

USER MANUAL FRONT END USER

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



MODUL UTAMA - CHANGE NOTIFICATION CLASS A

DISEDIAKAN OLEH :



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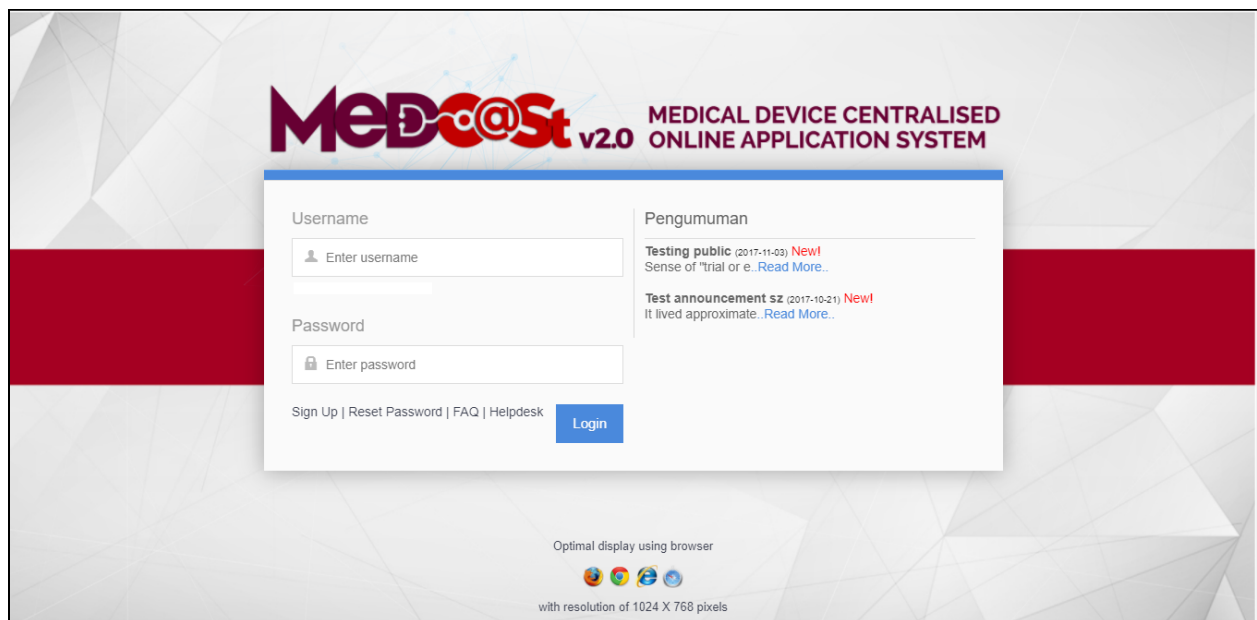
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1.0 INTRODUCTION

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>

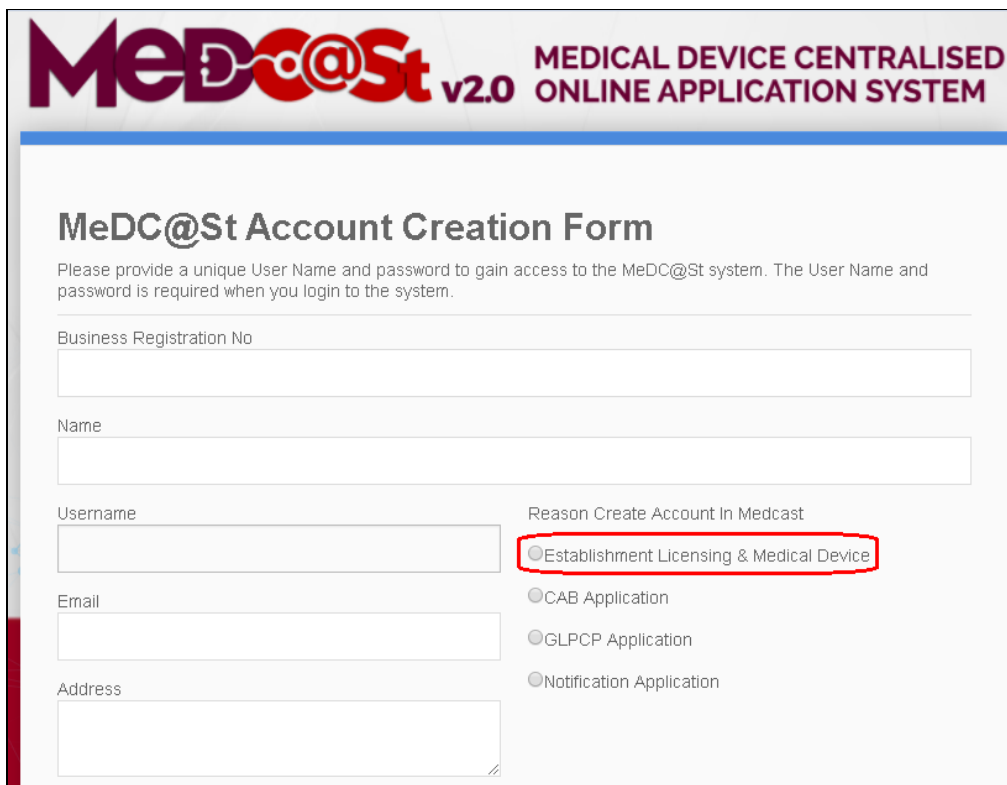
The screen below shows the expected webpage after the address has been keyed In.



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.



The image shows the 'MeDC@St Account Creation Form' for the 'MEDICAL DEVICE CENTRALISED ONLINE APPLICATION SYSTEM v2.0'. The form includes fields for Business Registration No, Name, Username, Email, and Address. On the right, there is a section titled 'Reason Create Account In Medcast' with four radio button options: 'Establishment Licensing & Medical Device' (which is highlighted with a red rectangle), 'CAB Application', 'GLPCP Application', and 'Notification Application'. Below the form, there is a small note about providing a unique User Name and password.

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

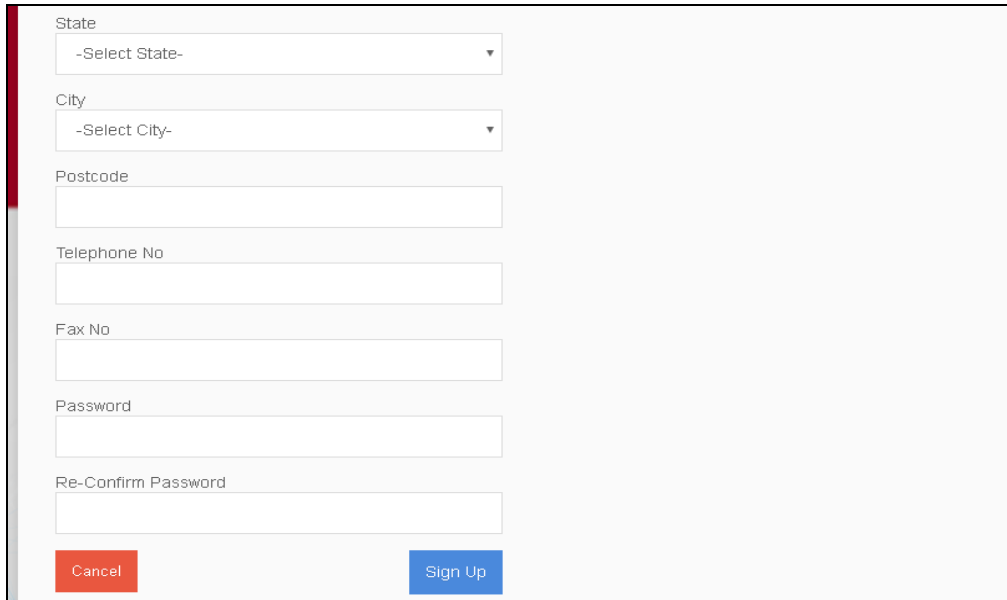
Username

Email

Address

Reason Create Account In Medcast

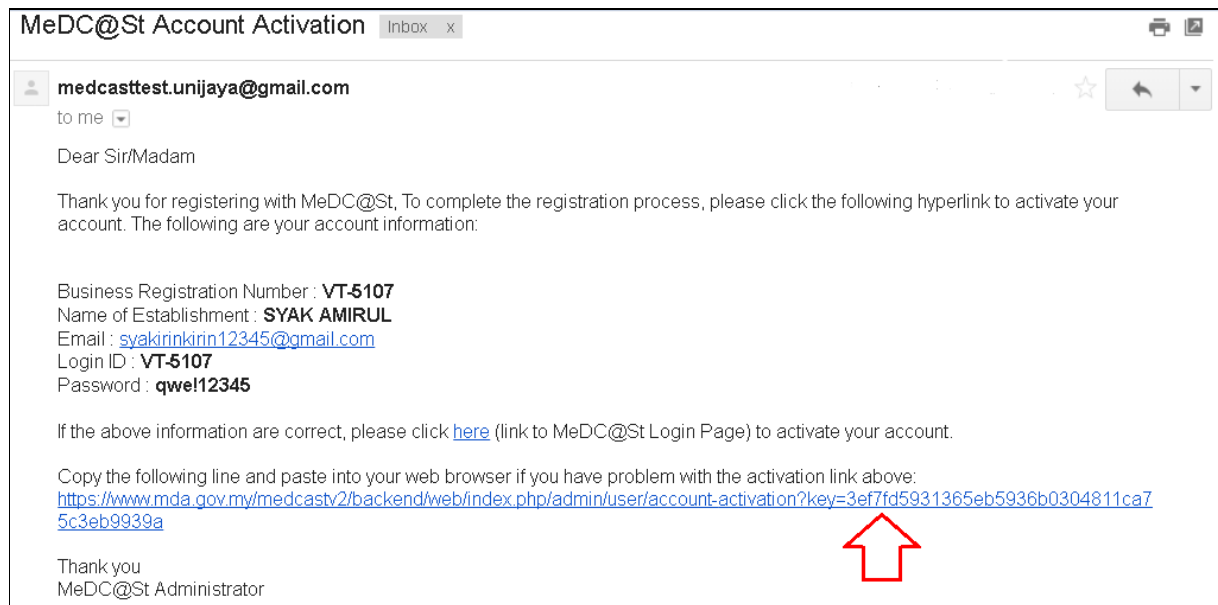
- ☒ Establishment Licensing & Medical Device
- ☐ CAB Application
- ☐ GLPCP Application
- ☐ Notification Application



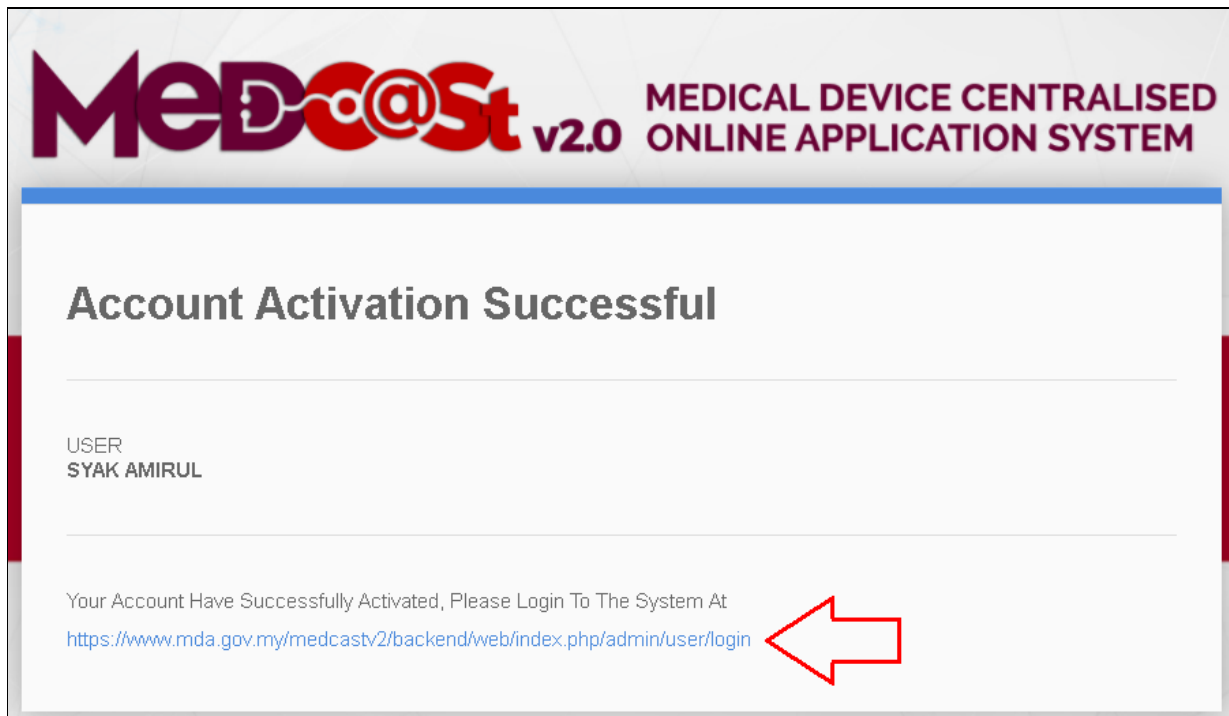
A registration form with the following fields: State (dropdown menu with '-Select State-'), City (dropdown menu with '-Select City-'), Postcode (text input), Telephone No (text input), Fax No (text input), Password (text input), and Re-Confirm Password (text input). At the bottom, there are two buttons: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

1.1.1 VERIFIED EMAIL FOR NEW ACCOUNT

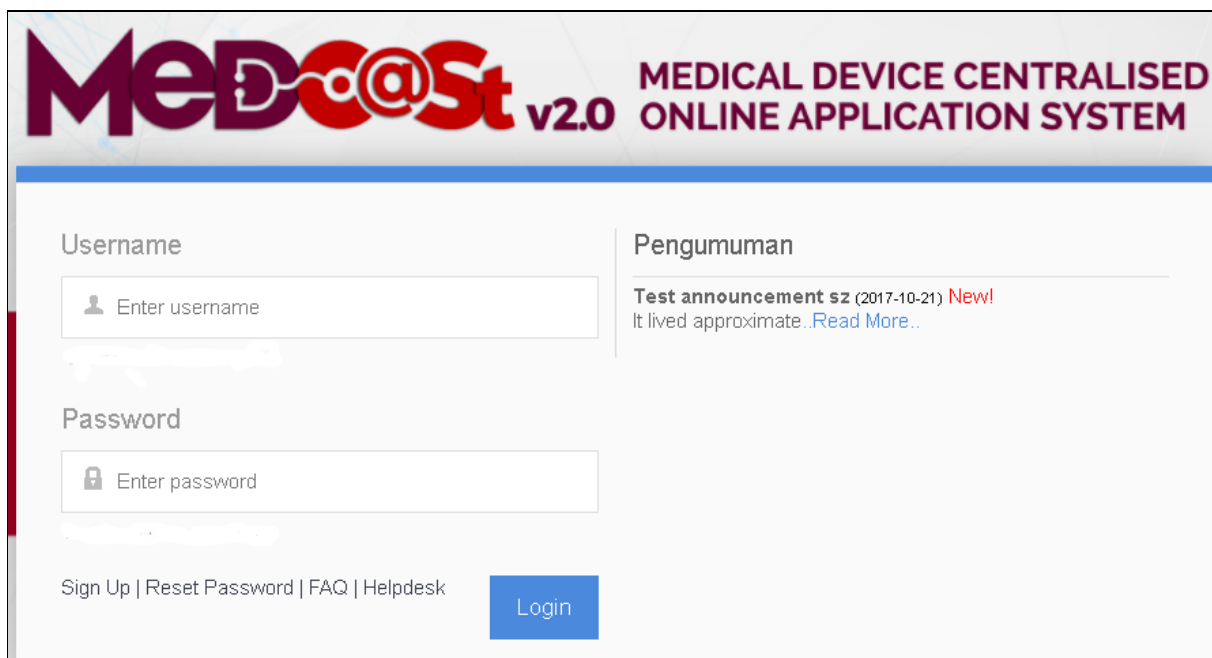
The user must verify email to complete the last step of the registration. Click at the link given to verify email in the system medcast V2.0.



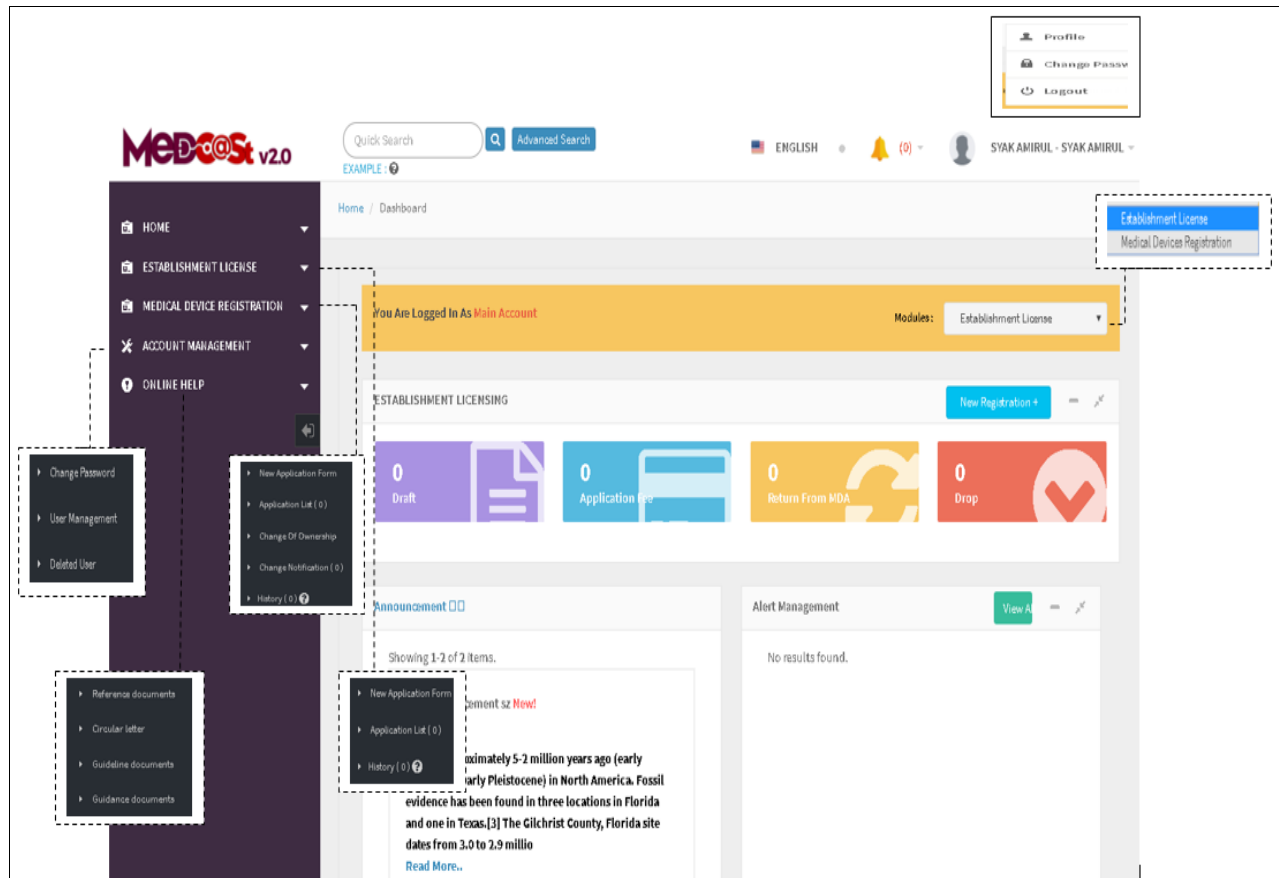
The account activation screen will display. The user must click at the link to login into the account.



The login screen will display.

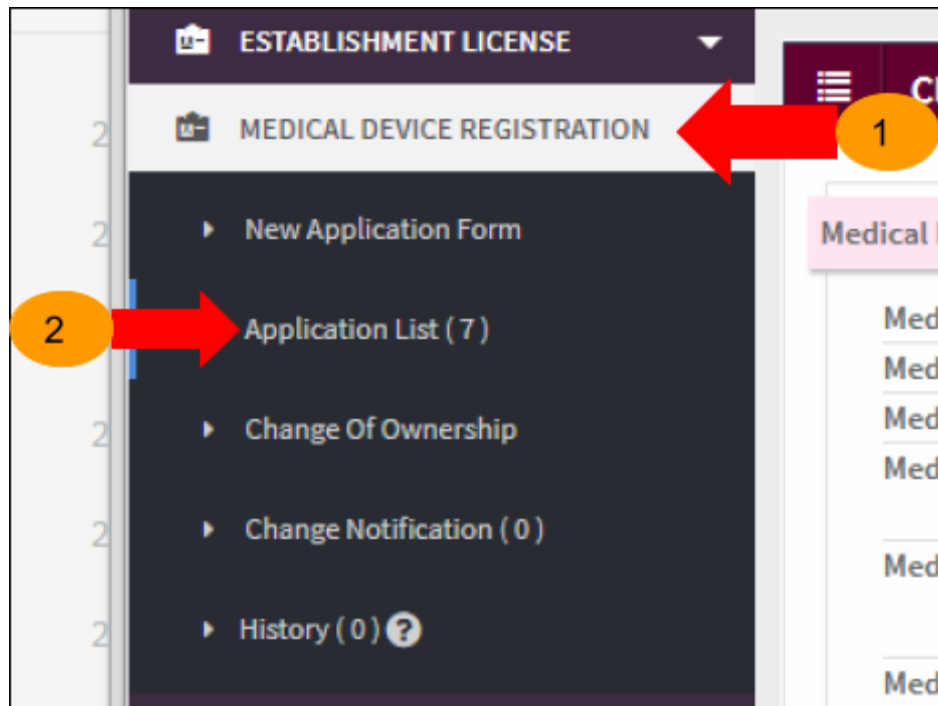


The user login successfully in the system medcast. It show the dashboard of the account.



2.0 CHANGE OF NOTIFICATION - SINGLE APPLICATION

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

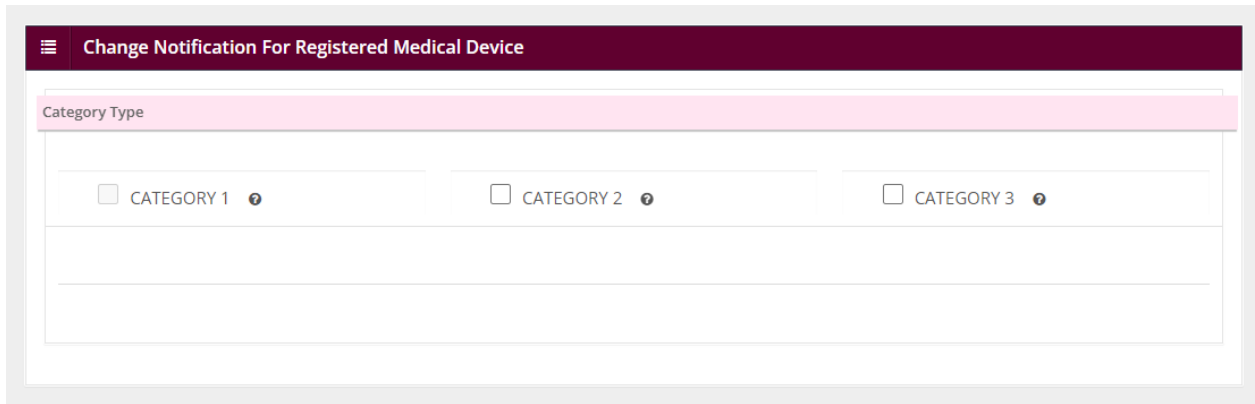


The diagram below show *Application List* page. Click [+ Change Of Notification](#) to change of notification application.

								Withdrawal Application	
								View	ReRegister
								PAdvice & Receipt	Withdrawal Certificate
								Change Of Notification	

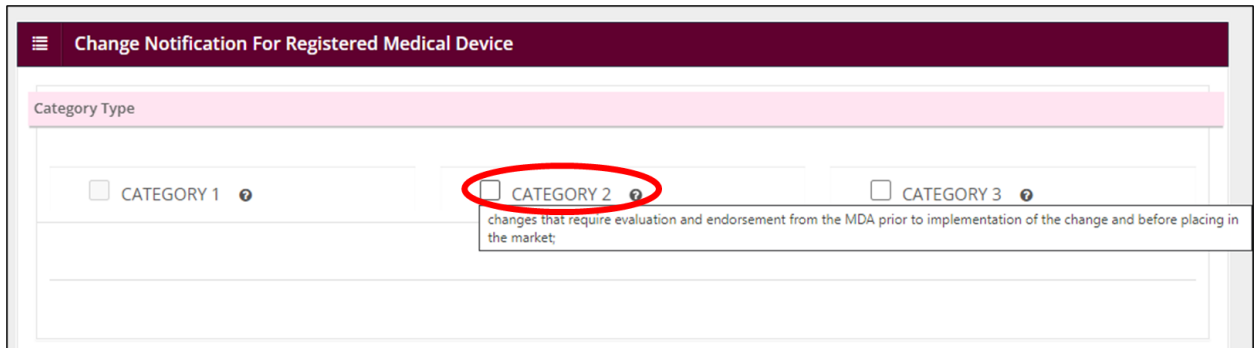
6	MDR-20171121-262	NEW REGISTRATION	21-11-2017	MANUFACTURER	CLOVIE	A	GENERAL MEDICAL DEVICE (GMD)	COMPLETE	
---	------------------	------------------	------------	--------------	--------	---	------------------------------	----------	--

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 has a small question mark icon to its right. The checkboxes are currently unchecked.

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 label, 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	☐	☒	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 new certificate of QMS

Documentation Requirements	Provided?		Upload document (applicable field)
	Yes	No	
Valid QMS certificate	☐	☒	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

The diagram illustrates the process for viewing and editing the Change Notification checklist. It starts with the 'Change Notification For Registered Medical Device' form, which includes a 'Category Type' section with three categories: CATEGORY 1, CATEGORY 2, and CATEGORY 3. CATEGORY 2 and CATEGORY 3 are selected. A red arrow points from the 'SHOW CHANGE OF NOTIFICATION CHECKLIST' button to the 'Click To See Change Of Notification checklist' button. Another red arrow points from the 'EDIT CHANGE NOTIFICATION CHECKLIST FORM' button to the 'Change Notification' checklist form.

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 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.

CATEGORY 3: SELECT TYPE OF CHANGES

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

☐ (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 of the multiple existing manufacturing facilities that is relevant.

Documentation Requirements

Provided?

Yes No

Upload document (applicable field)

☒ ☐ [Select File...](#) [Supported File Type](#)

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

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

A

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

Documentation Requirements	Provided?	Uploaded Document / Justification
Revised QMS certificate(s) (if applicable)	YES	Uploaded File : No Uploaded File
Medical Device labelling marking changes for each amended section (if applicable)	YES	Uploaded File : No Uploaded File
Declaration that there is no change to manufacturing and sterilisation process	NO	
Sterilisation validation report	NO	
Declaration of conformity	NO	
Access	NO	

Class A Application (Submission ID :MDR-20171207-283)

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

Medical Device Risk And Classification Details

Medical Device Type	:	NEW
Medical Device Risk Type	:	GENERAL MEDICAL DEVICE (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 A A Barrier, Or For Compression, Or Absorption Of Exudate
Medical Device Intended Uses	:	Act As A Mechanical Barrier 1. For Compression Or Maintain Wound Position
Medical Device Class	:	Class A

Establishment Details

1. BUSINESS REG NO	BAIMOR
2. ESTABLISHMENT	BAIZURA SYAIFULLAH

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

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

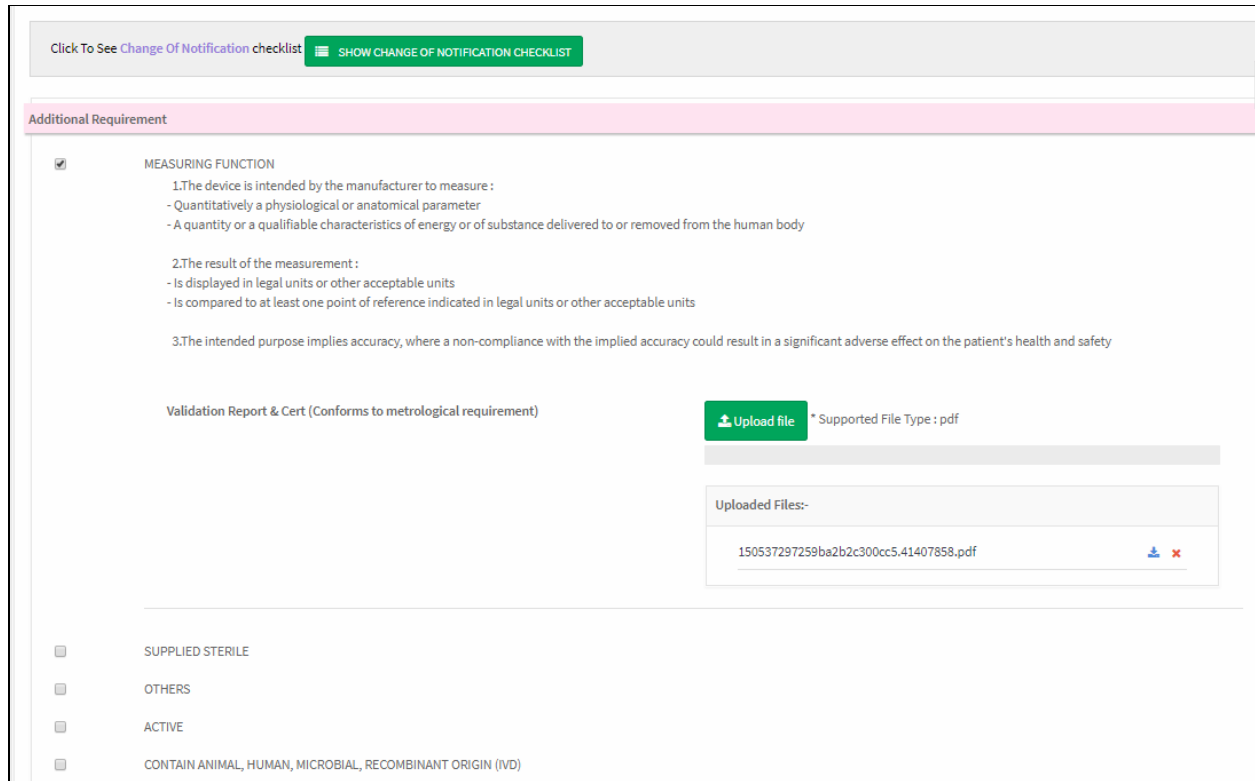
SECTION 7 : PRE-MARKET CLEARANCE / PRE-MARKET APPROVAL

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 [Download](#) [Delete](#)

☐ **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  to change the old upload file to the new upload file. **The file must be pdf format.**

☒ SUPPLIED STERILE

Sterilization Validation Report & Cert

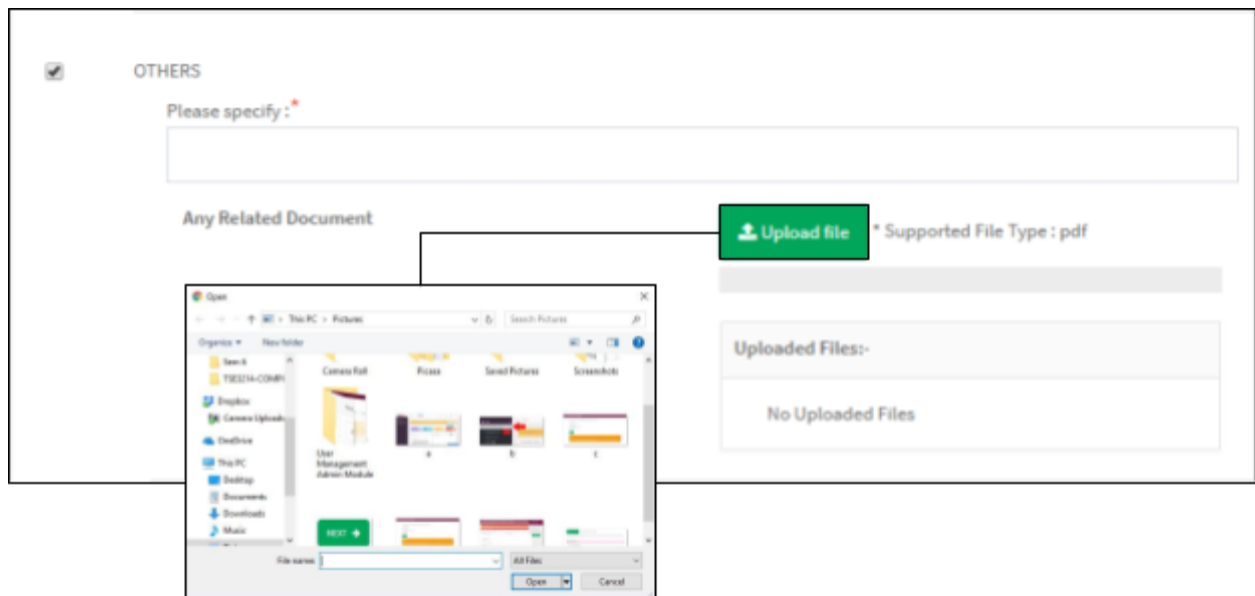
Upload file * Supported File Type : pdf

Uploaded Files:-
No Uploaded Files

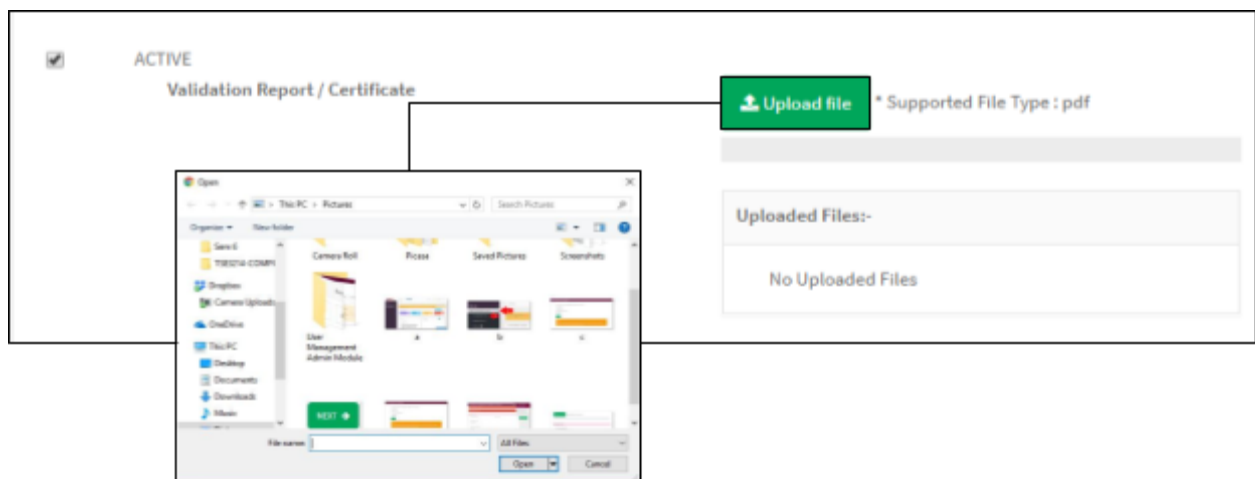
Application Details

- 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  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.**

CONTAIN ANIMAL, HUMAN, MICROBIAL, RECOMBINANT ORIGIN (IVD)
Package Insert Containing Information On All List Of Material

Upload file * Supported File Type : pdf

Uploaded Files:-
No Uploaded Files

Identify Of Immediate Sources Of All List Material

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  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 6 : 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	15857297259a26a389c541407f98.pdf	Upload File Update Delete

Below the table, two pop-up forms are shown:

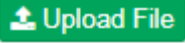
Manufacturing Site Information (Add New):

- 1. Name Of Manufacturing Site:
- 2. Address Of Manufacturing Site:
- 3. Post Code/Zip Code:
- [Submit](#)

Manufacturing Site Information (Update):

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

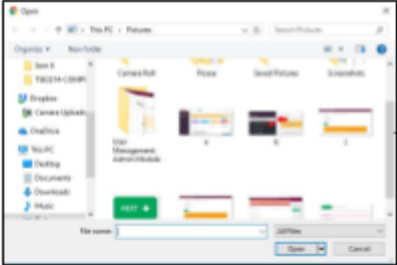
User click  to change the old upload file or to new upload files.

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	M33H0N	LOT M 12, MEZZANINE CENTRE, AMPANG POINT, SHOPPING CENTRE, JALAN MAMANDA 3,	54300	150637297259ba2b2c300cc5_41407858.pdf	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, 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 submission ID 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 'Click To View More' link and a 'Status' indicator:

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

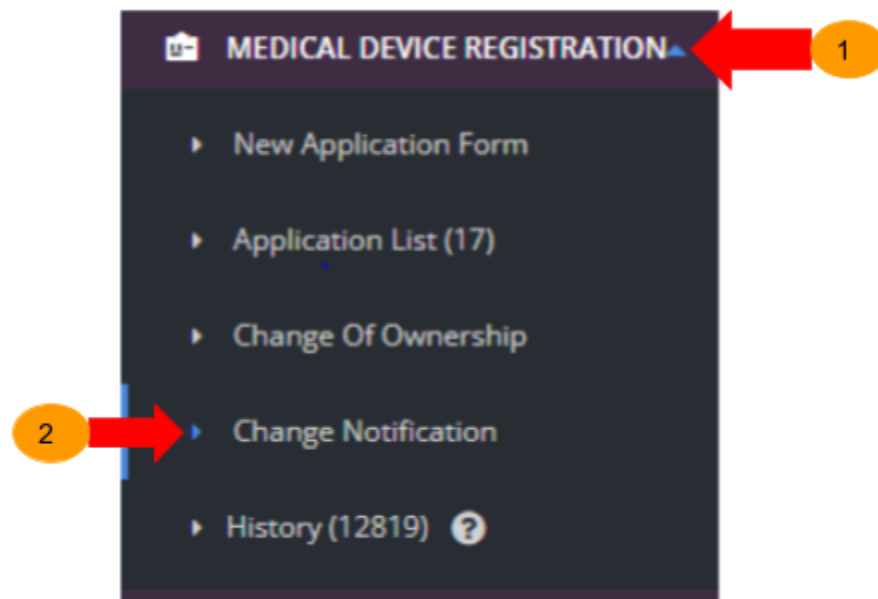
A central callout box labeled 'Click to see more details about form' has arrows pointing to each of the four 'Click To View More' links. A 'Status' box at the top right has arrows pointing to the 'Complete' status indicators for the first two items in Section 1.

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

Then, click  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* = A

and *Role of Establishment* = *Authorised of Representative* and then click

Search

1 Tick at of any application

2 Click "Proceed To Multiple Change Notification" button

Proceed To Multiple Change Notification

Select	No	Submission ID	Application Type	Submitted At	Role Of Establishment	Device Name	Brand	Device Class	Device Risk Type	Form Status	Action
☒	1	MDR-20201123-24501	NEW REGISTRATION	23-11-2020	AUTHORISED REPRESENTATIVE	Biometer Table	Ergo-Tec GmbH	A	GENERAL MEDICAL DEVICE (GMD)	COMPLETE	View ReRegister Withdrawal Certificate Change Of Notification
☒	2	MDR-20200930-22583	CHANGE OF NOTIFICATION	19-10-2020	AUTHORISED REPRESENTATIVE	SURGICAL DRAPE AND DRAPE ACCESSORIES	ALCON	A	GENERAL MEDICAL DEVICE (GMD)	COMPLETE	View ReRegister Withdrawal Certificate Change Of Notification
☒	3	MDR-20200827-21441	CHANGE OF NOTIFICATION	27-08-2020	AUTHORISED REPRESENTATIVE	QUICKLOCK CONNECTOR REUSABLE HANDLES	ALCON GRIESHABER	A	GENERAL MEDICAL DEVICE (GMD)	COMPLETE	View ReRegister Withdrawal Certificate Change Of Notification

- After click **Search**, the list of application from *Class A* 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.

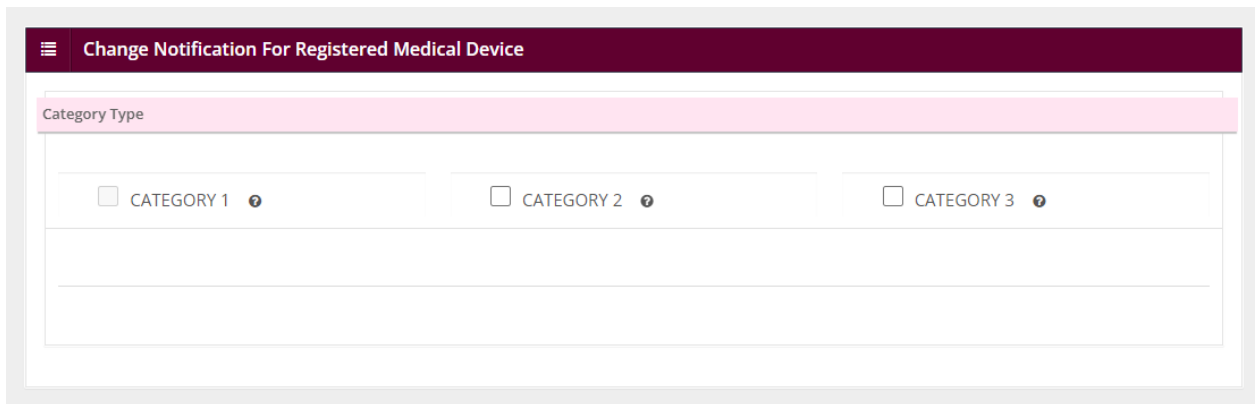
The multiple application can be made up until only 50 applications. If user tick more than 50 application, a pop-out message "Multiple Change Notification Limited to (50) applications" appeared. Then click "OK" to close the pop-out message.

Multiple Change Notification Limited to (50) applications

Click "OK"

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

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

Change Notification For Registered Medical Device

Category Type

☐ CATEGORY 1

☒ CATEGORY 2

☐ CATEGORY 3

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)

☒ Unless the change only—

All changes to certificates for manufacturing and sterilisation facilities

Documentation Requirements	Provided?		Upload document (applicable field)
	Yes	No	
Valid certificate and report	☐	☒	Please provide justification if no is selected

Unless the change only—

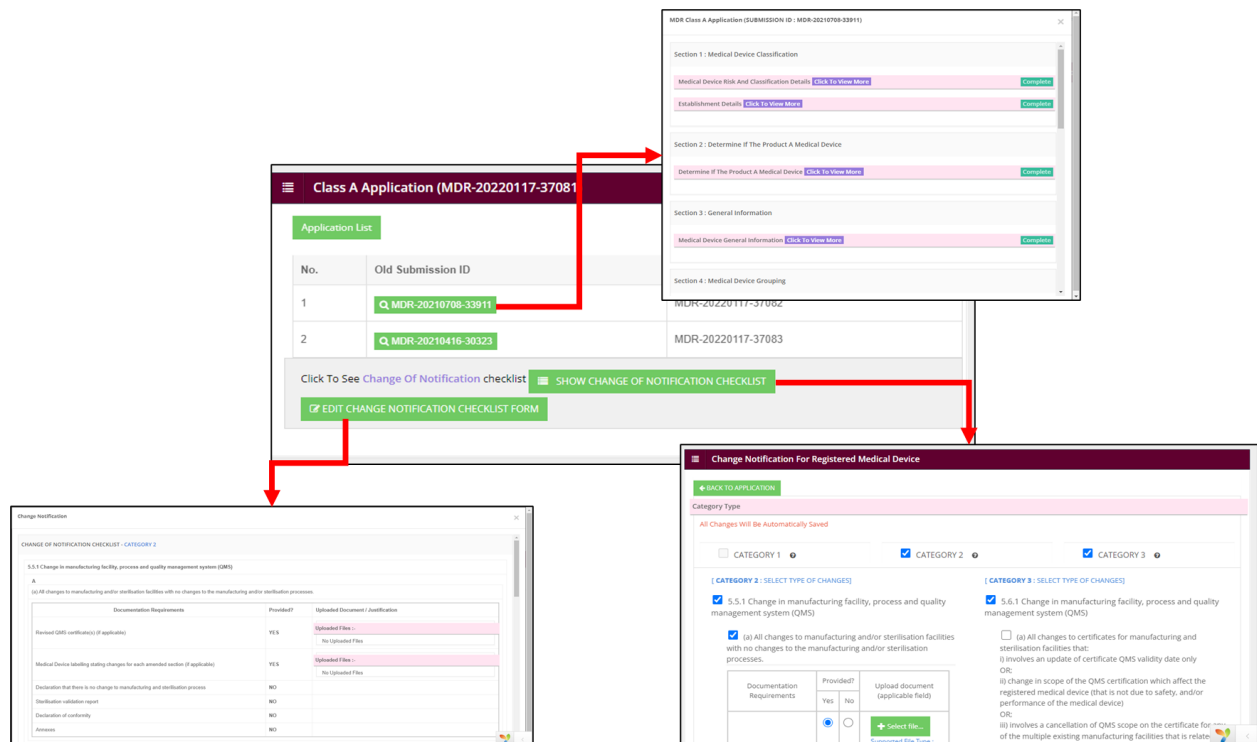
1) involves an update of certificate
QMS validity date only
QR
2) involves a modification of QMS

Documentation Requirements	Provided?		Upload document (applicable field)
	Yes	No	
Valid QMS certificate	☐	☒	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  **MDR-20210708-33911** to view the old application information.



Class A Application (MDR-20220117-37081)

Application List

No.	Old Submission ID
1	 MDR-20210708-33911
2	 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

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

A

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

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

[CATEGORY 3 : SELECT TYPE OF CHANGES]

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

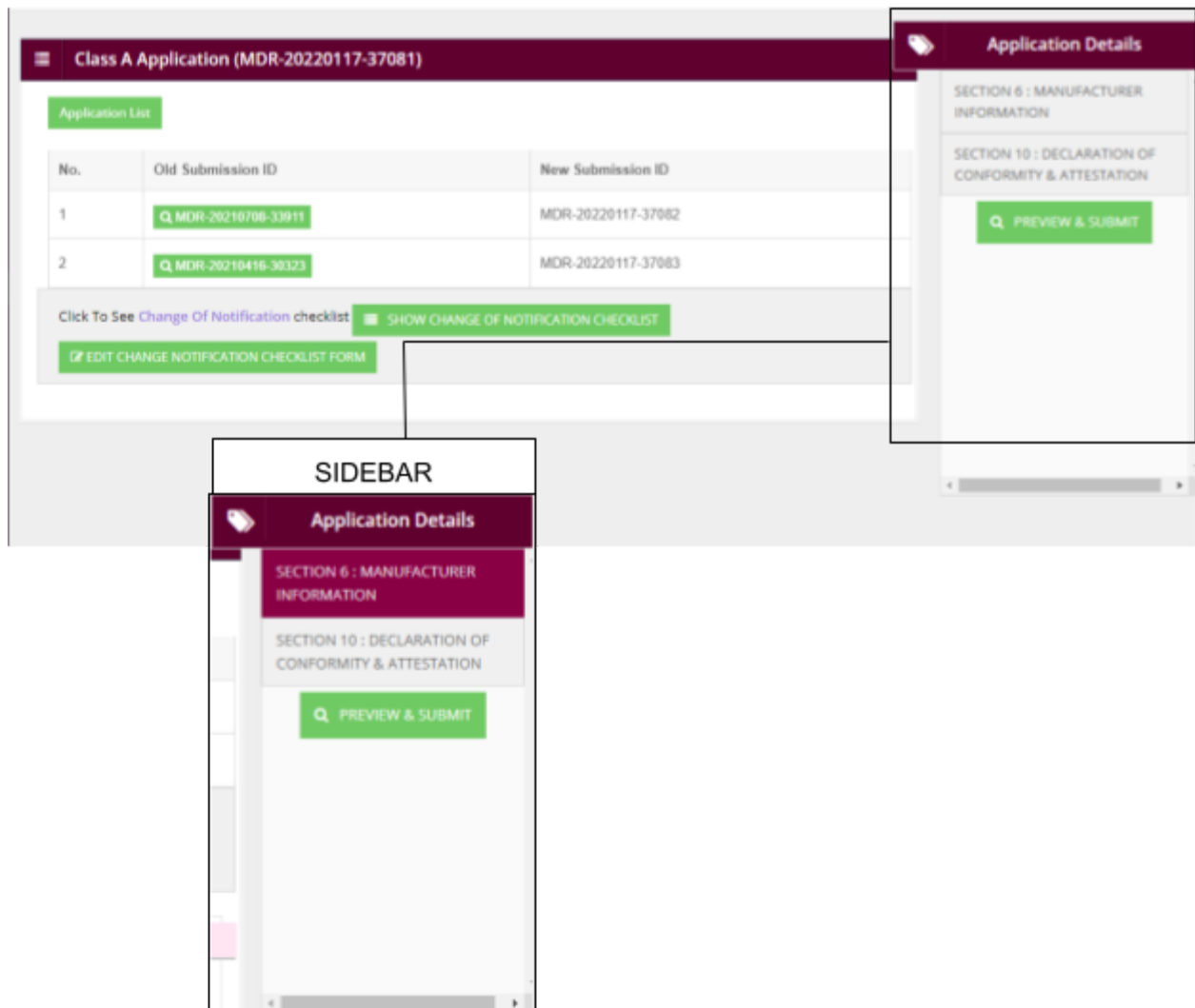
i) change in scope of the QMS certification which affect the registered medical device (that is not due to safety, and/or performance of the medical device)

OR:

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

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

 **Upload File**



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 6 : MANUFACTURER INFORMATION that need to be change.

The main interface displays the 'Manufacturer Information' section with the following details:

- 1. Name Of Manufacturer : 11
- 2. Manufacturer Registration No : PFRICAB
- 3. Name Of Registered Manufacturer Auditor : SHIN HAN EMBELI HAMBALI
- 4. Certificate Expiry Date : 2020-12-30

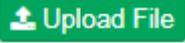
The 'Quality Management System Information' section shows the 'Quality Management System Certificate' and 'Uploaded Files' (IKLAK_NDV_2017.PDF, AT3T-Q4LPDF).

The 'List Of Manufacturing Site' section shows a table with one 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	158537297259a26a389a55 41407958.pdf	Upload File , Update , Delete

Below the main interface, two smaller screenshots show the 'Manufacturer Information' form with fields for Name, Address, and Post Code/Zip Code, and a 'Submit' button.

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

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	M33H0N	LOT M 12, MEZZANINE CENTRE, AMPANG POINT, SHOPPING CENTRE, JALAN MAMANDA 3,	54300	150637297259ba2b2c300cc5 41407858.pdf	+ Add Manufacturing Site Upload File Update Delete

File Explorer (This PC > Pictures) showing the upload file selection process.

Manufacturing Site Information form showing the upload file selection process.

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 a web application interface for MDR Class A applications. At the top left is a green 'Submit' button with a document icon. A callout box labeled 'Click to submit application' points to this button. The form is organized into three sections, each with a pink header bar 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 indicators at the end of each section's header bar. The sections are: 'Section 1 : Medical Device Classification' (containing 'Medical Device Risk And Classification Details' and 'Establishment Details'), 'Section 2 : Determine If The Product A Medical Device', and 'Section 3 : General Information' (containing 'Medical Device General Information'). All 'Complete' status indicators are green.

Section	Form 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.