

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:

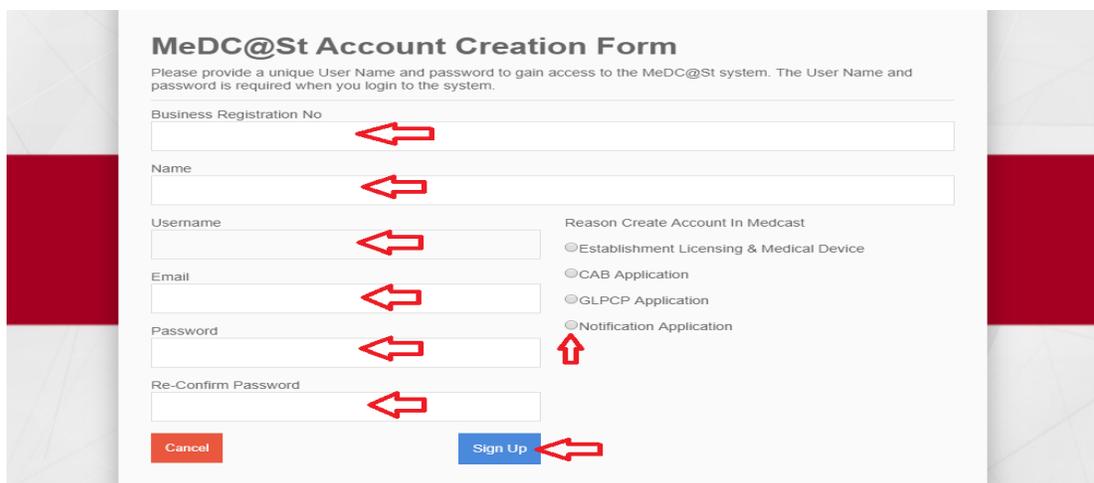
<https://medcast.mda.gov.my>

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  for new registration.



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

Password

Re-Confirm Password

Reason Create Account In Medcast

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

Complete the form and click  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.

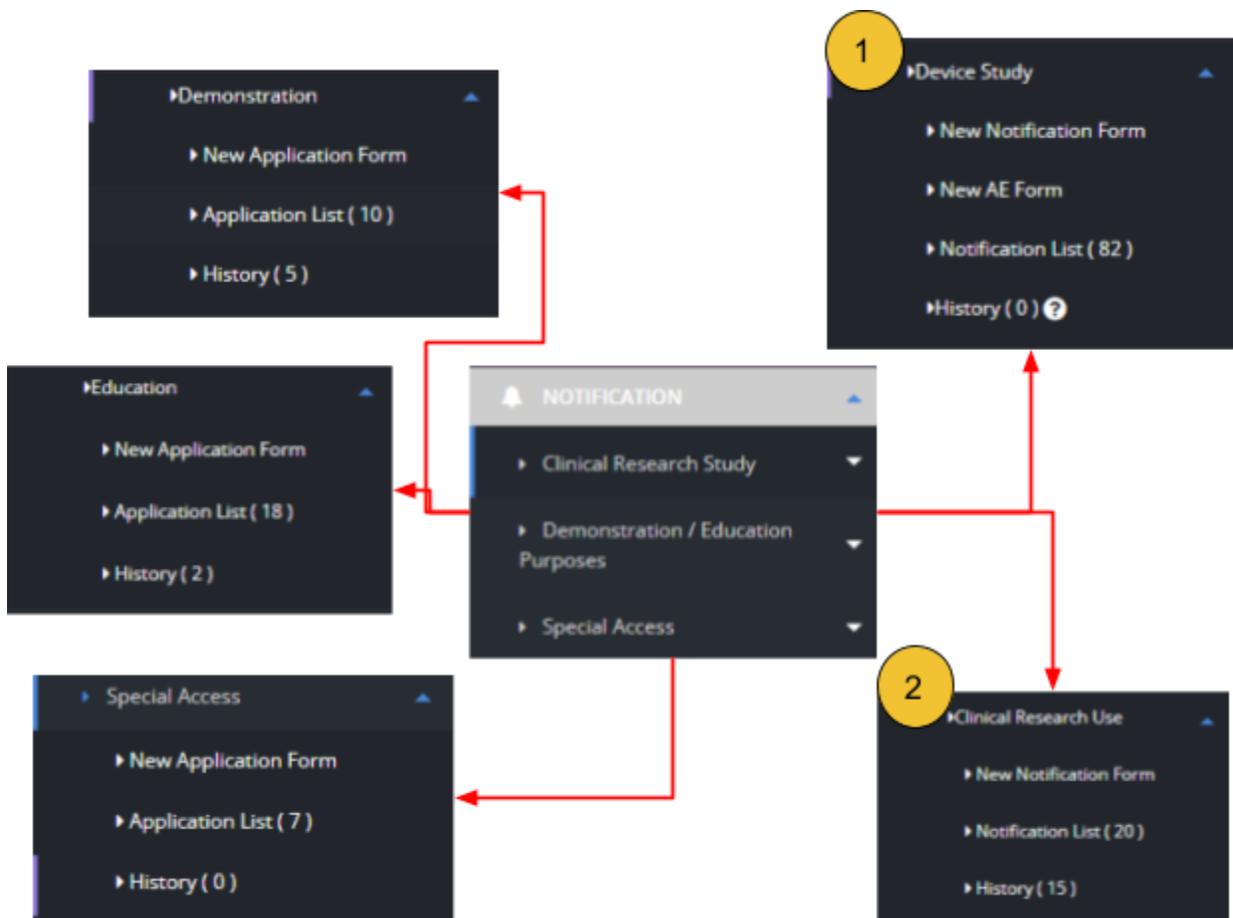
The screenshot displays the MeDC@SI v2.0 dashboard. At the top, there is a search bar with 'Quick Search' and 'Advance Search' options, and a user profile section showing 'ENGLISH', '(418)', and 'NEELOFA CO. - NEELOFA PU RIZ'. The main navigation menu on the left includes 'HOME', 'NOTIFICATION', 'ACCOUNT MANAGEMENT', 'ONLINE HELP', and 'HELP DESK'. A dropdown menu is open from the 'HOME' icon, listing: 'Clinical Research Study', 'Demonstraton / Education Purposes', 'Special Access', 'All Notification (116)', 'Return To Applicant (3)', and 'History (111)'. Another dropdown menu is open from the 'NOTIFICATION' icon, listing: 'User Management' and 'Deleted User'. A third dropdown menu is open from the 'HELP DESK' icon, listing: 'Circular Letter', 'Guideline Documents', 'Guidence Documents', and 'User Manual'. The dashboard content area shows a 'You Are Logged In As Main Account' notification, a 'Modules' dropdown set to '-All Modules-', and four summary cards: '48 Draft', '6 Unpaid Application', '15 Return From MOA', and '0 Drop'. Below these are sections for 'Announcement' (showing 1-4 of 1 item) and 'Alert' (showing 1-3 of 424 items). The announcement includes contact information for MeDC@SI 2.0 and support phone numbers. The alert shows a 'New!' application with ID 'CIU-20220103-5 (1)', status 'DRAFT', and title 'APPLICATION SUCCESSFULLY SUBMITTED FOR (ID: CIU-20220103-5 (1))'.

2.2 MENU NOTIFICATION REGISTRATION

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

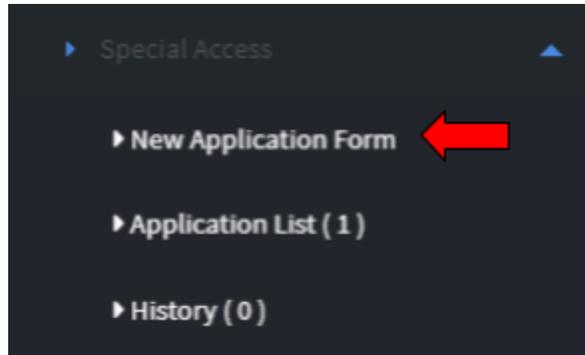
However, Clinical Investigational have three type which are *Investigational Use*, *Clinical Research Use* and *Notification of Change*. User should click on menu **NOTIFICATION** at left side menu for drop list sub menu Notification module.

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

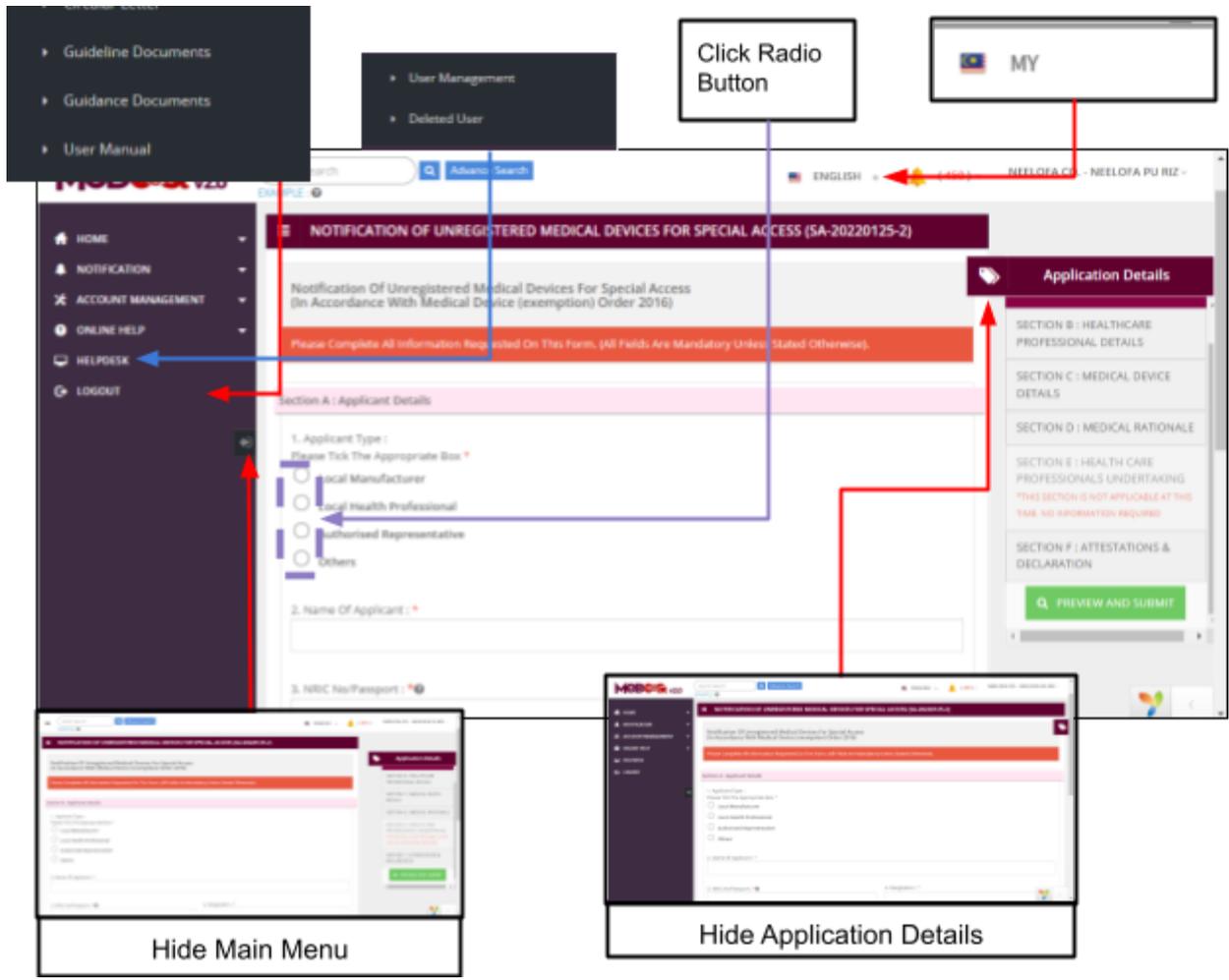
SECTION B : Healthcare Professional Details

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 a web form titled 'SECTION A : Applicant / Company Details'. The form is divided into several sections:

- 1. Applicant Type :** A group of radio buttons with the instruction 'Please Tick The Appropriate Box *'. The options are: Local Manufacturer, Local Health Professional, Authorised Representative, and Others. A red box labeled 'Click Radio Button' points to the 'Local Manufacturer' option.
- 2. Name Of Applicant : *** A text input field. A blue box labeled 'Fill in the text box' points to this field.
- 3. NRIC No/Passport : *** A text input field with a help icon (question mark) to its right. A blue box labeled 'Fill in the text box' points to the field, and another blue box labeled 'Fill in the text box' points to the help icon. A red box labeled 'Click Radio Button' points to the help icon.
- 4. Designation : *** A text input field. A blue box labeled 'Fill in the text box' points to this field.
- 5. Organisation Details :** A section containing:
 - Organisation Name *** and **Address Of Organisation ***: Text input fields. Blue boxes labeled 'Fill in the text box' point to both.
 - State ***: A dropdown menu with '-SELECT STATE-' selected. A red box labeled 'Click Radio Button' points to the dropdown arrow.
 - District ***: A dropdown menu with 'Select District' selected. A red box labeled 'Click Radio Button' points to the dropdown arrow.
 - Postcode ***: A text input field. A blue box labeled 'Fill in the text box' points to this field.

On the right side, there is a sidebar titled 'Application Details' with a list of sections: SECTION A: APPLICANT / COMPANY DETAILS (highlighted), SECTION B: HEALTHCARE PROFESSIONAL DETAILS, SECTION C: MEDICAL DEVICE DETAILS, SECTION D: MEDICAL RATIONALE, SECTION E: HEALTH CARE PROFESSIONALS UNDERTAKING (with a note: 'THIS SECTION IS NOT APPLICABLE AT THIS TIME. NO INFORMATION REQUIRED'), and SECTION F: ATTESTATIONS & DECLARATION.

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

1. Applicant Type

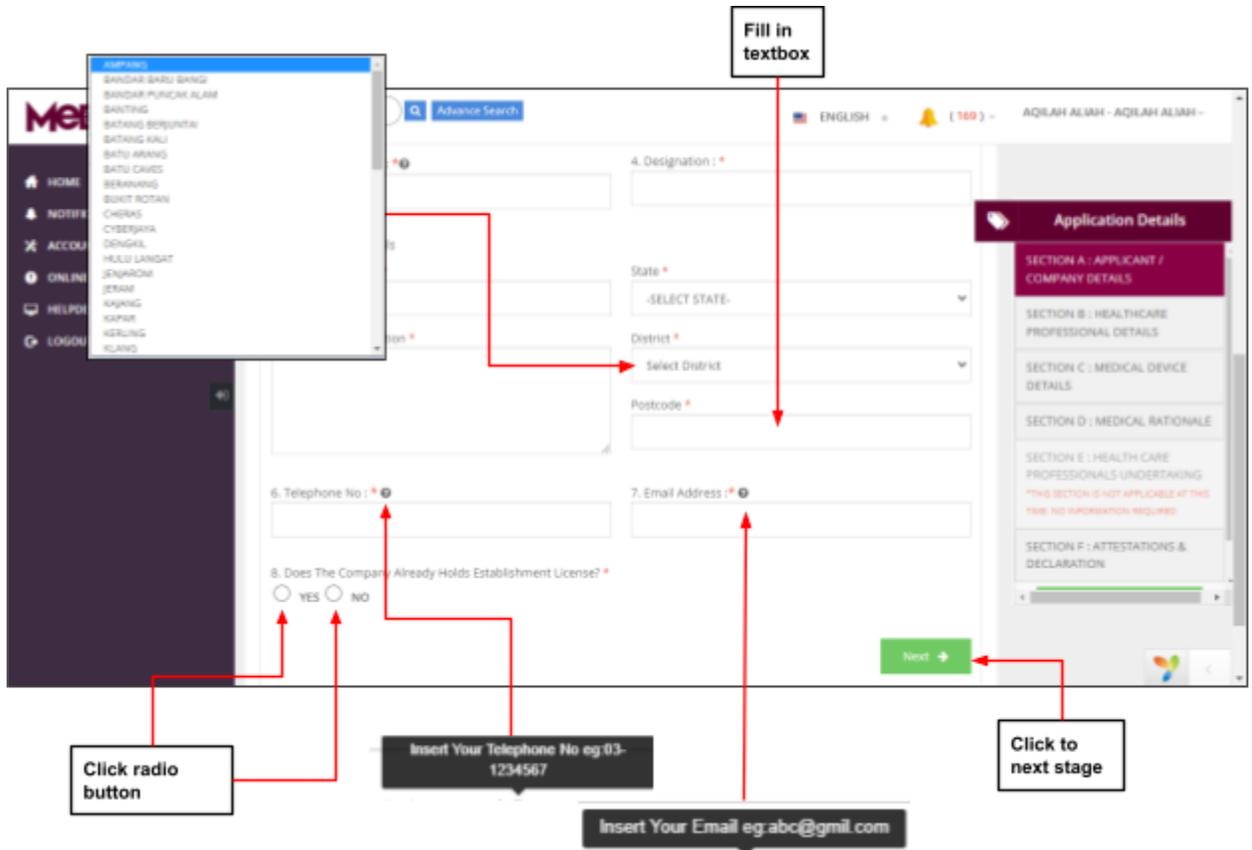
- User should choose whether Local Manufacturer, Local Health Professional, Authorised Representative or Others

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.



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



to the next section which is Section B.

SECTION B : Healthcare Professional Details

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)

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

1. Name :

2. Title :

3. Annual Practicing Certificate Number : ⓘ

4. Telephone No. : ⓘ

5. Email Address : ⓘ

6. Health Care Facility

Name :

Address :

← Previous

Next →

Click to previous stage

Insert Your Telephone No eg 010-12345678

Insert Your Annual Practicing Certificate Number

Insert Your Email eg abc@gmail.com

Click to next stage

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 contains several required fields, indicated by an asterisk (*):

- Name Of Medical Device *
- Grouping *
- Brief Description *
- Brand *
- Identifier/ Catalog or Model Number *
- Intended use *

The "Grouping" field includes four radio button options: Single, System, Family, and Set. A dashed box highlights these options, with a red arrow pointing to them from the label "Click radio button".

Other fields have red arrows pointing to them from the label "Field in the textbox".

On the right side, there is a sidebar titled "Application Details" with a list of sections: SECTION A : APPLICANT / COMPANY DETAILS, SECTION B : HEALTHCARE PROFESSIONAL DETAILS, SECTION C : MEDICAL DEVICE DETAILS (highlighted), SECTION D : MEDICAL RATIONALE, SECTION E : HEALTH CARE PROFESSIONALS UNDERTAKING (with a note: *THIS SECTION IS NOT APPLICABLE AT THIS TIME. NO INFORMATION REQUIRED), and SECTION F : ATTESTATIONS & DECLARATION.

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 mobile application interface for medical device registration. The main form area contains several text input fields with red arrows pointing to them from a box labeled "Field in textbox". The fields are: "Manufacturer's Name", "Contact Name and Title", "Address", "Postal Code", "Telephone", "Email", "Risk-Based Classification", and "Quantity to be Imported". A sidebar on the right, titled "Application Details", lists sections A through E. A "Phone No eg: 19498963648018" label points to the Telephone field, and an "Email eg: abc@gmail.com" label points to the Email field. The sidebar sections are: SECTION A: APPLICANT / COMPANY DETAILS, SECTION B: HEALTHCARE PROFESSIONAL DETAILS, SECTION C: MEDICAL DEVICE DETAILS, SECTION D: MEDICAL RATIONALE, SECTION E: HEALTH CARE PROFESSIONAL'S UNDERTAKING (with a note: "THIS SECTION IS NOT APPLICABLE AT THIS TIME. NO INFORMATION REQUIRED"), and SECTION F: ATTESTATIONS & DECLARATION.

- **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' and contains a text input field. Below the input field are three radio button options: 'Registered / Licensed', 'Exempted / Notified', and 'Others (please specify)'. A green '+ Select file...' button is positioned below the radio buttons. To the right of the main content area is a sidebar titled 'Application Details' with sections A through F. At the bottom of the main content area, there are two green buttons: 'Previous' and 'Next'. Red arrows point from text boxes to these elements: 'Click radio button' points to the radio buttons, 'Upload file' points to the '+ Select file...' button, 'Click to previous stage' points to the 'Previous' button, and 'Click to next stage' points to the 'Next' button.

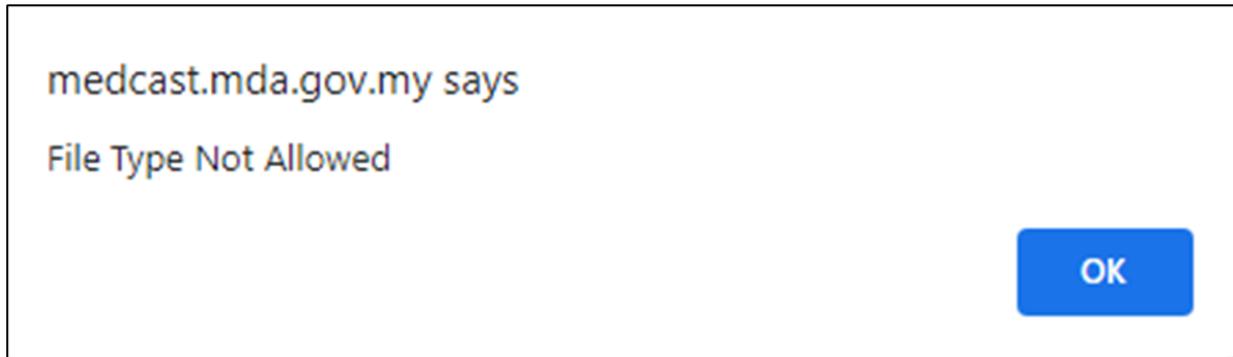
- Marketing Approval Status in other country(-ies)

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.

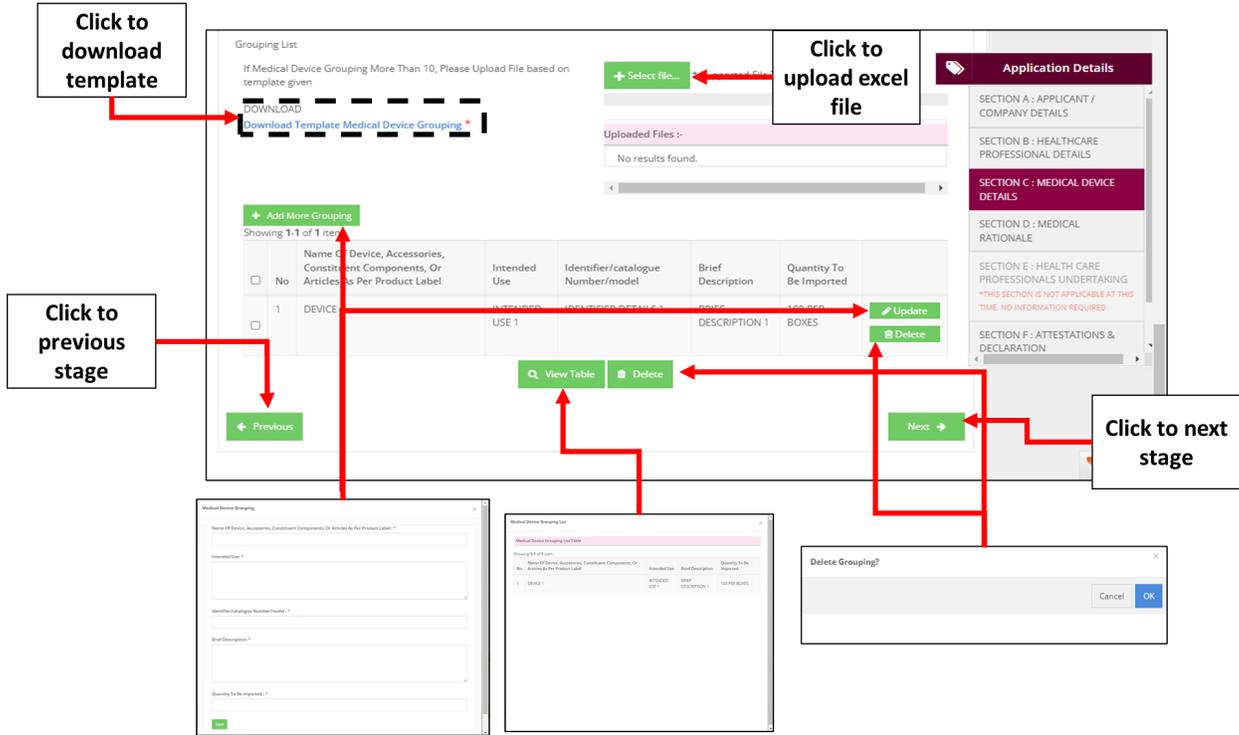


If user choose other than SINGLE as their grouping details, field below need to be fill.

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 a web form titled 'SECTION D : MEDICAL RATIONALE'. At the top, a pink header bar contains the title. Below it, a dashed purple line separates the header from the main content. The main content includes three numbered checkboxes, each with a sub-heading and a descriptive sentence. A red arrow points from a box labeled 'Tick at the checkbox' to the first checkbox. Below the checkboxes is a large text input area. A red arrow points from a box labeled 'Fill in the text box' to this area. To the right of the text area is a small icon of a question mark with an asterisk. A red arrow points from a box labeled 'Provide The Diagnosis, Treatment or Prevention And Your Reasons' to this icon. On the far right, a vertical sidebar titled 'Application Details' lists sections A through F, with 'SECTION D : MEDICAL RATIONALE' highlighted in a dark purple box.

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

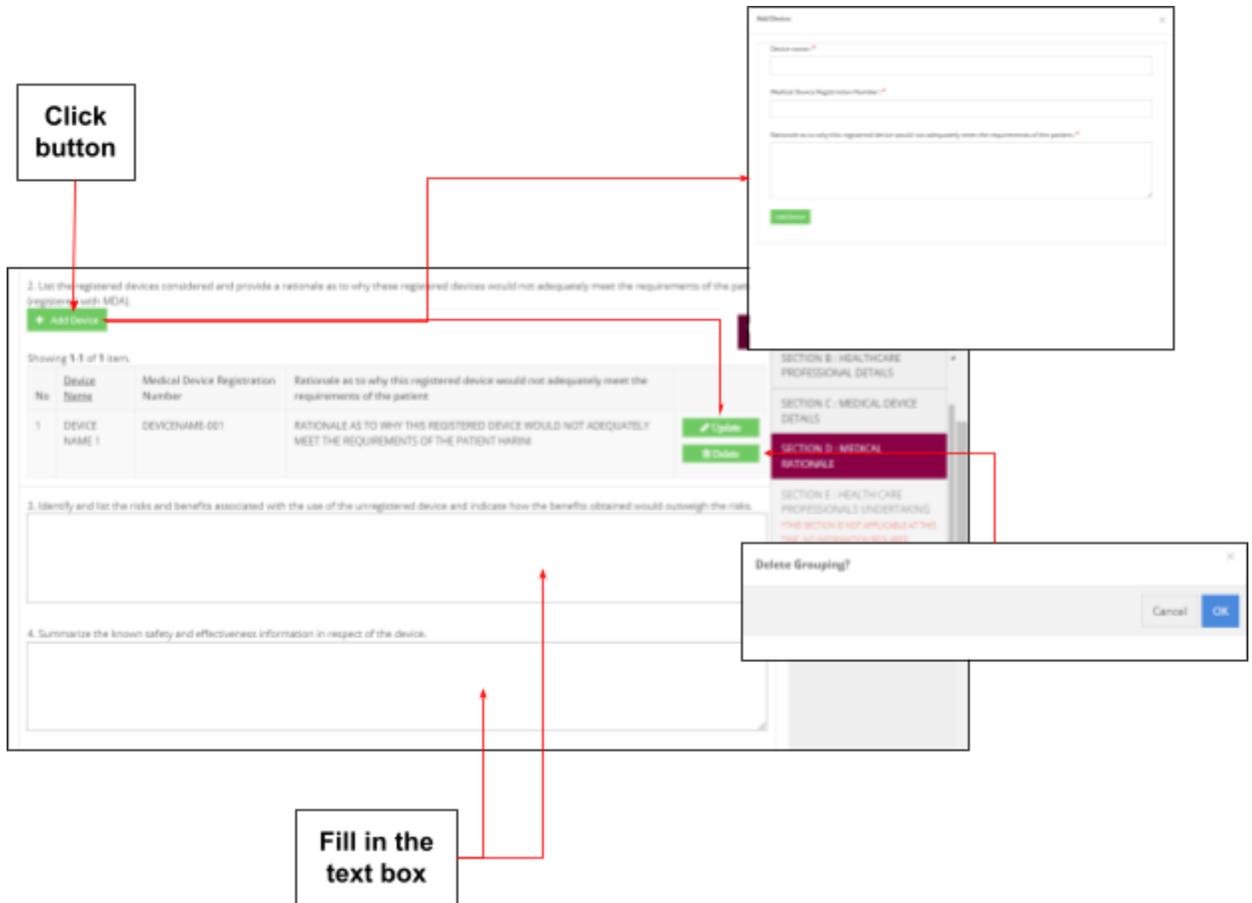
The symbol “*” means required field.

- 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 form with several annotations. A box labeled "Fill in the text box" has three red arrows pointing to three text input fields. The first field is for question 5: "5. In the event that conventional medical treatment has failed, is unavailable or unsuitable, Describe the condition for the treatment". The second field is for question 6: "6. In the case of emergency situation, Number of devices required for one month" with a question mark icon. The third field is for question 7: "7. Please define quantity for batch release (if required)". A box labeled "Click to the next stage" points to a green "Previous" button. A box labeled "Click to the previous stage" points to a green "Next" button. A box labeled "Total Device" points to the question mark icon in question 6. The form has a sidebar on the right with sections: "Application Details", "SECTION B : HEALTHCARE PROFESSIONAL DETAILS", "SECTION C : MEDICAL DEVICE DETAILS", "SECTION D : MEDICAL RATIONALE", "SECTION E : HEALTH CARE PROFESSIONALS UNDERTAKING" (with a note: "THIS SECTION IS NOT APPLICABLE AT THIS TIME. NO INFORMATION REQUIRED"), and "SECTION F : ATTESTATIONS & DECLARATION". At the bottom of the sidebar is a green "PREVIEW AND SUBMIT" button.

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).

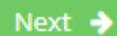
- The user must fill in the case of a request for batch release.

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

A green rectangular button with a white left-pointing arrow and the text "Previous" in white.

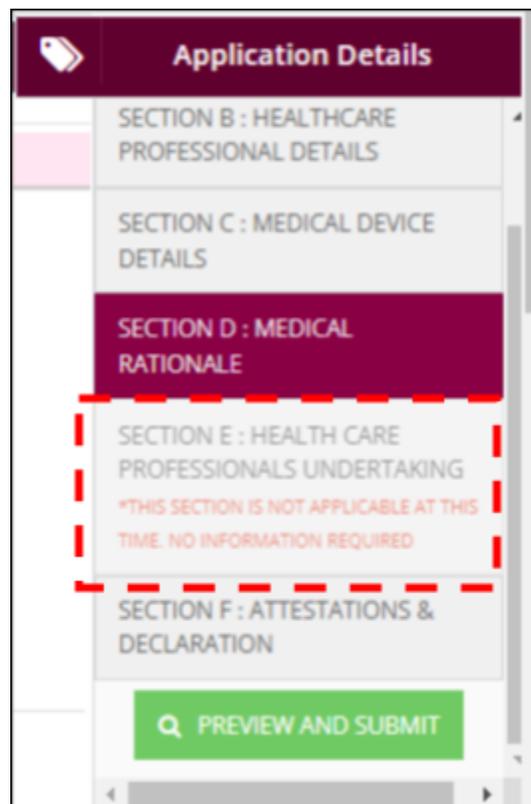
that shown in figure above. Then, user should click at button

to the next stage

A green rectangular button with the text "Next" in white and a white right-pointing arrow.

SECTION E : Healthcare Professionals Undertaking (Disabled)

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



SECTION F : Attestation & Declaration

The screenshot shows a web form titled "Section F : Attestations & Declaration". The form contains several paragraphs of text, including a declaration of accuracy and a checkbox labeled "I Have Read And Agree To The Above Terms And Conditions". A red box labeled "Click in checkbox" points to this checkbox. At the bottom left, a green button labeled "Previous" is annotated with "Click for previous section". At the bottom right, a green button labeled "PREVIEW AND SUBMIT" is annotated with "Click for preview". On the right side of the form, there is a sidebar titled "Application Details" with a list of sections: SECTION B: HEALTHCARE PROFESSIONAL DETAILS, SECTION C: MEDICAL DEVICE DETAILS, SECTION D: MEDICAL RATIONALE, SECTION E: HEALTH CARE PROFESSIONALS UNDERTAKING (with a note that it is not applicable), and SECTION F: ATTESTATIONS & DECLARATION (which is highlighted in red). Another "PREVIEW AND SUBMIT" button is visible in the sidebar area.

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.

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

SUBMIT 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

SUBMIT Click for submit

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

Confirm Submit Application?

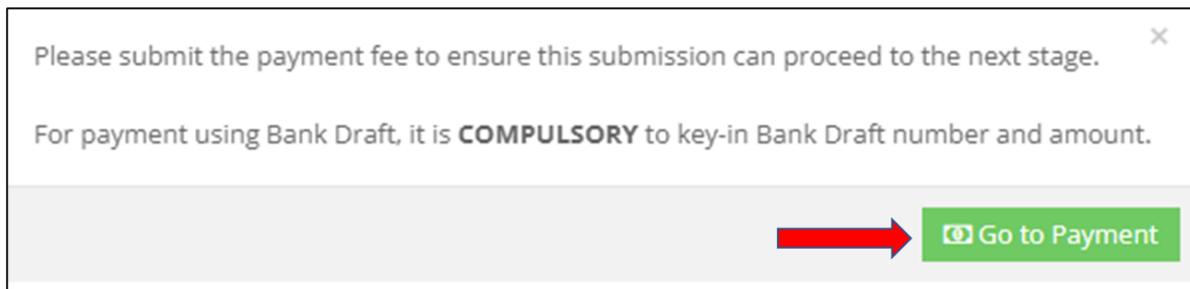
Click to proceed

Cancel OK

Click for cancel submitted

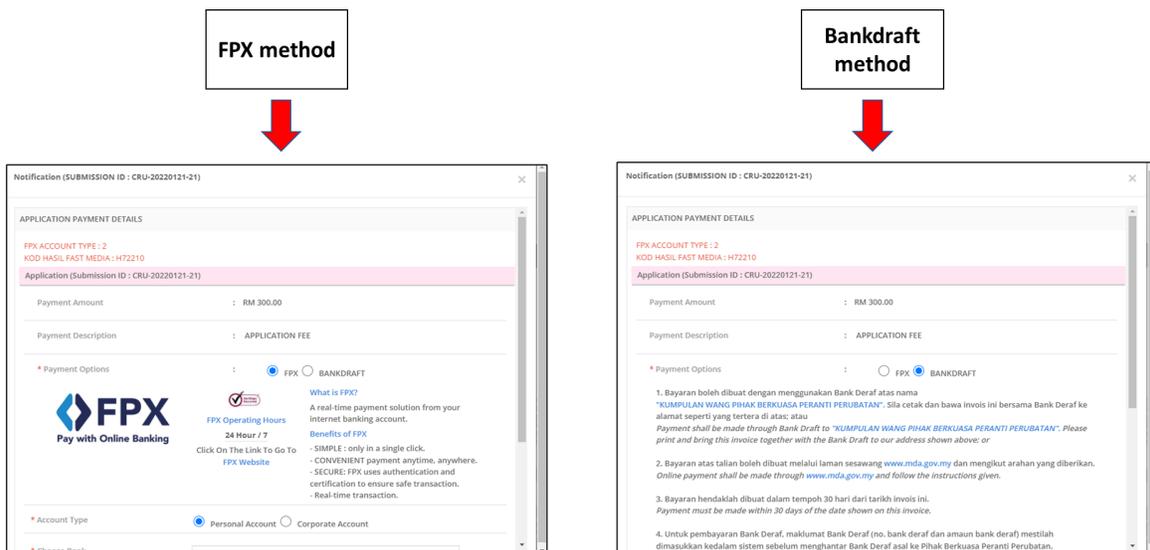
The user click “OK” to proceed to submit application and click “Cancel” to cancel the submitted application.

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.

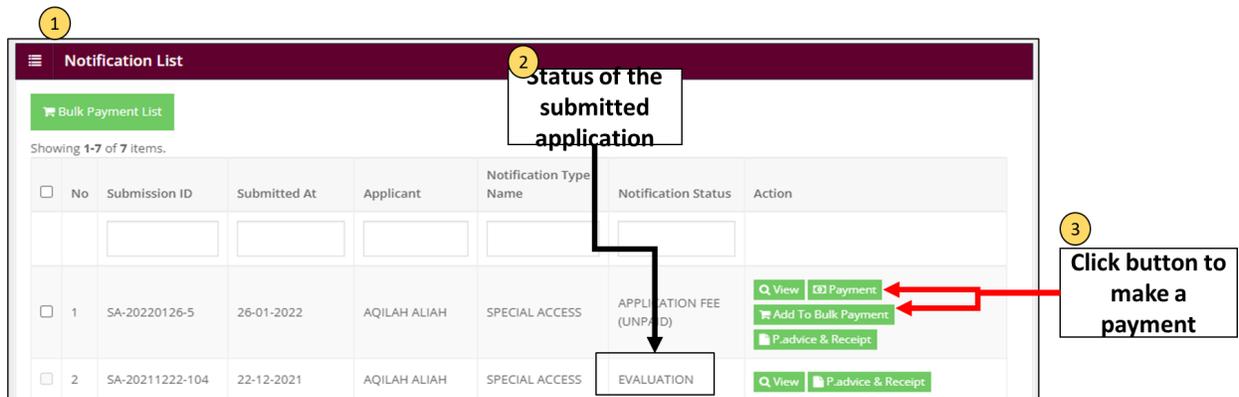
The Figure below shows the page once the user click . The user can pay using FPX method or Bankdraft method.



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  button or  to make a payment.
4. The user can pay using FPX method or Bankdraft method.

1



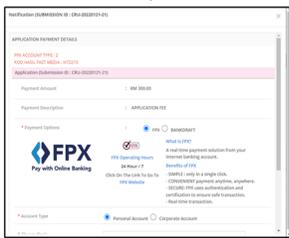
2 Status of the submitted application

No	Submission ID	Submitted At	Applicant	Notification Type Name	Notification Status	Action
1	SA-20220126-5	26-01-2022	AQILAH ALIAH	SPECIAL ACCESS	APPLICATION FEE (UNPAID)	View Payment Add To Bulk Payment P.advice & Receipt
2	SA-20211222-104	22-12-2021	AQILAH ALIAH	SPECIAL ACCESS	EVALUATION	View P.advice & Receipt

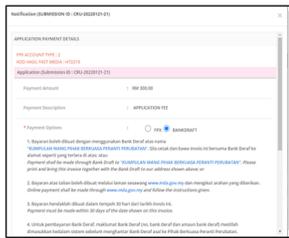
3 Click button to make a payment

4

FPX method



Bankdraft method



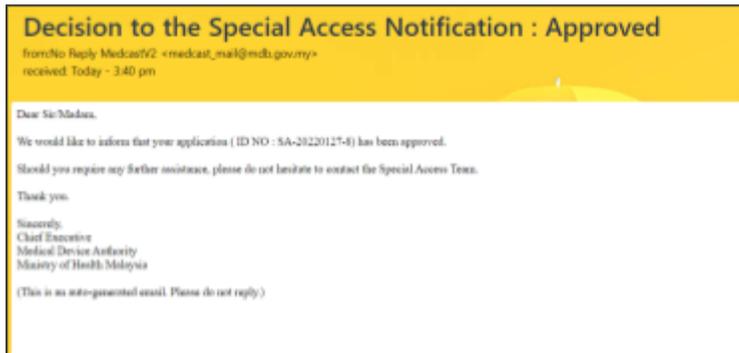
In addition, if application status “Draft” , the user can delete or update the application form.

The screenshot displays a web application interface titled "Notification List". At the top left, there is a search box with the text "Fill in box to search" and a red arrow pointing to it. Below the search box is a green button labeled "Bulk Payment List". The main content area shows a table with 7 items, displaying columns for "No", "Submission ID", "Submitted At", "Applicant", "Notification Type Name", "Notification Status", and "Action". The first row is highlighted with a red dashed box. The table contains the following data:

No	Submission ID	Submitted At	Applicant	Notification Type Name	Notification Status	Action
1	SA-20220126-5	26-01-2022	AQILAH ALIAH	SPECIAL ACCESS	APPLICATION FEE (UNPAID)	View, Payment, Add To Bulk Payment, Advice & Receipt
2	SA-20211222-104	22-12-2021	AQILAH ALIAH	SPECIAL ACCESS	EVALUATION	View, Advice & Receipt
3	SA-20211110-63	10-11-2021	AQILAH ALIAH	SPECIAL ACCESS	EVALUATION	View, Advice & Receipt
4	SA-20211216-92	Not Submitted Yet	AQILAH ALIAH	SPECIAL ACCESS	DRAFT	View, Update, Delete
5	SA-20211216-93	Not Submitted Yet	AQILAH ALIAH	SPECIAL ACCESS	DRAFT	View, Update, Delete
6	SA-20211216-94	Not Submitted Yet	AQILAH ALIAH	SPECIAL ACCESS	DRAFT	View, Update, Delete

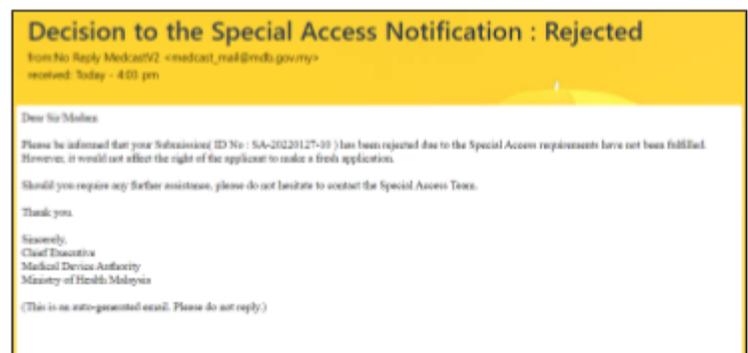
An inset window in the top right corner shows a detailed view of an application notification. A red arrow points from the "Delete" button in the table to a confirmation dialog box at the bottom of the page. The dialog box is titled "Delete application confirmation?" and contains "Cancel" and "OK" buttons.

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.

The screenshot displays a 'Notification List' table with the following data:

No	Submission ID	Submitted At	Applicant	Notification Type Name	Notification Status	Action
1	SA-20220126-5	26-01-2022	AQILAH ALIAH	SPECIAL ACCESS	RETURN FROM MDA (REQUIRE CHANGES)	View, Update, P.advice & Receipt
2	SA-20211222-104	22-12-2021	AQILAH ALIAH	SPECIAL ACCESS	EVALUATION	View, P.advice & Receipt
3	SA-20211110-63	10-11-2021	AQILAH ALIAH	SPECIAL ACCESS	EVALUATION	View, P.advice & Receipt
4	SA-20211216-92	Not Submitted Yet	AQILAH ALIAH	SPECIAL ACCESS	DRAFT	View, Update, Delete

Annotations in the image include a box labeled 'Status changed' pointing to the 'RETURN FROM MDA (REQUIRE CHANGES)' status in the first row, and a box labeled 'Click for update' pointing to the 'Update' button in the same row.

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



The screenshot displays a web interface for a medical device application. At the top, a dark purple header contains the text "NOTIFICATION OF UNREGISTERED MEDICAL DEVICES FOR SPECIAL ACCESS (SA-20220126-5)". Below the header, the main content area is titled "RETURN FOR FURTHER INFO". A pink box contains a "Comment By MDA Officer" section with the following text: "Dear Sr/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." Below this, "SECTION A : APPLICANT DETAILS/COMPANY DETAILS" is listed with a numbered list: 1. Telephone No, 2. Email Address, 3. Establishment License, 4. Establishment License Number, 5. Company's Role, 6. Extra Information. On the right side, a sidebar titled "Application Details" contains a vertical list of sections: SECTION A : APPLICANT / COMPANY DETAILS (highlighted in purple), SECTION B : HEALTHCARE PROFESSIONAL DETAILS, SECTION C : MEDICAL DEVICE DETAILS, SECTION D : MEDICAL RATIONALE, SECTION E : HEALTH CARE PROFESSIONALS UNDERTAKING (with a red note: "THIS SECTION IS NOT APPLICABLE AT THIS TIME. NO SUPERVISION REQUIRED"), and 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.

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	<input type="button" value="View"/>	<input type="button" value="P Advice & Receipt"/>
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The user should make the process EVALUATION at back end user.