

# USER MANUAL FRONT END USER

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



**MODUL UTAMA - SPECIAL ACCESS (FRONT-END  
USER)**

**DISEDIAKAN OLEH :**



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## **1.0 INTRODUCTION**

This manual is prepared for the purpose of operational functions of Medical Device Centralised Online Application System.

MeDC@St is a web-based Online Application System for Notification. It is a centralized system where only one account needs to be created by an applicant to apply for Notification Registration. This module that allows all Notification programme operations to run online and monitoring can be carried out in real time.

## **1.1 SYSTEM ACCESS**

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:

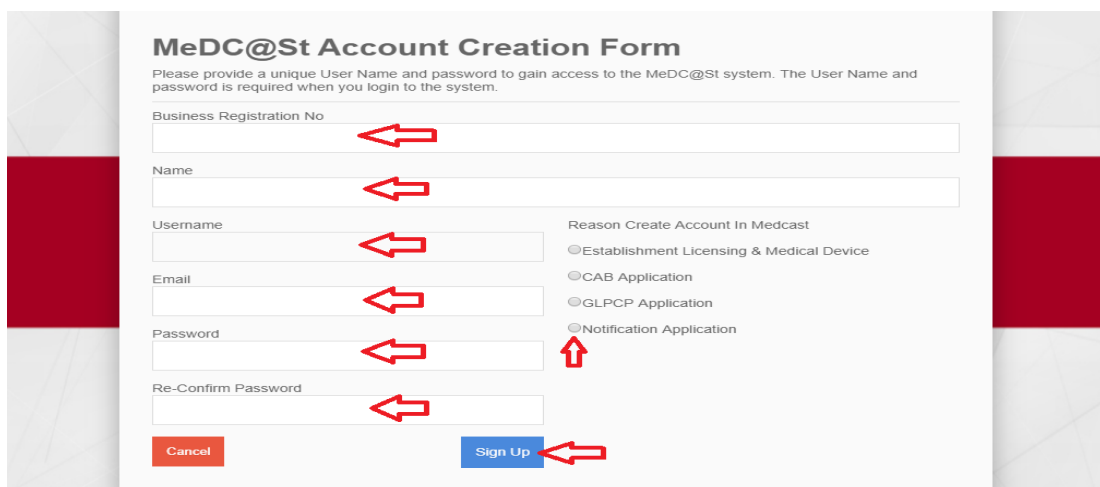
<https://medcast.mda.gov.my>

### 1.1.1 CREATE ACCOUNT

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

For new user need to sign up a new account before login the account. User need to

click **Sign Up** for new registration.



The image shows a web form titled "MeDC@St Account Creation Form". Below the title is a sub-header: "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", "Password", and "Re-Confirm Password". To the right of these fields is a section titled "Reason Create Account in Medcast" with four radio button options: "Establishment Licensing & Medical Device", "CAB Application", "GLPCP Application", and "Notification Application". At the bottom left is a red "Cancel" button, and at the bottom right is a blue "Sign Up" button. Red arrows point to each of the six input fields and the "Sign Up" button.

Complete the form and click **Sign Up** to sign up a new account. If you registration account have success, user need to check the email for confirmation.

### 1.1.2 LOGIN

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

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

Username

Enter username

Username cannot be blank.

Password

Enter password

Password cannot be blank.

Sign Up | Reset Password | FAQ | Helpdesk

Login


Pengumuman

**ANNOUNCEMENT - ABOUT MeDC@St (2017-11-16) New!**  
MeDC@St is a web-bas.. [Read More..](#)

**SEMINAR WITH MEDICAL DEVICE INDUSTRY 2017**  
(2017-11-16) **New!**  
Greetings from the A.. [Read More..](#)

Optimal display using browser

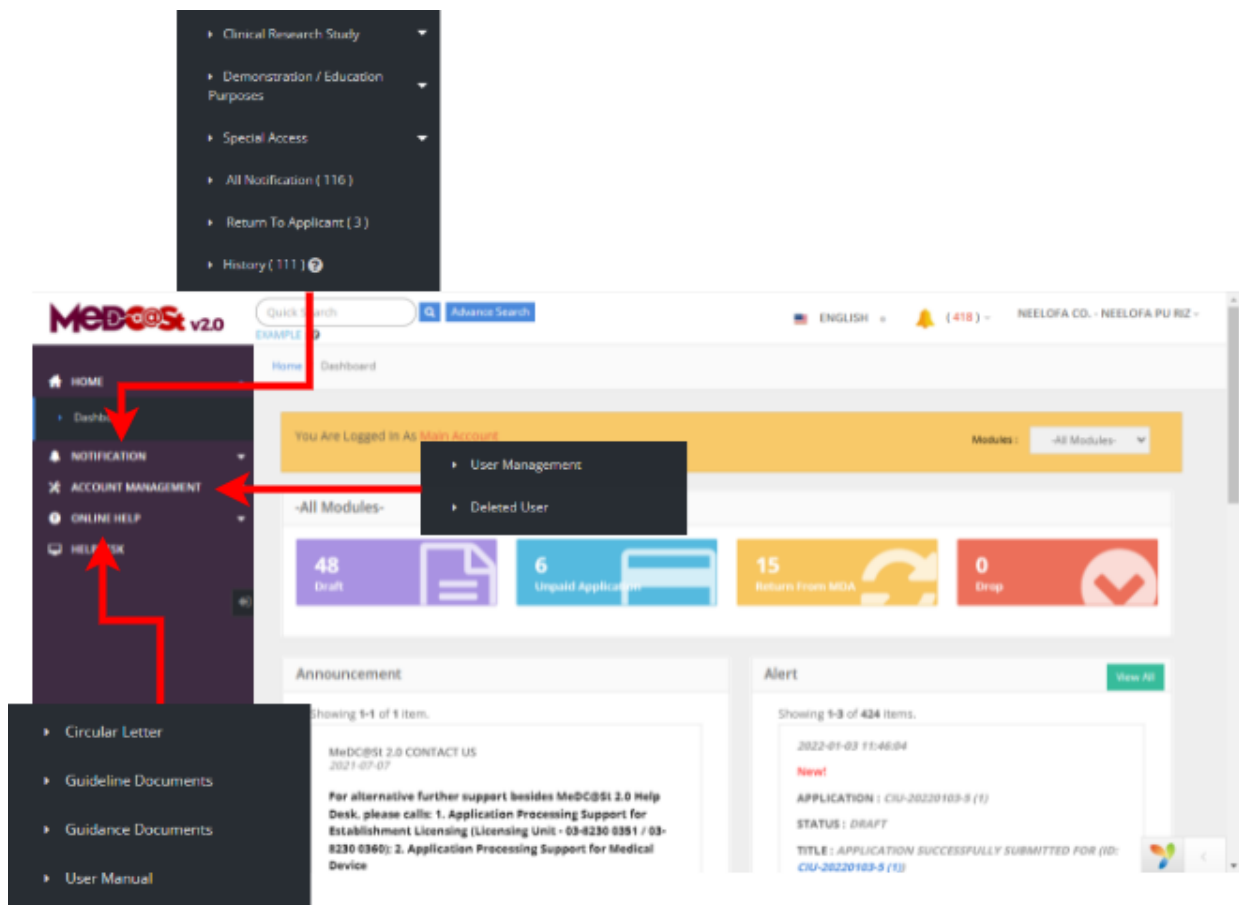
with resolution of 1024 X 768 pixels

User has to log into the system using registered Username and its respective Password. Click  to proceed.

## 2.0 FUNCTIONS

### 2.1 DASHBOARD

Below show the Dashboard page that will appear once Notification Module has logged into the system successfully.

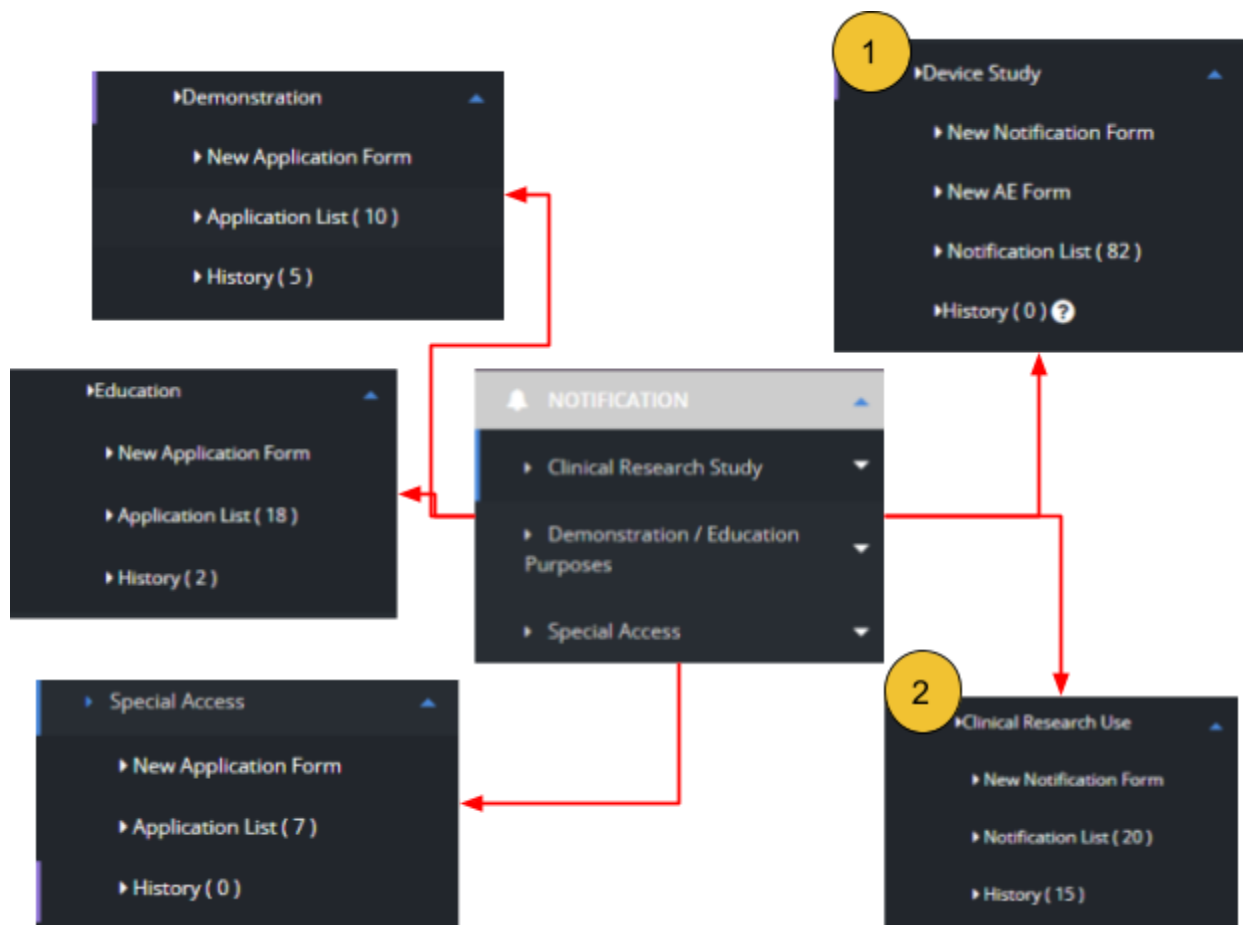


## 2.2 MENU NOTIFICATION REGISTRATION

Menu Notification Registration has four type of notification which are *Clinical Research Study*, *Demonstration/Education Purposes* and *Special Access*.

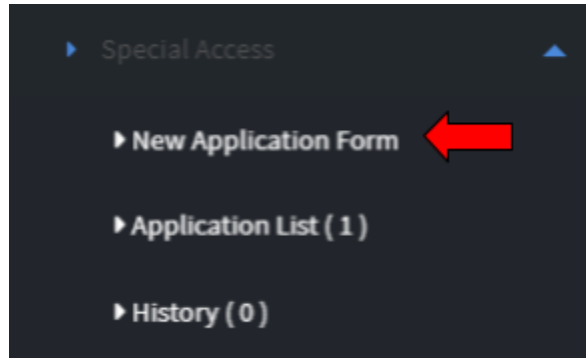
However, Clinical Investigational have three type which are *Investigational Use*, *Clinical Research Use* and *Notification of Change*. User should click on menu **NOTIFICATION** at left side menu for drop list sub menu Notification module.

### 2.2.1 NEW APPLICATION FORM



## SPECIAL ACCESS

First, user should click at sub menu **Special Access**. After click at sub menu Special Access, the list down of sub menu will be displayed that shown in Figure below.



The user should click at sub menu **New application** form to apply the registration form for Special Access Registration. The application form will appear. The figure below shows the application form for applicant fill it. The user should fill all the form. There has six sections which are:

**SECTION A :** Applicant / Company Details

**SECTION B :** Healthcare Professional Details

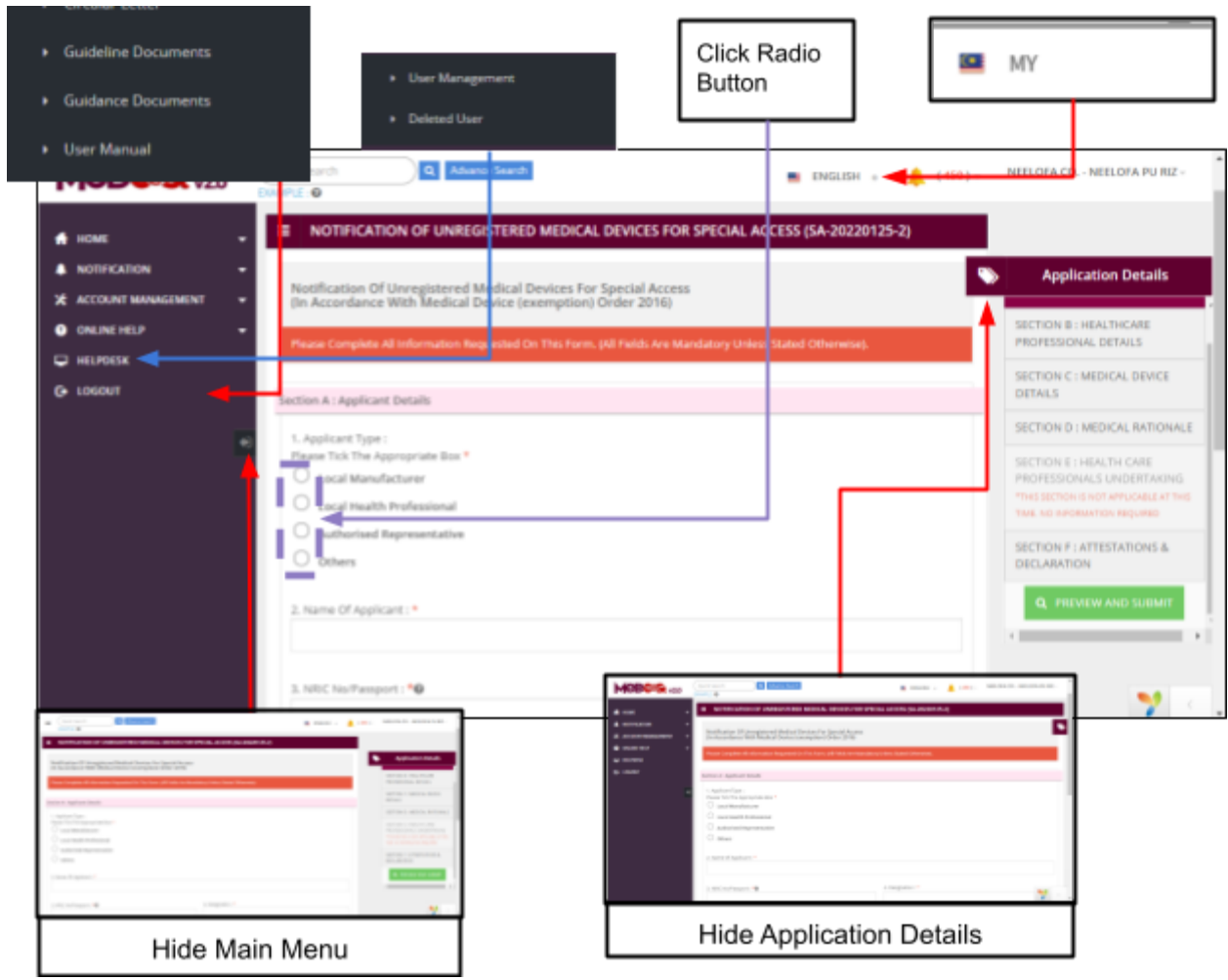
**SECTION C :** Medical Device Details

**SECTION D :** Medical Rationale

**SECTION E :** Healthcare Professionals Undertaking (Disabled)

**SECTION F :** Attestation & Declaration





## SECTION A : Applicant / Company Details

The screenshot shows the 'SECTION A : Applicant / Company Details' form. It includes a header with 'Insert Your NRIC/Passport no (1223-12-8888 / A0000000)'. The form has several sections: 1. Applicant Type (radio buttons for Local Manufacturer, Local Health Professional, Authorised Representative, Others), 2. Name Of Applicant, 3. NRIC No/Passport (with a help icon), 4. Designation, 5. Organisation Details (Organisation Name, Address Of Organisation, State, District, Postcode). A sidebar on the right lists sections A through F. Annotations include: 'Click Radio Button' pointing to the 'Local Manufacturer' radio button; 'Fill in the text box' pointing to the 'Name Of Applicant' field; another 'Fill in the text box' pointing to the 'Organisation Name' field; and a third 'Fill in the text box' pointing to the 'Postcode' field, which has a dropdown menu open showing a list of postcodes.

The symbol “\*” means required field. The user must fill it.


### 1. Applicant Type

- User should choose whether Local Manufacturer, Local Health Professional, Authorised Representative or Others

### 2. Name of Applicant

- User should fill name in the textbox that provided.

### 3. NRIC No/Passport

- The user should click at  to see the format and fill the form based on the format that given that shown in the figure above. If user fill the textbox with character or number more than 12, the message “Field can only contain number and word character and must between 5-12 character” will be displayed.

The screenshot shows a web application interface for 'Application Details'. The form is divided into several sections: SECTION A: APPLICANT / COMPANY DETAILS, SECTION B: HEALTHCARE PROFESSIONAL DETAILS, SECTION C: MEDICAL DEVICE DETAILS, SECTION D: MEDICAL RATIONALE, SECTION E: HEALTH CARE PROFESSIONALS UNDERTAKING, and SECTION F: ATTESTATIONS & DECLARATION. The form includes the following fields and annotations:

- Designation:** A dropdown menu is open, showing a list of locations. An annotation 'Fill in textbox' points to this field.
- State:** A dropdown menu with the text '-SELECT STATE-'. An annotation 'Click radio button' points to the 'YES' radio button for the license question.
- District:** A dropdown menu with the text 'Select District'. An annotation 'Insert Your Telephone No eg 03-1234567' points to the 'Telephone No' field.
- Postcode:** A text input field.
- Telephone No:** A text input field.
- Email Address:** A text input field. An annotation 'Insert Your Email eg: abc@gmail.com' points to this field.
- License Question:** A question '8. Does The Company Already Holds Establishment License?' with 'YES' and 'NO' radio buttons.
- Next Button:** A green button labeled 'next' with a right arrow. An annotation 'Click to next stage' points to this button.

#### 4. Designation

- The user should fill in the textbox with designation of applicant that shown in figure above.


#### 5. Organisation Details

- Organisation Name -> the user should fill name of organisation in the textbox that provided.
- Address of organisation -> the user should fill in the textbox with address of organisation.
- State -> User should click at textbox to drop down list and user should select the state that has shown in figure above.
- District -> If user select the state, automatically the city will appear in form and user should select specific city in drop down list. The user


should select the state before click city form to drop down list of city that shown in figure above.

- Postcode -> The field must contain exactly five numeric. If user fill the form with alphabet or more than five number, the message will appear “Field must contain exactly 5 numeric.”

#### 6. Telephone No.

- The user must fill in the number only and click at  to see the format. User should follow the format that shown in the figure above. If user fills in the form except number, the message “Field must only contain NUMBERS and allowed symbol ("-", "+", "/", ";") limited to 5 - 50 characters” will be displayed.

#### 7. Email address

- The user must fill the email based the format that shown in figure. User should click at  to see the format. The symbol “@” must have in email. If user fill the form incorrectly or not follow the format, the message will appear is “ Email address is not valid.”

#### 8. Does The Company Already Holds Establishment License?

- User should choose whether Yes or No.

If user click button  YES at number 8, field below will be displayed and user should fill it all.

8. Does The Company Already Holds Establishment License? \*

☒ YES ☐ NO

If Yes, Please State The Company Establishment License Number : \* ?

Company's Role : \* ?

- ☐ Local Manufacturer
- ☐ Authorized Representative
- ☐ Distributor
- ☐ Importer

Annotations:

- Click yes (points to YES radio button)
- Fill in textbox (points to license number input field)
- Click radio button (points to Distributor radio button)
- Insert Your Company Establish License Number eg:12345678 (points to license number input field)

After user fill all form for section A, the user should click at button

Next →

to the next section which is Section B.

## SECTION B : Healthcare Professional Details

The image shows a web form titled "Section B : Healthcare Professional Details" with a subtitle "( This Section Is For The Healthcare Professional Who Or Which Takes Responsibilities For The Importation And/or Supply The Unregistered Medical Devices In Malaysia)". The form contains several text input fields, some marked with a red asterisk (\*) to indicate they are required. Annotations with red arrows point to these fields and navigation buttons. A sidebar on the right lists sections A through F, with Section B highlighted. Below the form, three example input strings are shown with arrows pointing to their respective fields: "Insert Your Telephone No eg 010-12345678" for the Telephone No. field, "Insert Your Annual Practicing Certificate Number" for the Annual Practicing Certificate Number field, and "Insert Your Email eg abc@gmail.com" for the Email Address field. Navigation buttons "Previous" and "Next" are also annotated.

**Field in the textbox**

Section B : Healthcare Professional Details  
( This Section Is For The Healthcare Professional Who Or Which Takes Responsibilities For The Importation And/or Supply The Unregistered Medical Devices In Malaysia)

1. Name : \*

2. Title : \*

3. Annual Practicing Certificate Number : \*

4. Telephone No. : \*

5. Email Address : \*

6. Health Care Facility

Name : \*

Address : \*

Previous

Next

Application Details

SECTION A : APPLICANT / COMPANY DETAILS

SECTION B : HEALTHCARE PROFESSIONAL DETAILS

SECTION C : MEDICAL DEVICE DETAILS

SECTION D : MEDICAL RATIONALE

SECTION E : HEALTH CARE PROFESSIONALS UNDERTAKING  
\*THIS SECTION IS NOT APPLICABLE AT THIS TIME. NO INFORMATION REQUIRED

SECTION F : ATTESTATIONS & DECLARATION

Click to previous stage

Insert Your Telephone No eg 010-12345678

Insert Your Annual Practicing Certificate Number

Click to next stage

Insert Your Email eg abc@gmail.com

The symbol “\*” mean required field. The user must fill it.


### 1. Name

- The user should fill name in the textbox that provided in the figure above.


### 2. Title

- The user should fill their title in textbox that provided in the figure above.


### 3. Annual Practicing Certificate Number

- The user can click at  to see the format. The user should fill their Annual Practicing Certificate Number in textbox that provided in the figure above.

#### 4. Telephone No.

- The user must fill in the number only and click at  to see the format. User should follow the format that show “Field must only contain NUMBERS and allowed symbol (“-”, “+”, “/”, “.”) limited to 5 - 50 characters” will be displayed.

#### 5. Email address

- The user must fill the email based the format that shown in figure. User should click at  to see the format. The symbol “@” must has in email. If user fill the form incorrectly or not follow the format, the message will be appear is “Healthcare Email is not a valid email address”.

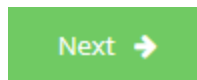
#### 6. Health Care Facility

- The user must fill their name and address in the textbox that provided in figure above.

If user want back to previous section, user should click at button



that shown in figure above. Then, user should click at button



to the next stage.

## SECTION C : Medical Device Details

The screenshot shows a web form titled 'SECTION C : MEDICAL DEVICE DETAILS'. The form includes a header bar with the title and a sidebar on the right with navigation links for sections A through F. The main form area contains the following fields:

- Name Of Medical Device \***: A text input field with a red arrow pointing to it from the 'Field in the textbox' label.
- Grouping \***: A group of radio buttons labeled 'Single', 'System', 'Family', and 'Set'. A red arrow points to the 'Single' radio button from the 'Click radio button' label.
- Brief Description \***: A text input field with a red arrow pointing to it from the 'Field in the textbox' label.
- Brand \***: A text input field with a red arrow pointing to it from the 'Field in the textbox' label.
- Identifier/ Catalog or Model Number \***: A text input field with a red arrow pointing to it from the 'Field in the textbox' label.
- Intended use \***: A text input field with a red arrow pointing to it from the 'Field in the textbox' label.

Annotations above the form include two boxes: 'Field in the textbox' and 'Click radio button', both with red arrows pointing to their respective fields in the form.

The symbol “\*” means required field. The user must fill it.

- **Name Of Medical Device**

The user must fill their Name Of Medical Device in the textbox that provided in the figure above.

- **Grouping**

User should choose group of their medical device whether single, system, family or set. If user choose single, no need to field in grouping list at the bottom form and for the other grouping, user need to field their grouping list.

- **Brief Description**

User must fill their Brief Description in the textbox that provided in the figure above.



- **Brand**

User must fill their Brand in the textbox that provided in the figure above.

- **Identifier / Catalogue or Model Number**

User must fill their Identifier in the textbox that provided in the figure above.

- **Intended use**

User must fill the use of the medical device in the textbox that provided in the figure above.

The image shows a screenshot of a web-based form for medical device registration. The form is divided into several sections. On the left, there is a large text area labeled 'Manufacturer's information \*'. Below this, there are fields for 'Risk-Based Classification \*' and 'Quantity to be Imported \*'. On the right, there is a sidebar with a list of sections: 'SECTION A: APPLICANT / COMPANY DETAILS', 'SECTION B: HEALTHCARE PROFESSIONAL DETAILS', 'SECTION C: MEDICAL DEVICE DETAILS' (highlighted in red), 'SECTION D: MEDICAL RATIONALE', 'SECTION E: HEALTH CARE PROFESSIONALS UNDERTAKING', and 'SECTION F: ATTESTATIONS & DECLARATION'. The main form area contains several textboxes with labels: 'Manufacturer's Name : \*', 'Contact Name and Title : \*', 'Address : \*', 'Postal Code : \*', 'Telephone : \*', 'Email : \*', and 'Intended Use : \*'. A box labeled 'Field in textbox' has red arrows pointing to each of these textboxes. A box labeled 'Phone No eg : 19498963648018' has a black arrow pointing to the 'Telephone : \*' field. A box labeled 'Email eg : abc@gmail.com' has a black arrow pointing to the 'Email : \*' field. The 'Intended Use : \*' field is located at the bottom right of the form.

- **Manufacturer's information**

User must fill Manufacturer's information in the textbox that provided in the figure above.

- **Risk-Based Classification**

User must fill Risk-Based Classification in the textbox that provided in the figure above.

### - Quantity to be Imported

User must fill Quantity to be Imported in the textbox that provided in figure above.


The screenshot shows the MEDOS v2.0 application interface. The main content area is titled 'Quantity to be Imported'. It includes a search bar at the top with 'Quick Search' and 'Advance Search' buttons. Below the search bar, there is a section for 'Marketing Approval Status in other country(-ies)' with three radio buttons: 'Registered / Licensed', 'Exempted / Notified', and 'Others (please specify)'. A red arrow points to the 'Registered / Licensed' radio button with the label 'Click radio button'. Below the radio buttons, there is a section for 'Please upload required supporting documents as follows:' with a list of seven items. A red arrow points to the 'Select file...' button with the label 'Upload file'. Below the list, there is a 'Grouping List' section with a 'Previous' button. A red arrow points to the 'Previous' button with the label 'Click to previous stage'. At the bottom right, there is a 'Next' button. A red arrow points to the 'Next' button with the label 'Click to next stage'. On the right side, there is a sidebar with 'Application Details' and sections A through F. The 'Previous' button is highlighted with a green border.

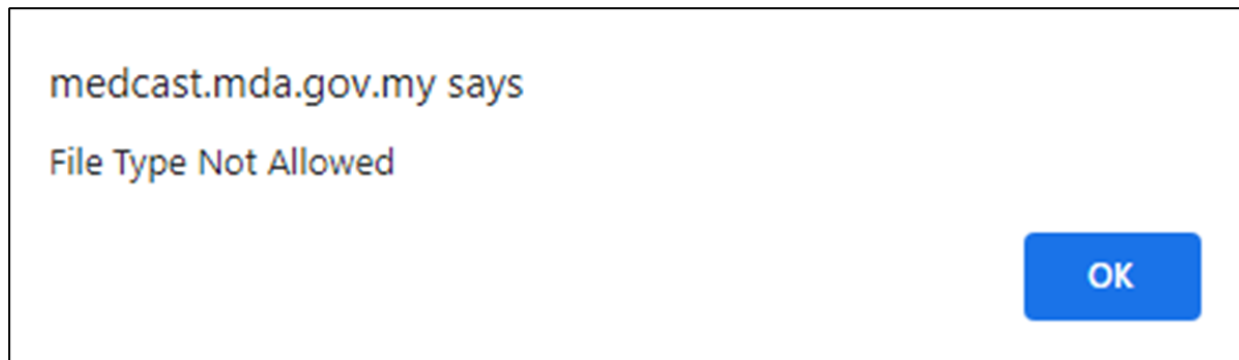
### - Marketing Approval Status in other country(-ies)

User should choose their Marketing Approval Status whether

- Registered/Licensed
- Exempted/Notified
- Other (please specify) - the user need to fill the textbox.

- **Please upload required supporting documents as follows:**




User must upload the supporting documents by clicking  button. The file must be in pdf. If the user upload file other than pdf, a pop-out message “File Type Not Allowed” appeared.




If user choose SINGLE as their grouping details, the grouping list don't need to be fill as figure below.

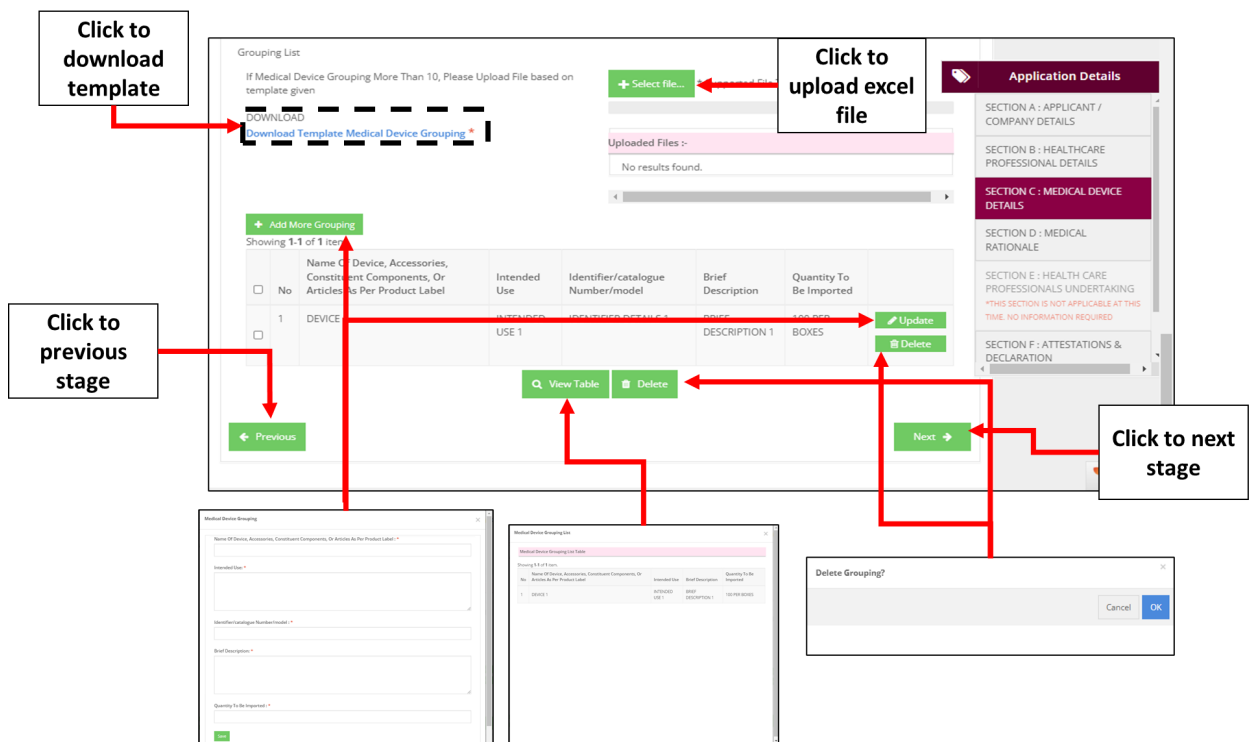


If user choose other than SINGLE as their grouping details, field below need to be fill.

User can add grouping list manually by clicking the  button. Also, the user can update and delete it back if needed by clicking the  button and  button. The alert message will be display to make sure if the user confirmed to delete their data.

If the user want to add more than one grouping list the user click at  button and upload the excel file. The template of the grouping list can be download

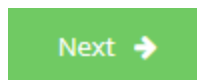
by click the [Download Template Medical Device Grouping](#)



If user want back to previous section, user should click at button



that shown in figure above. Then, user should click at button



to the next stage.

## SECTION D : Medical Rationale

The screenshot shows the 'SECTION D : MEDICAL RATIONALE' form. At the top, a pink header bar contains the section title. Below it, a dashed purple line separates the header from the content. A red arrow points from a box labeled 'Tick at the checkbox' to the first checkbox option. The form contains three checkbox options, each followed by a descriptive sentence. A red arrow points from a box labeled 'Fill in the text box' to a large text input area. To the right of the text input area, a red arrow points from a box labeled 'Provide The Diagnosis, Treatment or Prevention And Your Reasons' to a question mark icon. On the right side of the form, a vertical sidebar titled 'Application Details' lists sections A through F. Section D is highlighted in dark purple. Section E is marked as 'NOT APPLICABLE AT THIS TIME'.

**SECTION D : MEDICAL RATIONALE**

Please tick the appropriate box:

- ☐ Medical devices on compassionate use basis  
*In the absence of alternative treatment option, available alternative treatment failed or deemed ineffective or unsuitable for the patient according to the medical practitioner's clinical judgments and patients health will be clinically compromised without the request treatment*
- ☐ Alleviation of stock-out situation  
*In the absence of alternative treatment option, available alternative treatment failed or deemed ineffective or unsuitable for the patient according to the medical practitioner's clinical judgments and patients health will be clinically compromised without the request treatment*
- ☐ Design and/or operation that is likely to support or enhance the outcomes of the procedure or treatment for the patient.  
*In the absence of alternative treatment option, available alternative treatment failed or deemed ineffective or unsuitable for the patient according to the medical practitioner's clinical judgments and patients health will be clinically compromised without the request treatment*

1. Provide the diagnosis, treatment or prevention for which the unregistered device is requested and the reasons why this unregistered device was chosen. \*

Provide The Diagnosis, Treatment or Prevention And Your Reasons

**Application Details**

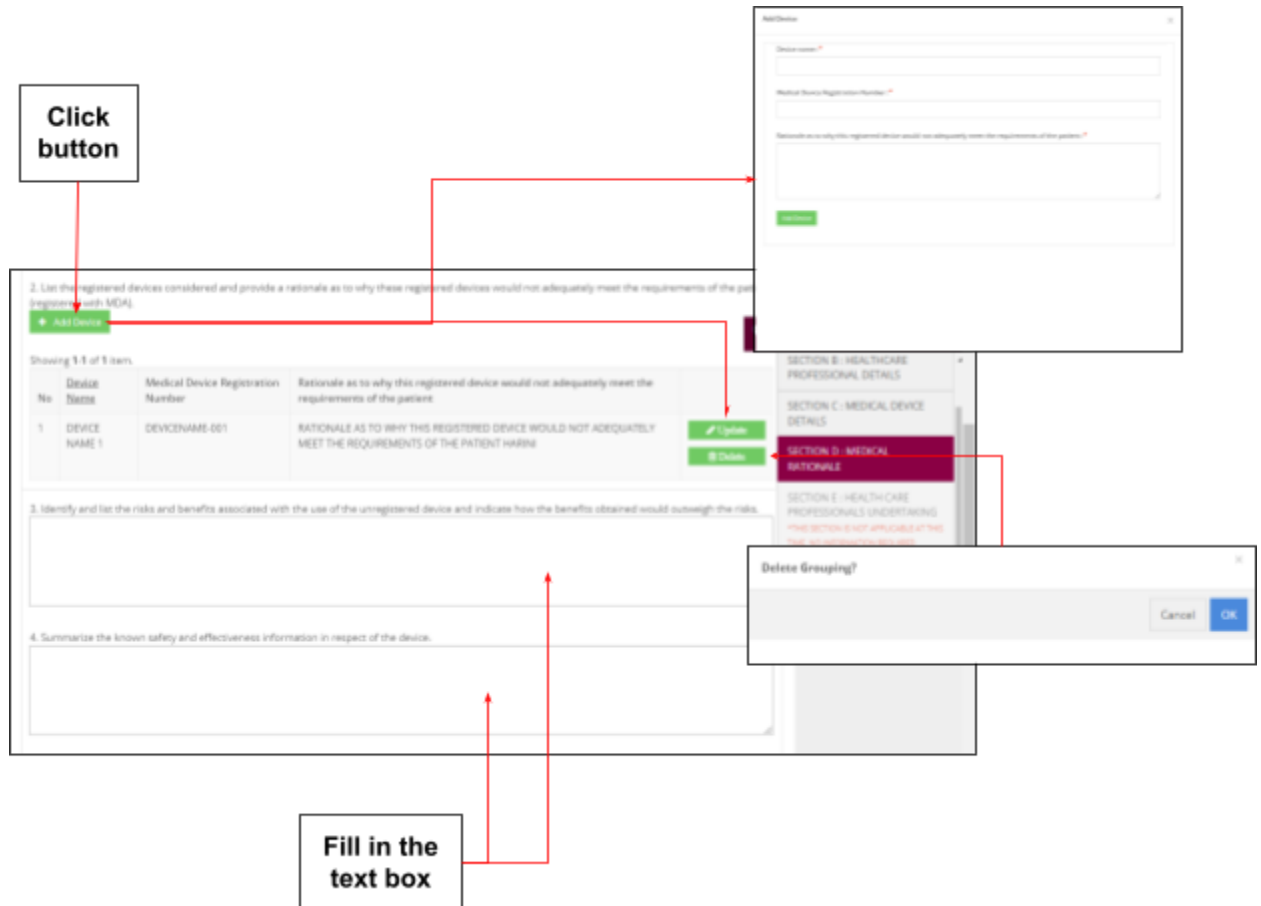
- SECTION A : APPLICANT / COMPANY DETAILS
- SECTION B : HEALTHCARE PROFESSIONAL DETAILS
- SECTION C : MEDICAL DEVICE DETAILS
- SECTION D : MEDICAL RATIONALE**
- SECTION E : HEALTH CARE PROFESSIONALS UNDERTAKING  
\*THIS SECTION IS NOT APPLICABLE AT THIS TIME. NO INFORMATION REQUIRED
- SECTION F : ATTESTATIONS & DECLARATION

The symbol “\*” means required field.

### - Please tick the appropriate box

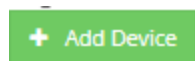
The user should tick at the checkboxes that provided in the figure above.

1. Provide the diagnosis, treatment or prevention for which the unregistered device is requested and the reasons why this unregistered device was chosen.
- The user must fill in their reasons and click at ? to see instructions.



2. List the registered devices considered and provide a rationale as to why these registered devices would not adequately meet the requirements of the patient (registered with MDA).

- The user must fill in their device detail by clicking button the



button. . Also, the user can update and delete it back if

needed by clicking the



button and



button.

The alert message will be display to make sure if the user confirmed to delete their data.

3. Identify and list the risks and benefits associated with the use of the unregistered device and indicate how the benefits obtained would outweigh the risks.

- The user must fill in the risk and benefits of unregistered device.

4. Summarize the known safety and effectiveness information in respect of the device.
  - The user must fill in the summary of their device.

The image shows a screenshot of a web-based application form for medical device registration. The form is divided into several sections, with a sidebar on the right titled 'Application Details'. The sidebar lists sections B through F, with section D 'MEDICAL RATIONALE' highlighted in red. The main form area contains three numbered questions with text input fields. Red arrows point from external text boxes to specific parts of the form: 'Fill in the text box' points to the top of the first input field; 'Click to the next stage' points to the 'Previous' button; 'Total Device' points to a question mark icon in question 6; and 'Click to the previous stage' points to the 'Next' button. A 'PREVIEW AND SUBMIT' button is located at the bottom right of the form area.

**Fill in the text box**

**Click to the next stage**

**Total Device**

**Click to the previous stage**

**Application Details**

SECTION B : HEALTHCARE PROFESSIONAL DETAILS

SECTION C : MEDICAL DEVICE DETAILS

**SECTION D : MEDICAL RATIONALE**

SECTION E : HEALTH CARE PROFESSIONALS UNDERTAKING  
\*THIS SECTION IS NOT APPLICABLE AT THIS TIME. NO INFORMATION REQUIRED

SECTION F : ATTESTATIONS & DECLARATION

**PREVIEW AND SUBMIT**

5. In the event that conventional medical treatment has failed, is unavailable or unsuitable, Describe the condition for the treatment

6. In the case of emergency situation, Number of devices required for one month ?

7. Please define quantity for batch release (if required).

**Previous**

**Next**

5. In the event that conventional medical treatment has failed, is unavailable or unsuitable, Describe the condition for the treatment
  - The user must fill in the condition for the treatment.
6. In the case of emergency situation, Number of devices required for one month.
  - The user must fill in the number of devices they required for one month and click at ? to see instructions.

7. Please define quantity for batch release (if required).

- The user must fill in the case of a request for batch release.

- If user want back to previous section, user should click at button

← Previous

that shown in figure above. Then, user should click at button

Next →

to  
the next stage

### **SECTION E : Healthcare Professionals Undertaking (Disabled)**

Section E: Healthcare Professionals Undertaking is disabled. The user unable to click Section E

The screenshot shows a mobile application interface for 'Application Details'. The form is divided into several sections, each with a corresponding icon on the left. The sections are:

- SECTION B : HEALTHCARE PROFESSIONAL DETAILS (pink icon)
- SECTION C : MEDICAL DEVICE DETAILS (grey icon)
- SECTION D : MEDICAL RATIONALE (dark red icon)
- SECTION E : HEALTH CARE PROFESSIONALS UNDERTAKING (grey icon, highlighted with a red dashed border)
- SECTION F : ATTESTATIONS & DECLARATION (grey icon)

Below the sections is a green button labeled 'PREVIEW AND SUBMIT' with a magnifying glass icon. A red dashed border highlights Section E, indicating it is disabled. Below the border, the text reads: '\*THIS SECTION IS NOT APPLICABLE AT THIS TIME. NO INFORMATION REQUIRED'.



## SECTION F : Attestation & Declaration

The screenshot shows the 'Section F : Attestations & Declaration' form. A red arrow points from a box labeled 'Click in checkbox' to the checkbox labeled 'I Have Read And Agree To The Above Terms And Conditions'. Another red arrow points from a box labeled 'Click for previous section' to the 'Previous' button. A third red arrow points from a box labeled 'Click for preview' to the 'PREVIEW AND SUBMIT' button. The form contains the following text:

**Section F : Attestations & Declaration**

I, The Undersigned Hereby Declare That :

- i. This/these Product(s) Is/are According To The Definition Of Medical Device Set Out In Section 2, Medical Device Act 2012 (act 737)
- ii. The Device(s) Conform(s) To All Relevant Essential Principles For Safety And Performance, Set Out In The Appendix 1 Of Third Schedule Of Mdr 2012
- iii. The Medical Device(s) Has/have Met All The Labeling Requirements Set Out In The Sixth Schedule Of The Mdr 2012
- iv. The Technical Documentation Of The Unregistered Device(s) Is/are Prepared In Accordance With The Format as Specified In Appendix 2 Of Schedules 3 Of Mdr 2012 And Is Are Available Upon Request By The Authority.

*Remark: Any Kind Of Deletion In Section D Please Provide Justification*

I Shall Be Responsible For The Establishment And Implementation Of A System To Monitor Safety And Performance Of This/these Medical Device(s) And Take The Necessary Actions Should There Be Any Adverse Incident Occurs For The Purpose Of Making Available This/these Unregistered Medical Device(s) For Use For Special Access;

I Hereby Attest That The Information And Attachment Provided On This Notification Is/are Accurate, Correct, Complete And Current To This Date.

**I, The Undersigned, Hereby Attest That** The Information And Attachment Provided On This Notification Is/are Accurate, Correct, Complete And Current To This Date. I Understand That Any Declaration By Me In This Application That Is Untrue, Inaccurate Or Misleading Shall Be Liable To A Fine Not Exceeding **Rm 500,000.00** Or To Imprisonment For A Term Not Exceeding 3 Years Or To Both. (s.76 Act 737 Refers)

☐ I Have Read And Agree To The Above Terms And Conditions

[Previous](#) [PREVIEW AND SUBMIT](#)

**Application Details**

- SECTION B : HEALTHCARE PROFESSIONAL DETAILS
- SECTION C : MEDICAL DEVICE DETAILS
- SECTION D : MEDICAL RATIONALE
- SECTION E : HEALTH CARE PROFESSIONALS UNDERTAKING  
*\*THIS SECTION IS NOT APPLICABLE AT THIS TIME. NO INFORMATION REQUIRED*
- SECTION F : ATTESTATIONS & DECLARATION**

[PREVIEW AND SUBMIT](#)

The user must click on checkbox ☒ I Have Read And Agree To The Above Terms And Conditions that agree in term and conditions that shown in figure above

After all form in each section completed, the user should click at [PREVIEW AND SUBMIT](#) to preview and submit the application form.

The page view will be showed after click button “PREVIEW AND SUBMIT”. The figure below show the details of preview.

Click for view details

Notification Of Unregistered Medical Devices For Special Access



\*Submit only can be done if all fields mandatory are complete

|   |                |
|---|----------------|
| SECTION A : APPLICANT DETAILS                     | Complete       |
| SECTION B : HEALTHCARE PROFESSIONAL DETAILS       | Complete       |
| SECTION C : MEDICAL DEVICE DETAILS                | Complete       |
| SECTION D : MEDICAL RATIONALE                     | Complete       |
| SECTION E : HEALTH CARE PROFESSIONALS UNDERTAKING | Not Applicable |
| SECTION F : ATTESTATIONS & DECLARATION            | Not Complete   |



\*Submit only can be done if all fields mandatory are complete

If status **Not Complete** , the user should fill it again to change status **Complete** and the button “submit” will be displayed.

Notification Of Unregistered Medical Devices For Special Access

  Click for submit

|   |                |
|---|----------------|
| SECTION A : APPLICANT DETAILS                     | Complete       |
| SECTION B : HEALTHCARE PROFESSIONAL DETAILS       | Complete       |
| SECTION C : MEDICAL DEVICE DETAILS                | Complete       |
| SECTION D : MEDICAL RATIONALE                     | Complete       |
| SECTION E : HEALTH CARE PROFESSIONALS UNDERTAKING | Not Applicable |
| SECTION F : ATTESTATIONS & DECLARATION            | Complete       |

  Click for submit

After click “submit”, message alert will be displayed to confirmation of submitted.

Confirm Submit Application?

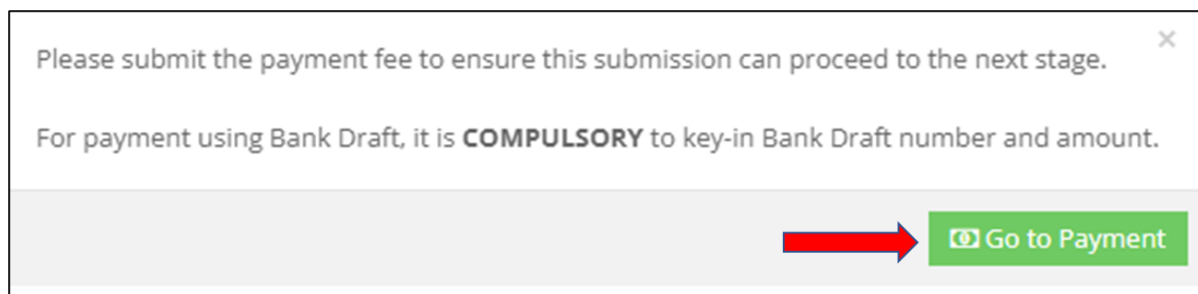
Cancel OK

Click to proceed 

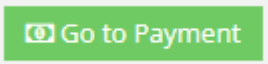
Click for cancel submitted 

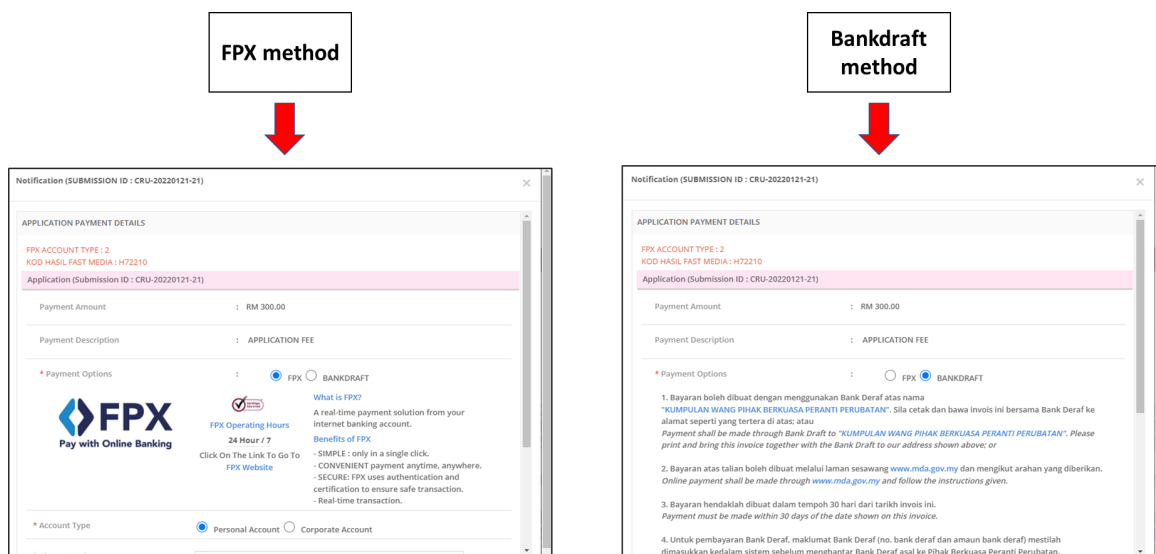
The user click “OK” to proceed to submit application and click “Cancel” to cancel the submitted application.

After the application is successfully submitted, a message “Please submit the payment fee to ensure this submission can proceed to the next stage. For payment using Bank Draft, it is **COMPULSORY** to key-in Bank Draft number and amount.” appeared.



The user can click  button to make a payment or the user can click the  icon to make a payment later.

The Figure below shows the page once the user click . The user can pay using FPX method or Bankdraft method.



The Figure below shows the page if the user click the ✕ icon to make a payment later.

1. The user at the notification list page.
2. Status of the submitted application -> **APPLICATION FEE (UNPAID)**
3. The user click **Payment** button or **Add To Bulk Payment** to make a payment.
4. The user can pay using FPX method or Bankdraft method.

**1**

**2** Status of the submitted application

**3** Click button to make a payment

**4**

**FPX method**

**Bankdraft method**

**Notification List**

Bulk Payment List

Showing 1-7 of 7 items.

| <input type="checkbox"/> | No | Submission ID   | Submitted At | Applicant    | Notification Type Name | Notification Status      | Action  |
|--------------------------|----|-----------------|--------------|--------------|------------------------|--------------------------|---|
| <input type="checkbox"/> | 1  | SA-20220126-5   | 26-01-2022   | AQILAH ALIAH | SPECIAL ACCESS         | APPLICATION FEE (UNPAID) | <a href="#">Q View</a> <a href="#">Payment</a> <a href="#">Add To Bulk Payment</a> <a href="#">P.advice &amp; Receipt</a> |
| <input type="checkbox"/> | 2  | SA-20211222-104 | 22-12-2021   | AQILAH ALIAH | SPECIAL ACCESS         | EVALUATION               | <a href="#">Q View</a> <a href="#">P.advice &amp; Receipt</a>   |

**FPX method**

**Bankdraft method**

**APPLICATION PAYMENT DETAILS**

Application ID: SA-20220126-5

Payment Amount: RM 50.00

Payment Description: APPLICATION FEE

**Payment Options**

☒ FPX ☐ BANKDRAFT

**FPX**

Pay with Online Banking

**Bankdraft method**

**APPLICATION PAYMENT DETAILS**

Application ID: SA-20220126-5

Payment Amount: RM 50.00

Payment Description: APPLICATION FEE

**Payment Options**

☐ FPX ☒ BANKDRAFT

**Bankdraft**

Pay with Bank Draft

In addition, if application status “Draft” , the user can delete or update the application form.

**Fill in box to search**

**Notification List**

**Bulk Payment List**

Showing 1-7 of 7 items.

| <input type="checkbox"/> | No | Submission ID   | Submitted At      | Applicant    | Notification Type Name | Notification Status      | Action   |
|--------------------------|----|-----------------|-------------------|--------------|------------------------|--------------------------|--|
| <input type="checkbox"/> |    |                 |                   |              |                        |                          |  |
| <input type="checkbox"/> | 1  | SA-20220126-5   | 26-01-2022        | AQILAH ALIAH | SPECIAL ACCESS         | APPLICATION FEE (UNPAID) | <a href="#">View</a> <a href="#">DD Payment</a><br><a href="#">Add To Bulk Payment</a><br><a href="#">P Advice &amp; Receipt</a> |
| <input type="checkbox"/> | 2  | SA-20211222-104 | 22-12-2021        | AQILAH ALIAH | SPECIAL ACCESS         | EVALUATION               | <a href="#">View</a> <a href="#">P Advice &amp; Receipt</a>  |
| <input type="checkbox"/> | 3  | SA-20211110-63  | 10-11-2021        | AQILAH ALIAH | SPECIAL ACCESS         | EVALUATION               | <a href="#">View</a> <a href="#">P Advice &amp; Receipt</a>  |
| <input type="checkbox"/> | 4  | SA-20211216-92  | Not Submitted Yet | AQILAH ALIAH | SPECIAL ACCESS         | DRAFT                    | <a href="#">View</a> <a href="#">Update</a> <a href="#">Delete</a>   |
| <input type="checkbox"/> | 5  | SA-20211216-93  | Not Submitted Yet | AQILAH ALIAH | SPECIAL ACCESS         | DRAFT                    | <a href="#">View</a> <a href="#">Update</a> <a href="#">Delete</a>   |
| <input type="checkbox"/> | 6  | SA-20211216-94  | Not Submitted Yet | AQILAH ALIAH | SPECIAL ACCESS         | DRAFT                    | <a href="#">View</a> <a href="#">Update</a> <a href="#">Delete</a>   |

**Delete application confirmation?**

Cancel OK

The screenshot displays a web application interface for managing notifications. At the top, there's a 'Notification List' header with a 'Bulk Payment List' button. Below this, a table lists 7 items. The first row is a search bar with a red dashed box and a label 'Fill in box to search'. The table columns are: checkbox, No, Submission ID, Submitted At, Applicant, Notification Type Name, Notification Status, and Action. The first three rows show applications with statuses 'APPLICATION FEE (UNPAID)', 'EVALUATION', and 'EVALUATION'. The last three rows show applications with status 'DRAFT'. For the 'DRAFT' applications, the 'Action' column contains 'View', 'Update', and 'Delete' buttons. A red arrow points from the 'Delete' button of the first 'DRAFT' application to a 'Delete application confirmation?' dialog box at the bottom. The dialog box has 'Cancel' and 'OK' buttons.

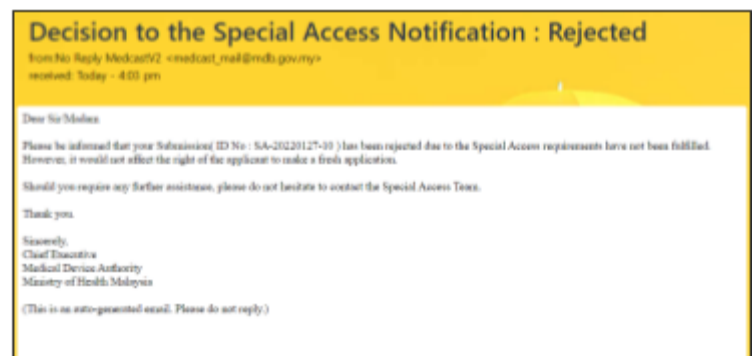

Then, after the application goes through all the stages, the user will get email notification once the application is approved or rejected. Figure below shows the “Approval” and “Rejection” notification email that received by the user.



Approved Application Email Notice



Rejected Application Email Notice



## 2.2.2 RETURN FOR FURTHER INFO

If back end user make the process “RETURN FOR FURTHER INFO” to front end user, the status of application will be changed and the Front End User should make the changed at application form that applied.

The figure below shows the application status that changed in front end user.

Status changed

Notification List


Bulk Payment List

Showing 1-7 of 7 items.



| <input type="checkbox"/> | No | Submission ID   | Submitted At      | Applicant    | Notification Type Name | Notification Status               | Action   |
|--------------------------|----|-----------------|-------------------|--------------|------------------------|-----------------------------------|--|
| <input type="checkbox"/> | 1  | SA-20220126-5   | 26-01-2022        | AQILAH ALIAH | SPECIAL ACCESS         | RETURN FROM MDA (REQUIRE CHANGES) | <a href="#">View</a> <a href="#">Update</a> <a href="#">P.advice &amp; Receipt</a> |
| <input type="checkbox"/> | 2  | SA-20211222-104 | 22-12-2021        | AQILAH ALIAH | SPECIAL ACCESS         | EVALUATION                        | <a href="#">View</a> <a href="#">P.advice &amp; Receipt</a>                        |
| <input type="checkbox"/> | 3  | SA-20211110-63  | 10-11-2021        | AQILAH ALIAH | SPECIAL ACCESS         | EVALUATION                        | <a href="#">View</a> <a href="#">P.advice &amp; Receipt</a>                        |
| <input type="checkbox"/> | 4  | SA-20211216-92  | Not Submitted Yet | AQILAH ALIAH | SPECIAL ACCESS         | DRAFT                             | <a href="#">View</a> <a href="#">Update</a> <a href="#">Delete</a>                 |

Click for update



After that, user should click at  to update or make changes at application form. The details of information that the Evaluation Officer click “NO” at EVALUATION process will be displayed that shown in the figure below.

Details for update



**NOTIFICATION OF UNREGISTERED MEDICAL DEVICES FOR SPECIAL ACCESS (SA-20220126-5)**

**RETURN FOR FURTHER INFO**

**Comment By MDA Officer**

Dear Sir/Madam,  
You need to provide following information based on the comments given.  
Only the following information Section has been opened for the purpose of updating information.

**SECTION A : APPLICANT DETAILS/COMPANY DETAILS**

1. Telephone No
2. Email Address
3. Establishment License
4. Establishment License Number
5. Company's Role
6. Extra Information

**Application Details**

**SECTION A : APPLICANT / COMPANY DETAILS**

**SECTION B : HEALTHCARE PROFESSIONAL DETAILS**

**SECTION C : MEDICAL DEVICE DETAILS**

**SECTION D : MEDICAL RATIONALE**

**SECTION E : HEALTH CARE PROFESSIONALS UNDERTAKING**  
*\*THIS SECTION IS NOT APPLICABLE AT THIS TIME. NO INFORMATION REQUIRED*

**SECTION F : ATTESTATIONS & DECLARATION**

Then, user should update the details of application information at the form. The user can edit at detail that changed only. If the Evaluation Officer requires extra information of the user, the user should upload file by clicking the button and fill in the textbox in Section A.

Details can  
be edited



6. Telephone No : \* ⓘ  
0334567890/+60123456789

7. Email Address : \* ⓘ  
izzah@getnada.com

8. Does The Company Already Holds Establishment License? \*  
☐ YES ☒ NO

Any extra information required for this notification:  
Extra Information ⓘ

Upload file for  
extra information  
attachment


Extra Information Attachment ⓘ  
+ Select file... \* Supported File Type : pdf

Uploaded Files :-  
No results found.

🔍 PREVIEW AND SUBMIT

And then, click to submit the application.

Notification Of Unregistered Medical Devices For Special Access

 **Click for submitted**

|   |                |
|---|----------------|
| SECTION A : APPLICANT DETAILS                     | Complete       |
| SECTION B : HEALTHCARE PROFESSIONAL DETAILS       | Complete       |
| SECTION C : MEDICAL DEVICE DETAILS                | Complete       |
| SECTION D : MEDICAL RATIONALE                     | Complete       |
| SECTION E : HEALTH CARE PROFESSIONALS UNDERTAKING | Not Applicable |
| SECTION F : ATTESTATIONS & DECLARATION            | Complete       |

 **Click for submitted**

The status will be changed to EVALUATION again that shown in figure below.

|               |            |              |                |            |  |
|---------------|------------|--------------|----------------|------------|--|
| SA-20220126-5 | 26-01-2022 | AQILAH ALIAH | SPECIAL ACCESS | EVALUATION |  View<br> Advice & Receipt |
|---------------|------------|--------------|----------------|------------|--|

The user should make the process EVALUATION at back end user.