

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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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.

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

Username
Enter username

Password
Enter password

Sign Up | Reset Password | FAQ | Helpdesk **Login**

Pengumuman

Testing public (2017-11-03) **New!**
Sense of "trial or e..[Read More..](#)

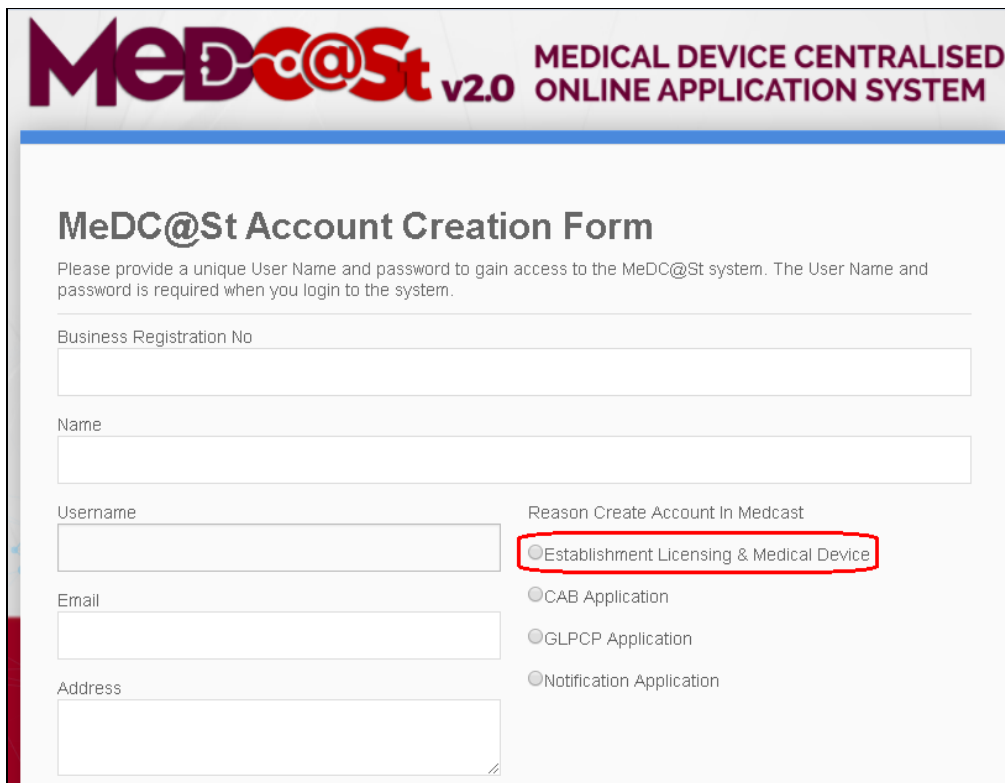
Test announcement sz (2017-10-21) **New!**
It lived approximate..[Read More..](#)

Optimal display using browser
with resolution of 1024 X 768 pixels

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.



The image shows the 'MeDC@St Account Creation Form' interface. At the top, the logo 'MeDC@St v2.0' is displayed next to the text 'MEDICAL DEVICE CENTRALISED ONLINE APPLICATION SYSTEM'. Below the header, the form title 'MeDC@St Account Creation Form' is followed by a note: '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.' The form contains several input fields: 'Business Registration No', 'Name', 'Username', 'Email', and 'Address'. To the right of these fields, under the heading 'Reason Create Account In Medcast', there are three radio button options. The first option, 'Establishment Licensing & Medical Device', is selected and highlighted with a red rectangular box. The other two options are 'CAB Application' and 'GLPCP Application', both of which are unselected.

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

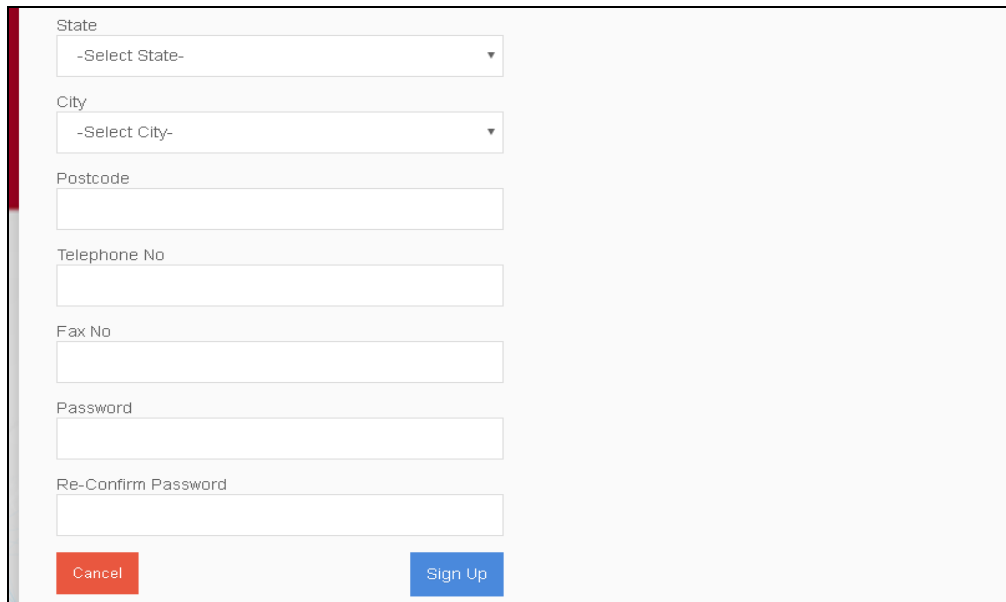
Username

Email

Address

Reason Create Account In Medcast

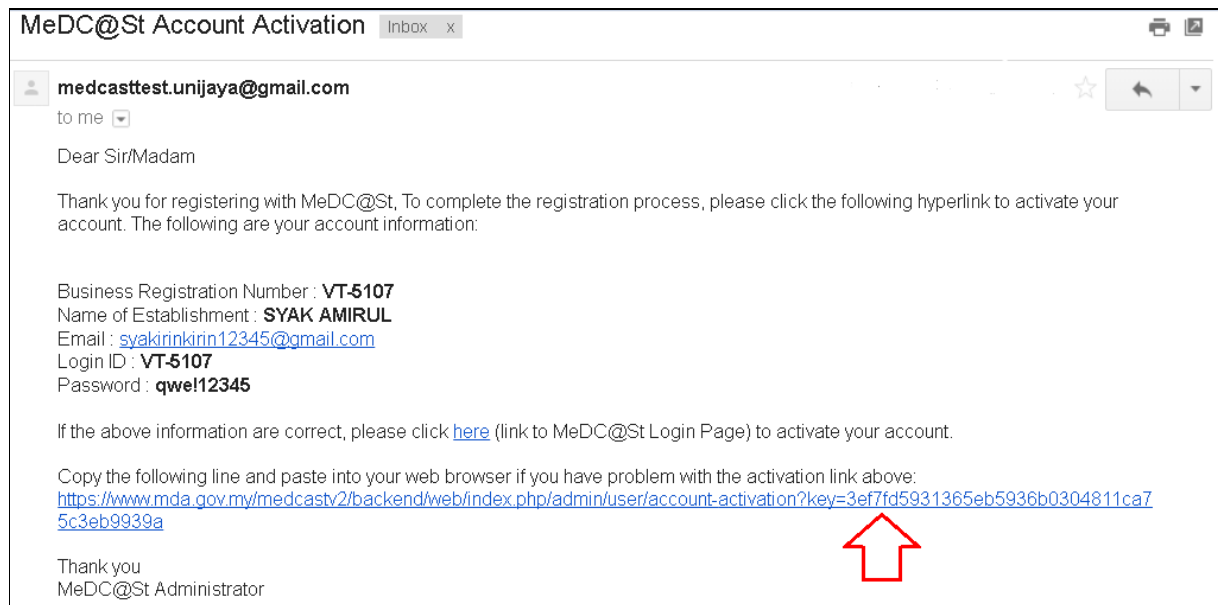
- ☒ Establishment Licensing & Medical Device
- ☐ CAB Application
- ☐ GLPCP Application
- ☐ Notification Application



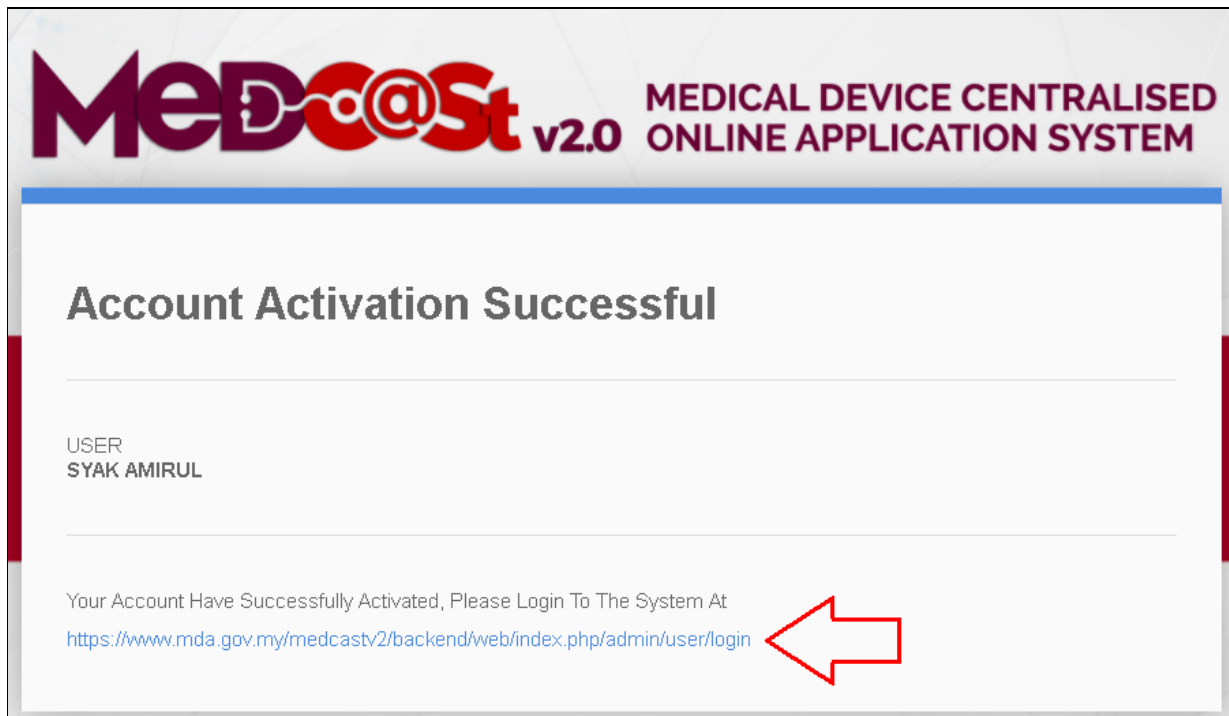
A registration form with the following fields: State (dropdown menu with '-Select State-'), City (dropdown menu with '-Select City-'), Postcode (text input), Telephone No (text input), Fax No (text input), Password (text input), and Re-Confirm Password (text input). At the bottom, there are two buttons: 'Cancel' (red) and 'Sign Up' (blue).

1.1.1 VERIFIED EMAIL FOR NEW ACCOUNT

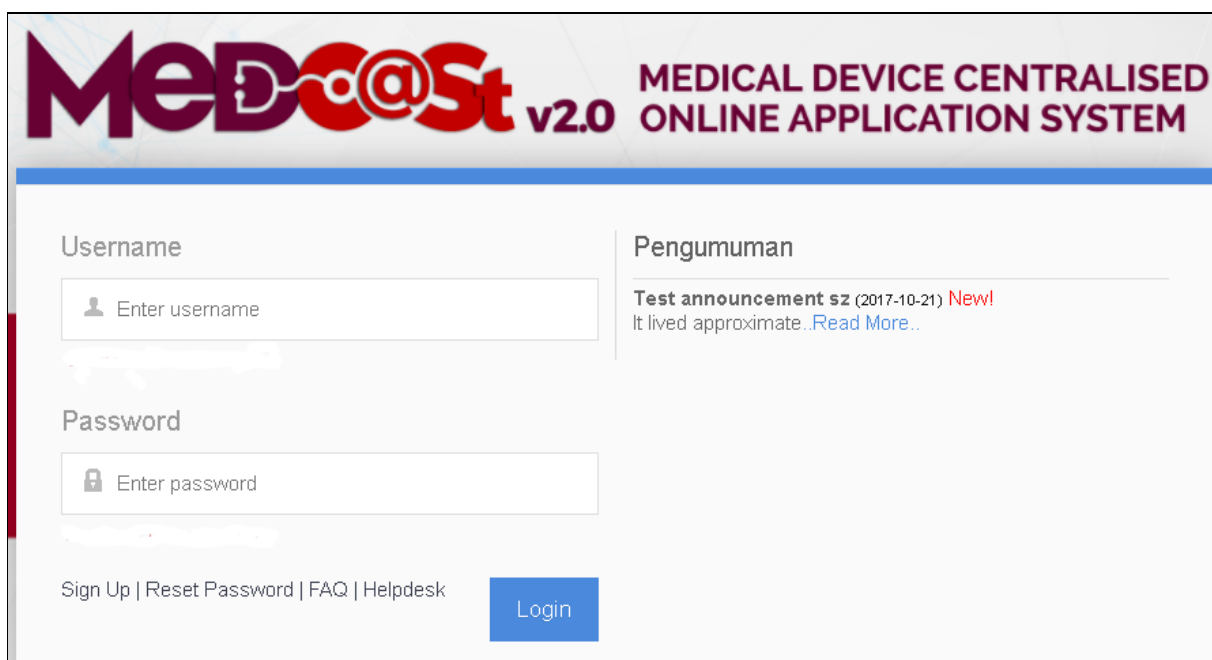
The user must verify email to complete the last step of the registration. Click at the link given to verify email in the system medcast V2.0.



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.

The screenshot displays the MeDC@St v2.0 dashboard for a user named SYAK AMIRUL. The interface includes a top navigation bar with a search bar, language selector (ENGLISH), and user profile. A left sidebar contains a navigation menu with categories: HOME, ESTABLISHMENT LICENSE, MEDICAL DEVICE REGISTRATION, ACCOUNT MANAGEMENT, and ONLINE HELP. The main content area shows a 'You Are Logged In As Main Account' notification, a 'Modules' dropdown set to 'Establishment License', and a 'New Registration +' button. Below this, a 'ESTABLISHMENT LICENSING' section displays four status cards: Draft (0), Application (0), Return From MDA (0), and Drop (0). An 'Announcement' section shows a list of items, and an 'Alert Management' section displays 'No results found.'.

MeDC@St v2.0

Quick Search **Q** Advanced Search

EXAMPLE:

ENGLISH SYAK AMIRUL - SYAK AMIRUL

Home / Dashboard

Navigation Menu:

- HOME
- ESTABLISHMENT LICENSE
- MEDICAL DEVICE REGISTRATION
- ACCOUNT MANAGEMENT
- ONLINE HELP

Account Management Sub-menu:

- Change Password
- User Management
- Deleted User

Establishment License Sub-menu:

- New Application Form
- Application List (0)
- Change Of Ownership
- Change Notification (0)
- History (0)

Dashboard Content:

You Are Logged In As Main Account

Modules: Establishment License

New Registration +

ESTABLISHMENT LICENSING

0 Draft 0 Application 0 Return From MDA 0 Drop

Announcement

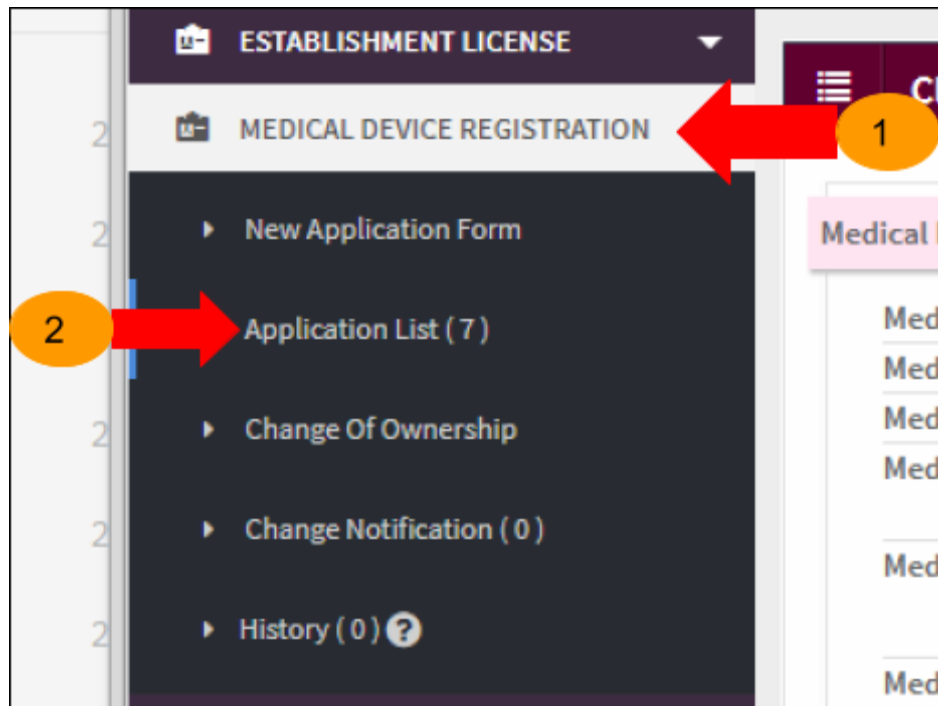
Showing 1-2 of 2 items.

Alert Management

No results found.

2.0 CHANGE OF NOTIFICATION - SINGLE APPLICATION

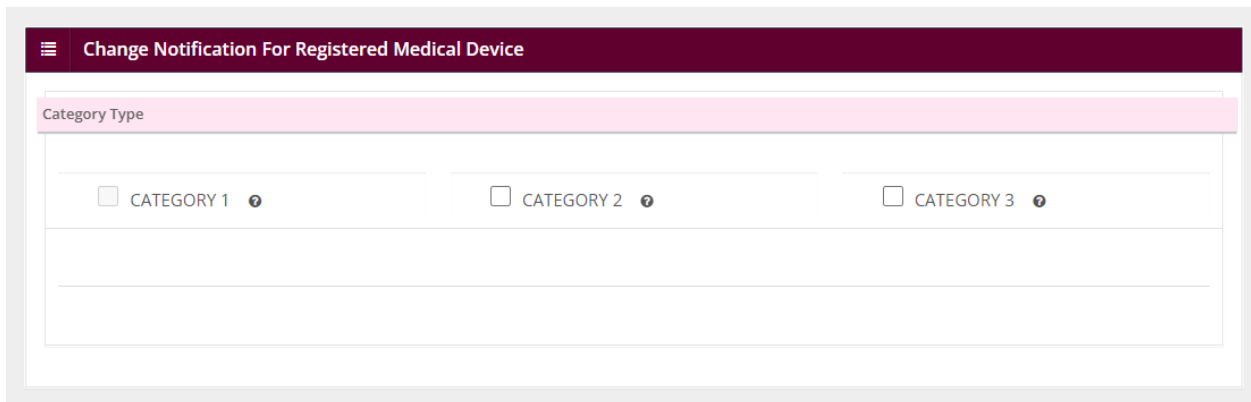
User go to *Application List* page to change of notification application.



The diagram below show *Application List* page. Click [+ Change Of Notification](#) to change of notification application.

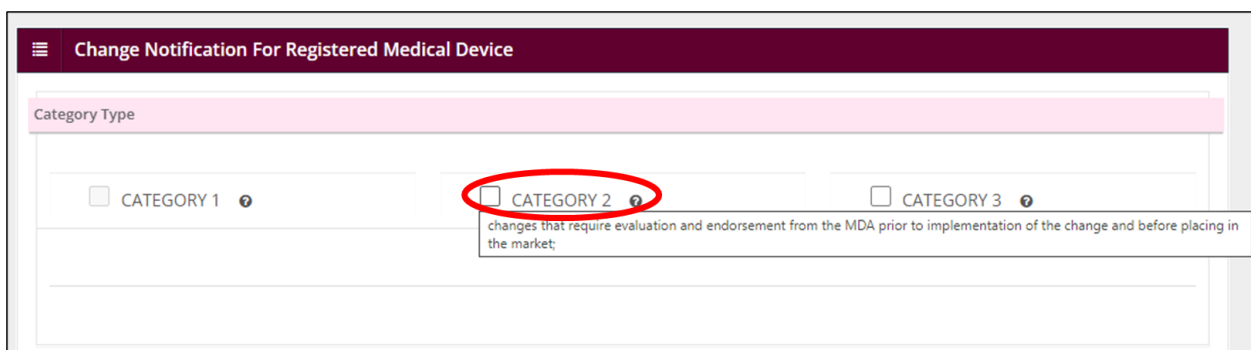
10	MDR-20201119-24334	NEW REGISTRATION	11-05-2021	AUTHORISED REPRESENTATIVE	BLOOD TRANSFUSION SET	B	GENERAL MEDICAL DEVICE (GMD)	COMPLETE	View ReRegister P Advice & Receipt Withdrawal Certificate Certificate List Change Notification Application History
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Create 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 screenshot shows a web form titled "Change Notification For Registered Medical Device". Below the title bar, there is a section labeled "Category Type" with a pink header. Under this header, there are three checkboxes labeled "CATEGORY 1", "CATEGORY 2", and "CATEGORY 3". Each checkbox is currently unchecked and has a small question mark icon to its right. Below the checkboxes is a large empty text area for additional information.

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 includes a tooltip for "CATEGORY 2". The "CATEGORY 2" checkbox and its label are circled in red. A tooltip box is visible below the circled area, containing the text: "changes that require evaluation and endorsement from the MDA prior to implementation of the change and before placing in the market;".

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 a modification 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

Then, click

PROCEED TO REGISTRATION APPLICATION CHANGE OF NOTIFICATION

to proceed the registration of the change of notification application.

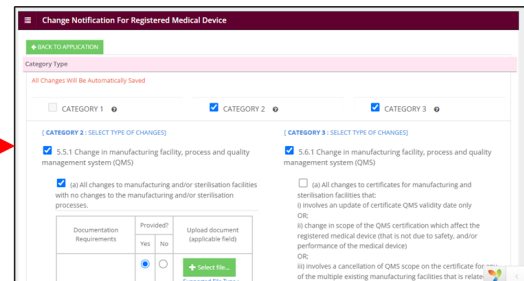
At the top of the page, user can view the checklist of the Change Notification by clicking the

 **SHOW CHANGE OF NOTIFICATION CHECKLIST**

and user also can edit the checklist of Change

Notification by clicking the

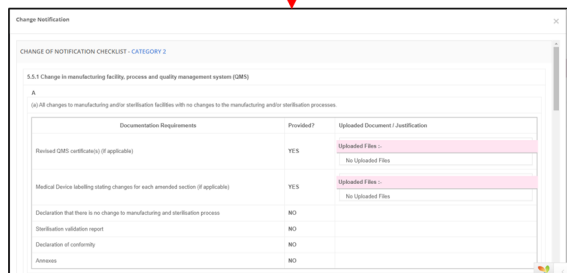
 **EDIT CHANGE NOTIFICATION CHECKLIST FORM**



Click To See [Change Of Notification](#) checklist

 **SHOW CHANGE OF NOTIFICATION CHECKLIST**

 **EDIT CHANGE NOTIFICATION CHECKLIST FORM**



Home / Class BCD / Medical Device Registration (MDR-20220117-37084) - GENERAL MEDICAL DEVICE (GMD) - CLASS B

Medical Device Registration (MDR-20220117-37084)

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

1.0 Risk Type Classification

1. Class Of Device * CLASS B

2. Device Condition * New

3. Medical Device Risk Type * GENERAL MEDICAL DEVICE (INVASIVE DEVICE)

4. Classification Rules * RULE 7

1. Rule Can Only Be Changed By Altering Risk Type
2. Tick The Necessary Rule Detail Below To Indicate The Risk Type
(If more than one rule is applicable, the highest risk rule will be applied)
3. Risk Rule Available For Class B - GENERAL MEDICAL DEVICE (INVASIVE DEVICE)

- RULE 5
- RULE 5

SIDEBAR

- 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

Application Detail

- 1.0 ESTABLISHMENT DETAILS
- 2.0 GENERAL INFORMATION
- 3.0 MEDICAL DEVICE GROUPING
- 4.0 CSDT
- 5.0 MANUFACTURER INFORMATION
- 6.0 PRE-MARKET CLEARANCE/PRE-MARKET APPROVAL
- 7.0 CONFORMITY ASSESSMENT

Next ➔

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 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

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)

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)

Maximum File Size : 300MB
Supported File Type : PDF Only

Upload file * Supported File Type : pdf

Uploaded Files:-
No Uploaded Files

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

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

SUPPLIED STERILE

Sterilization Validation Report & Cert

Upload file * Supported File Type : pdf

Uploaded Files:-
No Uploaded Files

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

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

☒ OTHERS

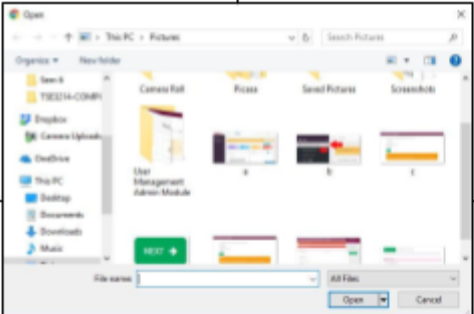
Please specify : *

Any Related Document

 Upload file * Supported File Type : pdf

Uploaded Files:-

No Uploaded Files



User has fill 'Please specify' text box first then click


 Upload file

to upload file. **The file must**

be pdf format.

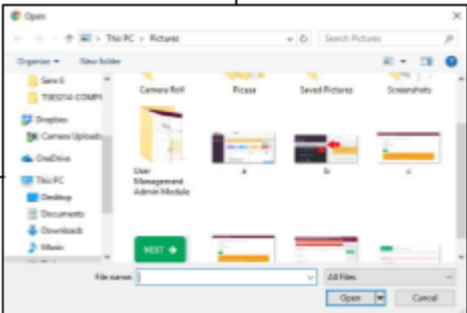
☒ ACTIVE

Validation Report / Certificate

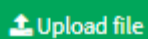
 Upload file * Supported File Type : pdf

Uploaded Files:-

No Uploaded Files




User click


 Upload file

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

The screenshot displays the 'Application Details' sidebar on the right, which includes sections for Medical Device Classification, Determine if the product is a medical device, General Information, Medical Device Grouping, and Additional Requirements. The main area contains two file upload sections. The first section, titled 'CONTAIN ANIMAL, HUMAN, MICROBIAL, RECOMBINANT ORIGIN (IVD)', has a sub-header 'Package Insert Containing Information On All List Of Material' and an 'Upload file' button. Below it, a box indicates 'No Uploaded Files'. The second section, titled 'Identify Of Immediate Sources Of All List Material', also has an 'Upload file' button and a 'No Uploaded Files' box. A file explorer window is open, showing the 'Pictures' folder with various image files.

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 'List Of Manufacturing Site' table with the following data:


No	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 MAMANGA 3,	54300	15857297259a26a389a55 41407958.pdf	Upload File Update Delete

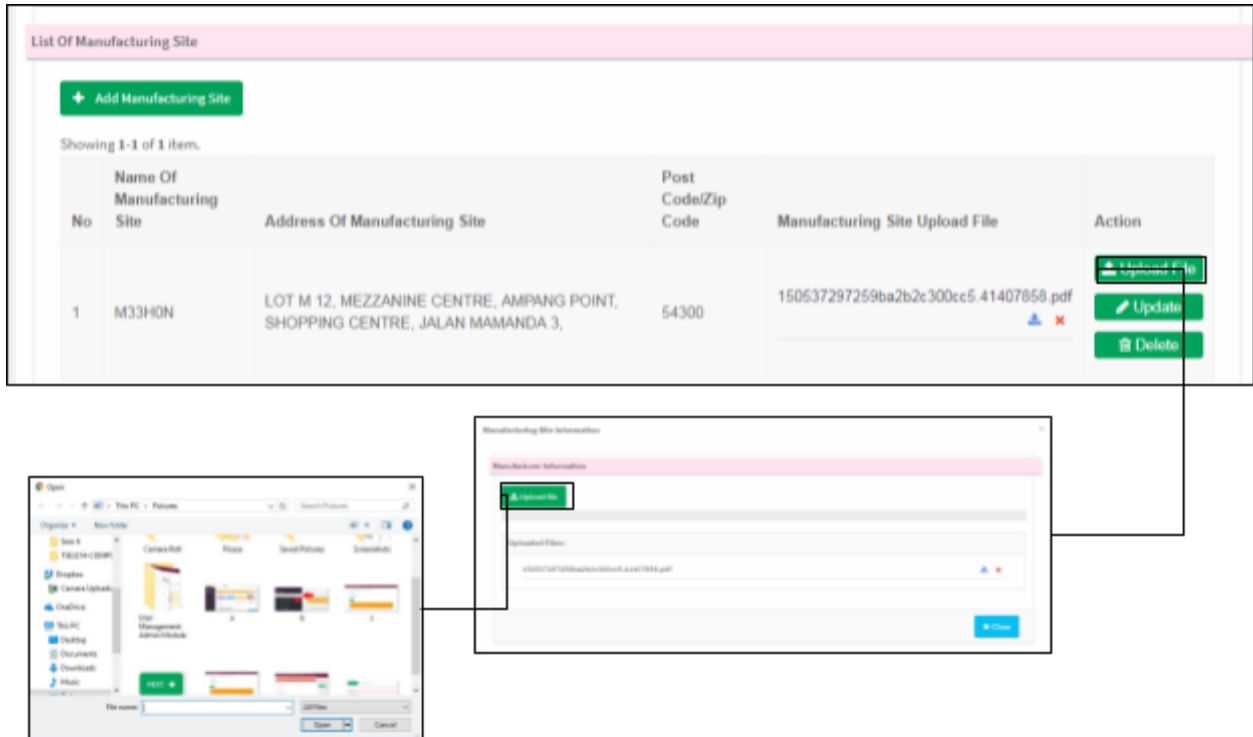
Below the table are two detail forms for 'Manufacturing Site Information':

Form 1 (Left): Contains text boxes for '1. Name Of Manufacturing Site:', '2. Address Of Manufacturing Site:', and '3. Post Code/Zip Code:', with a 'Submit' button at the bottom.




Form 2 (Right): Contains text boxes for '1. Name Of Manufacturing Site:' (filled with 'M33-EN'), '2. Address Of Manufacturing Site:' (filled with 'LOT M 12, MEZZANINE CENTRE, AMPANG POINT, SHOPPING CENTRE, JALAN MAMANGA 3,'), and '3. Post Code/Zip Code:' (filled with '54300'), with a 'Submit' button at the bottom.

User click [+ Add Manufacturing Site](#) to add new data or click [Update](#) to change the old data. User has to fill all the text box then click [Submit](#). The new data will display in 'List Of Manufacturing Site' table.

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



The screenshot displays the 'List Of Manufacturing Site' interface. At the top, there is a green button labeled '+ Add Manufacturing Site'. Below it, a message states 'Showing 1-1 of 1 item.' A table lists the manufacturing site details:

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	<div> Upload File  Update  Delete</div>

A callout shows a file explorer window with the path 'This PC > Pictures' and a 'Manufacturing Site Information' form. The form has a tab labeled 'Manufacturing Site Information' and a green 'Upload File' button. The 'Upload File' button is highlighted with a green box, and a line connects it to the 'Upload File' button in the table's action column.

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.

 **PREVIEW & SUBMIT**

User click **PREVIEW & SUBMIT** to preview before submit application.

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

The screenshot displays the 'MDR Class A Application' interface with a submission ID of MDR-20171114-254. At the top left is a green 'Submit' button. A callout box labeled 'Click to submit application' points to this button. The form is organized into three sections, each with a pink bar indicating completion status and a 'Click To View More' link. A callout box labeled 'Click to see more details about form' points to these links. A 'Status' box at the top right has arrows pointing to the 'Complete' status labels in each section's bar.

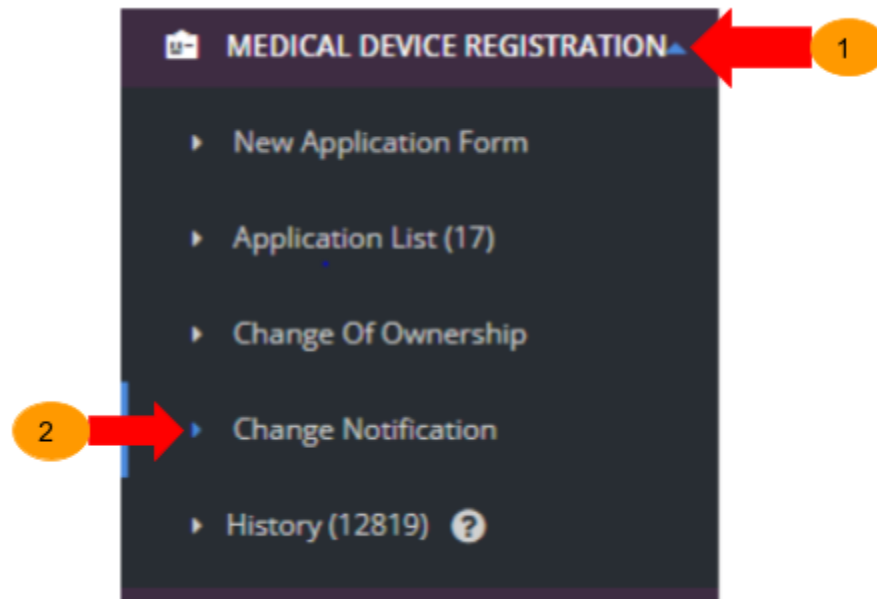
Section	Item	Link	Status
Section 1 : Medical Device Classification	Medical Device Risk And Classification Details	Click To View More	Complete
	Establishment Details	Click To View More	Complete
Section 2 : Determine If The Product A Medical Device	Determine If The Product A Medical Device	Click To View More	Complete
Section 3 : General Information	Medical Device General Information	Click To View More	Complete

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

Then, click  to submit application.

3.0 CHANGE OF NOTIFICATION APPLICATION - MULTIPLE APPLICATION

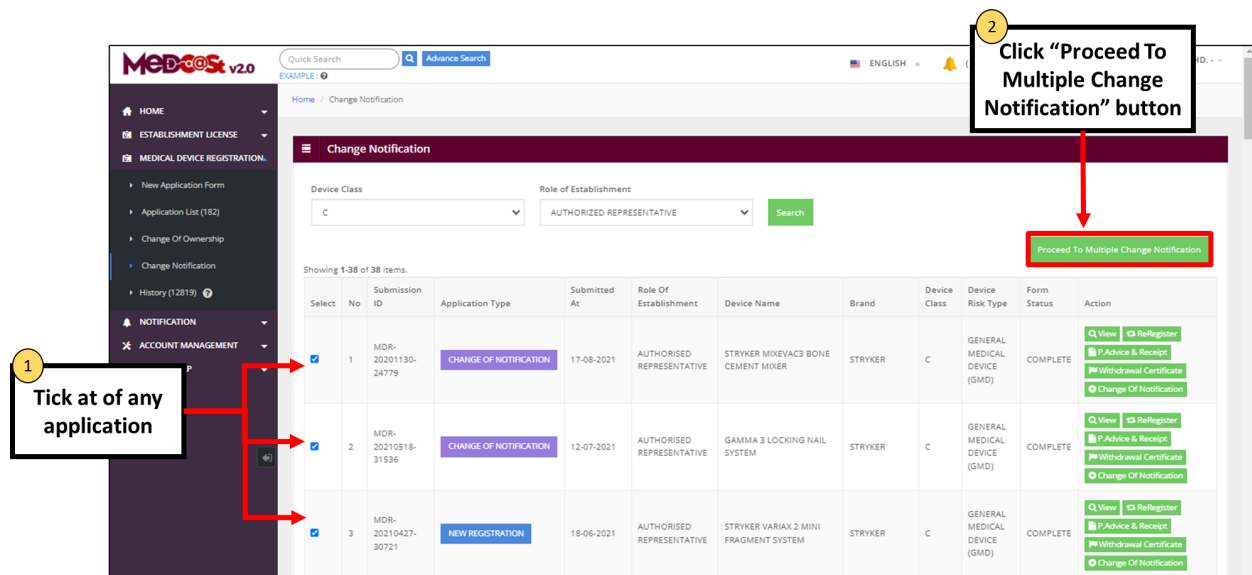
User go to *Change Notification* page to make multiple change notification application.



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

Establishment = Authorised of Representative and then click

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

Application List

No.	Old Submission ID	New Submission ID
1	Q D1391-20160523-48409	MDR-20220119-37086
2	Q D1391-20160523-48388	MDR-20220119-37087

Application Detail

1.0 ESTABLISHMENT DETAILS

2.0 GENERAL INFORMATION

3.0 MEDICAL DEVICE GROUPING

4.0 CSDT

5.0 MANUFACTURER INFORMATION

6.0 PRE-MARKET

1.0 Risk Type Classification

Change Notification

1. Class

2. Device

Change Notification For Registered Medical Device

Category Type

All Changes Will Be Automatically Saved

CATEGORY 1

CATEGORY 2

CATEGORY 3

CATEGORY 2 : SELECT TYPE OF CHANGE

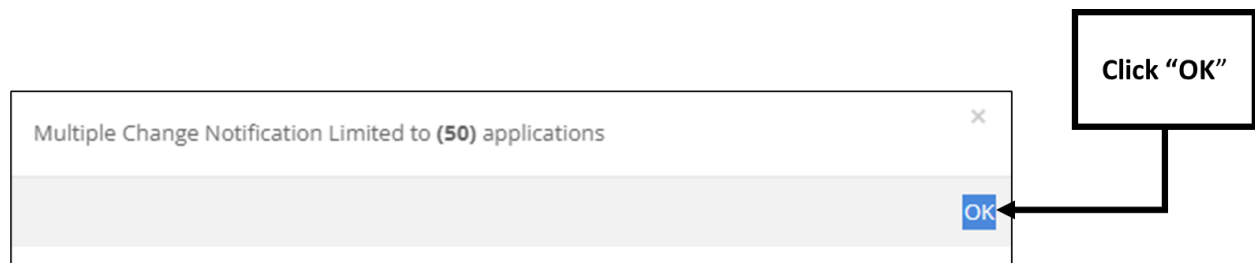
5.5.1 Change in manufacturing facility, process and quality management systems (QMS)

(a) All changes to manufacturing and/or sterilisation facilities with no changes to the manufacturing and/or sterilisation processes.

(b) change in scope of the QMS certification which affect the registered medical device (that is not due to safety, and/or performance of the medical device)

(c) involves a cancellation of QMS scope on the certificate for of the multiple existing manufacturing facilities that is relate

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.

A screenshot of the "Change Notification For Registered Medical Device" form. The form has a header bar with a menu icon and the title "Change Notification For Registered Medical Device". Below the header, there is a section titled "Category Type" with a pink background. Under this section, there are three checkboxes labeled "CATEGORY 1", "CATEGORY 2", and "CATEGORY 3", each with a help icon (i) to its right.

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

A screenshot of the "Change Notification For Registered Medical Device" form, similar to the previous one. In this version, the "CATEGORY 2" checkbox and its help icon are circled in red. A tooltip is visible below the circled area, containing the text: "changes that require evaluation and endorsement from the MDA prior to implementation of the change and before placing in the market".

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 a modification 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

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.

The diagram illustrates the user's navigation path through the MeDC@St 2.0 system to view and update application information. It starts with a 'Class A Application (MDR-20220117-37081)' list. A red arrow points from the 'Old Submission ID' column, specifically to the ID 'Q MDR-20210708-33911'. Another red arrow points from the 'SHOW CHANGE OF NOTIFICATION CHECKLIST' button to the 'CHANGE NOTIFICATION' form. A third red arrow points from the 'EDIT CHANGE NOTIFICATION CHECKLIST FORM' button to the 'Change Notification For Registered Medical Device' form.

Class A Application (MDR-20220117-37081)

No.	Old Submission ID
1	Q MDR-20210708-33911
2	Q MDR-20210416-30323

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

Change Notification

CHANGE OF NOTIFICATION CHECKLIST - CATEGORY 2

A

(i) All changes to manufacturing facility, process and quality management system (QMS)

Documentation Requirements	Provided?	Upload document / Justification
Revised (QMS certificate) (if applicable)	YES	Upload File / No Upload File
Medical Device labelling status changes for each amended section (if applicable)	YES	Upload File / No Upload File
Declaration that there is no change in manufacturing and distribution process	NO	
Declaration validation report	NO	
Declaration of conformity	NO	
Annexes	NO	

Change Notification For Registered Medical Device

[BACK TO APPLICATION](#)

Category Type

All Changes Will Be Automatically Saved

☐ CATEGORY 1 ☒ CATEGORY 2 ☒ CATEGORY 3

[CATEGORY 2 : SELECT TYPE OF CHANGES]

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

☒ (a) All changes to manufacturing and/or sterilisation facilities with no changes to the manufacturing and/or sterilisation processes.

Documentation Requirements

Provided?	Upload document (applicable field)
Yes	
No	Select File

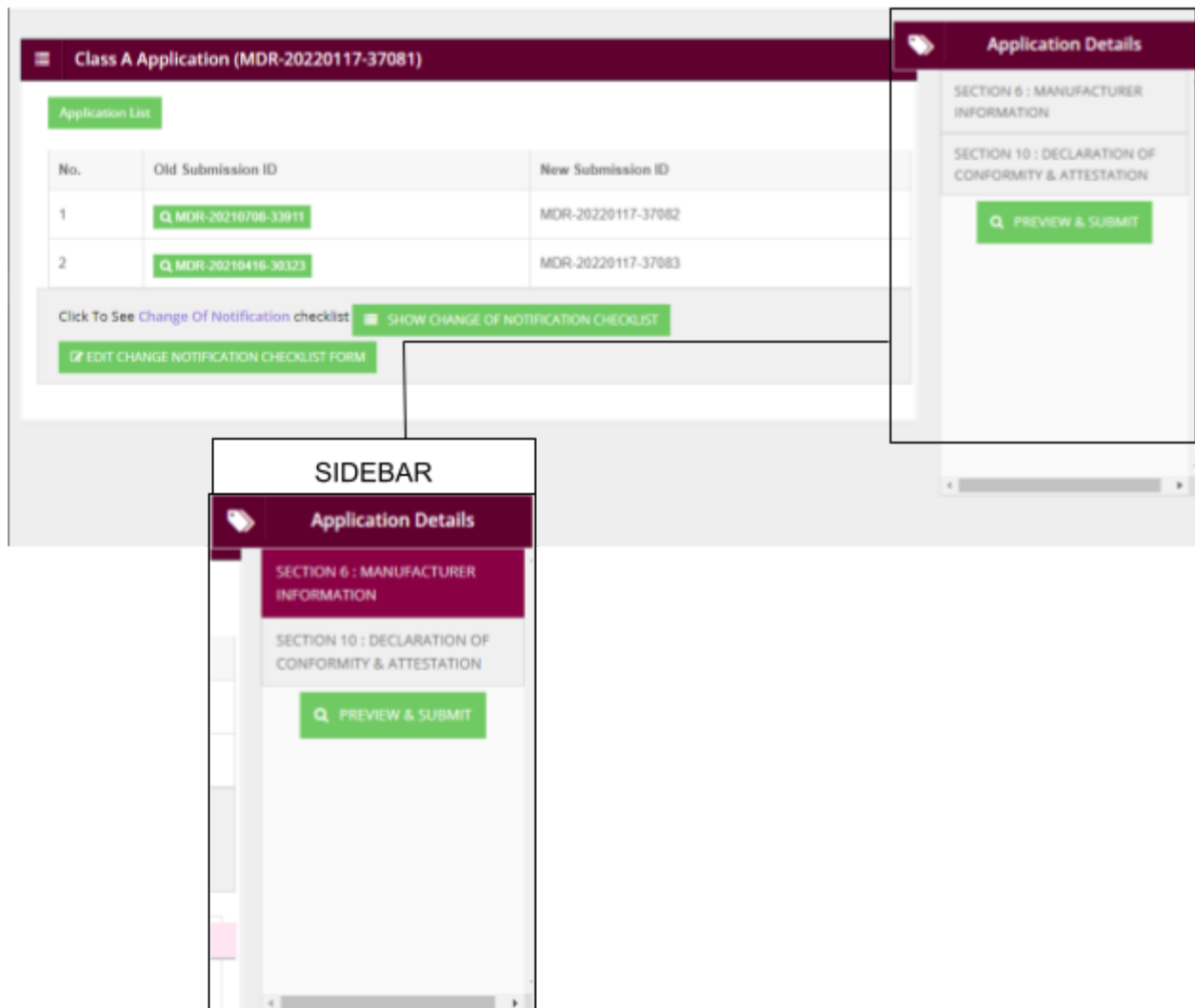
☐ (a) All changes to certificates for manufacturing and sterilisation facilities that:

i) involves an update of certificate QMS validity date only OR

ii) change in scope of the QMS certification which affect the registered medical device (that is not due to safety, and/or performance of the medical device)

OR

iii) involves a cancellation of QMS scope on the certificate for the multiple existing manufacturing facilities that is related



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.

Manufacturer Information

1. Name Of Manufacturer : 11

2. Manufacturer Registration No : PFR008

3. Name Of Registered Manufacturer Auditor : SHIN HAN EMBELI HAMBALI

4. Certificate Expiry Date : 2020-12-30

Quality Management System Information

Quality Management System Certificate

Uploaded Files:

IKLAK_NDV_2017.PDF

AT37-Q4LPDF

List Of Manufacturing Site

+ Add Manufacturing Site

Showing 1-1 of 1 item.

No	Name Of Manufacturing Site	Address Of Manufacturing Site	Post Code/Zip Code	Manufacturing Site Upload File	Action
1	M33-EN	LOT M 12, MEZZANINE CENTRE, AMPANG POINT, SHOPPING CENTRE, JALAN MAMANGA 3,	54300	15857297259a26a389a55 41407f958.pdf	Upload File Update Delete

Manufacturer Information

1. Name Of Manufacturing Site :

2. Address Of Manufacturing Site :

3. Post Code/Zip Code :

[Submit](#)

Manufacturer Information


1. Name Of Manufacturing Site : M33-EN

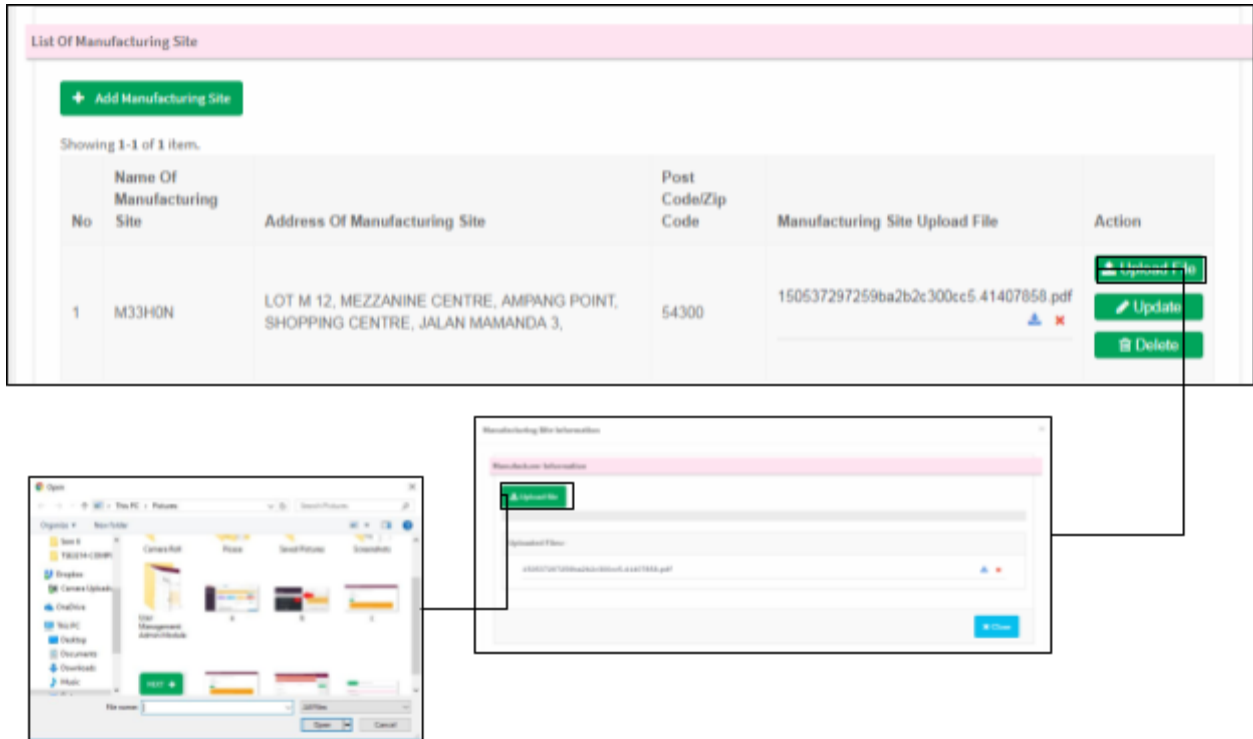
2. Address Of Manufacturing Site : LOT M 12, MEZZANINE CENTRE, AMPANG POINT, SHOPPING CENTRE, JALAN MAMANGA 3,

3. Post Code/Zip Code : 54300




[Submit](#)

User click [+ Add Manufacturing Site](#) to add new data or click [Update](#) to change the old data. User has to fill all the text box then click [Submit](#). The new data will display in 'List Of Manufacturing Site' table.

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



The screenshot displays the 'List Of Manufacturing Site' interface. At the top, there is a green button labeled '+ Add Manufacturing Site'. Below it, a message states 'Showing 1-1 of 1 item.' A table lists the manufacturing site details:

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_41407858.pdf	  

A callout shows a file explorer window with the path 'This PC > Pictures' and a 'Manufacturing Site Information' modal. The modal has a tab labeled 'Manufacturing Site Information' and a green 'Upload File' button. Below the button, the 'Uploaded File' section shows the file 'a200070af700bba2b2c300cc5_41407858.pdf'.

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.

 **PREVIEW & SUBMIT**

User click **PREVIEW & SUBMIT** to preview before submit application.

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

The screenshot displays the MDR Class A Application form with the following sections and their completion status:

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

Annotations on the screenshot:

- A green **Submit** button is located at the top left.
- A box labeled "Click to submit application" points to the **Submit** button.
- A box labeled "Status" points to the "Complete" status indicators for the first two items in Section 1.
- A box labeled "Click to see more details about form" points to the "Click To View More" links for the first two items in Section 1, the item in Section 2, and the item in Section 3.

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.