

USER MANUAL FRONT END USER

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



**MODUL UTAMA - DEMONSTRATION &
EDUCATION (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:

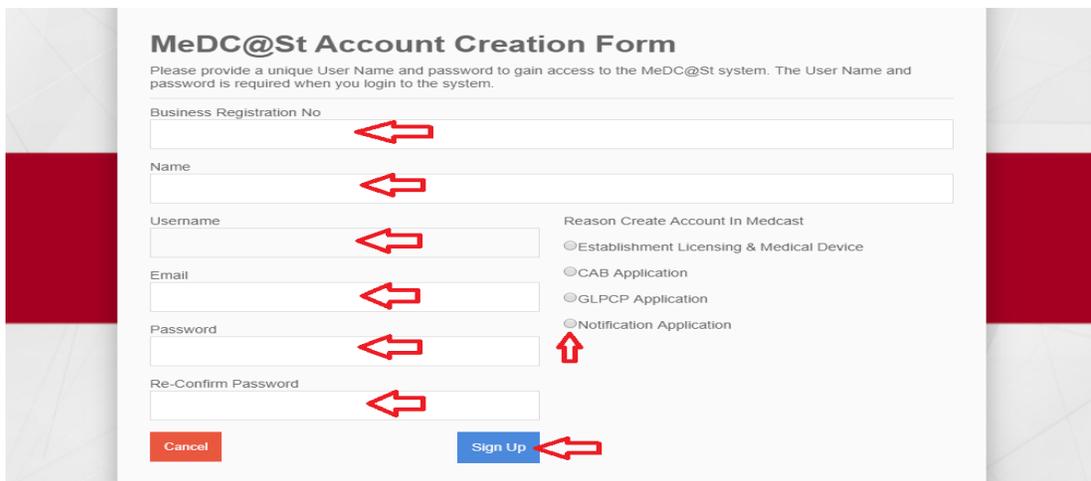
<https://medcast.mda.gov.my>

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.

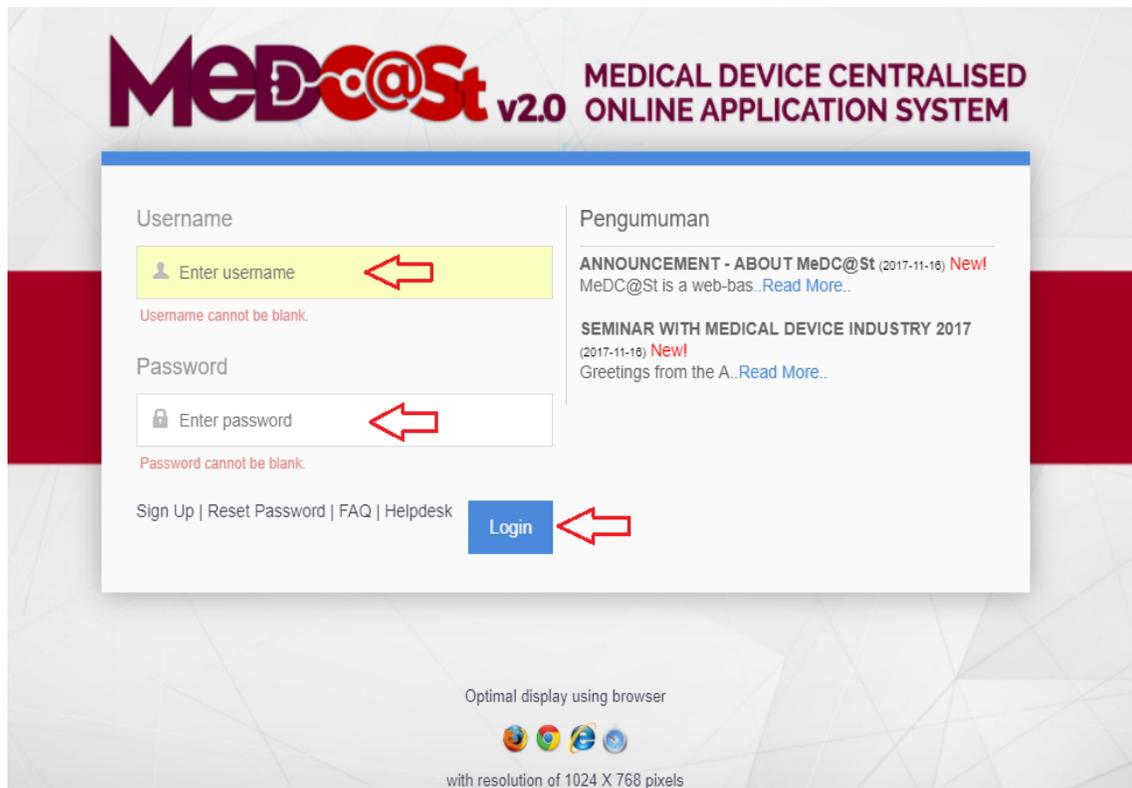


The image shows a screenshot of the 'MeDC@St Account Creation Form'. The form title is 'MeDC@St Account Creation Form'. Below the title, there is a sub-header: 'Please provide a unique User Name and password to gain access to the MeDC@St system. The User Name and password is required when you login to the system.' The form contains several input fields: 'Business Registration No', 'Name', 'Username', 'Email', 'Password', and 'Re-Confirm Password'. To the right of the 'Password' field, there is a section titled 'Reason Create Account In Medcast' with three radio button options: 'Establishment Licensing & Medical Device', 'CAB Application', and 'Notification Application'. At the bottom of the form, there are two buttons: a red 'Cancel' button and a blue 'Sign Up' button. Red arrows point to each of the input fields and the 'Sign Up' button.

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.



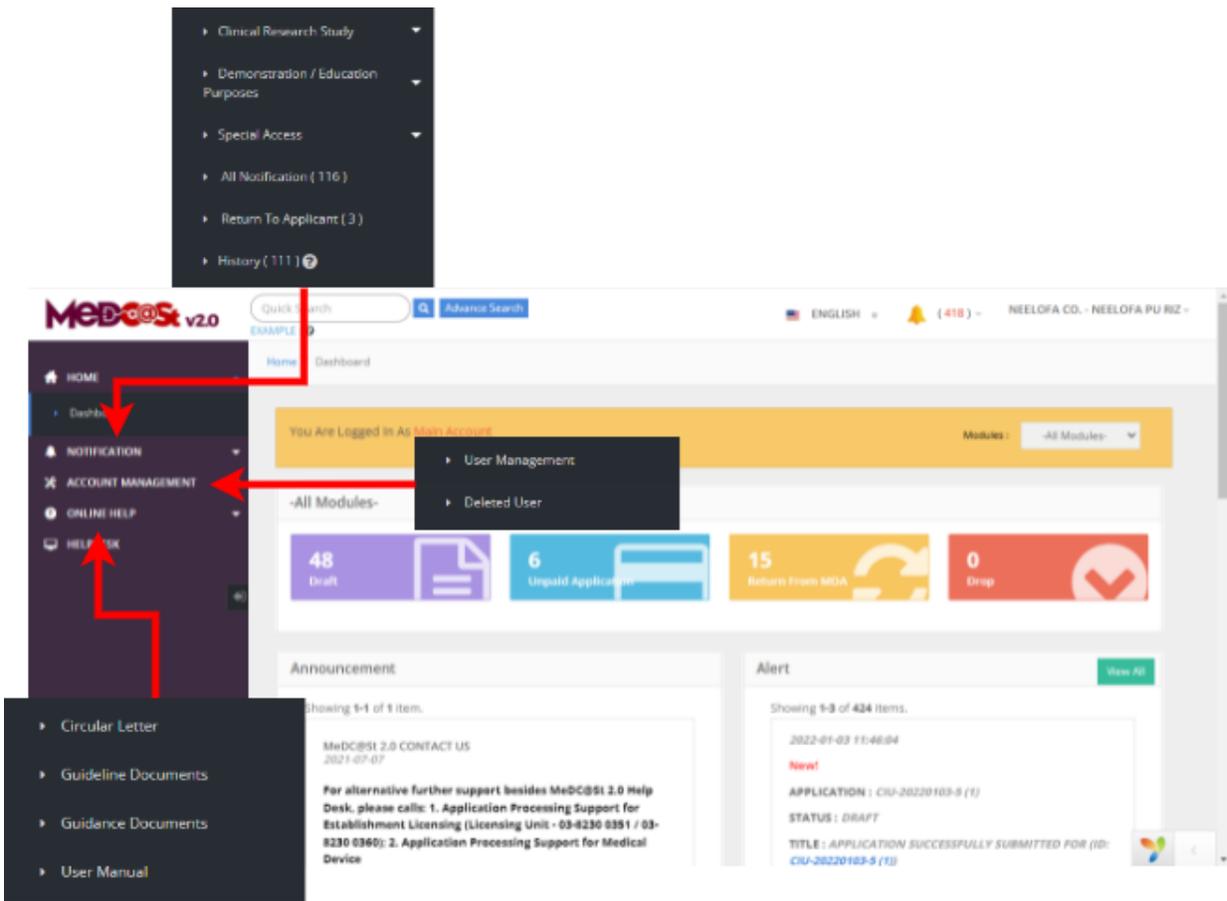
User has to log into the system using registered Username and its respective

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.

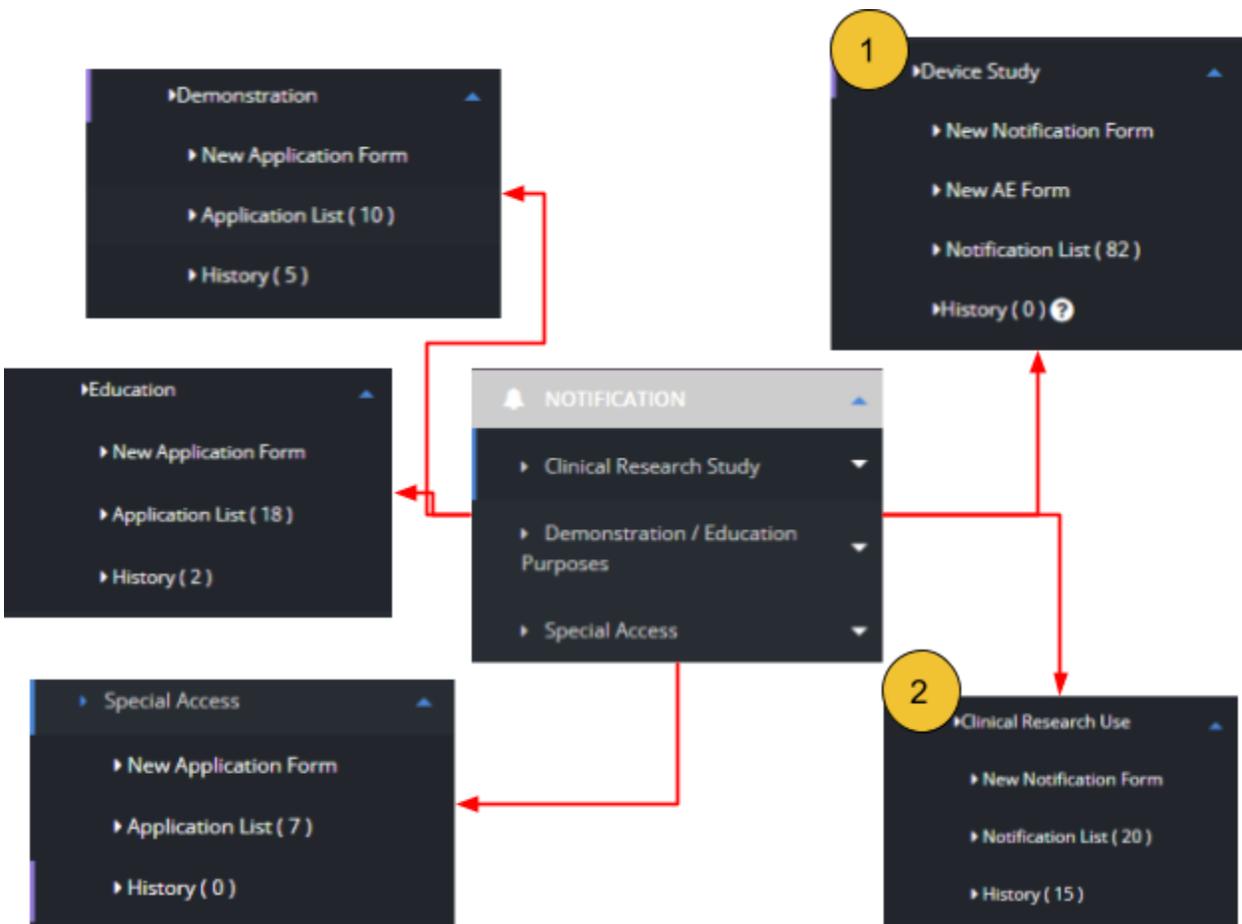


2.2 MENU NOTIFICATION REGISTRATION

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

However, Clinical Research Study have two types which are Device Study and *Clinical Research Use*. User should click on menu **NOTIFICATION** at left side menu for drop list sub menu Notification module.

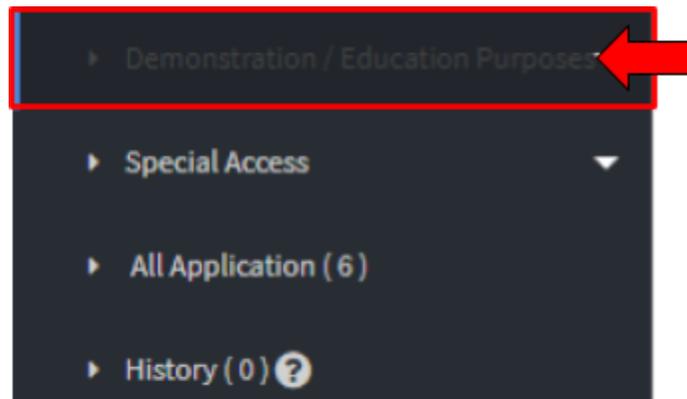
2.2.1 NEW APPLICATION FORM



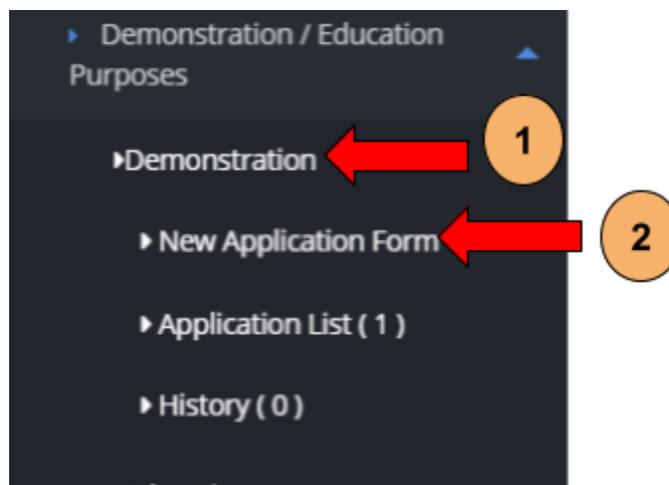
DEMONSTRATION

1) New Application

Firstly, user should click **Demonstration / Education Purpose** at sub menu to create new registration like shown below.



Next, it will show like below and user have to click “Demonstration” then “New Application Form” to create new application.

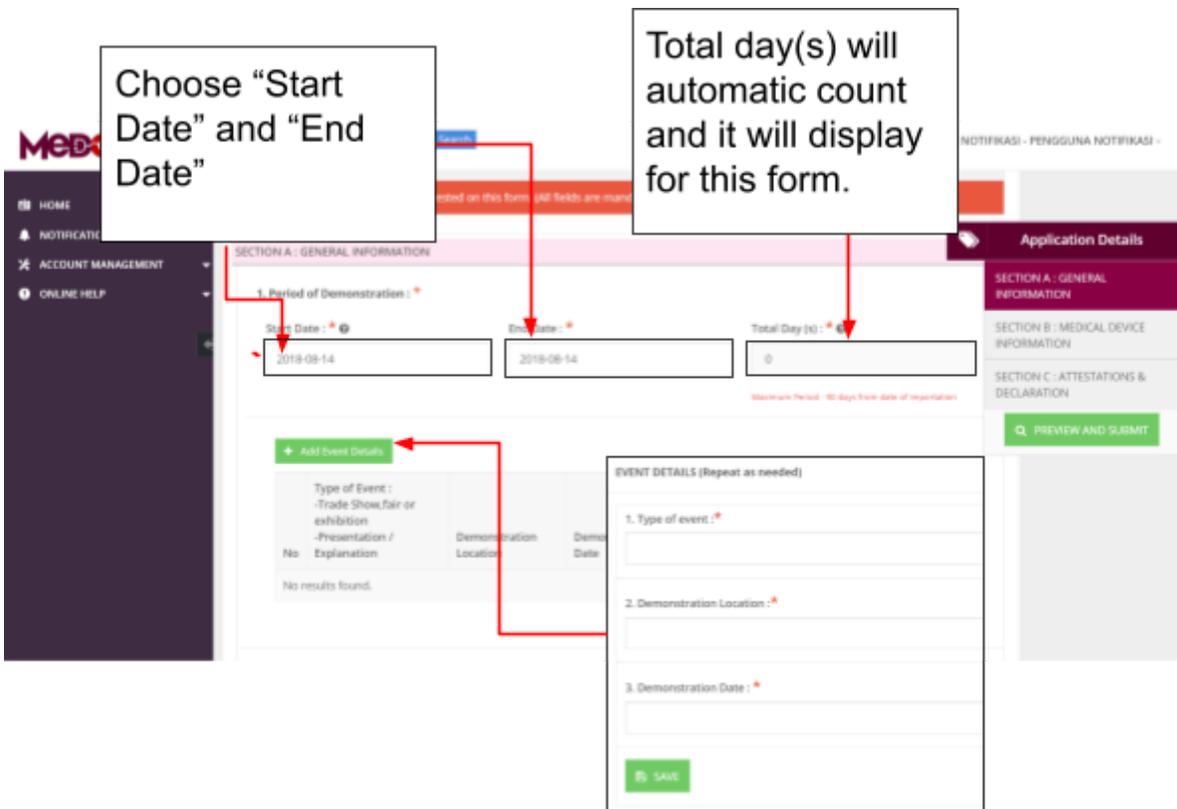


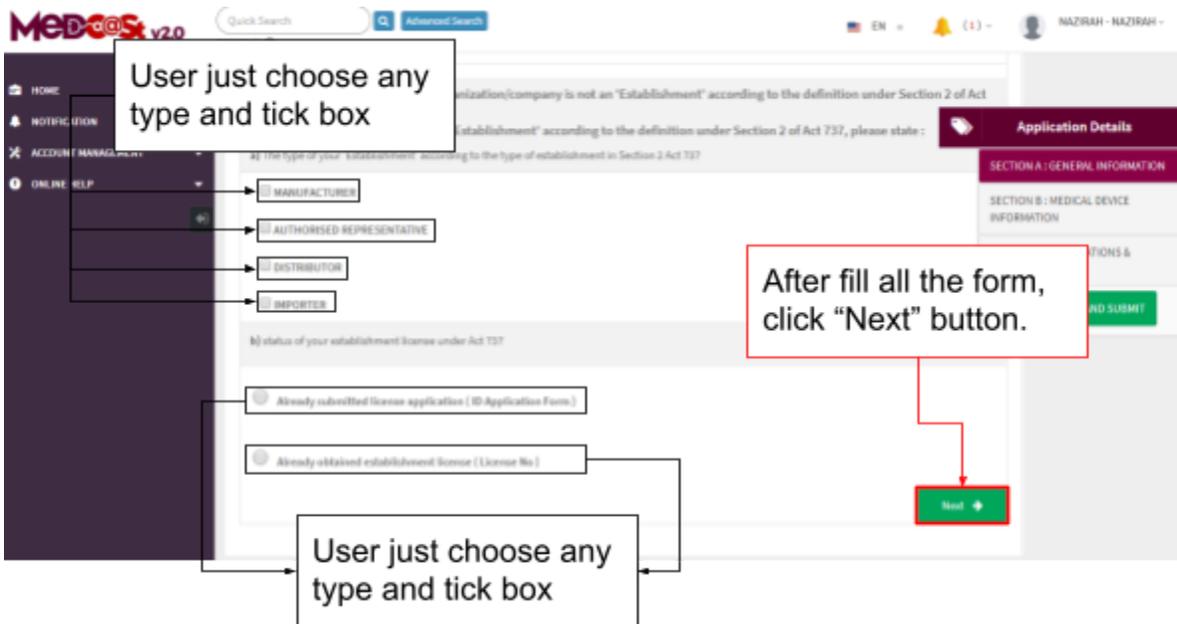
The user should click at sub menu **New application form** to apply the registration form for **Demonstration** Purpose. The application form will appear. The figure below shows the application form for applicant fill it. The user should fill all demonstration form. There are three sections which are:

- SECTION A : General information
- SECTION B : Medical Device Information
- SECTION C : Attestation and declaration

Section A: General information

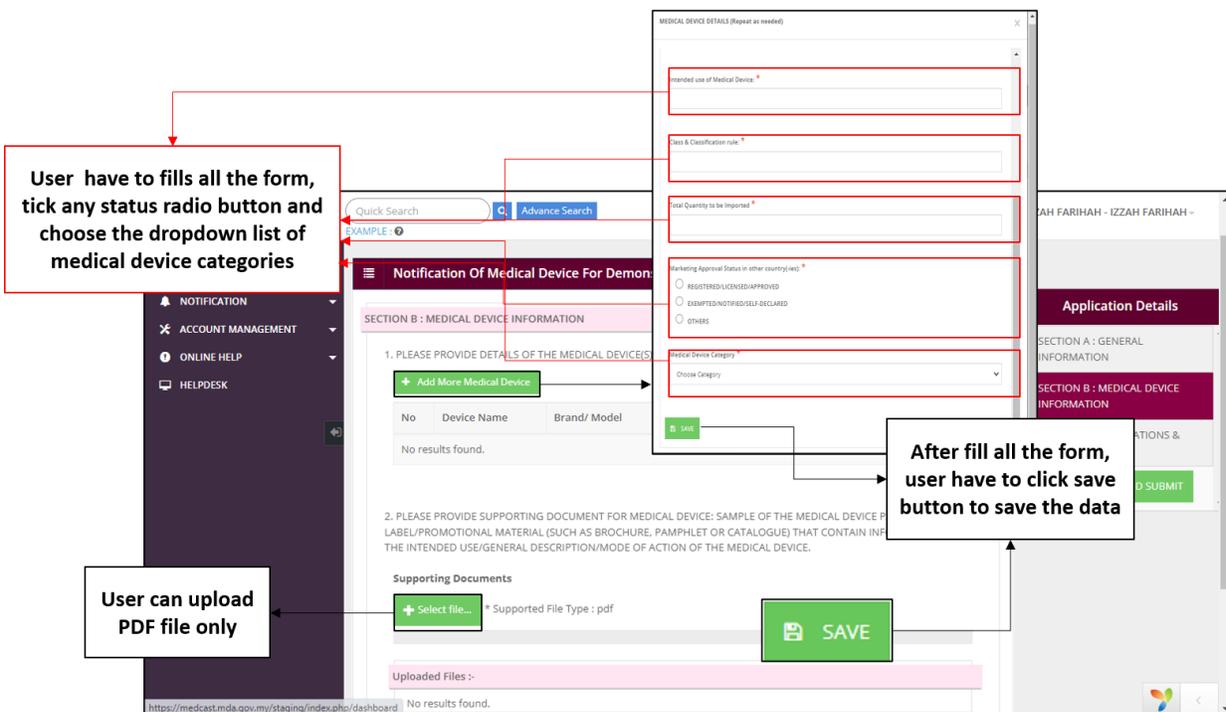
Figure below are shown the layout for Section A : GENERAL INFORMATION. User have to fill all the form and that symbol “*” means required field. The user must fill it. For total date is already show like “ **Maximum Period - 90 days from date of importation** ”.



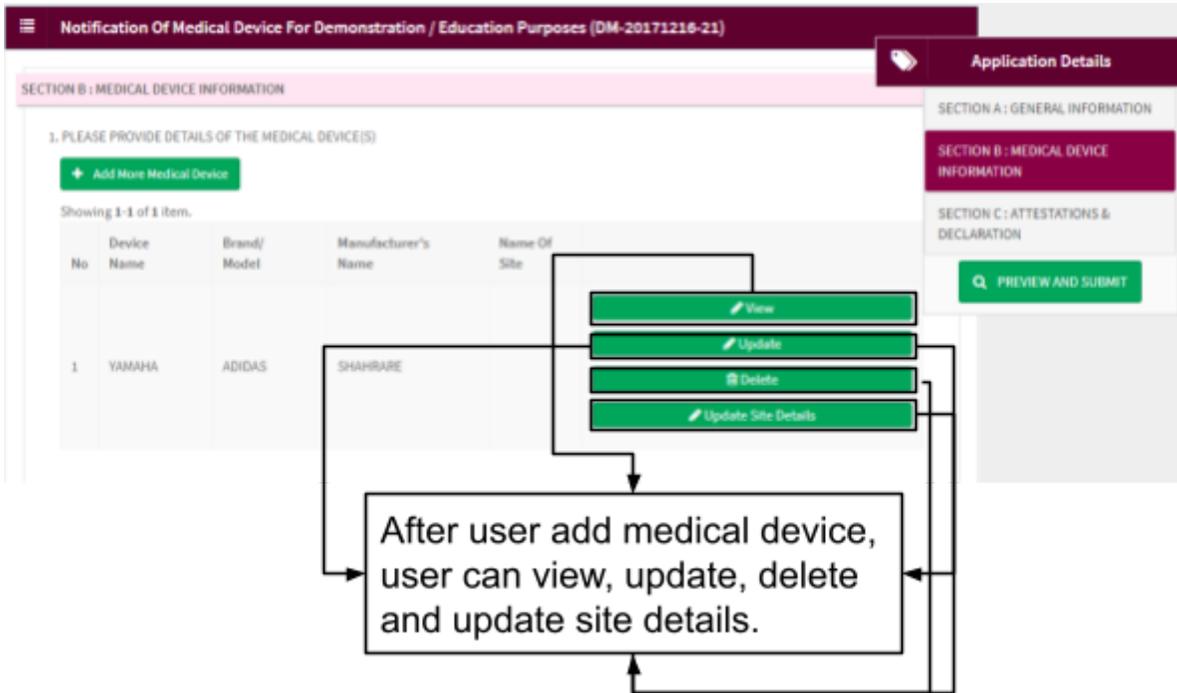


Section B: Medical Device Information

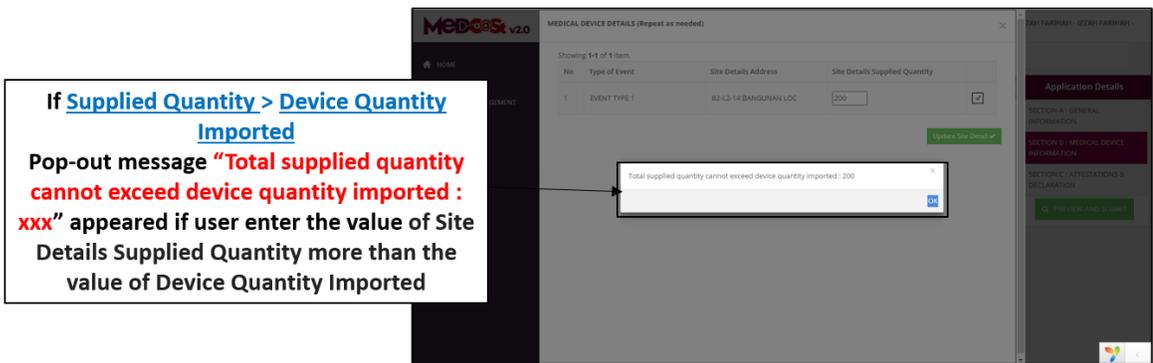
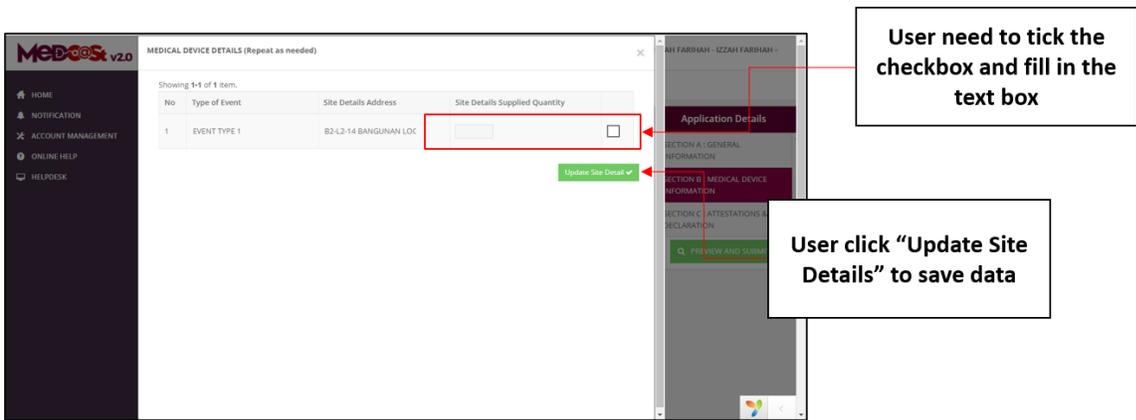
After clicks "  " button at section A, it will display section B like shown below.



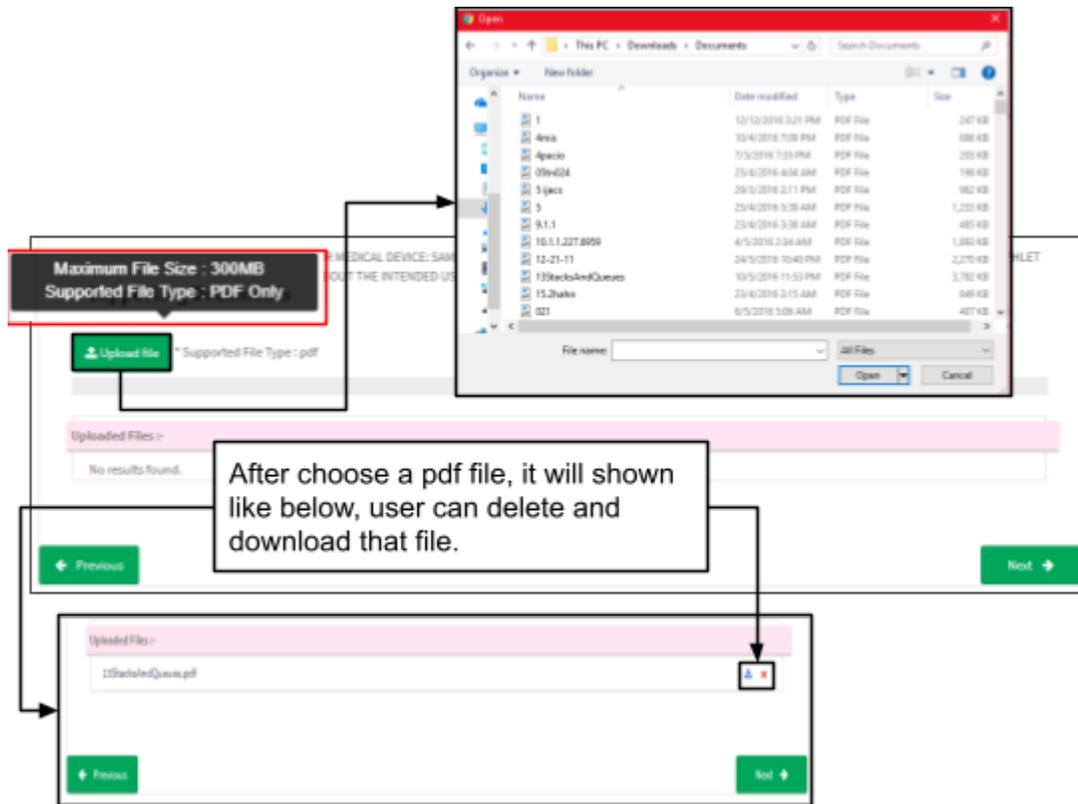
After user click “  ” and fill all the form, it will be shown like below.



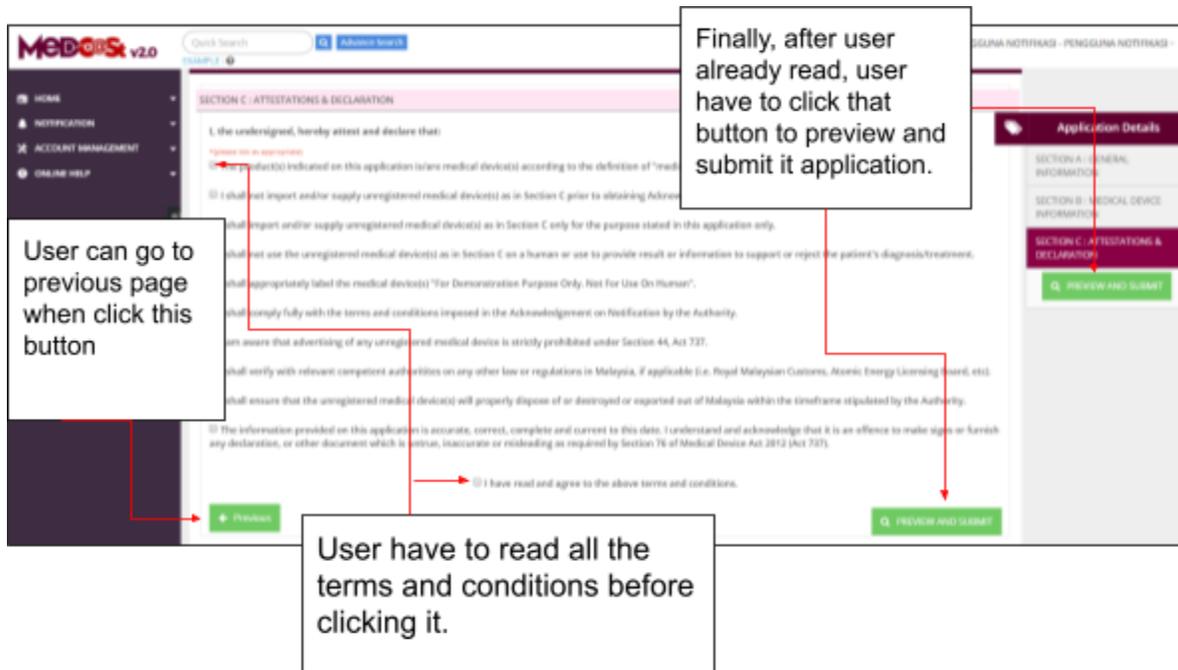
For  , users have to tick the checkbox and enter the Site Details Supplied Quantity since the  data are extracted from Section A. The value of Supplied Quantity must be less or same with the value of Device Quantity Imported. If users enter the value of Supplied Quantity more than the value of Device Quantity Imported, a pop-message as below appeared and the value of Supplied Quantity will reset same as the value of Device Quantity Imported.



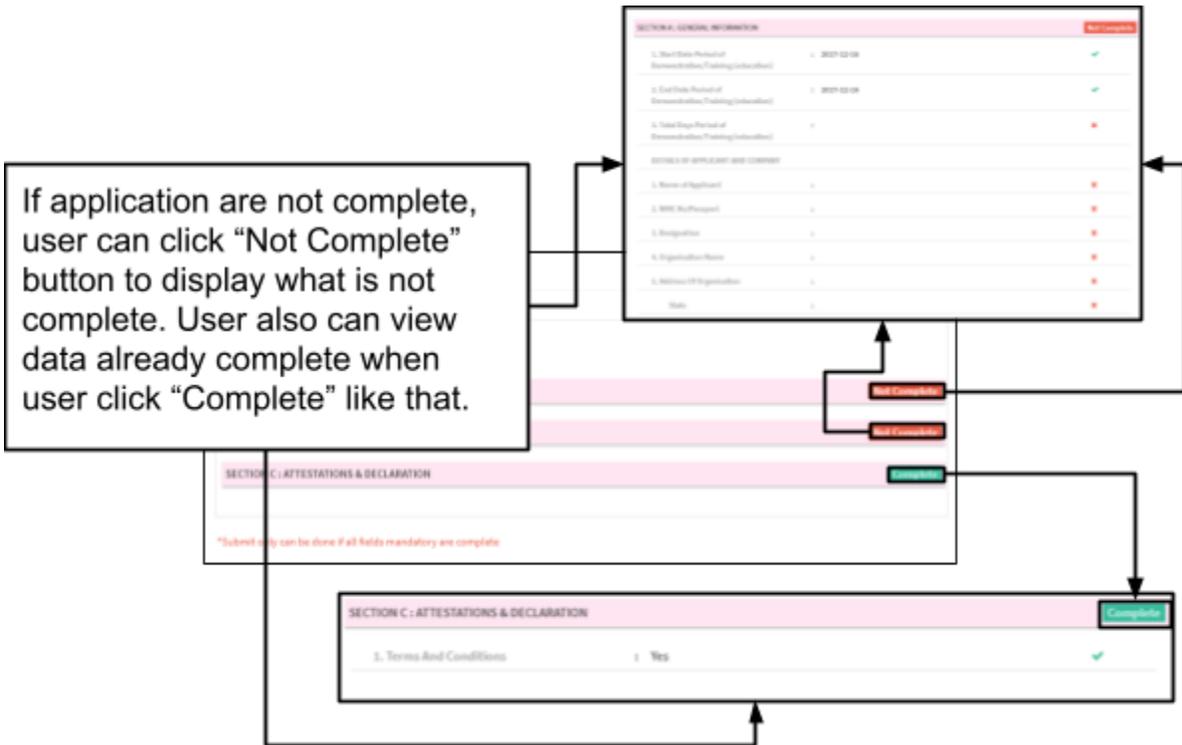
After the user fill all form, users have to click "  " button to the last section.



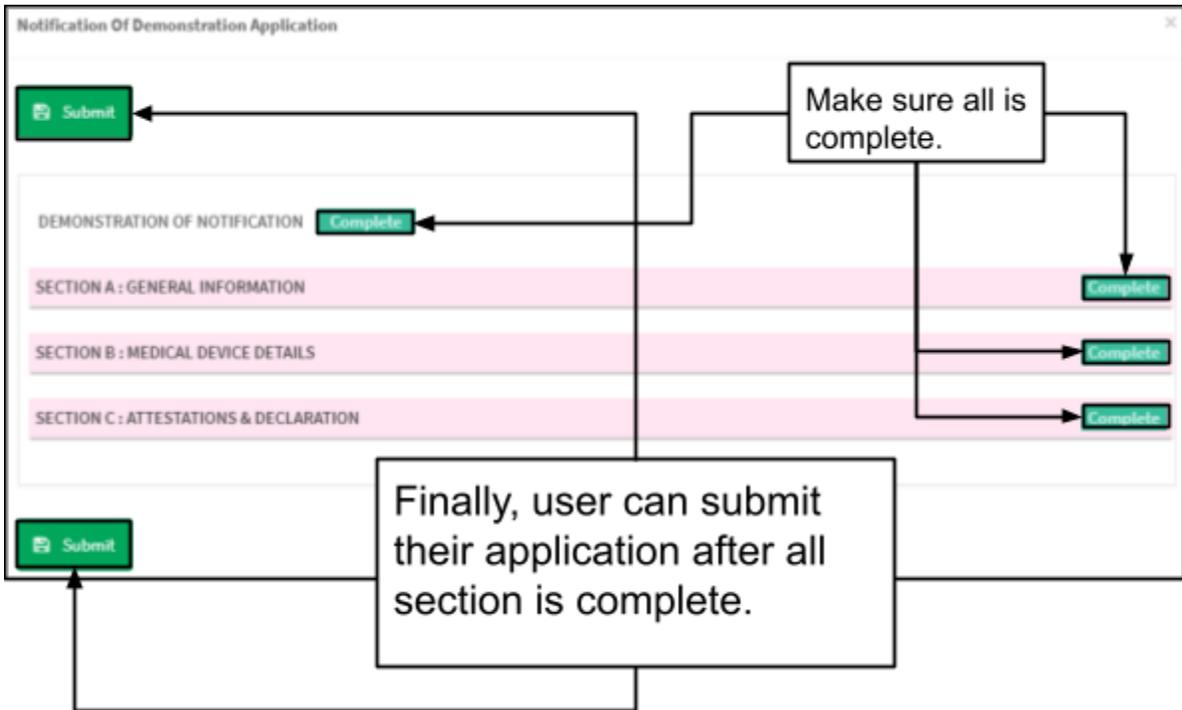
Section C: Attestation And Declaration



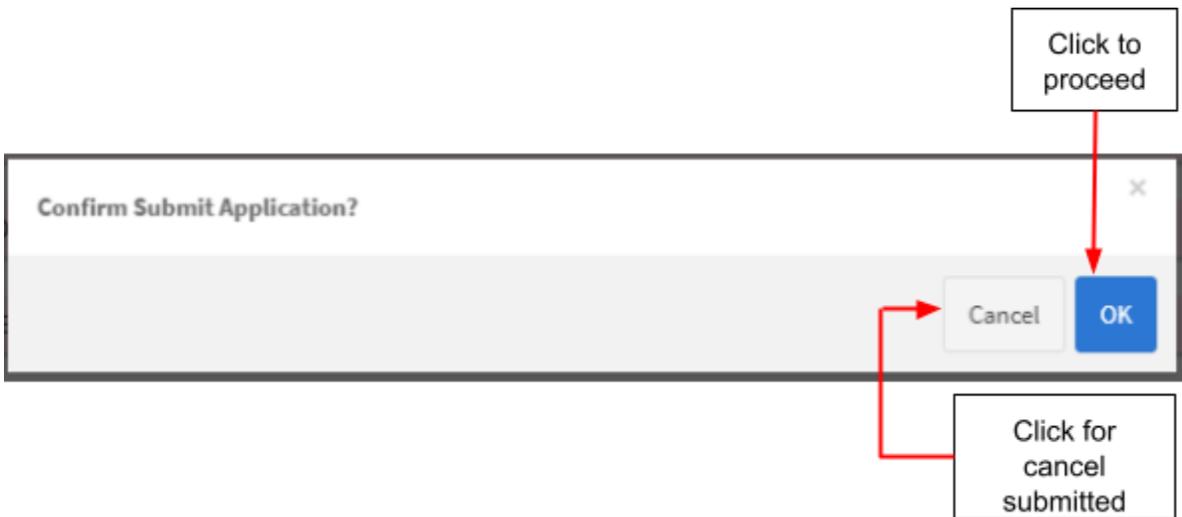
After clicking “PREVIEW AND SUBMIT” button, it will display all the section are already complete fill out or not complete like shown below.



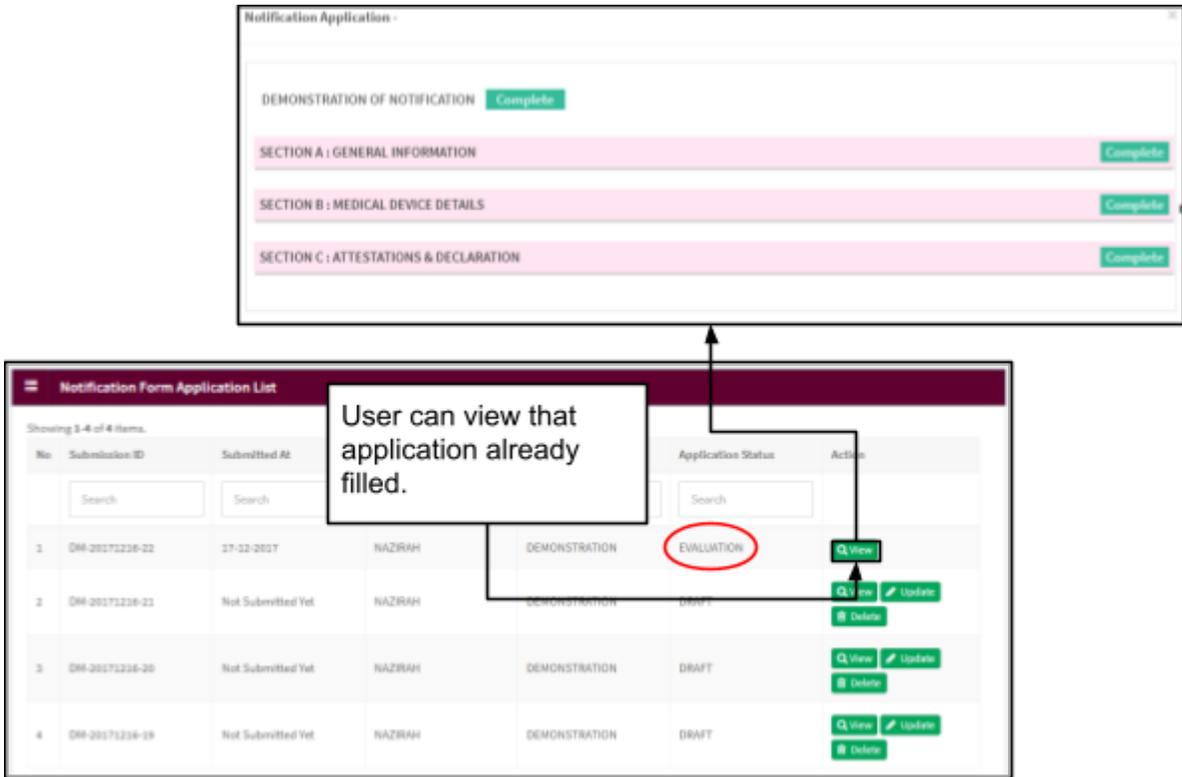
User cannot submit the application yet because, users have to complete that application first before submitting it. User can submit their application after all applications are complete like shown below.



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

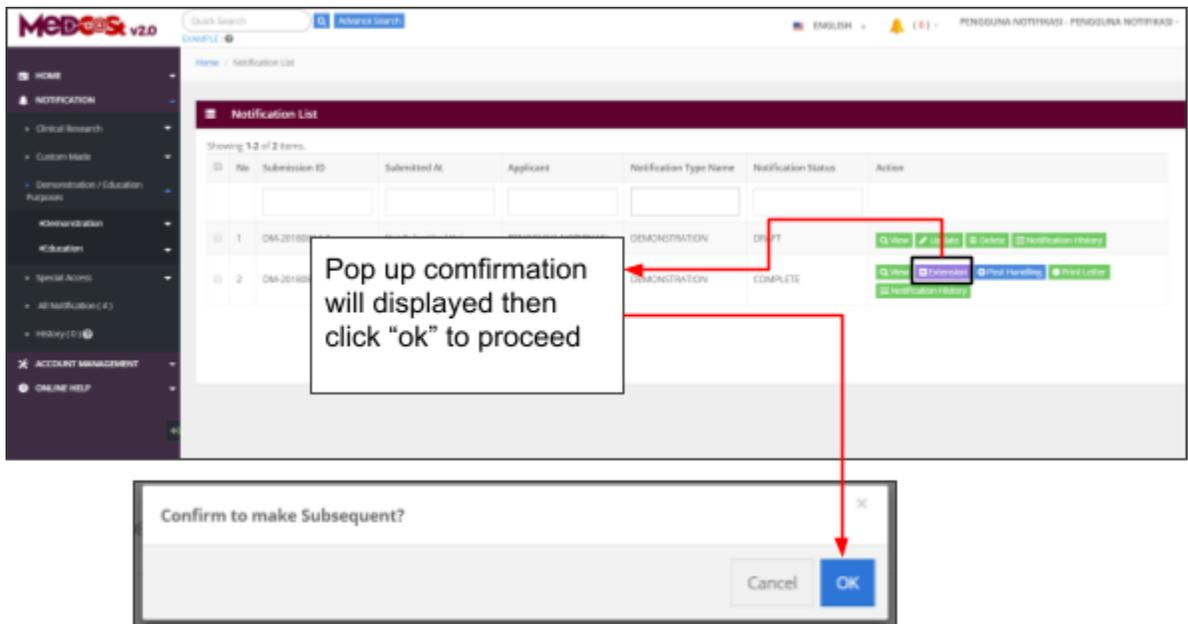


If user click “ok” , the application status will be changed to “EVALUATION”. It will automatically jump to all application page like shown below.

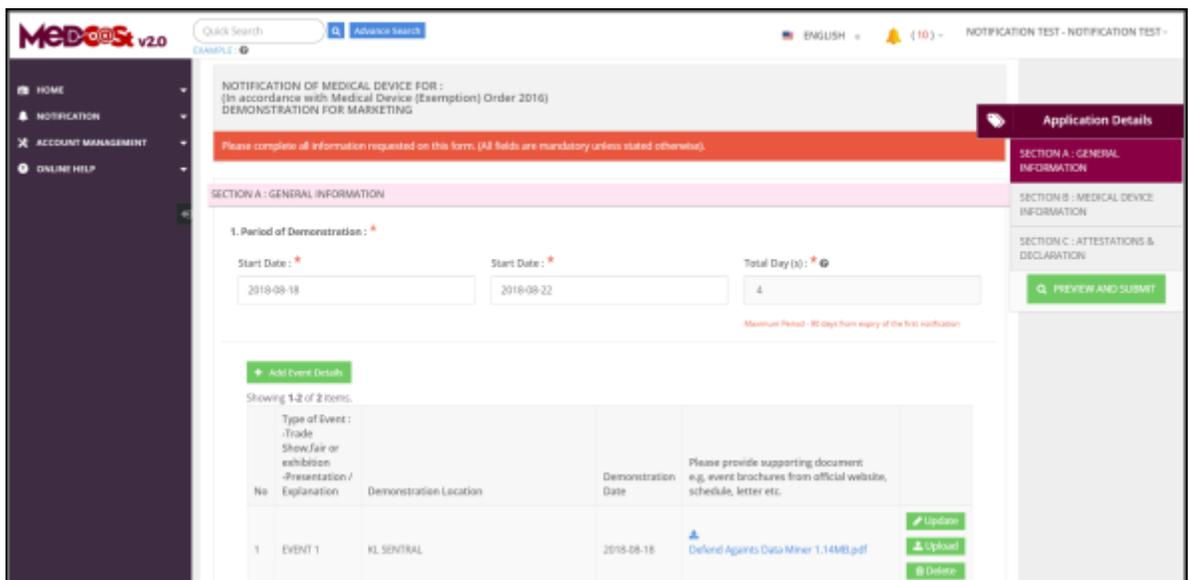


2) **Extension application**

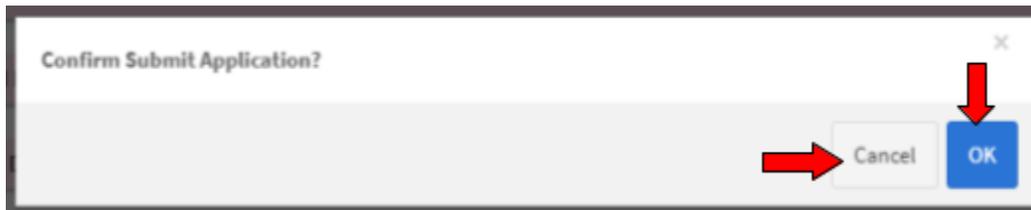
Extension application for demonstration can be registered from new application demonstration that have been completely registered. To register for extension demonstration, user can click button  .



After user click button "Ok", form extension as below will be displayed. User only have permission to update their previous application data at section A (Event Details) and Section B (Site Details).



After all the forms are completed, the user must click button “PREVIEW AND SUBMIT” to view and click button “Submit” to submit the application. The alert message will be displayed and user should click “OK” to proceed and “Cancel” to cancel the submitted.



If user click “OK”, the status at application will be changed to EVALUATION.

3) *Post Handling*

Post Handling can be registered after application in status complete. To

register for post handling, user can click button  “
”.

POST HANDLING NOTICE TO AUTHORITY

1. Please provide details on the method used for post handling of unregistered medical device.

Showing 1-1 of 1 item.

No	Device Name	Brand/ Model	Manufacturer's Name	Post Method	
1	SCOPE	SONY	HISENCE	(not set)	<input type="button" value="+ Add Post Method"/>

2. Please provide supporting document related to the post handling process which had been used.

Supporting Documents

Supported File Type : pdf

Uploaded Files >

No results found.

3. Declaration:
I hereby declare that:

- The demonstration event is over and all medical devices involved are properly disposed of or destroyed, or exported out of Malaysia.
- The information provided on this application is accurate, correct, complete and current to this date. I understand and acknowledge that it is an offence to make false or furnish any declaration, or other document which is incorrect.

User need to fill post method for their device.

User upload supporting document in pdf type.

User click attestation if agree with the term and conditions.

Post Handling

1	SCOPE	SONY	HISENCE	POS LAJU	+ Add Post Method
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2. Please provide supporting document related to the post handling process which had been used.

Supporting Documents

[+ Select file...](#) * Supported File Type : pdf

Uploaded Files :-

Defend Againts Data Miner 1.14MB.pdf	📄 ✖
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3. Declaration:
I hereby declare that:

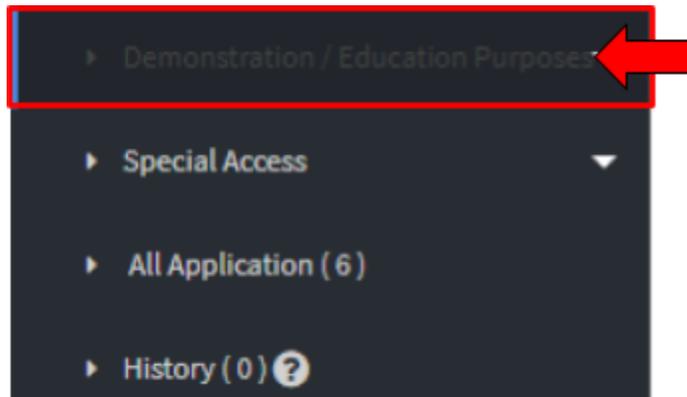
- The demonstration event is over and all medical devices involv out of Malaysia.
- The information provided on this application is accurate, corre and acknowledge that it is an offence to make signs or furnish any inaccurate or misleading as required by Section 76 of Medical Dev

[📄 SAVE](#)

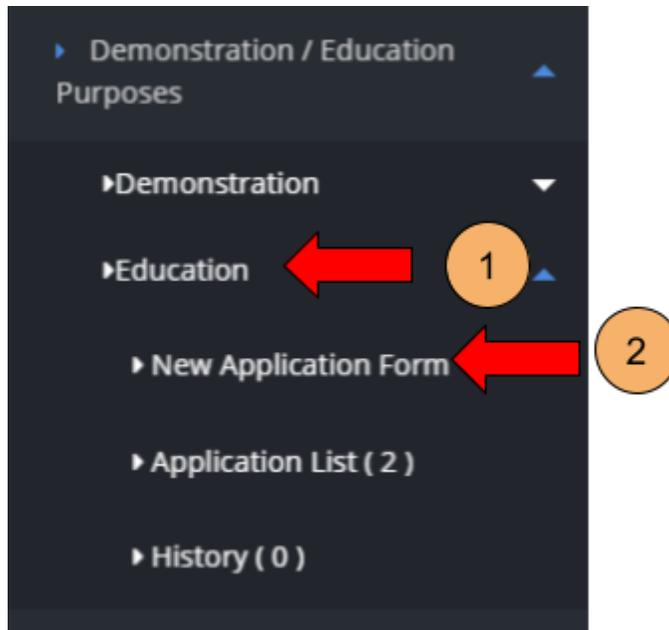
After fill all the required information, button "save" will appear. User can click it to proceed submit post handling.

EDUCATION

Firstly, user should click **Demonstration / Education Purpose** at sub menu to create new registration like shown below.



Next, it will show like below and user have to click “Education” then “New Application Form” to create new application.



The user should click at sub menu **New application form** to apply the registration form for **Education** Purpose. The application form will appear. The figure below

shows the application form for applicant fill it. The user should fill all education form. There are three sections which are:

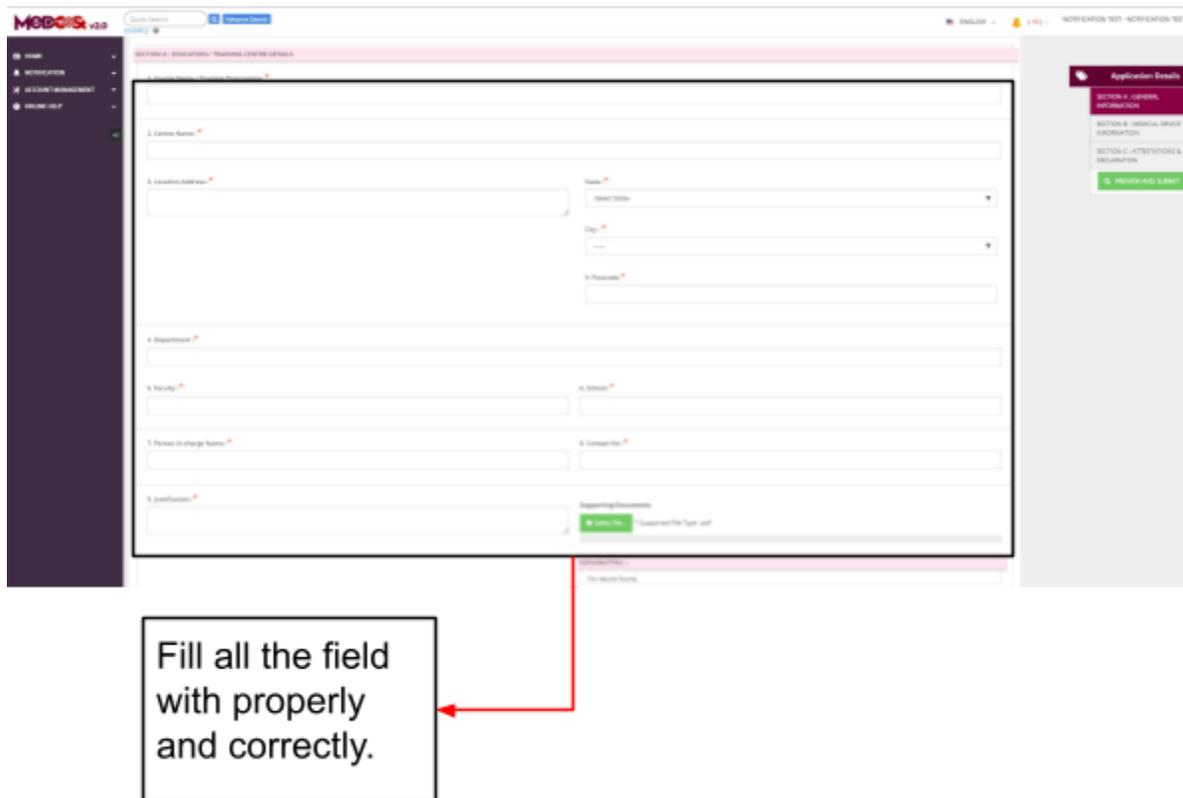
SECTION A : General information

SECTION B : Medical Device Information

SECTION C : Attestation and declaration

Section A: General information

Figure below are shown the layout for Section A : EDUCATION / TRAINING CENTRE DETAILS. User have to fill all the form and that symbol “*” means required field.



The screenshot displays the 'MOBC@St v2.0' interface for the 'NOTIFICATION TEST - NOTIFICATION TEST' section. The main content area is titled 'SECTION A - EDUCATION / TRAINING CENTRE DETAILS'. The form includes the following fields:

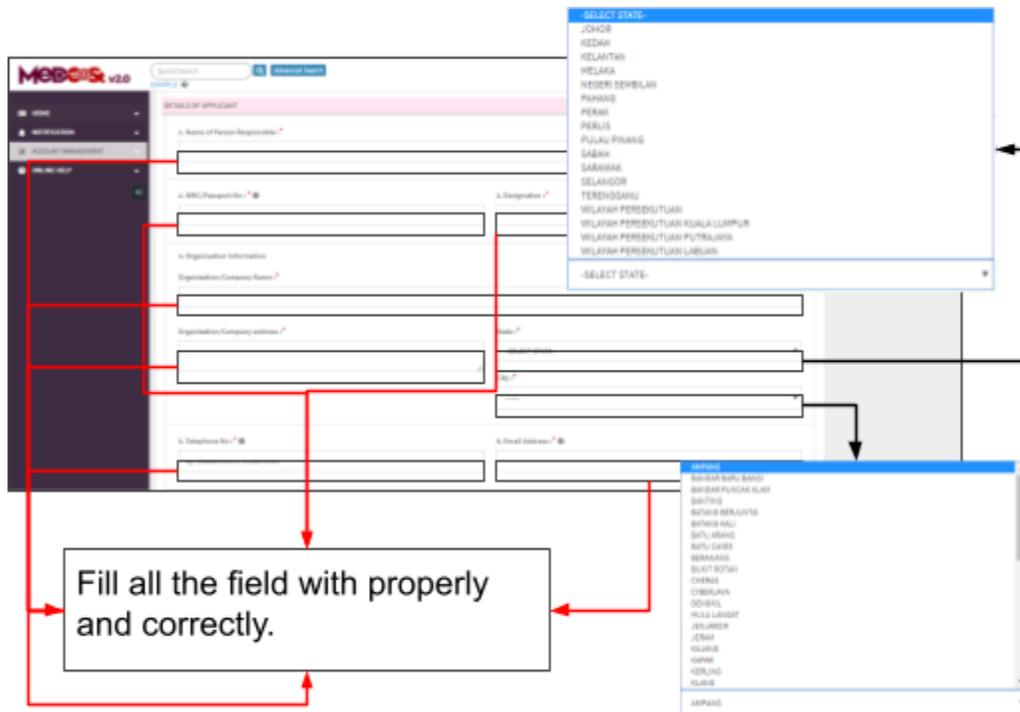
- 1. Name Name *
- 2. Education Address *
- 3. Institution Name *
- 4. Registration *
- 5. Faculty *
- 6. Specialization *
- 7. Previous In-Charge Name *
- 8. Contact No. *
- 9. Qualification *
- 10. Training/Qualification *

Additional fields on the right side include:

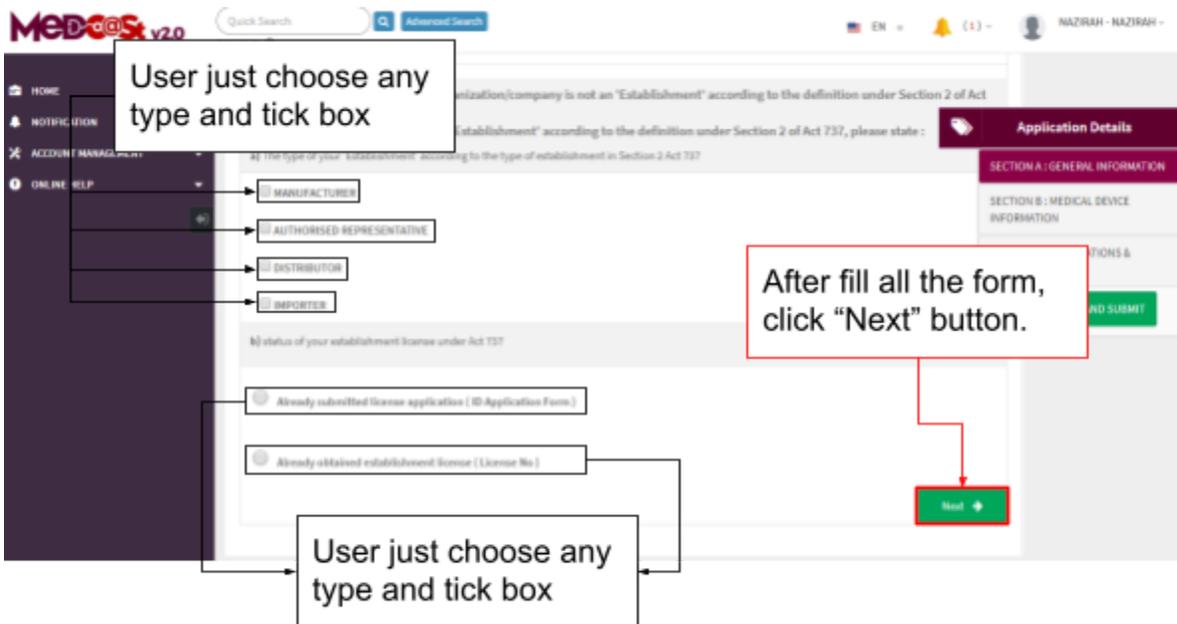
- 11. Gender *
- 12. City *
- 13. Phone No. *
- 14. Email *
- 15. Contact No. *

At the bottom right, there is a 'Save' button and a 'Cancel/Go Back' button. A red box highlights the entire form area, and a callout box with a red arrow points to it, containing the text: 'Fill all the field with properly and correctly.'

This is form for Details of Applicant, user have to fill all the form properly like shown below.

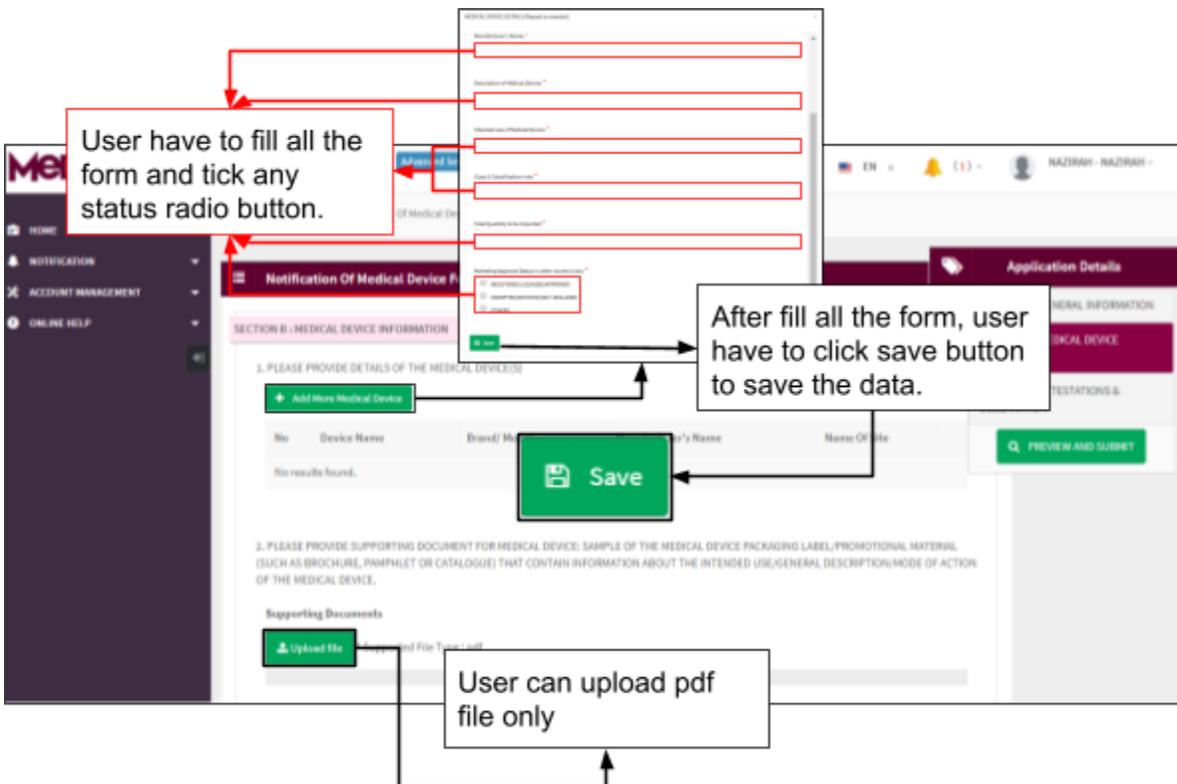


After user fill all the form with properly, they have to click “  ” button to next section like shown below.



Section B: Medical Device Information

After clicking “  ” button at section A, it will display section B like shown below.



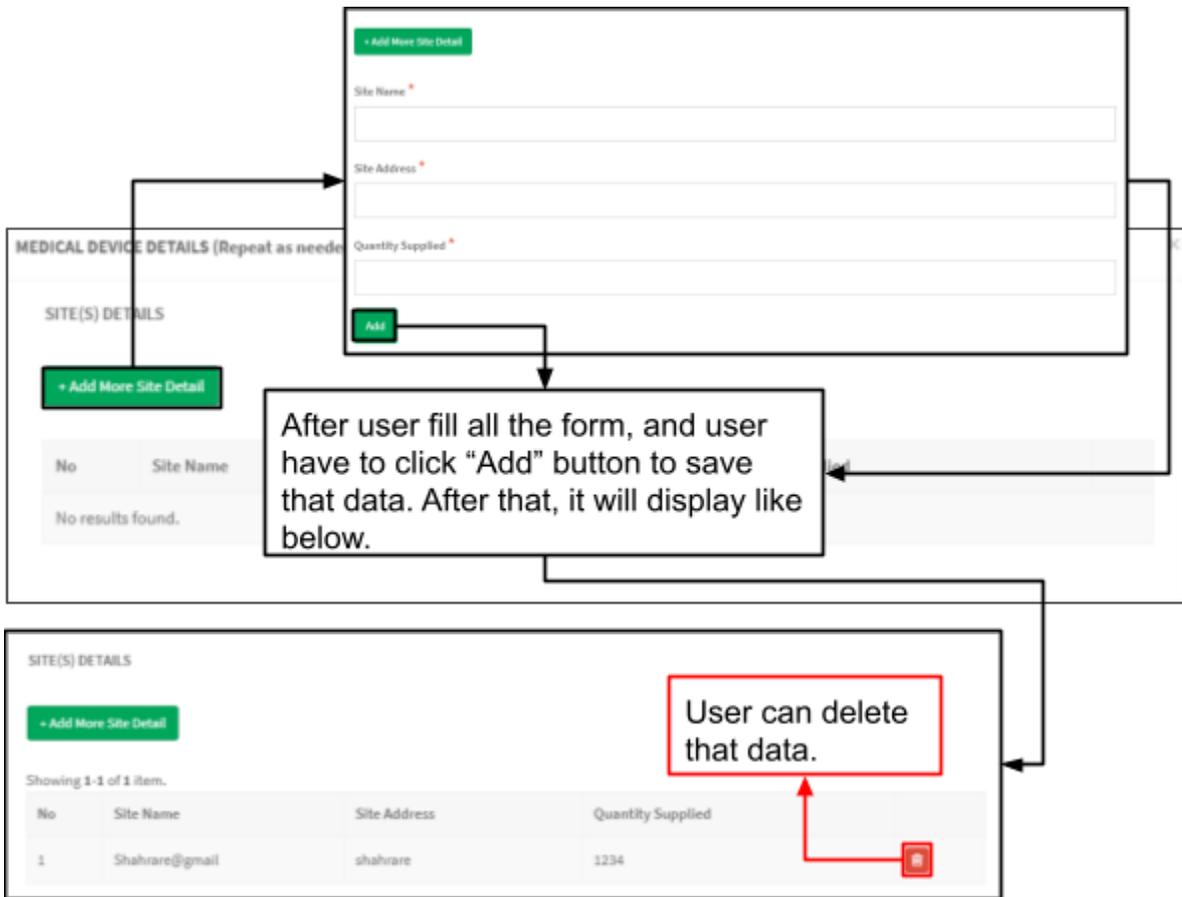
After user click “  ” and fill all the form, it will be shown like below.

The screenshot displays the 'Notification Of Medical Device For Demonstration / Education Purposes (DM-20171216-21)' interface. It features a sidebar with 'Application Details' and three sections: 'SECTION A : GENERAL INFORMATION', 'SECTION B : MEDICAL DEVICE INFORMATION' (highlighted), and 'SECTION C : ATTESTATIONS & DECLARATION'. A 'PREVIEW AND SUBMIT' button is visible in the sidebar. The main content area is titled 'SECTION B : MEDICAL DEVICE INFORMATION' and contains a heading '1. PLEASE PROVIDE DETAILS OF THE MEDICAL DEVICE(S)' with an 'Add More Medical Device' button. Below this, it says 'Showing 1-1 of 1 item.' and shows a table with one entry:

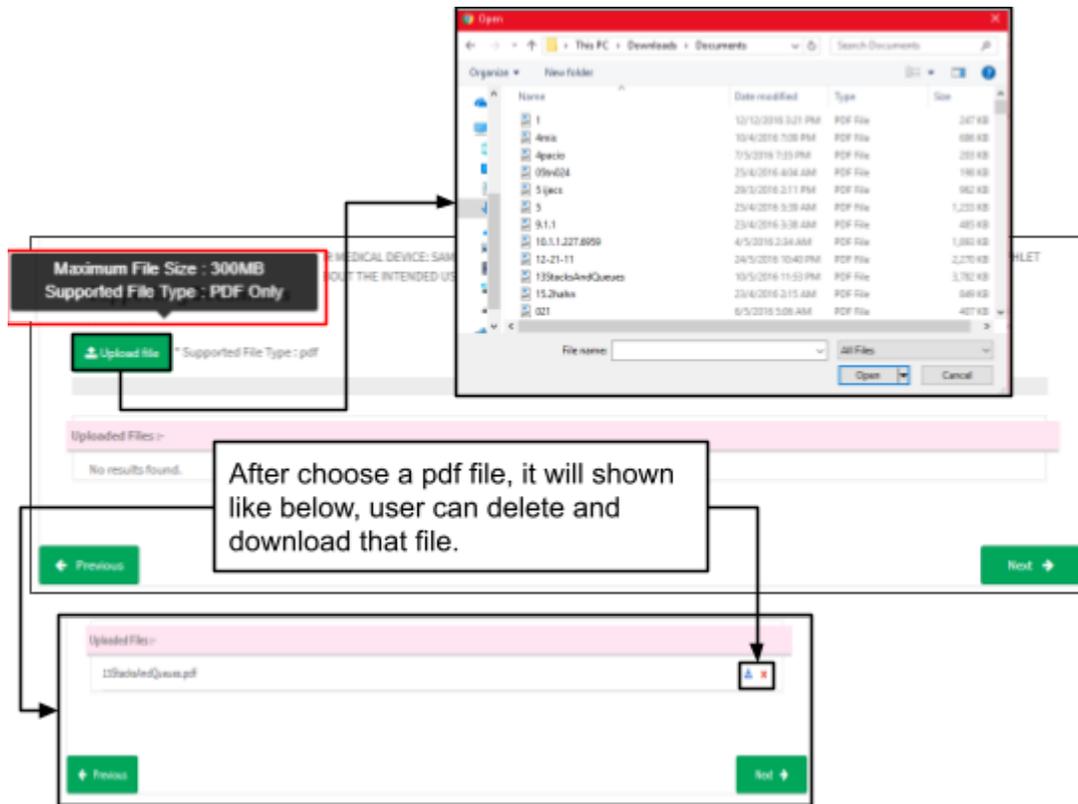
No	Device Name	Brand/ Model	Manufacturer's Name	Name Of Site
1	YAMAHA	ADIDAS	SHAHBARE	

Next to the table entry are four green action buttons: 'View', 'Update', 'Delete', and 'Update Site Details'. A callout box with arrows pointing to these buttons contains the text: 'After user add medical device, user can view, update, delete and update site details.'

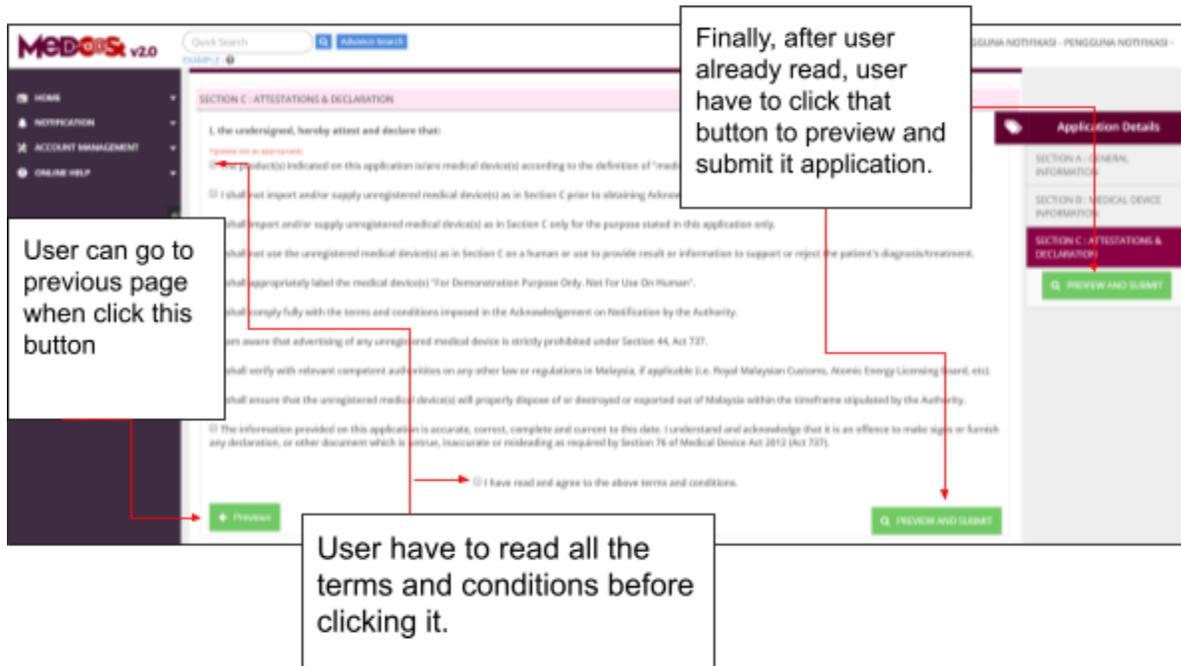
For  users have to add first like shown below.



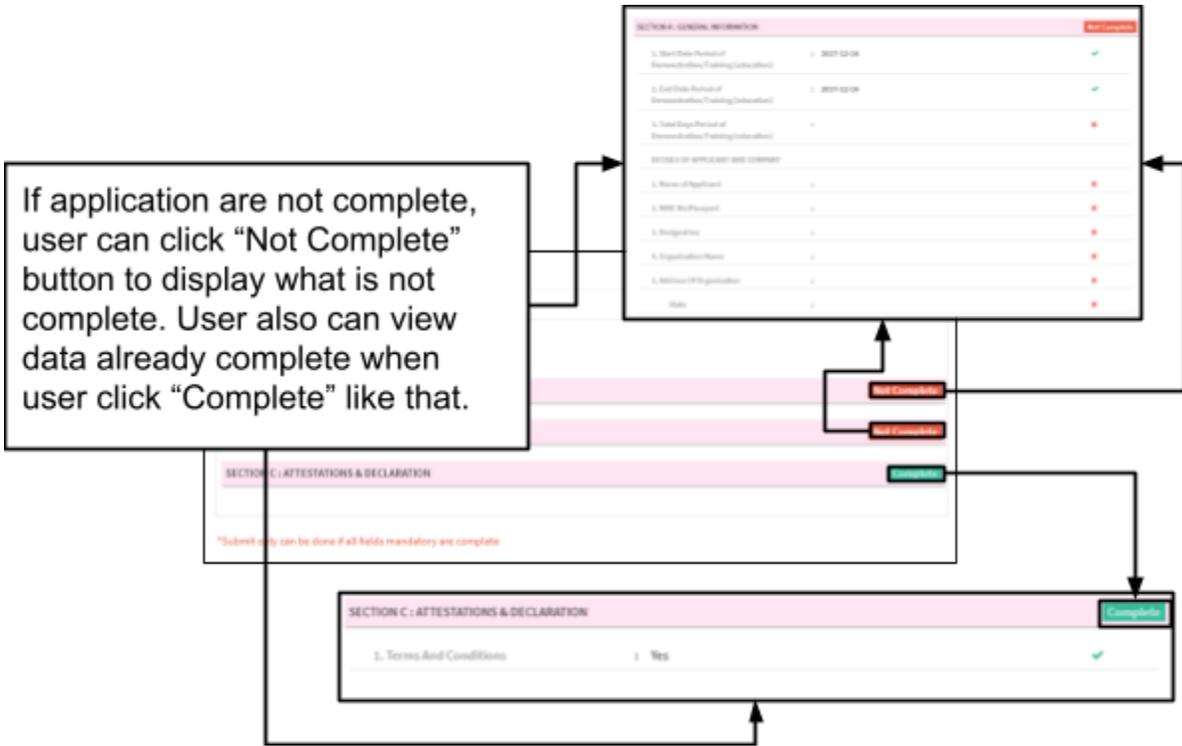
After the user fill all form, users have to click "  " button to the last section.



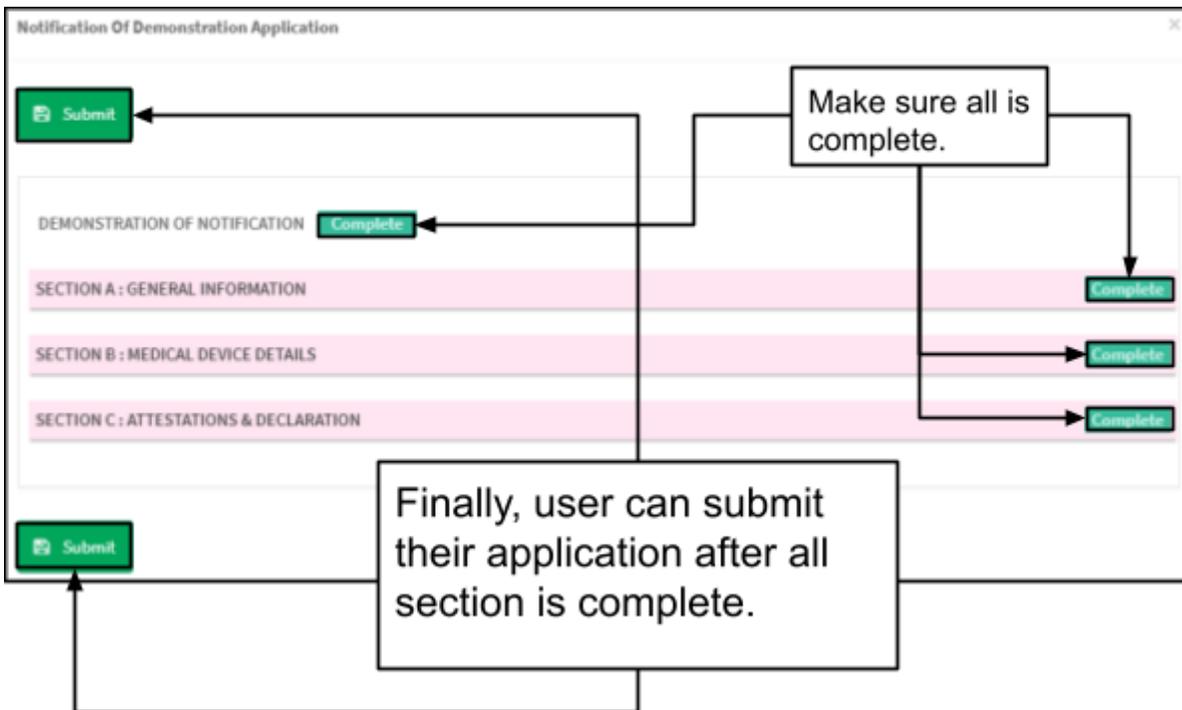
Section C: Attestation And Declaration



After clicking “PREVIEW AND SUBMIT” button, it will display all the section are already complete fill out or not complete like shown below.



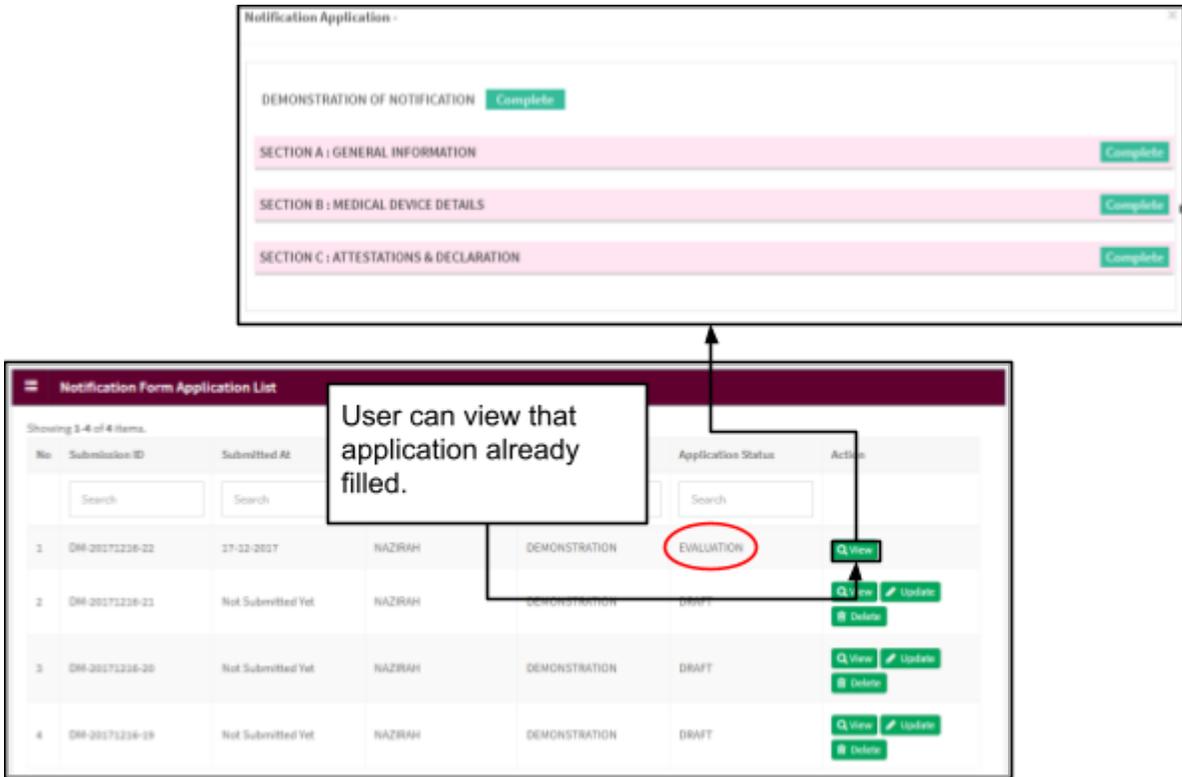
User cannot submit the application yet because, users have to complete that application first before submitting it. User can submit their application after all applications are complete like shown below.



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



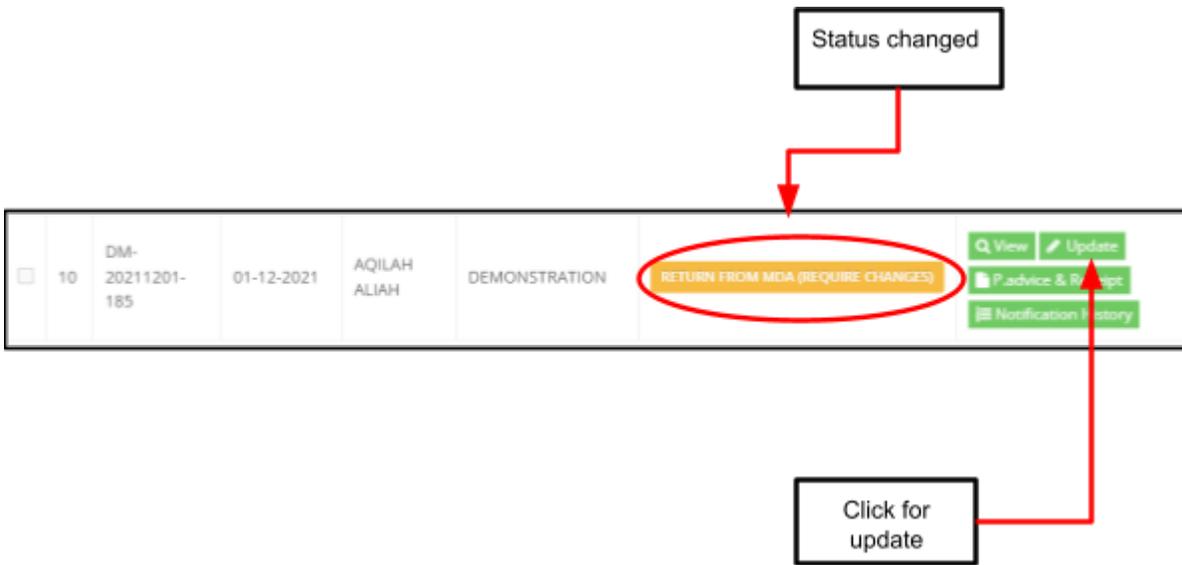
If user click “ok” , the application status will be changed to “EVALUATION”. It will automatically jump to all application page like shown below.



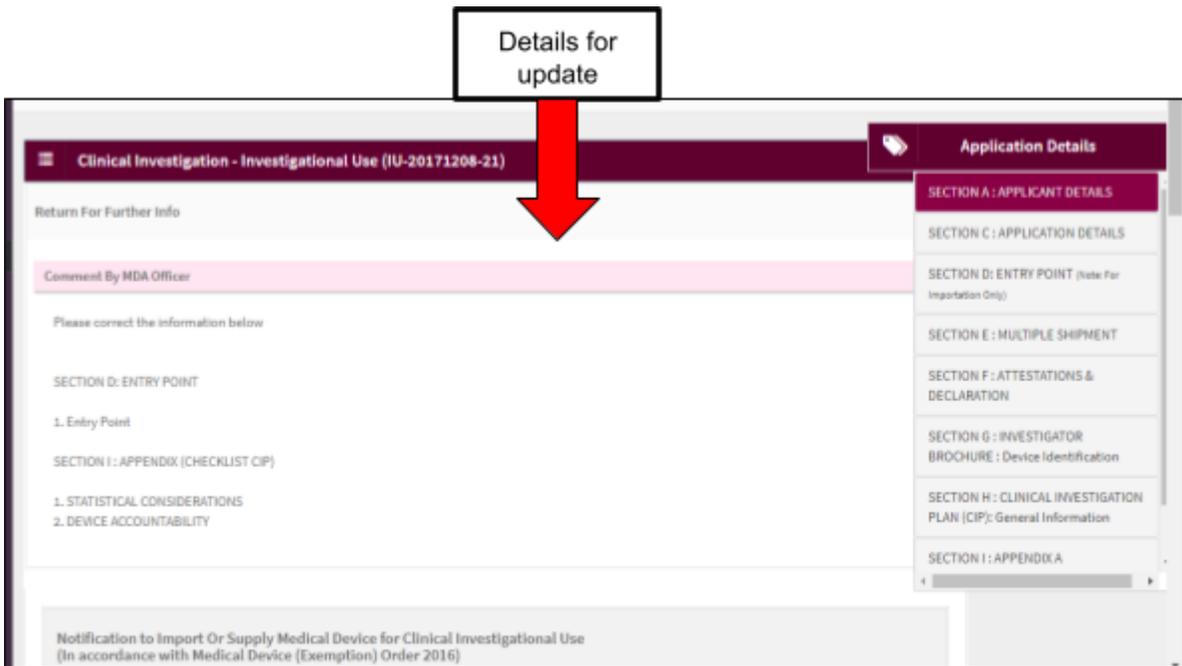
2.2.2 RETURN FOR CHANGES

If back end user make the process “RETURN FOR CHANGES” 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.



After that, user should click at  Update to update or make changes at application form. The details of information that user click “NO” at EVALUATION process will be



displayed that shown in the figure below.

Then, user should update the details of application information at the form. The user can edit at detail that changed only.

The screenshot displays a web form for 'SECTION D: ENTRY POINT'. At the top, it says 'Please correct the information below'. The form is divided into sections: SECTION D: ENTRY POINT, SECTION I: APPENDIX (CHECKLIST CIP), and SECTION I: APPENDIX (CHECKLIST CIP) with sub-sections 1. STATISTICAL CONSIDERATIONS and 2. DEVICE ACCOUNTABILITY. The 'SECTION D: ENTRY POINT' section is highlighted in pink and contains a red callout box with the text 'Details can be edited' and a red arrow pointing to the section header. Below the header, there is a red instruction: '(please tick the appropriate box) *'. The form contains several checkboxes for entry points: 'Lapangan Terbang Antarabangsa Kuala Lumpur 1' (checked), 'Lapangan Terbang Antarabangsa Kuala Lumpur 2', 'Pelabuhan Klang', 'Lapangan Sultan Abdul Aziz Shah Subong', 'Pelabuhan Tanjung Pelepas Johor', 'Pelabuhan Pulau Pinang', 'Pelabuhan Johor Pasir Gudang' (checked), and 'Others'. At the bottom of the form, there are 'Previous' and 'Next' buttons. On the right side, there is a sidebar titled 'Application Details' with a list of sections: SECTION A: APPLICANT DETAILS, SECTION C: APPLICATION DETAILS, SECTION D: ENTRY POINT (Note For Importation Only), SECTION E: MULTIPLE SHIPMENT, SECTION F: ATTESTATIONS & DECLARATION, SECTION G: INVESTIGATOR BROCHURE: Device Identification, SECTION H: CLINICAL INVESTIGATION PLAN (CIP): General Information, and SECTION I: APPENDIX A.

And then, click  to submit the application.

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

1	IU-20171208-21	22-12-2017	NAZIRAH	INVESTIGATIONAL USE	EVALUATION	
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The user should make the process EVALUATION at back end user.