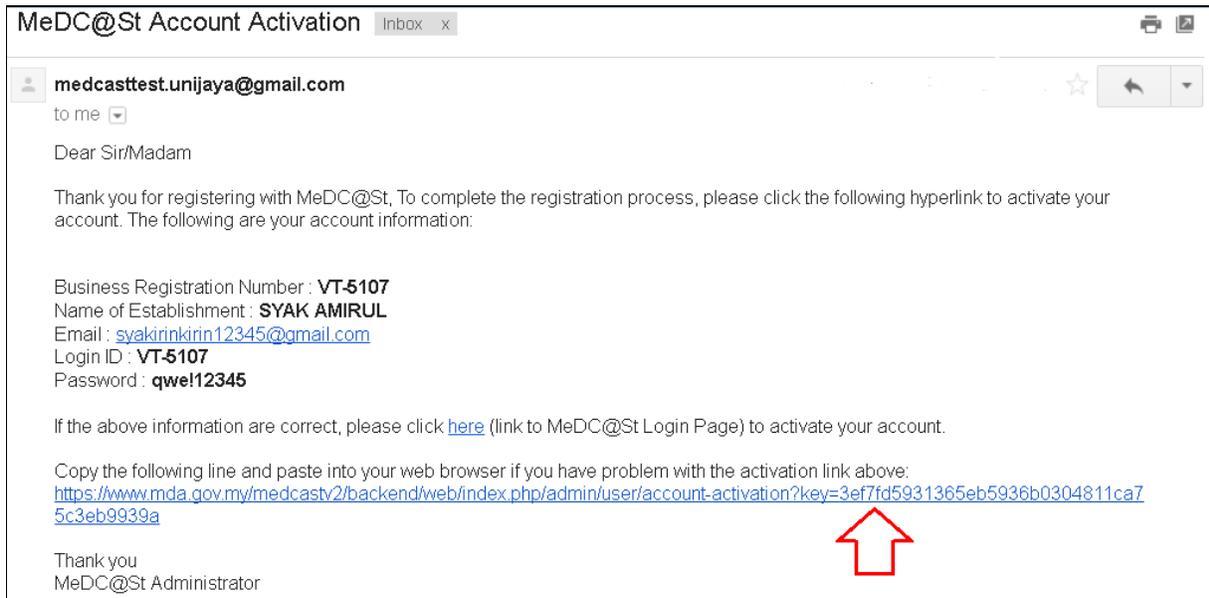
- Establishment Licensing & Medical Device
- CAB Application
- GLPCP Application
- Notification Application

The registration form contains the following fields and buttons:

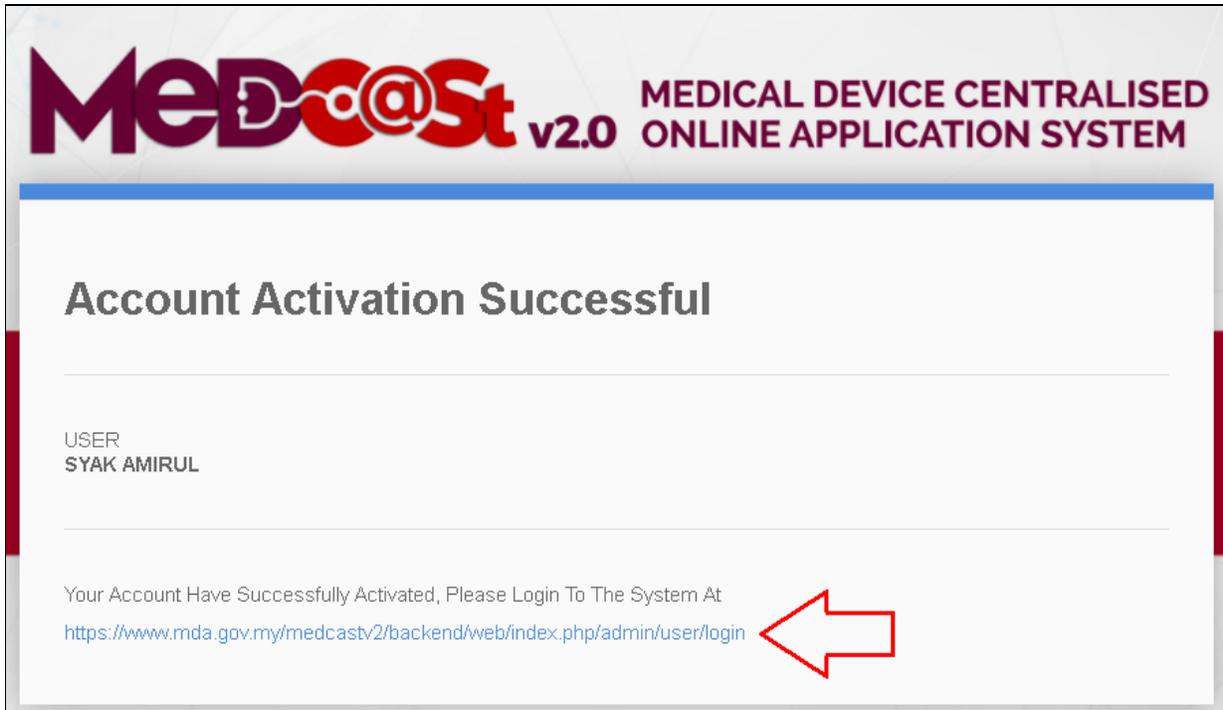
- State: Dropdown menu with "-Select State-" selected.
- City: Dropdown menu with "-Select City-" selected.
- Postcode: Text input field.
- Telephone No: Text input field.
- Fax No: Text input field.
- Password: Text input field.
- Re-Confirm Password: Text input field.
- Buttons: "Cancel" (red) and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

1.1.1 VERIFIED EMAIL FOR NEW ACCOUNT

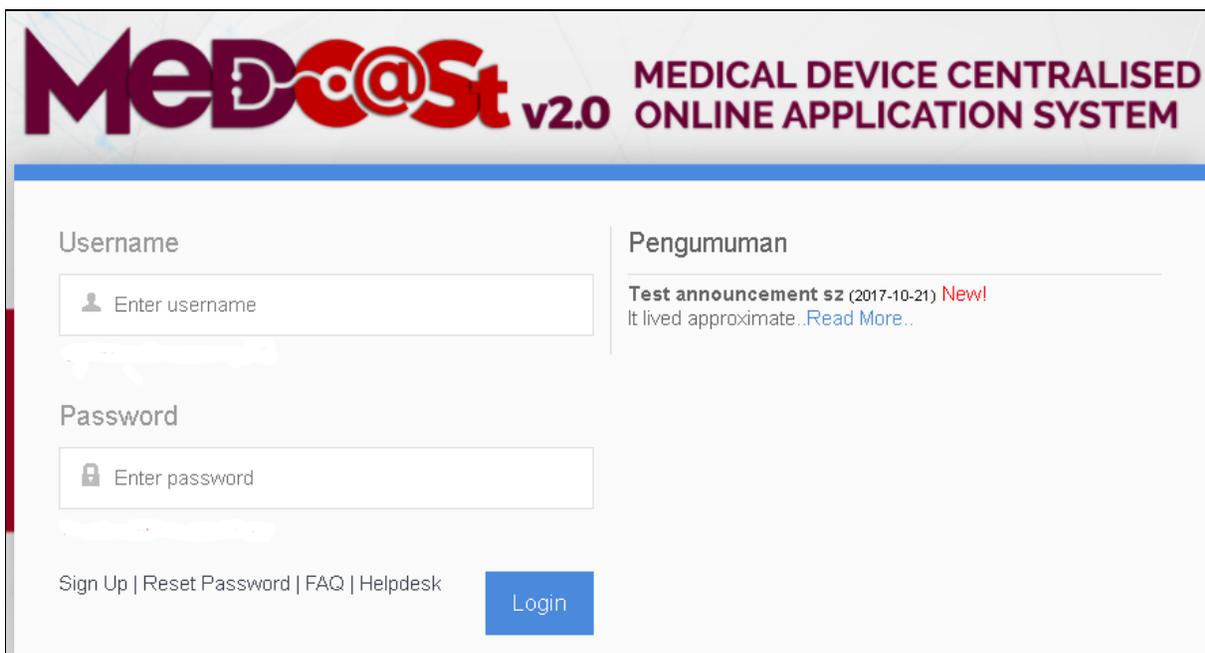
The user must verified email to completed the last step of the registration. Click at the link given to verified email in the system medcast V2.0.



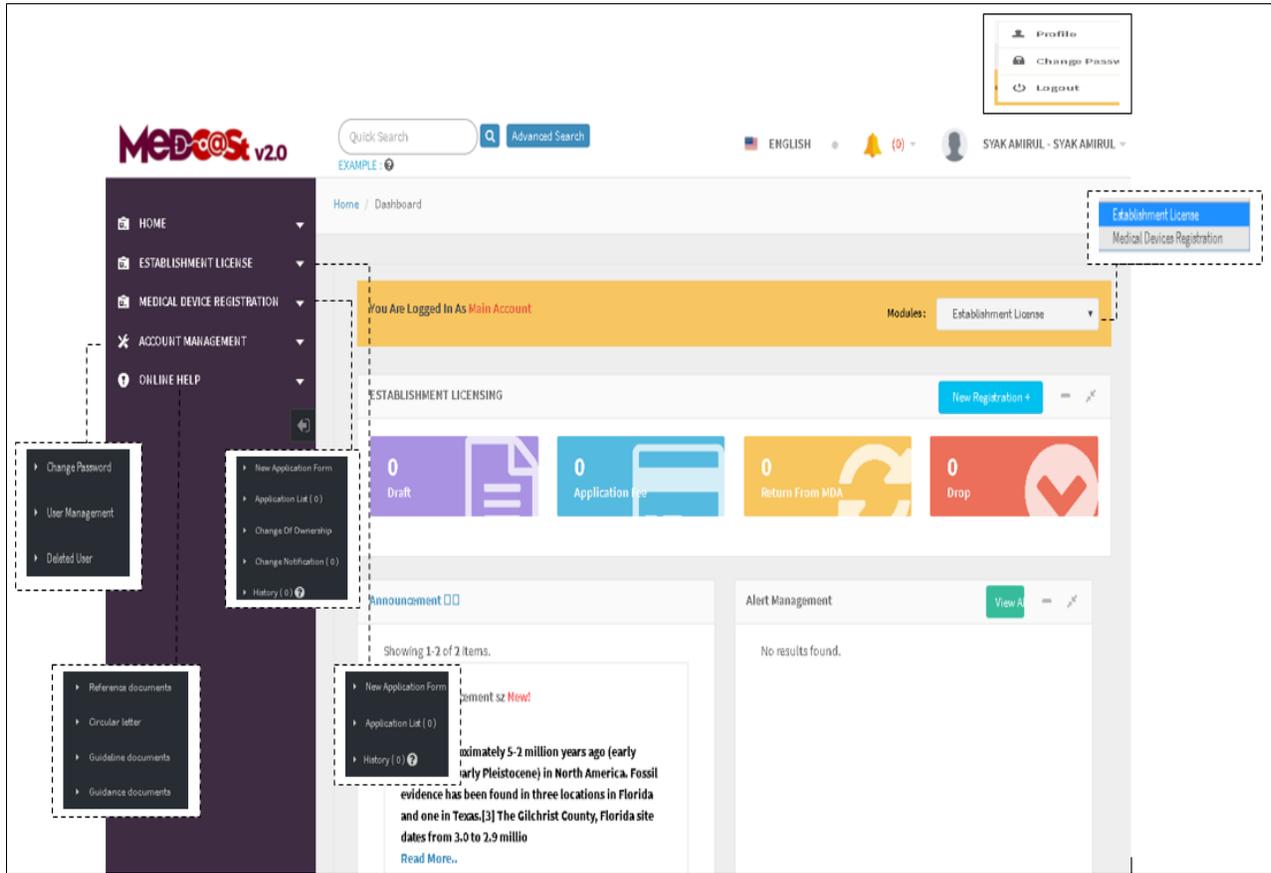
The account activation screen will display. The user must click at the link to login into the account.



The login screen will display.

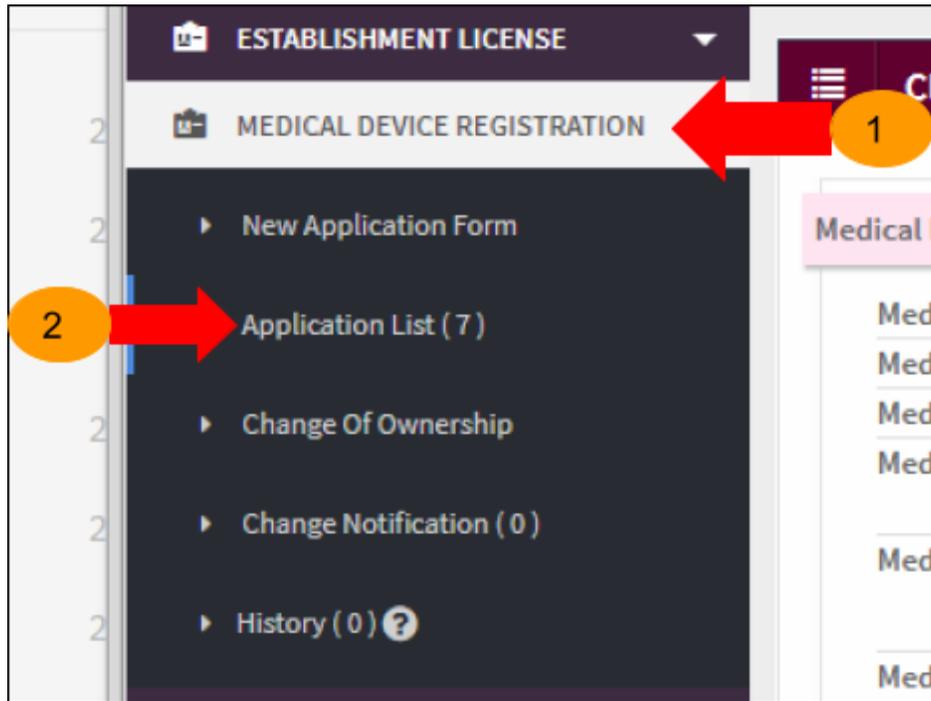


The user login successfully in the system medcast. It show the dashboard of the account.



2.0 CHANGE OF NOTIFICATION - SINGLE APPLICATION

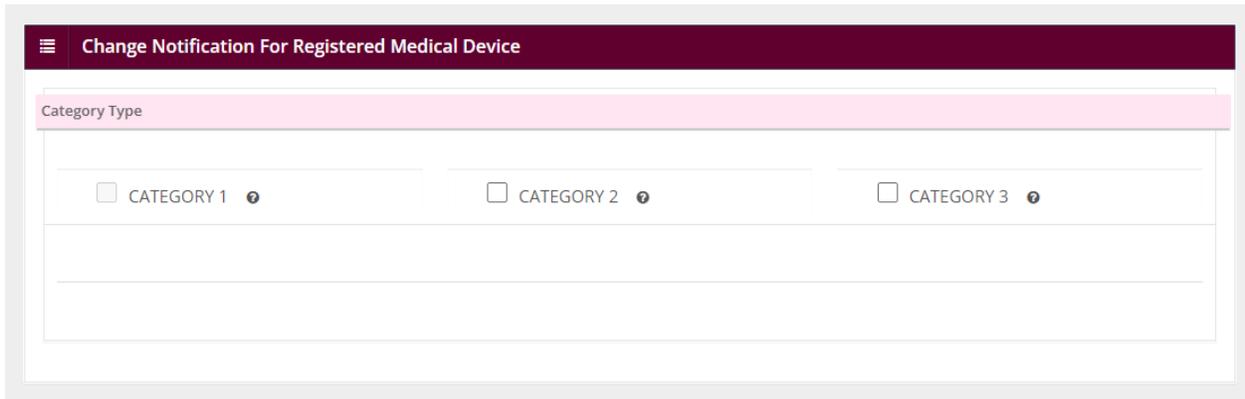
User go to *Application List* page to change of notification application.



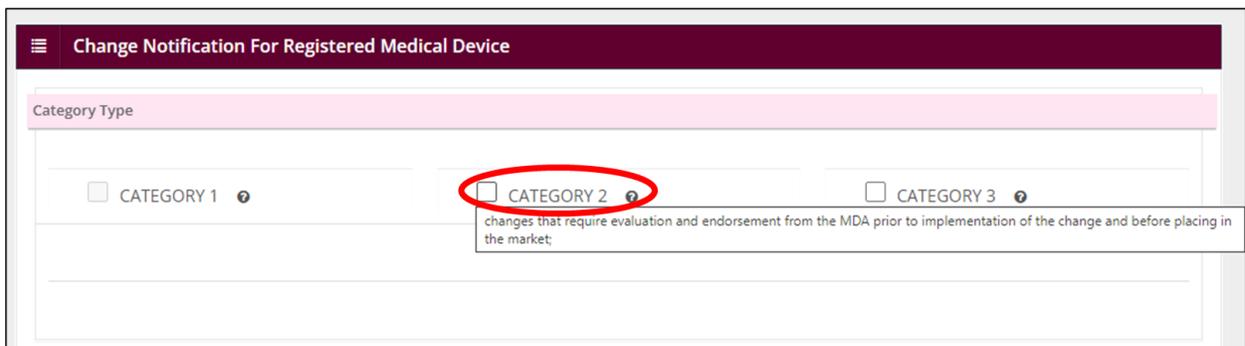
The diagram below show *Application List* page. Click + Change Of Notification to change of notification application.

10	MDR-20201119-24334	NEW REGISTRATION	11-05-2021	AUTHORISED REPRESENTATIVE	BLOOD TRANSFUSION SET	B	GENERAL MEDICAL DEVICE (GMD)	COMPLETE	<div style="display: flex; flex-direction: column; gap: 5px;"> View ReRegister P.Advice & Receipt Withdrawal Certificate Certificate List Change Notification Application History </div>
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Create a Change of Notification application. Category type will be display. The user can tick one of any category or can tick both of the category.



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



The user can select more than one type of changes.

The screenshot shows a form titled "Category Type" with three radio buttons for "CATEGORY 1", "CATEGORY 2", and "CATEGORY 3". Below this is a section "[SELECT TYPE OF CHANGES]" with two checked items:

- Change in manufacturing facility, process and quality management system (QMS)
 - All changes to certificates for manufacturing and sterilisation facilities
 - Documentation Requirements table:

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 table:

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

Then, click



to proceed the

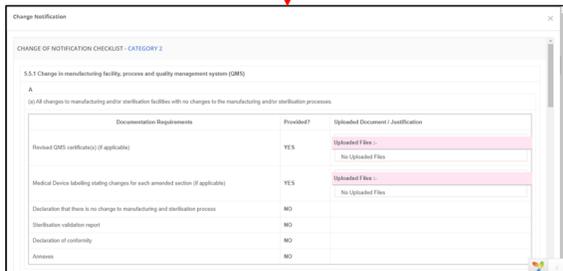
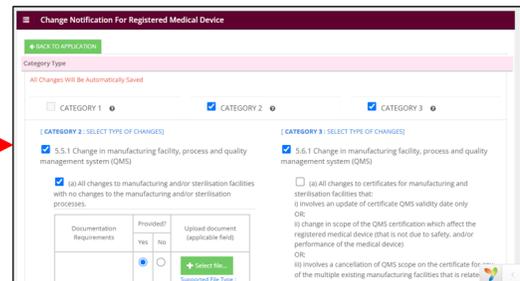
registration of the change of notification application.

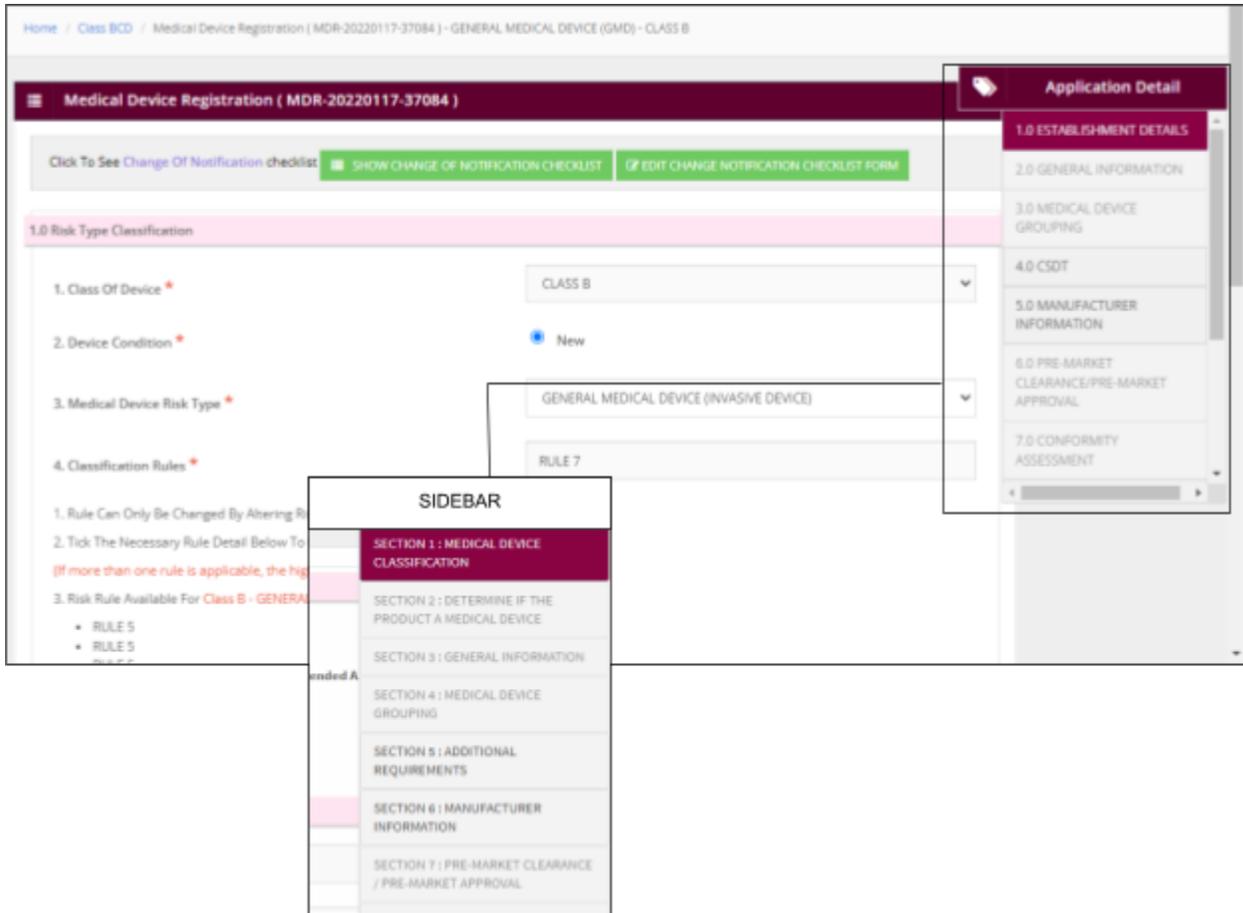
At the top of the page, user can view the checklist of the Change Notification by clicking the



and user also can edit the checklist of Change

Notification by clicking the



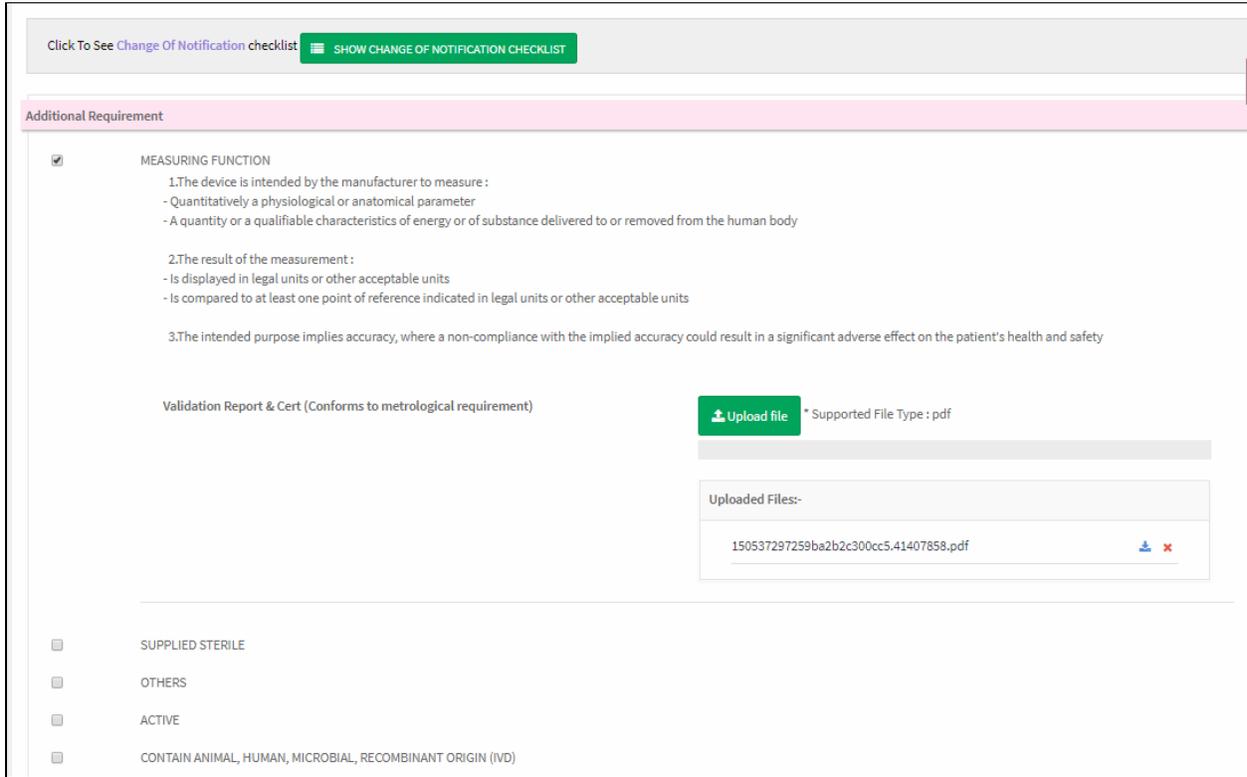


To edit a certain section, the user can click  to go to the editable section or click the sidebar to go directly to the editable section.

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

User can tick checkbox other than previous in other to make a change and user can tick more

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



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

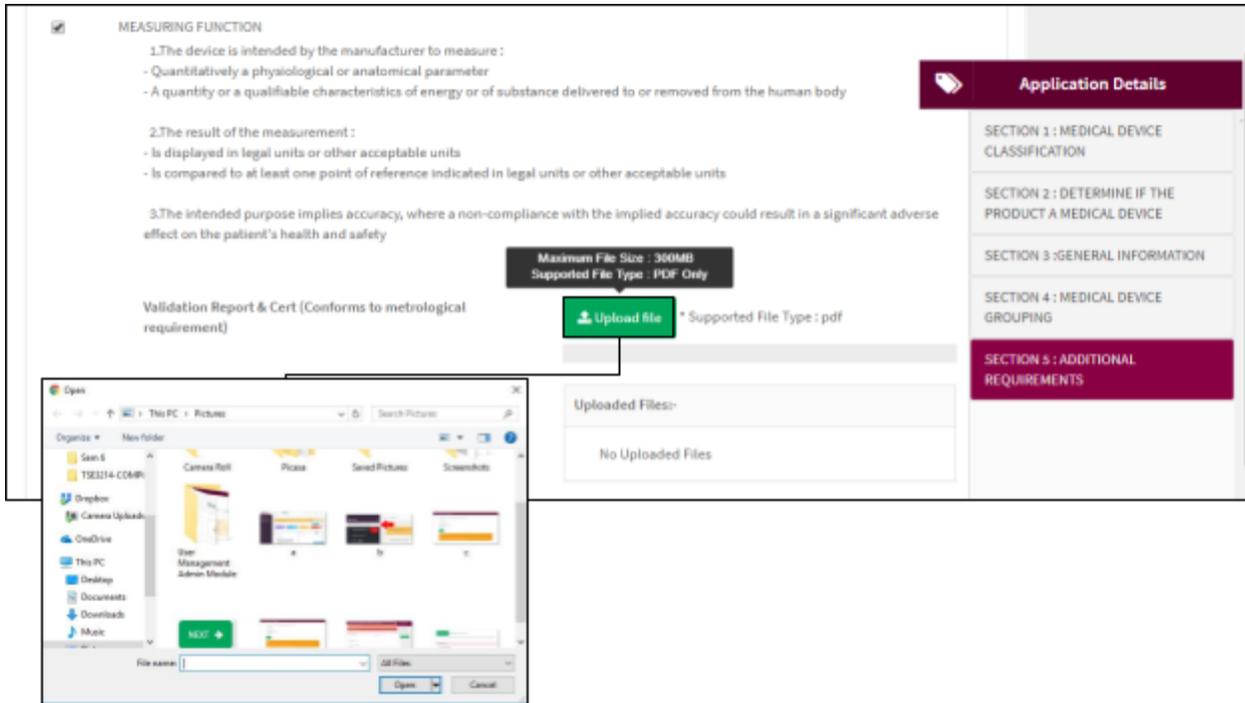
Additional Requirement

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

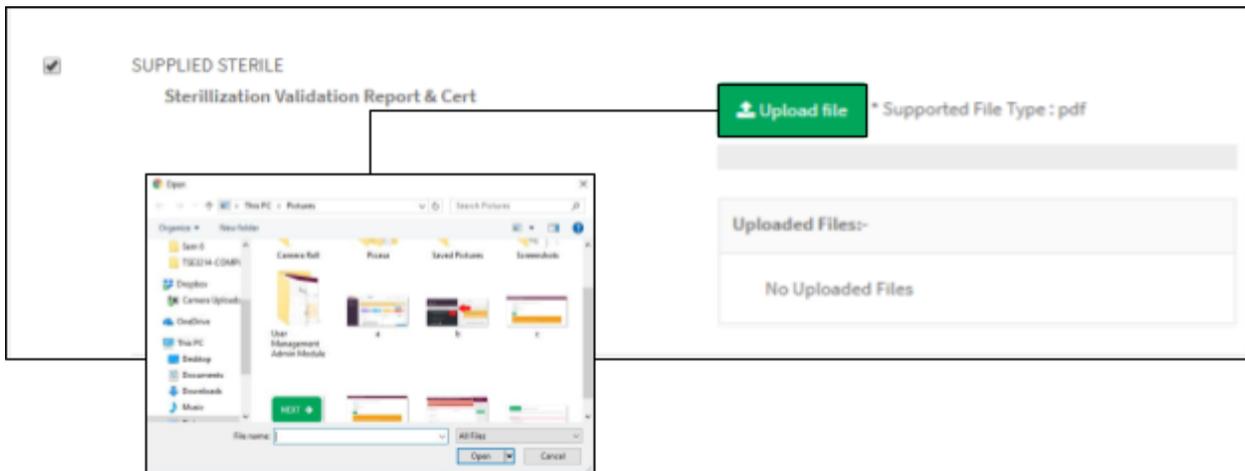
Validation Report & Cert (Conforms to metrological requirement) Upload file * Supported File Type : pdf

Uploaded Files:-

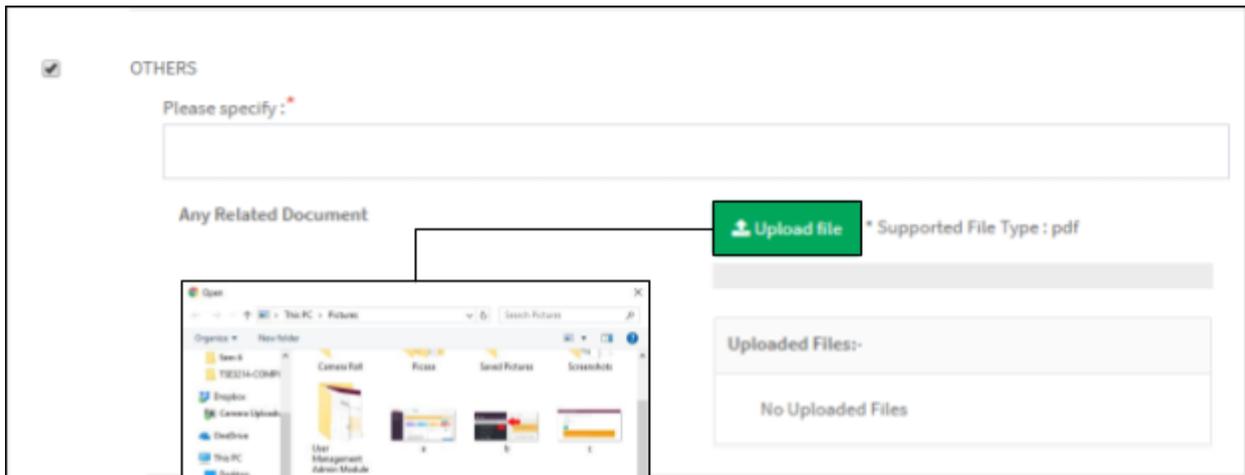
150537297259ba2b2c300cc5.41407858.pdf	 
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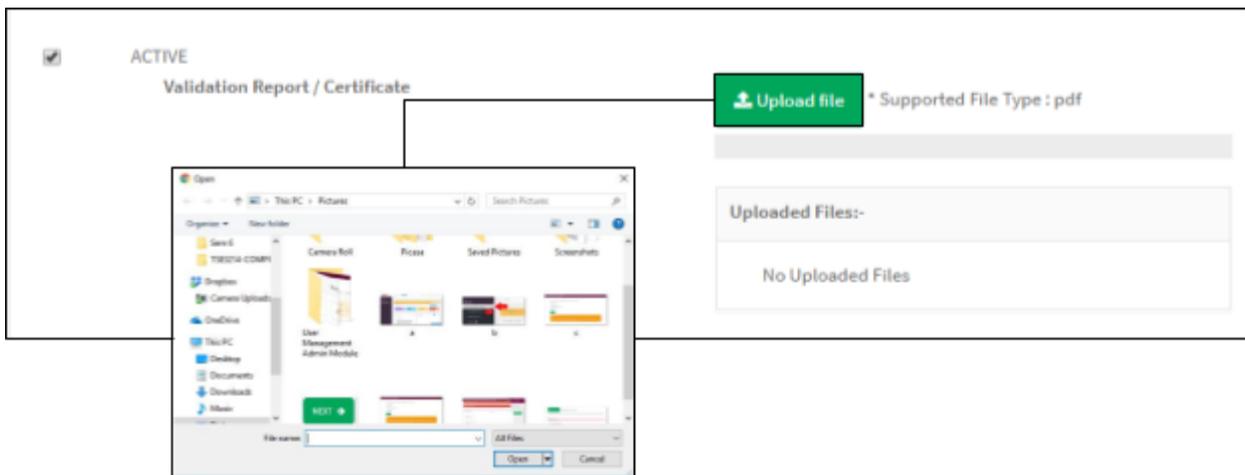
User click  to change the old upload file to the new upload file. **The file must be pdf format.**



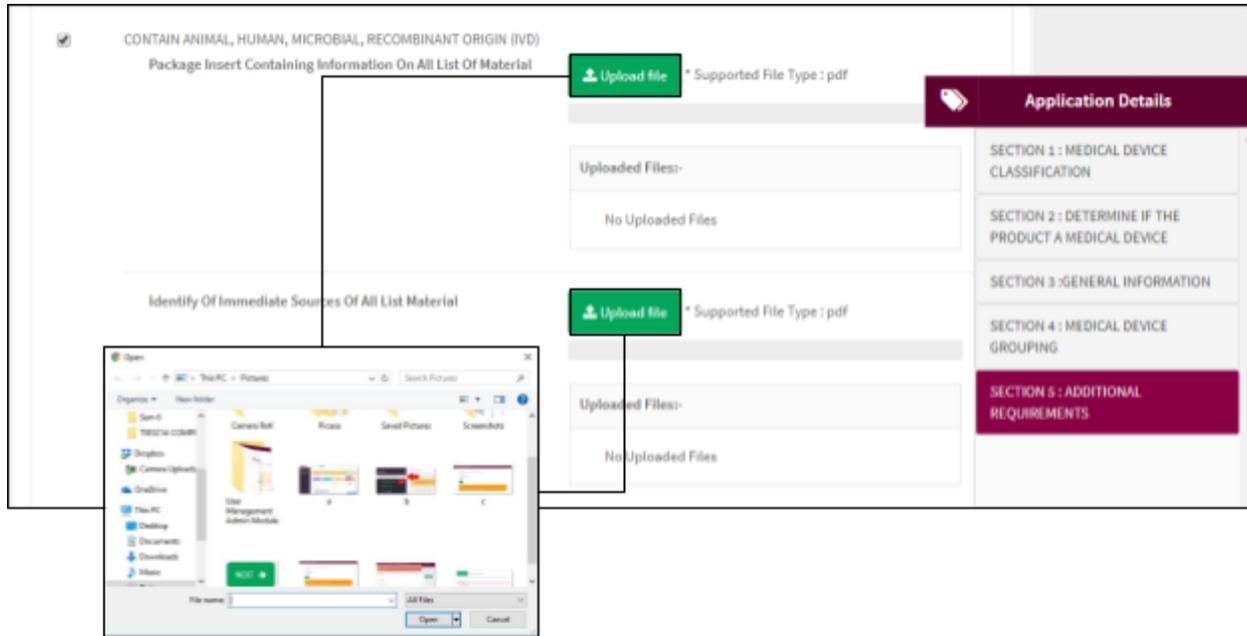
User click  to upload file. **The file must be pdf format.**



User has fill 'Please specify' text box first then click  to upload file. **The file must be pdf format.**



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



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

The user can click  to go to the editable section

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

The diagram below show SECTION 5 : MANUFACTURER INFORMATION that need to be change.

The screenshot displays the MeDC@St 2.0 application interface. It features a top navigation bar with 'Manufacturer Information' and 'Application Details'. The 'Manufacturer Information' section includes fields for Name of Manufacturer, Registration No., Registered Manufacturer Auditor, and Certificate Expiry Date. The 'Quality Management System Information' section shows a 'Quality Management System Certificate' field and an 'Uploaded Files' list with two PDF files. The 'List of Manufacturing Site' section contains a table with columns for Name of Manufacturing Site, Address of Manufacturing Site, Post Code/Zip Code, Manufacturing Site Upload File, and Action. A green '+ Add Manufacturing Site' button is highlighted with a red box, and a red box also highlights the 'Update' button in the table's action column.

Name Of Manufacturing Site	Address Of Manufacturing Site	Post Code/Zip Code	Manufacturing Site Upload File	Action
1 M33-EN	LOT M 12, MEZZANINE CENTRE, AMPANG POINT, SHOPPING CENTRE, JALAN MAMANDA 3,	54300	15957297259a26a399c55 41407958.pdf	Upload File Update Details

This screenshot shows the 'Add Manufacturing Site' form. It includes three text input fields: '1. Name Of Manufacturing Site', '2. Address Of Manufacturing Site', and '3. Post Code/Zip Code'. A blue 'Submit' button is located at the bottom right of the form.

This screenshot shows the 'Update Manufacturing Site' form. It includes three text input fields: '1. Name Of Manufacturing Site' (containing 'M33EN'), '2. Address Of Manufacturing Site' (containing 'LOT M 12, MEZZANINE CENTRE, AMPANG POINT, SHOPPING CENTRE, JALAN MAMANDA 3,'), and '3. Post Code/Zip Code' (containing '54300'). A blue '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.

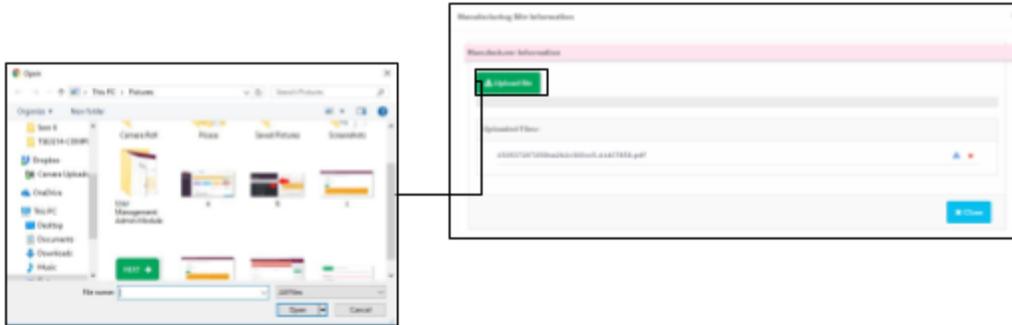
User click  to change the old upload file or to new upload files.

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	150537297259ba2b2c300cc5.41407858.pdf	+ Add Manufacturing Site Upload File 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, 11111111111111), 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.

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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)

The screenshot shows a web interface for submitting 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 application is divided into three 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)

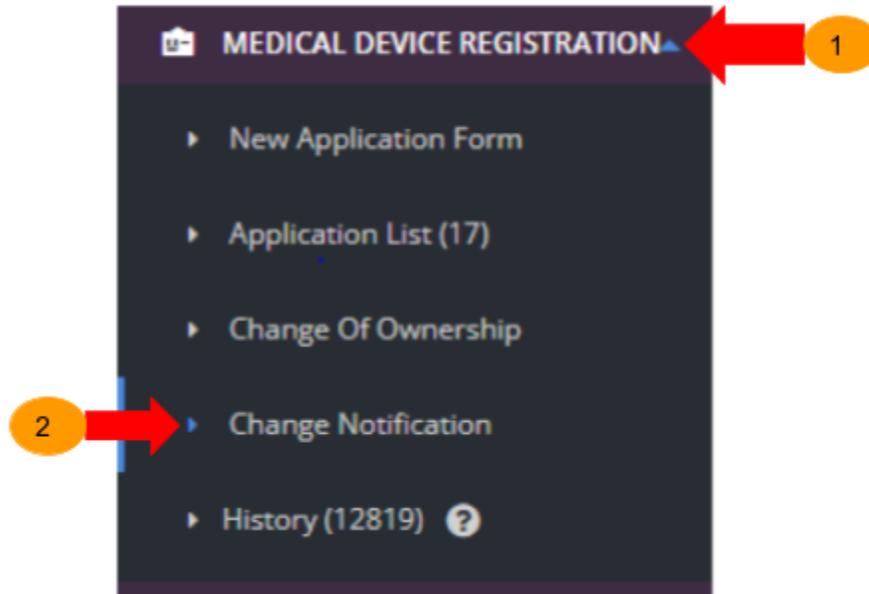
A callout box labeled 'Click to see more details about form' points to the 'Click To View More' buttons in all three sections. A 'Status' callout box points to the 'Complete' indicators for the first two items in Section 1.

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

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

3.0 CHANGE OF NOTIFICATION APPLICATION - MULTIPLE APPLICATION

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



The diagram below show *Change Notification* page. User choose *Device Class = C* and *Role of*

Establishment = Authorised of Representative and then click



A screenshot of the 'Change Notification' page in the MeDC@St v2.0 system. Callout 1 points to the 'Change Notification' option in the left sidebar. Callout 2 points to the 'Proceed To Multiple Change Notification' button. The page shows a search filter for Device Class 'C' and Role of Establishment 'AUTHORIZED REPRESENTATIVE'. Below the filter is a table of applications.

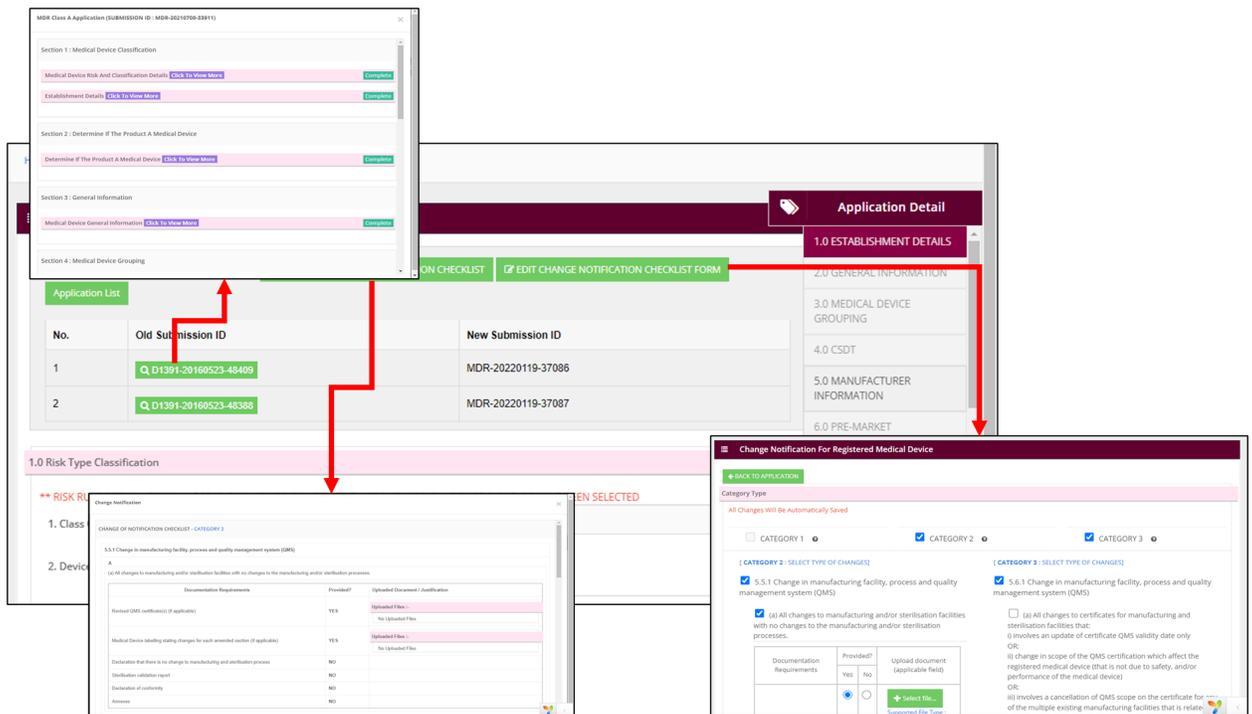
Select	No	Submission ID	Application Type	Submitted At	Role Of Establishment	Device Name	Brand	Device Class	Device Risk Type	Form Status	Action
<input checked="" type="checkbox"/>	1	MDR-20201130-24779	CHANGE OF NOTIFICATION	17-08-2021	AUTHORISED REPRESENTATIVE	STRYKER MIXEVA3 BONE CEMENT MIXER	STRYKER	C	GENERAL MEDICAL DEVICE (GMD)	COMPLETE	View, ReRegister, P Advice & Receipt, Withdrawal Certificate, Change Of Notification
<input checked="" type="checkbox"/>	2	MDR-20210518-31536	CHANGE OF NOTIFICATION	12-07-2021	AUTHORISED REPRESENTATIVE	GAMMA 3 LOCKING NAIL SYSTEM	STRYKER	C	GENERAL MEDICAL DEVICE (GMD)	COMPLETE	View, ReRegister, P Advice & Receipt, Withdrawal Certificate, Change Of Notification
<input checked="" type="checkbox"/>	3	MDR-20210427-30721	NEW REGISTRATION	18-06-2021	AUTHORISED REPRESENTATIVE	STRYKER VARIAX 2 MINI FRAGMENT SYSTEM	STRYKER	C	GENERAL MEDICAL DEVICE (GMD)	COMPLETE	View, ReRegister, P Advice & Receipt, Withdrawal Certificate, Change Of Notification

Search

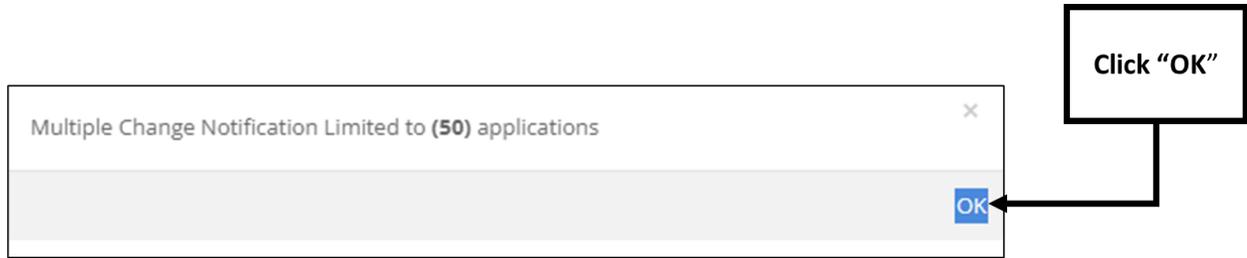
- After click **Search**, the list of application from *Class C* and *Authorised of Representative* are appeared.
- The user can select more than one application. The user tick at the checkbox at “*Select*” column to make multiple application change notification.

Proceed To Multiple Change Notification

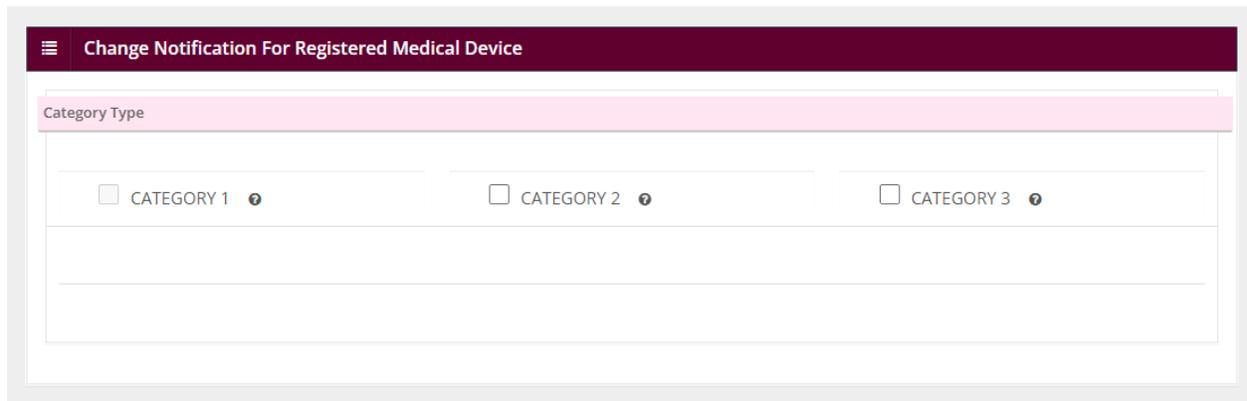
- Click **Proceed To Multiple Change Notification** to make multiple Change Notification application.



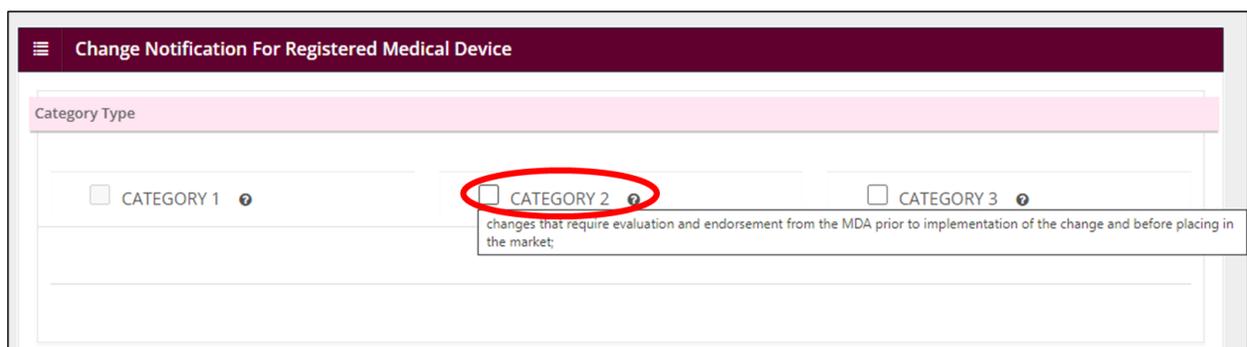
The multiple application can be made up until only 50 applications. If user tick more than 50 application, a pop-out message “*Multiple Change Notification Limited to (50) applications*” appeared. Then click “OK” to close the pop-out message.



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



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



The user can select more than one type of changes.

The screenshot shows a form titled 'Category Type' with three radio buttons for 'CATEGORY 1', 'CATEGORY 2', and 'CATEGORY 3'. Below this is a section '[SELECT TYPE OF CHANGES]' with two checked items:

- Change in manufacturing facility, process and quality management system (QMS)
 - Sub-section: All changes to certificates for manufacturing and sterilisation facilities
 - Table:

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--
 - Sub-section: i) involves an update of certificate QMS validity date only OR; ii) involves an update of certificate QMS validity date only
 - Table:

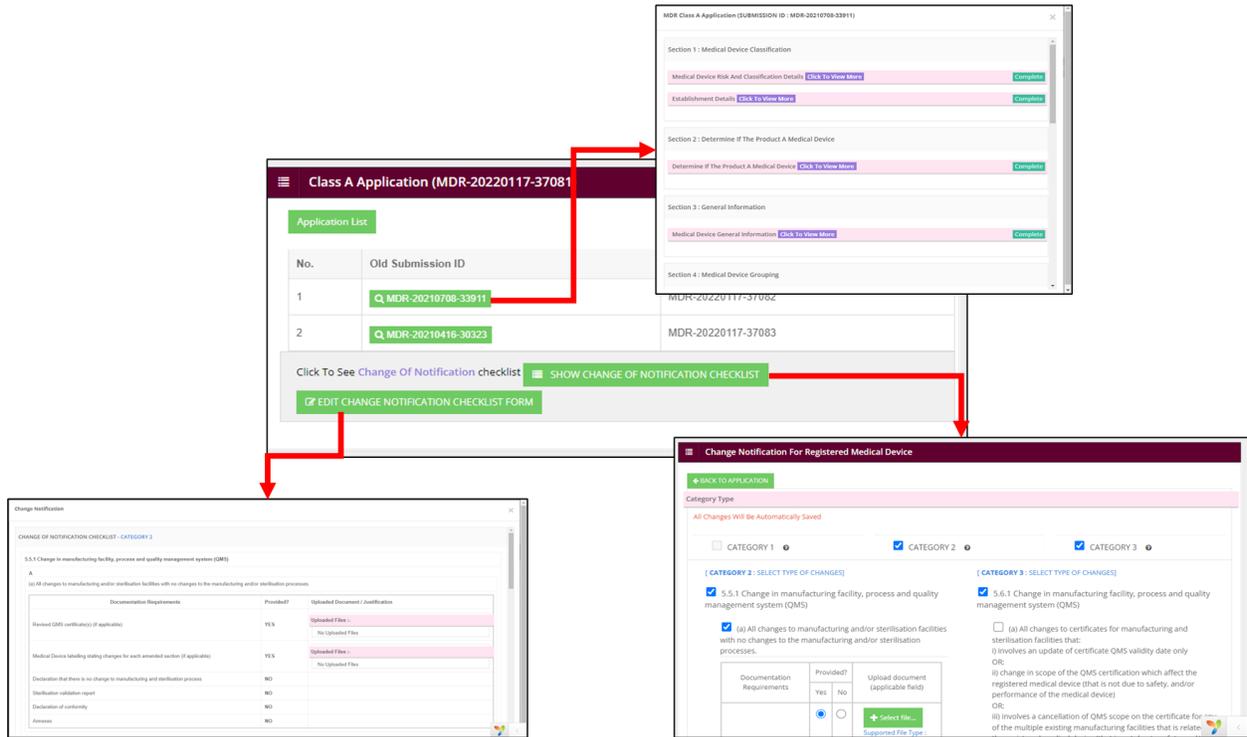
Documentation Requirements	Provided?		Upload document (applicable field)
	Yes	No	
Valid QMS certificate	<input type="radio"/>	<input checked="" type="radio"/>	Please provide justification if no is selected

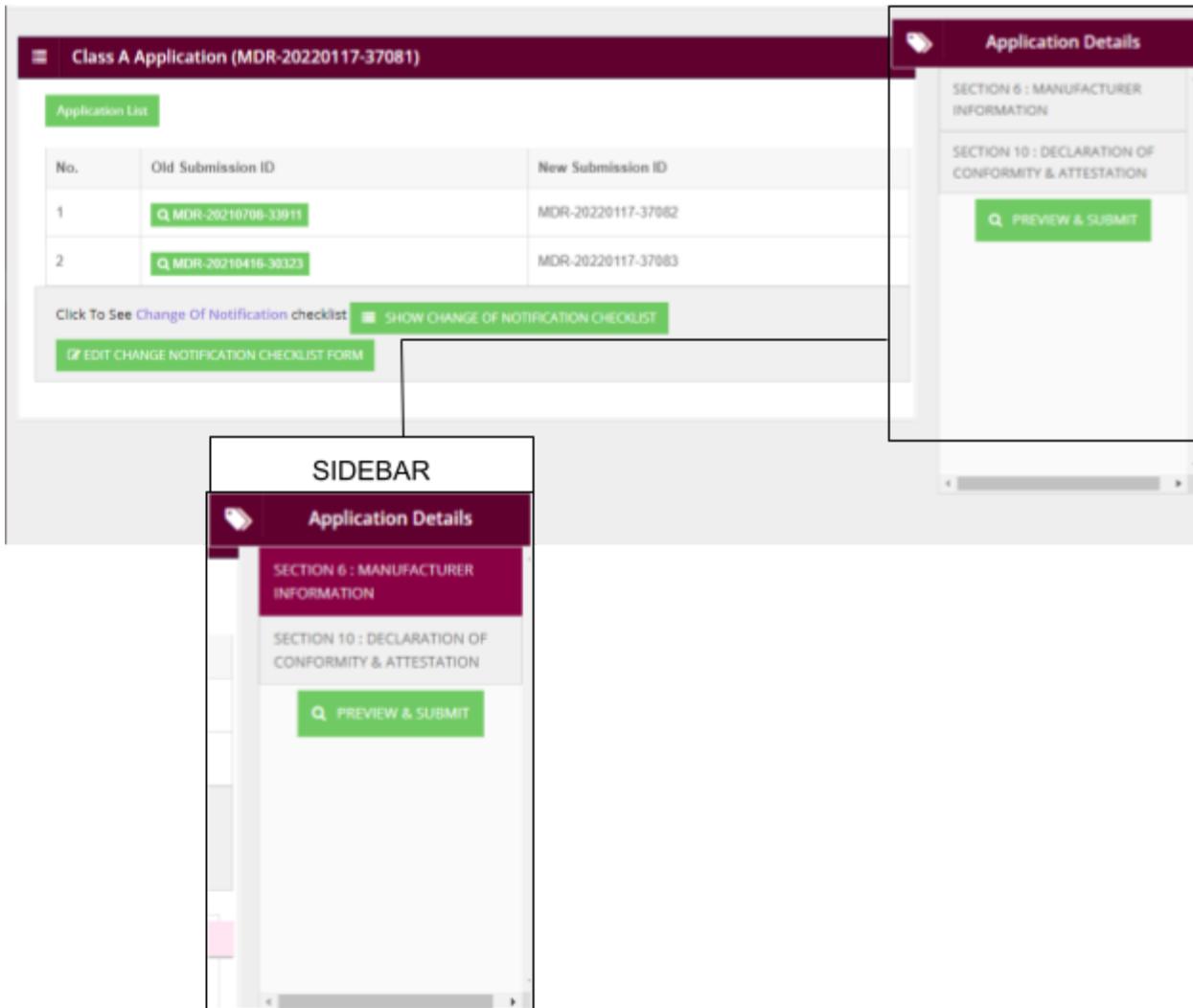
For the change of notification application. User can register new application or to edit certain section based on their change of notification category

Then, click [PROCEED TO REGISTRATION APPLICATION CHANGE OF NOTIFICATION](#) to proceed the registration of the change of notification application.

- At the top of the page, user can view the checklist of the Change Notification by clicking the [SHOW CHANGE OF NOTIFICATION CHECKLIST](#)
- The user also can edit the checklist of Change Notification by clicking the [EDIT CHANGE NOTIFICATION CHECKLIST FORM](#)

- The user click Q D1391-20160523-48409 to view the old application information.





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 : MANUFACTURER INFORMATION that need to be change.

The screenshot displays the MeDC@St 2.0 application interface. It features a top navigation bar with 'Manufacturer Information' and 'Application Details'. The 'Manufacturer Information' section includes fields for Name Of Manufacturer, Manufacturer Registration No, Name Of Registered Manufacturer Auditor, and Certificate Expiry Date. The 'Quality Management System Information' section shows a 'Quality Management System Certificate' field and an 'Uploaded Files' list containing 'IKLAL_MDU_2017.PDF' and 'A737-Q4LR.PDF'. Below this is a 'List Of Manufacturing Site' table with columns for Name Of Manufacturing Site, Address Of Manufacturing Site, Post Code/Zip Code, Manufacturing Site Upload File, and Action. A table with one row is shown, and a green '+ Add Manufacturing Site' button is highlighted. The 'Action' column for the row contains 'Upload File', 'Update', and 'Details' buttons.

This screenshot shows the 'Add Manufacturing Site' form. It has three text input fields: '1. Name Of Manufacturing Site', '2. Address Of Manufacturing Site', and '3. Post Code/Zip Code'. A blue 'Submit' button is located at the bottom right of the form.

This screenshot shows the 'Update Manufacturing Site' form. It has three text input fields: '1. Name Of Manufacturing Site' (containing 'MEASRI'), '2. Address Of Manufacturing Site' (containing 'LOT M 12, MEZZANINE CENTRE, AMPANG POINT, SHOPPING CENTRE, JALAN MAMANDA 3'), and '3. Post Code/Zip Code' (containing '54300'). A blue '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.

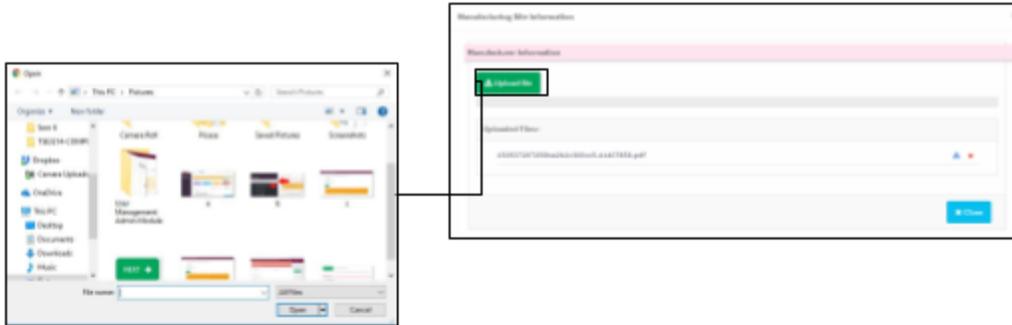
User click  to change the old upload file or to new upload files.

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
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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, 1111111111111), the Manufacturer of this/these device(s), have obtained the objective evidence from the foreign manufacturer that:

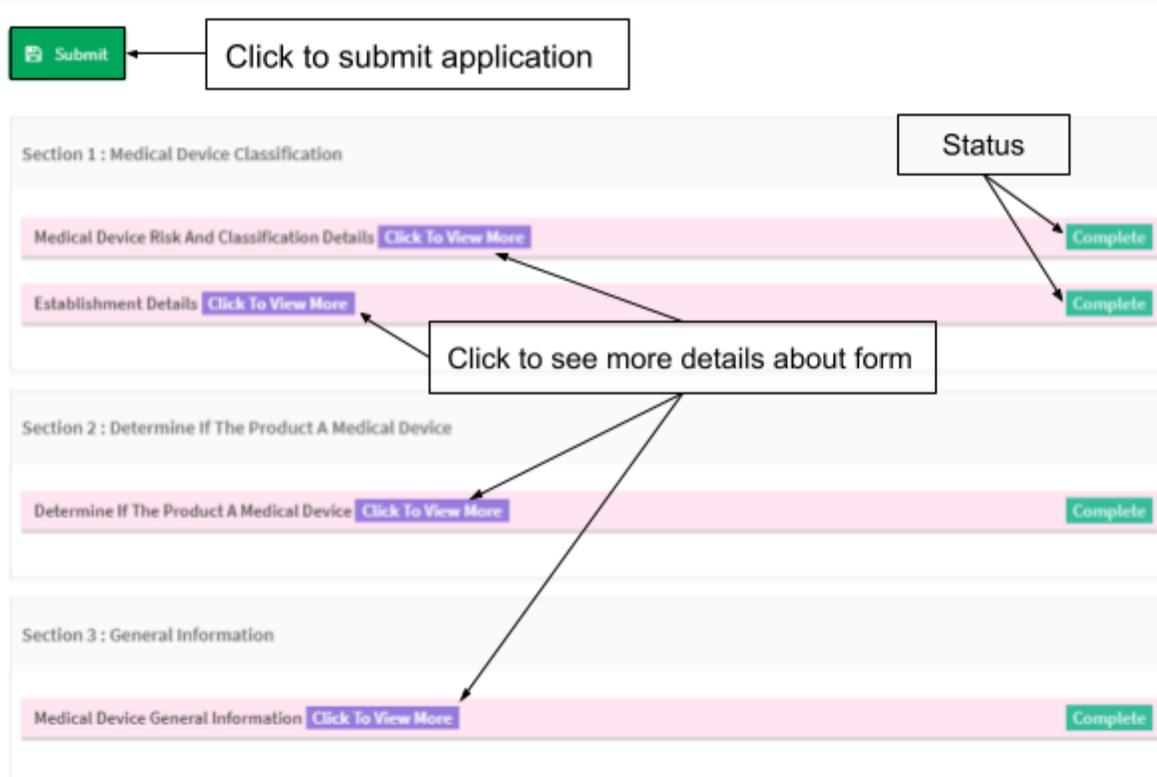
- This product is a medical device according to the definition of medical device set out in Section 2, Medical Device Act 2012 (Act 737)
- This medical device is classified as Class A according to Rules of Classification of Medical Device, as set out in the First Schedule of the Medical device Regulations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

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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.