

USER MANUAL FRONT END USER

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

MODUL UTAMA - ESTABLISHMENT LICENSE

DISEDIAKAN OLEH :



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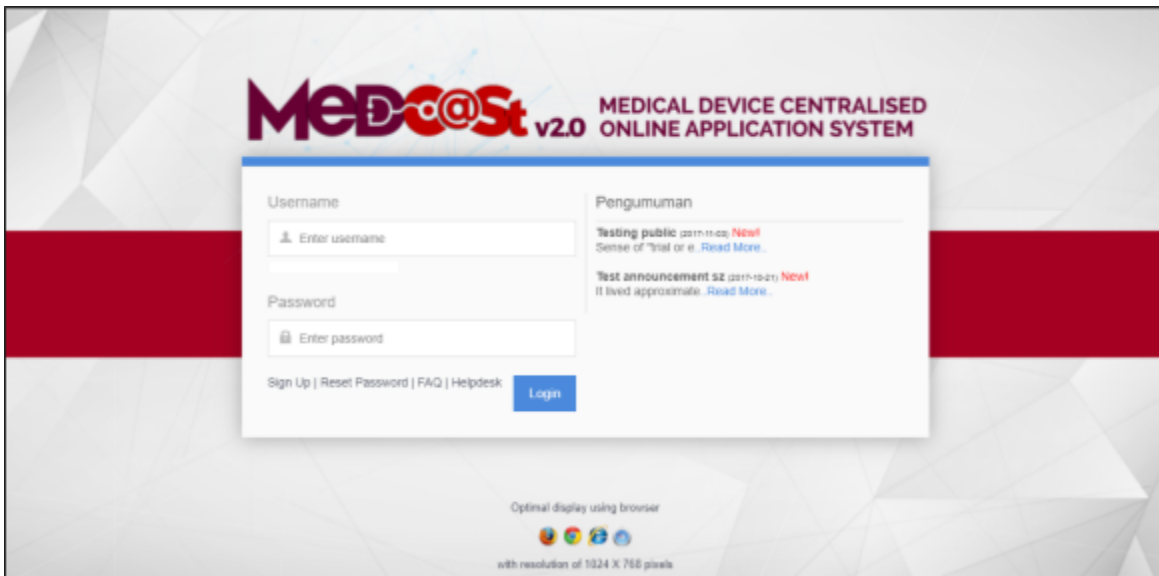
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1.0 INTRODUCTION

MeDC@st v.20 (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>

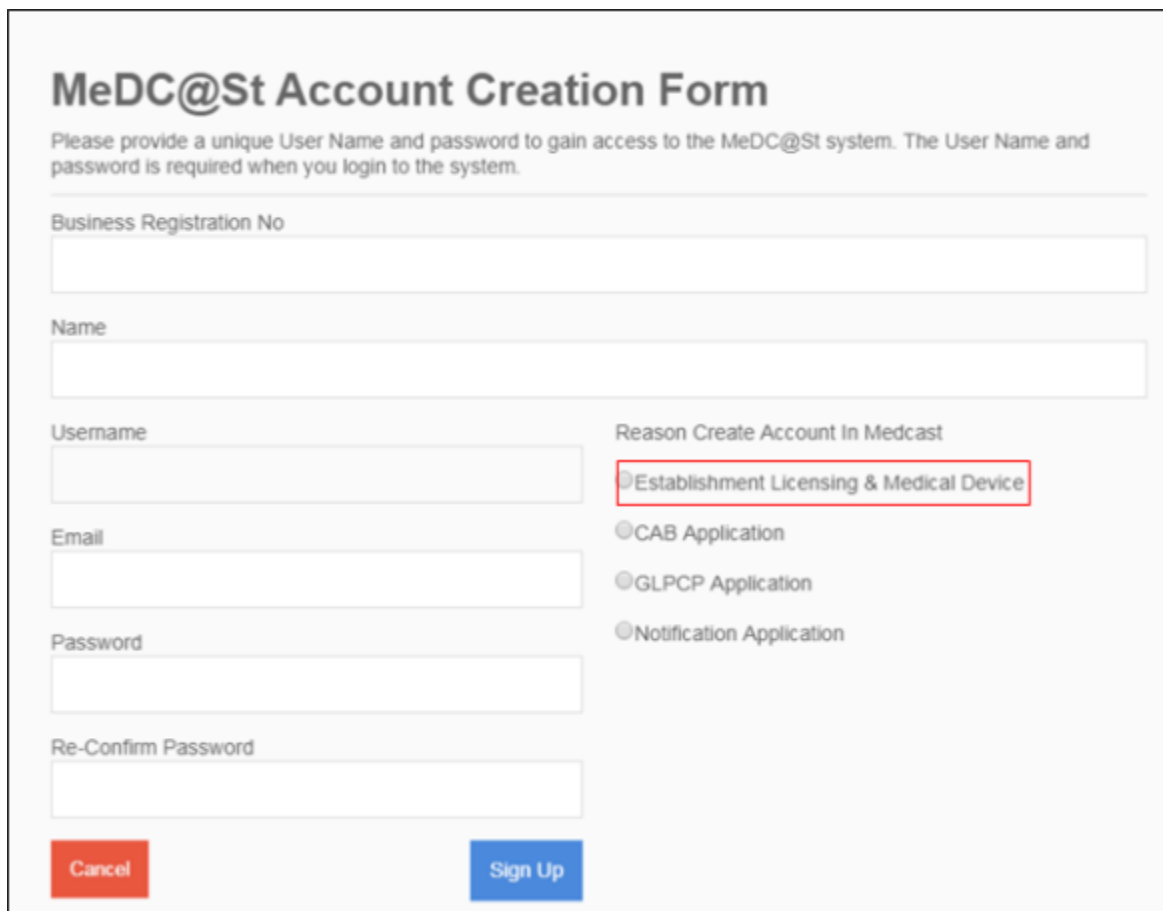
The screen below shows the expected webpage after the address has been keyed in.



User has to log into the system using registered User ID and its respective password. Click the [Login] button to proceed.

1.1 SIGN UP

Click on the **Sign Up** at the bottom of login form to display the following screen. Fill the following empty form and choose drop down list such as Business Registration No, Name, Username, Email, Password, Reconfirm Password and choose the radio button that has been highlighted to create new MDR-BCD account. After complete fill registration form user must verified email.



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

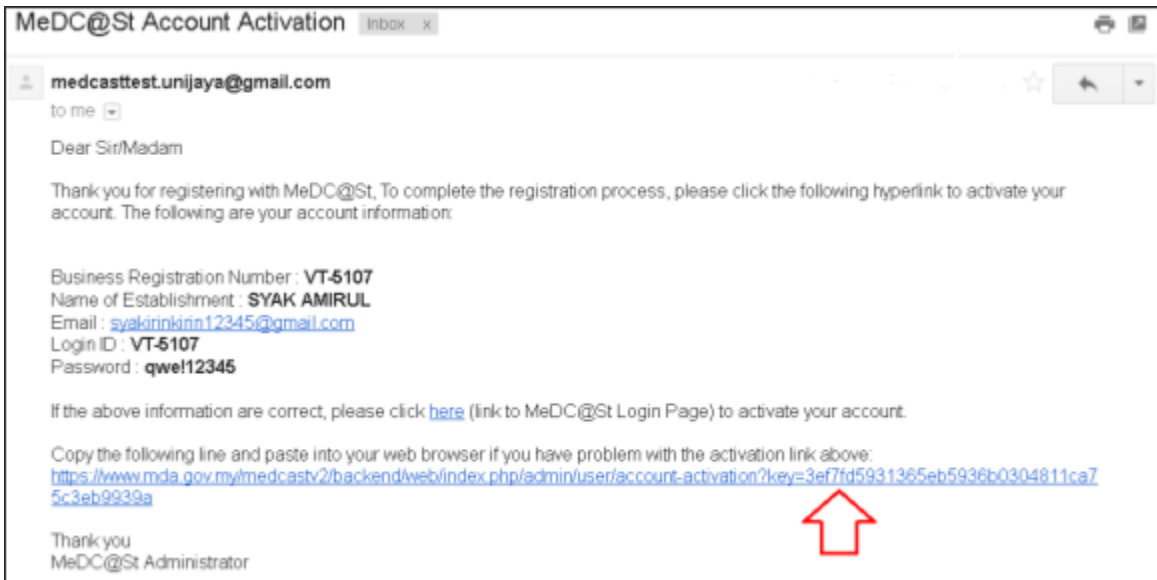
Re-Confirm Password

Reason Create Account In Medcast

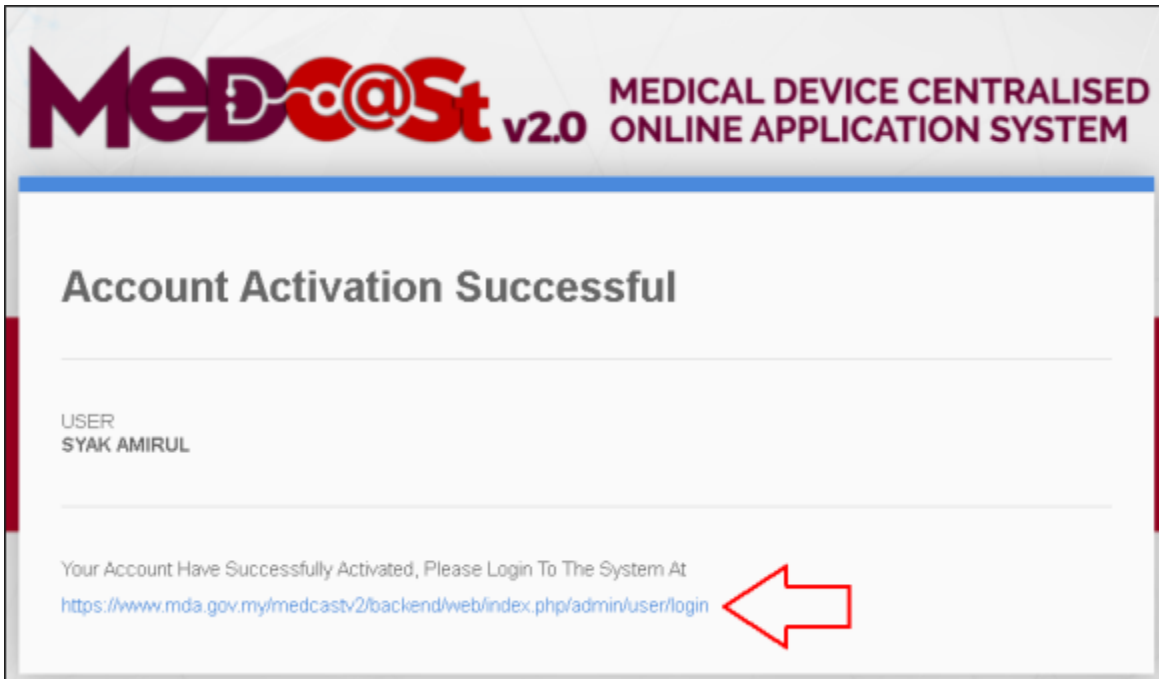
- Establishment Licensing & Medical Device
- CAB Application
- GLPCP Application
- Notification Application

1.1.1 VERIFIED EMAIL FOR NEW ACCOUNT

The user must verified email to completed the last step of the registration. Click on the link given to verified email in the system medcast V2.0.



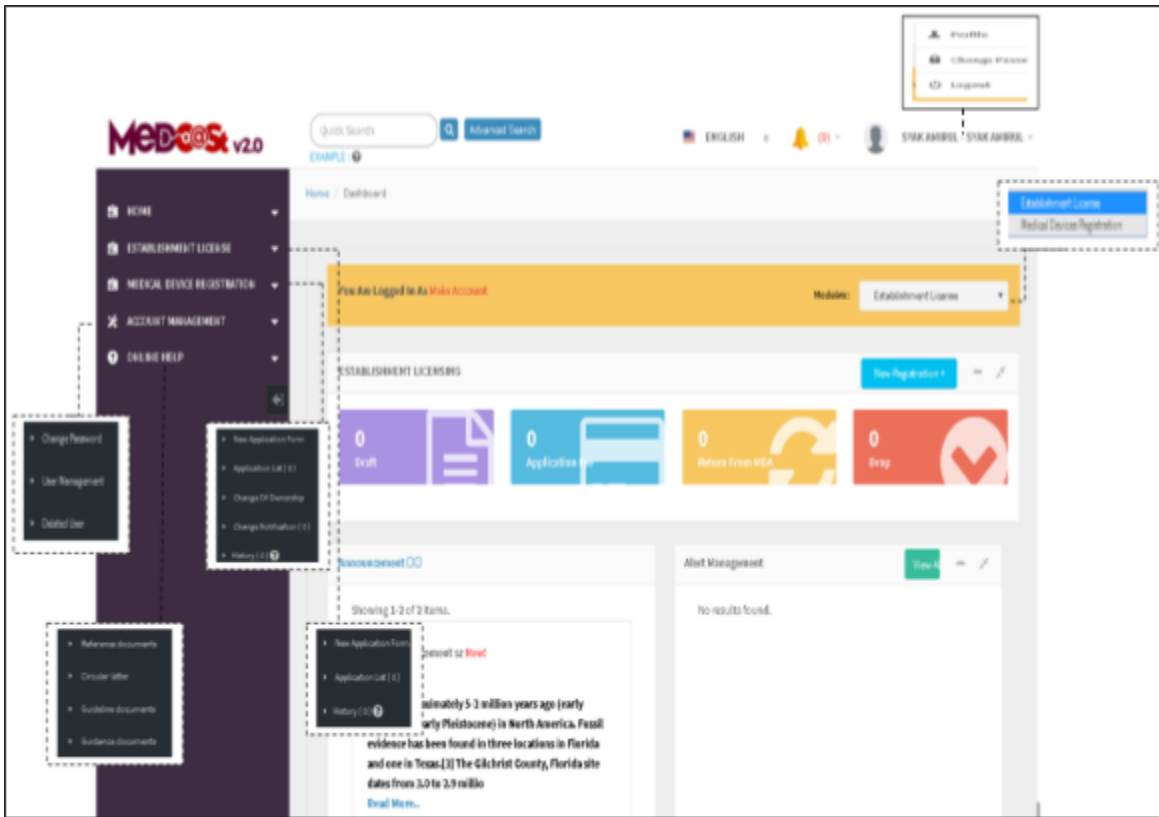
The account activation screen will display. The user must click on the link to login into the account.



The login screen will display.

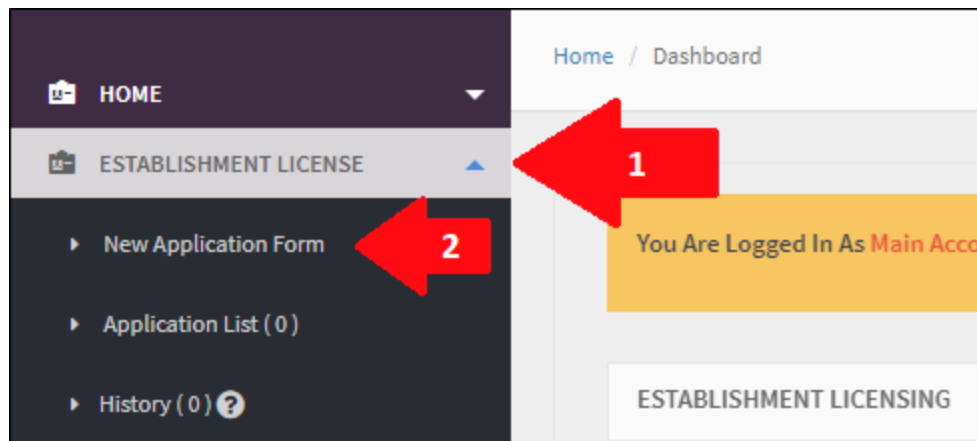


The user login successfully in the system medcast. It shows the dashboard of the account.




2.0 NEW REGISTRATION

User click at [ESTABLISHMENT LICENSE] then click at [New Application Form] to go New Establishment Licensing Application page.



User tick at MANUFACTURER or AUTHORISED REPRESENTATIVE or DISTRIBUTOR or

IMPORTER checkbox and then click  to go to the next step. If user tick 'MANUFACTURER' checkbox, then user cannot tick others application. If user tick 'AUTHORISED REPRESENTATIVE' checkbox, then user can tick others application except 'MANUFACTURER'.



The screenshot displays a web application interface for "Medical Device Registration Application". The title bar is dark red with a white hamburger menu icon on the left. Below the title bar, the text "ROLE OF ESTABLISHMENT TO THE MEDICAL DEVICE" is centered. There are two radio button options, each preceded by a red arrow pointing to the right: "MANUFACTURER" and "AUTHORISED REPRESENTATIVE". Below these options is a green "Next" button.

2.1 ESTABLISHMENT DETAILS FORM

The diagram below show Establishment Licensing Form - 1.0 ESTABLISHMENT DETAILS.

Establishment Licensing Registration Form (SUBMISSION ID : EL-20171031-100)

All fields marked with * are mandatory

Hover at ⓘ on field input for help

1.0 Establishment Detail

1. Type Of Establishment : - MANUFACTURER

2. Bumiputra Status *
 YES NO

3. Business Registration No *
FRONTEND

4. Establishment Name *
ZAED

Application Details

- 1.0 ESTABLISHMENT DETAIL
- 2.0 PERSON RESPONSIBLE DETAILS
- 3.0 CONTACT PERSON DETAILS
- 4.0 QUALITY MANAGEMENT DETAILS
- 5.0 ATTESTATION FOR ESTABLISHMENT

PREVIEW & SUBMIT

MOBO@S v2.0

Establishment Licensing Registration Form (SUBMISSION ID: EL-20171031-100)

1. Type Of Establishment : - MANUFACTURER

2. Bumiputra Status *
 YES NO

3. Business Registration No *
FRONTEND

4. Establishment Name *
ZAED

Hide the sidebar for full display

Establishment Licensing Application

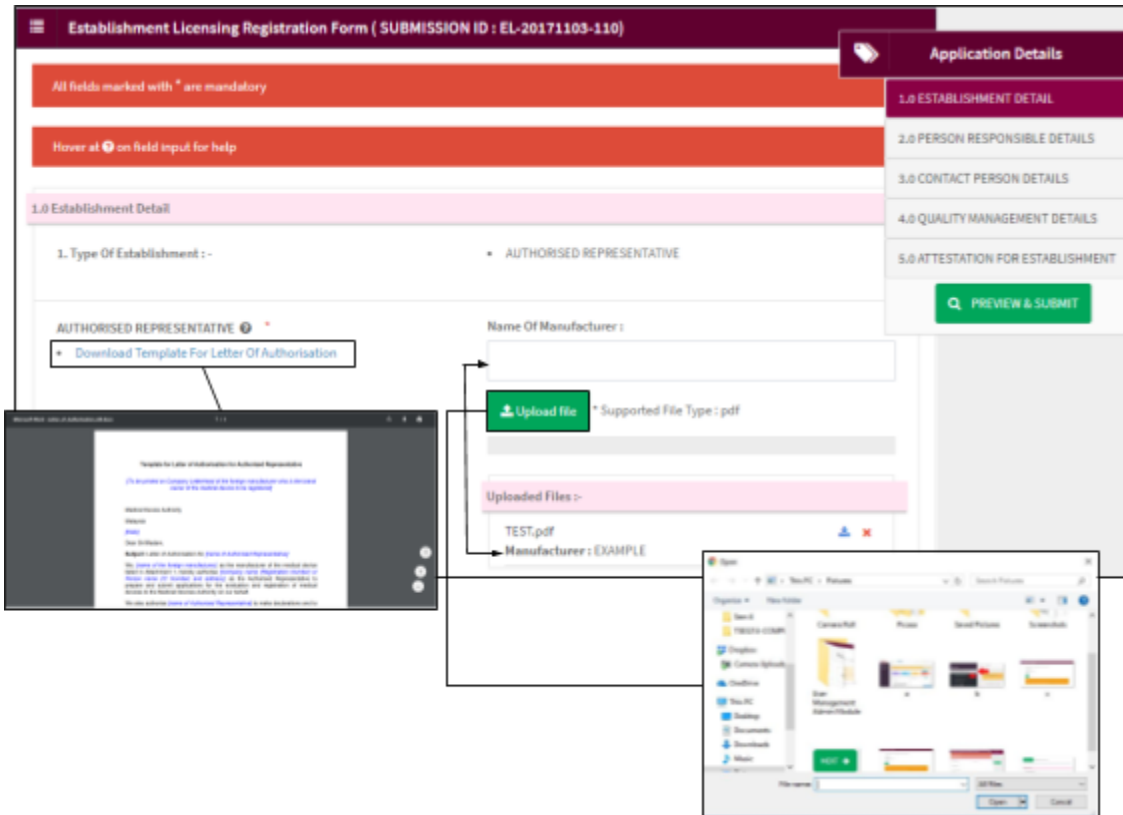
*Submit only can be done if all fields mandatory are complete

- 1.0 Establishment Detail [Click To View More](#) Not Complete
- 2.0 Person Responsible Details [Click To View More](#) Not Complete
- 3.0 Contact Person Details [Click To View More](#) Not Complete
- 4.0 Quality Management Details [Click To View More](#) Not Complete
- 5.0 Attestation For Establishment [Click To View More](#) Not Complete

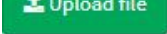
*Submit only can be done if all fields mandatory are complete

1. Type of Establishment*

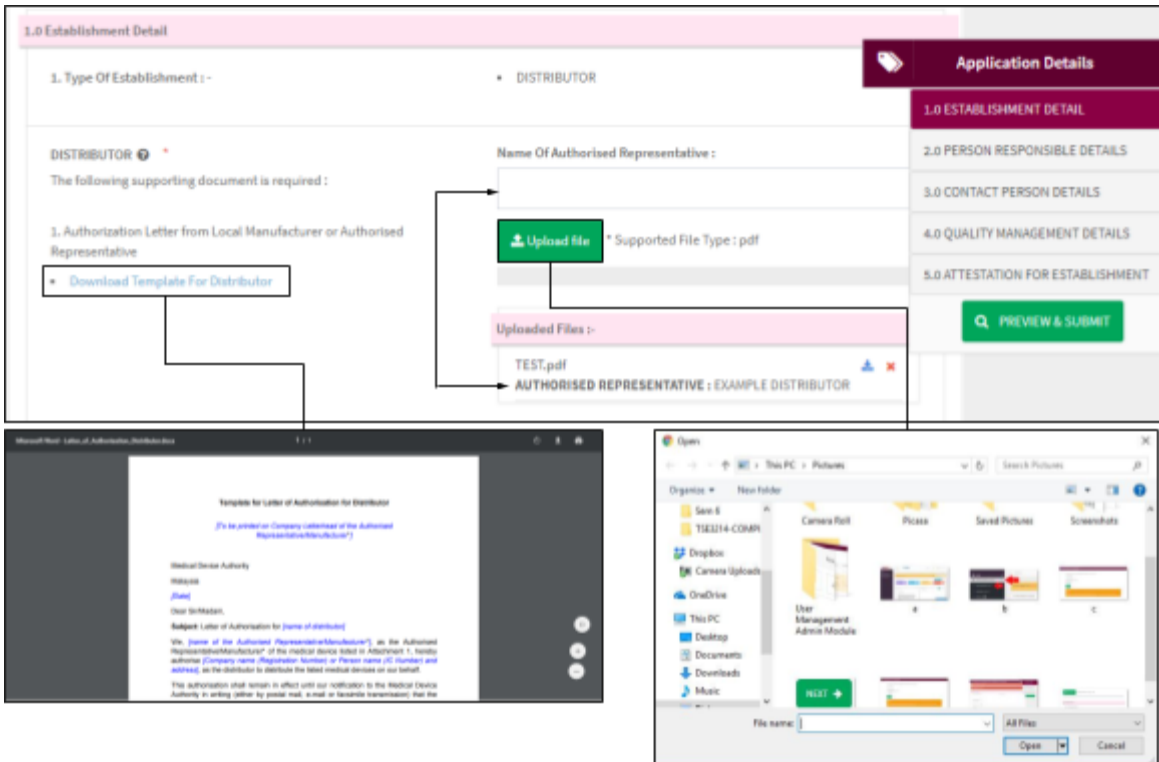
List of Type Of Establishment



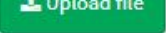
User click [Download Template For Letter Of Authorisation](#) to download template for letter of authorisation.

User fills 'Name of Manufacturer' textbox. Next, user click  to upload file. **The file must be pdf format and size not more than 300 MB.** Text that wrote in 'Name of Manufacturer' text box will display in 'Upload Files :-' section. **This step just for Authorised Representative application only.**

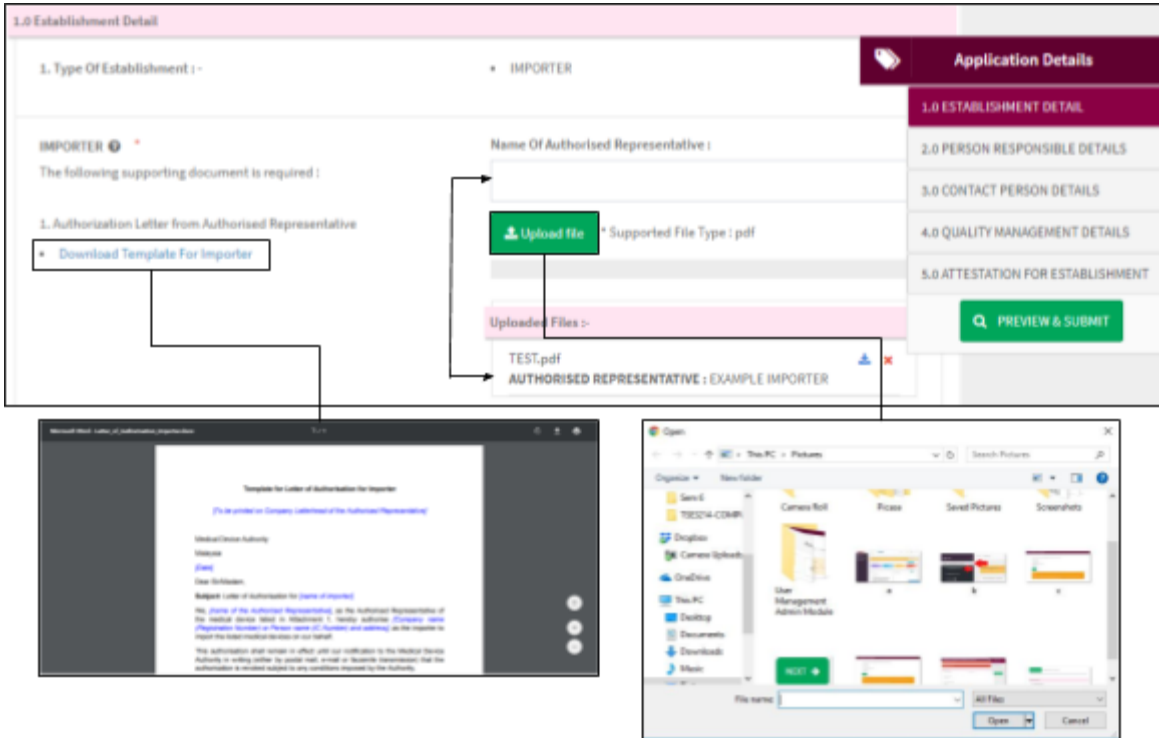
This step just for Distributor application only.



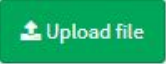
User click [Download Template For Distributor](#) to download template for distributor.

User fills 'Name of Authorised Representative' text box. Next, user click  to upload file. **The file must be pdf format and size not more than 300 MB.** Text that wrote in 'Name of Authorised Representative text box will display in 'Upload Files :-' section. **This step just for Distributor application only.**

❖ **This step just for Importer application only.**



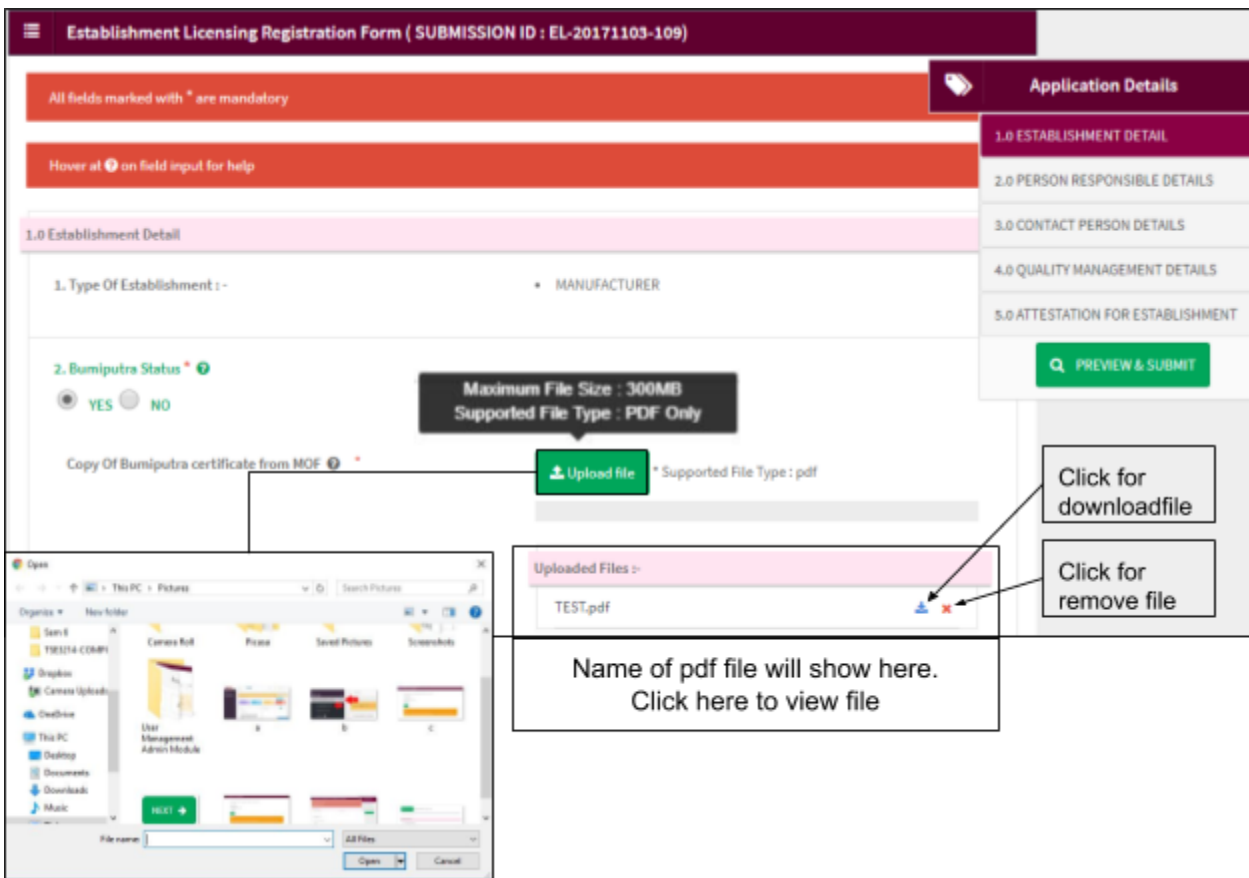
User click [Download Template For Importer](#) to download template for importer.

User fills 'Name of Authorised Representative' text box. Next, user click  to upload file. **The file must be pdf format and size not more than 300 MB.** Text that wrote in 'Name of Authorised Representative text box will display in 'Upload Files :-' section.

2. Bumiputera Status*

User choose to tick YES or NO at Bumiputera Status radio button.

If user tick at 'YES', user click  to upload Copy Of Bumiputra certificate from MOF file. **The file must be pdf format and size not more than 300 MB.**



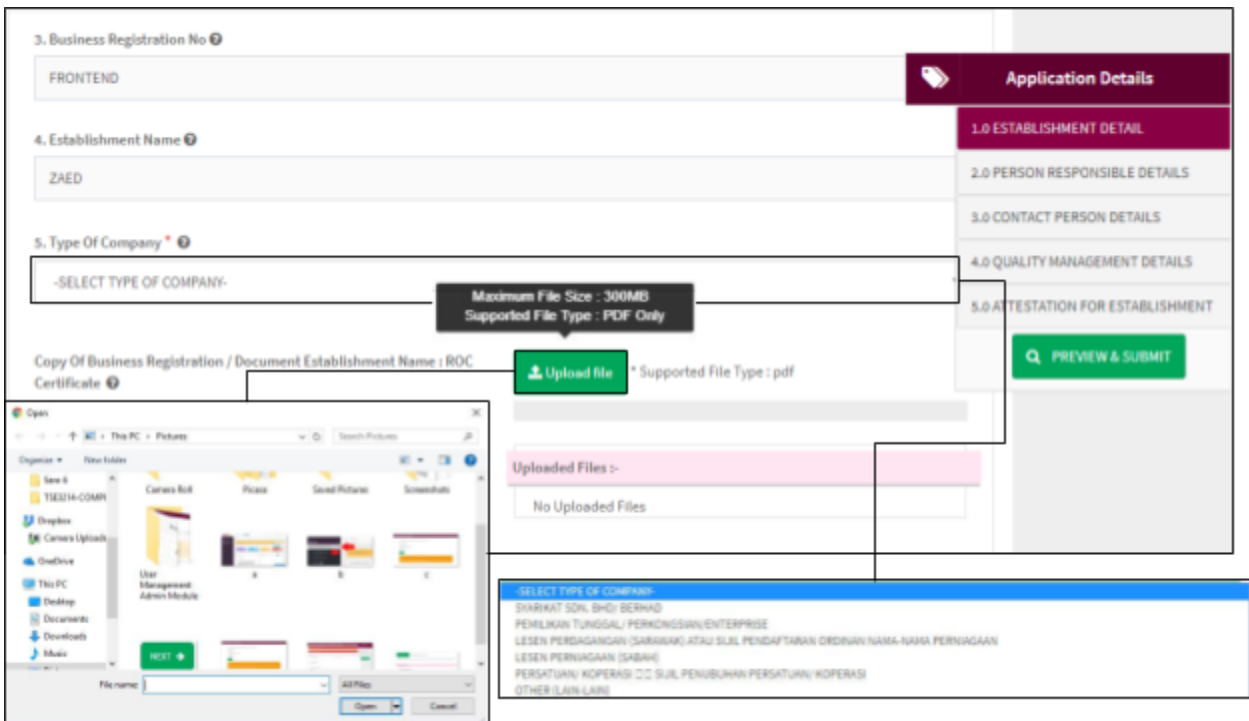
If user tick 'NO' radio button, user can go to the next step.

3. Business Registration No*

System automatically fill this text box. User cannot edit that data in text box.
 System automatic fill the text box with data from registration process.

4. Establishment Name*


System automatically fill this text box. User cannot edit that data in text box.
 System automatically fill the text box with data from registration process.



5. Type of Company*

That dropdown text box, if user select 'OTHER (LAIN-LAIN)' at Type Of Company text box, automatically text box 'Other (Please Specify)' will appear.

The screenshot displays a web form for an establishment license application. The main form area is titled "5. Type Of Company*" and contains a dropdown menu with the selected option "OTHER (LAIN-LAIN)". Below the dropdown is a text box labeled "Other (Please Specify)*" which is currently empty. To the right of the form is a sidebar menu titled "Application Details" with a list of sections: "1.0 ESTABLISHMENT DETAIL", "2.0 PERSON RESPONSIBLE DETAILS", "3.0 CONTACT PERSON DETAILS", "4.0 QUALITY MANAGEMENT DETAILS", and "5.0 ATTESTATION FOR ESTABLISHMENT". At the bottom of the sidebar is a green button labeled "PREVIEW & SUBMIT". Below the form, there is a section for uploading files, titled "Copy Of Business Registration / Document Establishment Name : ROC Certificate", with an "Upload file" button and a note "* Supported File Type : pdf". Below this is a section for "Uploaded Files :-" which currently shows "No Uploaded Files". Two red arrows on the left side of the form point to the dropdown menu and the "Other (Please Specify)" text box.

User has to complete this field (6 to 12) and then click  to go to next form.

The screenshot shows a web form for an establishment license application. The form includes the following fields and components:

- 6. Address ***: A text input field with a red asterisk and a help icon.
- 7. State ***: A dropdown menu with the option "-SELECT STATE-".
- 8. City ***: A dropdown menu.
- 9. Postcode ***: A text input field.
- 10. Telephone No ***: A dropdown menu with "603" selected, followed by a text input field.
- 11. Fax ***: A dropdown menu with "603" selected, followed by a text input field.
- 12. Company Website ***: A text input field containing "Company website in Malaysia".
- Application Details Panel**: A vertical sidebar on the right with a maroon header and a list of sections: 1.0 ESTABLISHMENT DETAIL, 2.0 PERSON RESPONSIBLE DETAILS, 3.0 CONTACT PERSON DETAILS, 4.0 QUALITY MANAGEMENT DETAILS, and 5.0 ATTESTATION FOR ESTABLISHMENT. A green "PREVIEW & SUBMIT" button is located at the bottom of this panel.
- Next Button**: A green button with a white arrow and the text "Next" is positioned below the form fields.
- Dropdown Menus**: Three dropdown menus are shown with their lists expanded:
 - State Dropdown**: Lists Malaysian states including JOHOR, KEDAH, KELANTAN, MELAKA, Negeri Sembilan, PAHANG, PERAK, PERLIS, PULAU PINANG, SABAH, SARAWAK, SELANGOR, TERENGGANU, and Wilayah Persekutuan (Kuala Lumpur, Putrajaya, Labuan).
 - City Dropdown**: Lists city codes from 6010 to 6083, with 6003 highlighted.
 - Postcode Dropdown**: Lists Malaysian postcodes from AMPANG to KLANG.

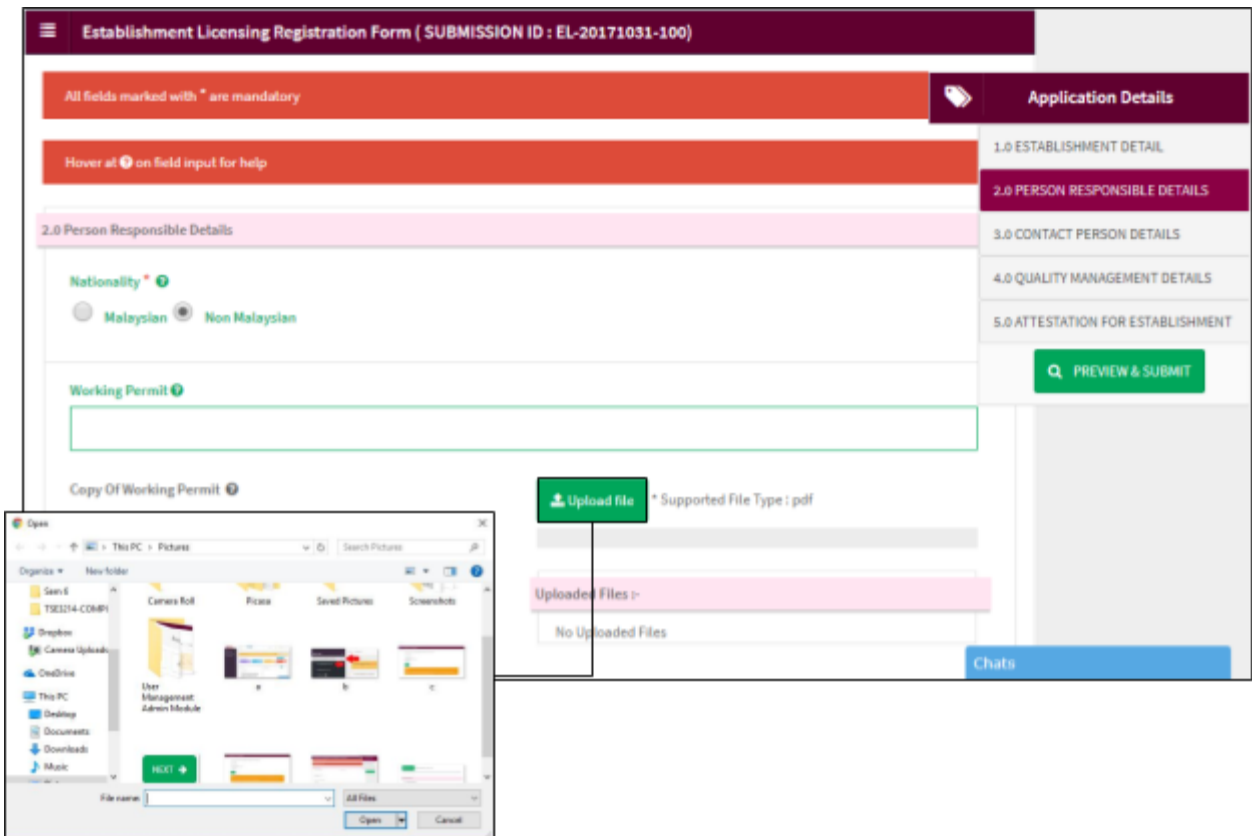
2.2 PERSON RESPONSIBLE DETAILS

Nationality*

User choose to tick Malaysian or Non Malaysian .

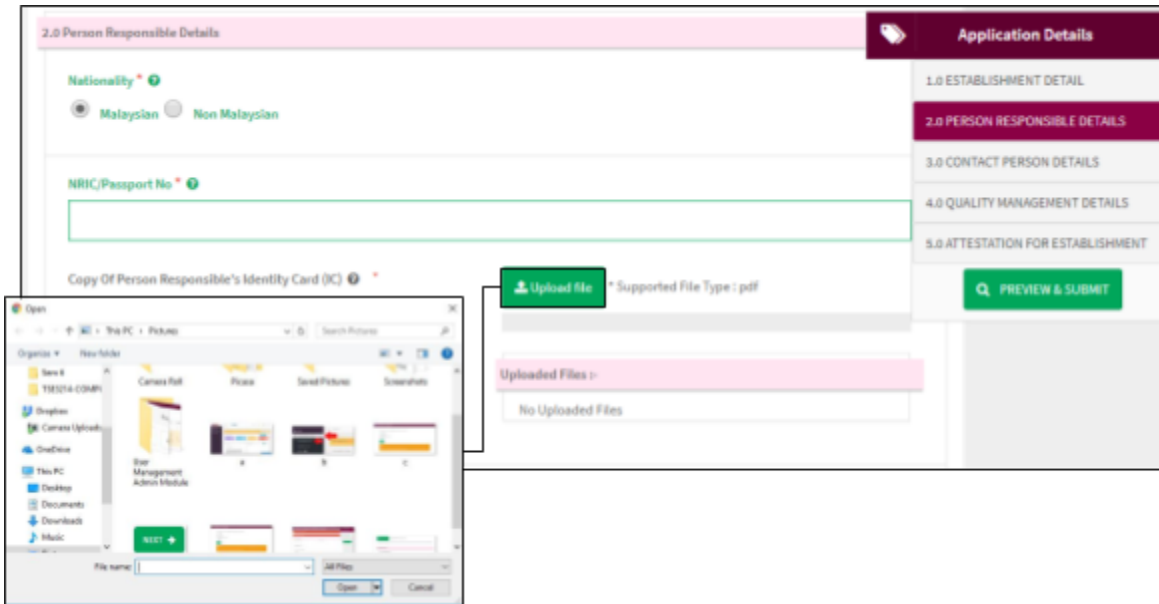
If user tick at 'Non Malaysia' radio button, user has to fill Working Permit

textbox and click to upload Copy Of Working Permit file. **The file must be pdf format and size not more than 300 MB.**



If user tick 'Malaysian' check box, user has to fill NRIC/Passport No* text box and

Upload Copy Of Person Responsible Identity Card (IC) file. **The file must be pdf format and size not more than 300 MB.**



User has to complete this field. For 'Date of Birth', user select date in calendar textbox or user can write the date using **YYYY-MM-DD** format.

The image shows a screenshot of a web application interface. At the top, there is a calendar pop-up for November 2017. Below the calendar is a form titled 'Application Details' with several input fields and a dropdown menu. The fields are: 'Full Name *', 'Place Of Birth *', 'Date Of Birth *', and 'Designation From Top Management *'. The 'Date Of Birth' field has a calendar pop-up showing the month of November 2017. The 'Designation From Top Management' field has a dropdown menu with the following options: '-SELECT DESIGNATION-', DIRECTOR, MANAGING DIRECTOR, MANAGER, GENERAL MANAGER, MD DIRECTOR, CEO, PRESIDENT, VICE PRESIDENT, and OTHER. To the right of the form is a sidebar with a table of contents for the application details, including sections 1.0 to 5.0, and a 'PREVIEW & SUBMIT' button.

Su	Mo	Tu	We	Th	Fr	Sa
			1	2	3	4
5	6	7	8	9	10	11
12	13	14	15	16	17	18
19	20	21	22	23	24	25
26	27	28	29	30		

Application Details

- 1.0 ESTABLISHMENT DETAIL
- 2.0 PERSON RESPONSIBLE DETAILS**
- 3.0 CONTACT PERSON DETAILS
- 4.0 QUALITY MANAGEMENT DETAILS
- 5.0 ATTESTATION FOR ESTABLISHMENT

PREVIEW & SUBMIT

Designation From Top Management *

- SELECT DESIGNATION-
- DIRECTOR
- MANAGING DIRECTOR
- MANAGER
- GENERAL MANAGER
- MD DIRECTOR
- CEO
- PRESIDENT
- VICE PRESIDENT
- OTHER

If user select 'OTHER' at Designed From Top Management dropdown text box, automatically text box 'If Other, please specify' will appear.

The screenshot displays a web form for an establishment license application. On the right side, there is a vertical navigation menu titled 'Application Details' with the following sections: 1.0 ESTABLISHMENT DETAIL, 2.0 PERSON RESPONSIBLE DETAILS (highlighted in purple), 3.0 CONTACT PERSON DETAILS, 4.0 QUALITY MANAGEMENT DETAILS, and 5.0 ATTESTATION FOR ESTABLISHMENT. Below the menu is a green 'PREVIEW & SUBMIT' button. The main form area contains several input fields: 'Full Name', 'Place Of Birth', and 'Date Of Birth'. The 'Designation From Top Management' dropdown menu is currently set to 'OTHER'. Two red arrows point to the 'OTHER' selection and the 'If other, please specify' text box that has appeared below the dropdown.

User has to complete this field. User click



to go to the next step or click



to go to the previous form.

The screenshot shows a web form for 'Application Details' with the following fields and callouts:

- Correspondence Address ***: A text input field with a callout box titled 'SELECT STATE' listing Malaysian states: JOHORE, KEDAH, KELANTAN, MELAKA, NEGERI SEMBILAN, PANGANG, PERAK, PERLIS, PULAU PINANG, SABAH, SARAWAK, SELANGOR, TERENGGANU, WILAYAH PERSEKUTUAN KUALA LUMPUR, WILAYAH PERSEKUTUAN PUTRAJAYA, and WILAYAH PERSEKUTUAN LABUAN.
- Postcode ***: A text input field with a callout box listing postcodes from 6010 to 6083.
- State ***: A dropdown menu currently showing 'SELANGOR'.
- City ***: A dropdown menu currently showing 'AMPANG'.
- Telephone No ***: A text input field with a callout box showing '603' as the selected area code.
- Fax ***: A text input field with a callout box showing '603' as the selected area code.
- Email ***: A text input field.

Navigation buttons include 'Previous' (left arrow) and 'Next' (right arrow). A 'PREVIEW & SUBMIT' button is located at the bottom right of the form area.

2.3 CONTACT PERSON DETAILS

Establishment Licensing Registration Form (SUBMISSION ID : EL-20171031-100)

All fields marked with * are mandatory

Hover at ⓘ on field input for help

3.0 Contact Person Details

SAME AS PERSON RESPONSIBLE FOR ESTABLISHMENT * ⓘ

YES NO

← Previous Next →

Application Details

- 1.0 ESTABLISHMENT DETAIL
- 2.0 PERSON RESPONSIBLE DETAILS
- 3.0 CONTACT PERSON DETAILS
- 4.0 QUALITY MANAGEMENT DETAILS
- 5.0 ATTESTATION FOR ESTABLISHMENT

PREVIEW & SUBMIT

SAME AS PERSON RESPONSIBLE FOR ESTABLISHMENT*

User choose to click YES or NO .

If user tick at 'YES' radio button, user click to go to the next form
or click to go to the previous form.

Establishment Licensing Registration Form (SUBMISSION ID : EL-20171103-109)

All fields marked with * are mandatory

Hover at ⓘ on field input for help

3.0 Contact Person Details

SAME AS PERSON RESPONSIBLE FOR ESTABLISHMENT * ⓘ

YES NO

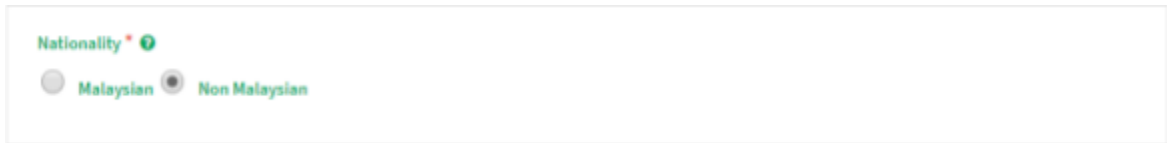
← Previous Next →

Application Details

- 1.0 ESTABLISHMENT DETAIL
- 2.0 PERSON RESPONSIBLE DETAILS
- 3.0 CONTACT PERSON DETAILS
- 4.0 QUALITY MANAGEMENT DETAILS
- 5.0 ATTESTATION FOR ESTABLISHMENT

PREVIEW & SUBMIT

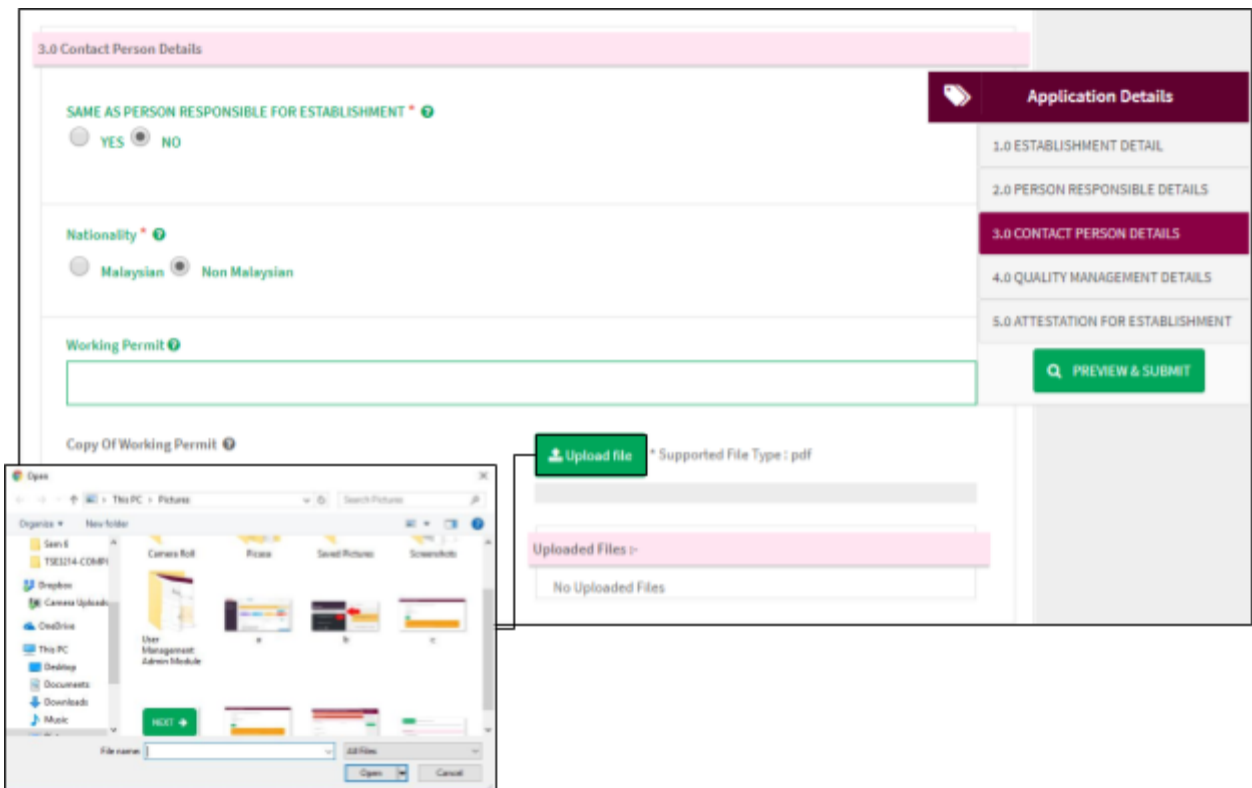
If user tick 'NO', then the user will be asked additional questions. User fill information about Nationality* of contact person.



User choose to tick Malaysian or Non Malaysian .

If user tick 'NON MALAYSIAN' radio button. User has fills Working Permit* text

box and click  to upload Copy Of Working Permit file. **The file must be pdf format and size not more than 300 MB.**



NRIC/Passport No*

User enter NRIC/Passport No to the text box.

The screenshot shows a web form titled "3.0 Contact Person Details". The form is divided into several sections:


- 3.0 CONTACT PERSON DETAILS** (Header)
- 4.0 QUALITY MANAGEMENT DETAILS** (Section)
- 5.0 ATTESTATION FOR ESTABLISHMENT** (Section)

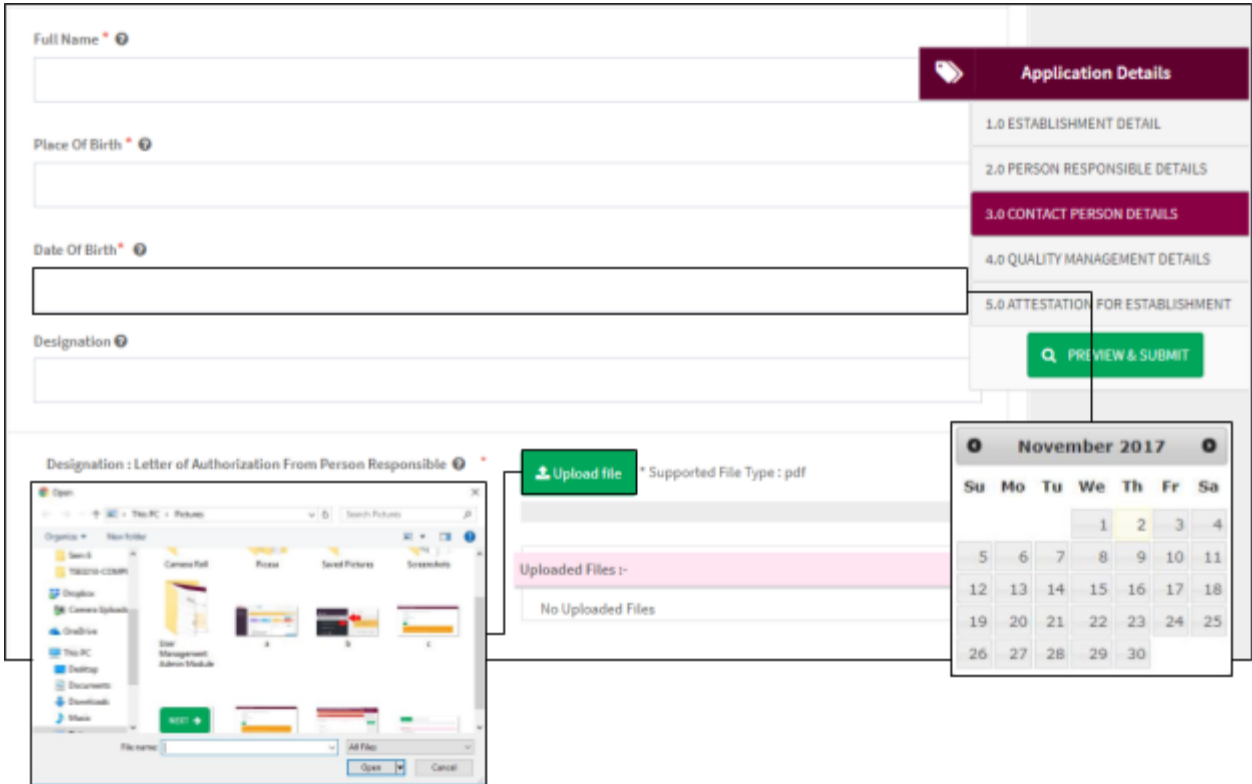
The form contains the following fields and controls:

- SAME AS PERSON RESPONSIBLE FOR ESTABLISHMENT ***: Radio buttons for YES and NO. The NO option is selected.
- Nationality ***: Radio buttons for Malaysian and Non Malaysian. The Malaysian option is selected.
- NRIC/Passport No ***: A text input field with a green border.

A green button labeled "PREVIEW & SUBMIT" is located in the bottom right corner of the form area.

User has to complete this field. For 'Date of Birth' user select date in calendar textbox

or user can write the date using **YYYY-MM-DD** format. User click  to upload Designation : Letter of Authorization From Person Responsible file. **The file must be pdf format and size not more than 300 MB.**



User need to complete this field. User click



to go to the next step or click



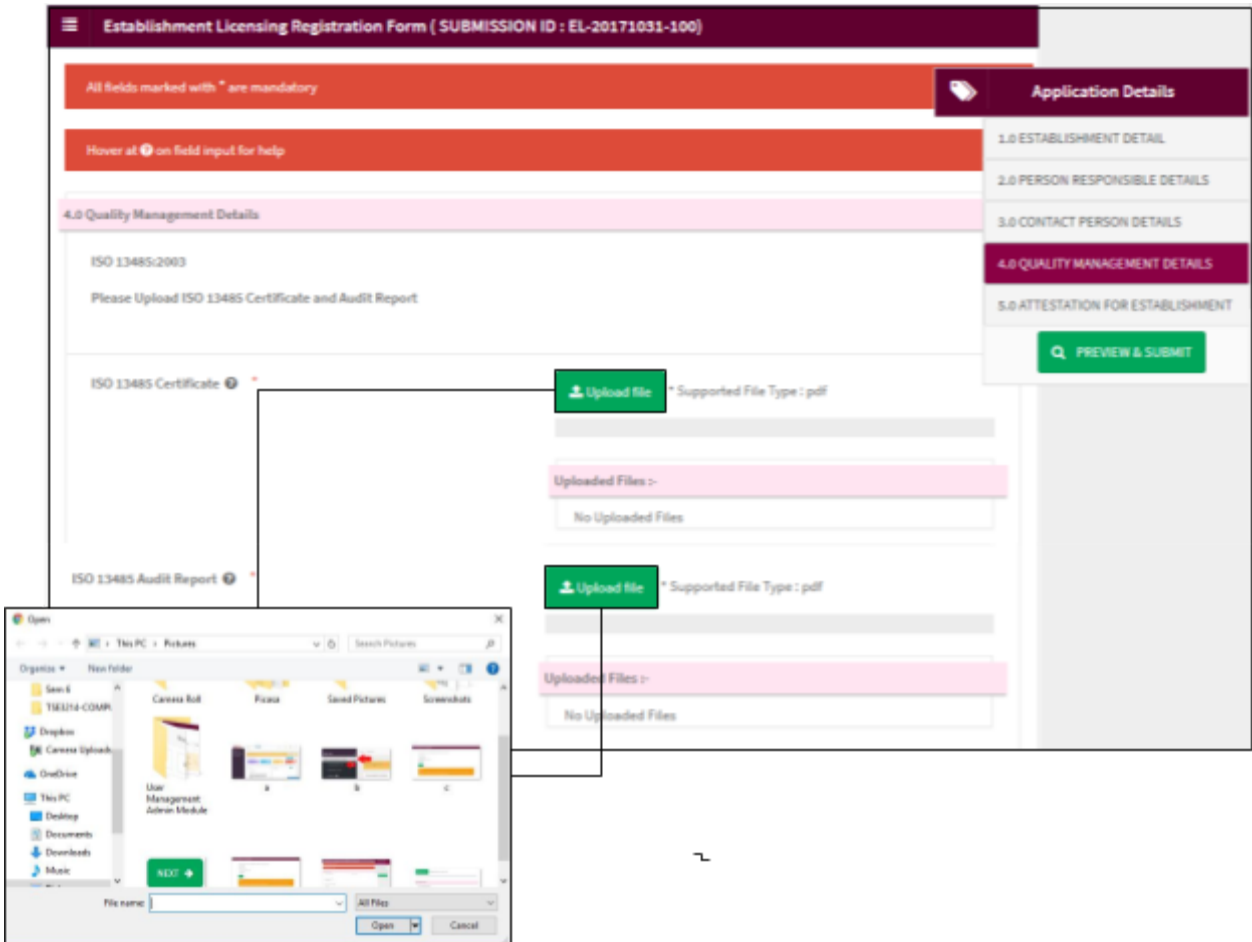
to go to the previous form.

The screenshot shows a web form for 'Application Details' with the following fields and annotations:

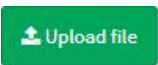
- Correspondence Address ***: Text input field.
- Postcode ***: Text input field.
- Telephone No ***: Text input field with a dropdown menu showing '603'.
- Fax ***: Text input field with a dropdown menu showing '603'.
- Email ***: Text input field.
- State ***: Dropdown menu with a list of Malaysian states: JOHOR, KEDAH, KELANTAN, MELAKA, NEGERI SEMBILAN, PAHANG, PERAK, PERLIS, PULAU PINANG, SABAH, SARAWAK, SELANGOR, TERENGGANU, WILAYAH PERSEKUTUAN KUALA LUMPUR, WILAYAH PERSEKUTUAN PUTRAJAYA, WILAYAH PERSEKUTUAN LABUAN.
- City ***: Text input field.
- Application Details**: A sidebar menu with items: 1.0 ESTABLISHMENT DETAIL, 2.0 PERSON RESPONSIBLE DETAILS, 3.0 CONTACT PERSON DETAILS (highlighted), 4.0 QUALITY MANAGEMENT DETAILS, 5.0 ATTESTATION FOR ESTABLISHMENT.
- Navigation Buttons**: 'Previous' (left arrow) and 'Next' (right arrow) buttons.

Annotations show lines connecting the 'Next' button to the 'City' field and the 'Previous' button to the 'Telephone No' field. Two dropdown menus are also shown: one for 'Postcode' with values from 6010 to 6083, and one for 'City' with values from BANDAR BARU BANGI to KLANG.


2.4 QUANTITY MANAGEMENT DETAILS



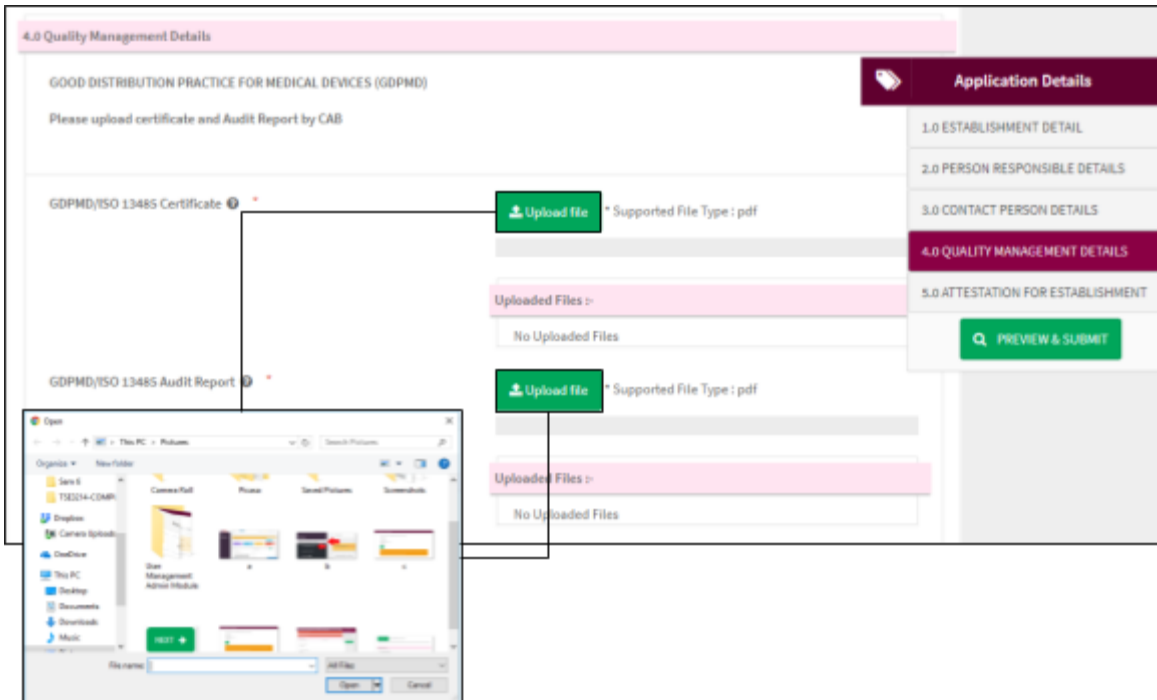
ISO 13485 Certificate*

User click  to upload ISO 13485 Certificate file. **The file must be pdf format and size not more than 300 MB.**

ISO 13485 Audit Report*

User click  to upload ISO 13485 Audit Report file. **The file must be pdf format and size not more than 300 MB.**

This step just for Authorised Representative, Distributor and Importer application only.



GDPMD/ISO 13485 Certificate*

User click  to upload GDPMD/ISO 13485 Certificate file. **The file must be pdf format and size not more than 300 MB.**

GDPMD/ISO 13485 Audit Report*

User click  to upload GDPMD/ISO 13485 Audit Report file. **The file must be pdf format and size not more than 300 MB.**

User has to complete this field. User click



to go to the next step or click



to go to the previous form.

The screenshot shows a web application form for establishing a license. The form includes the following fields:

- Name of CAB ***: A dropdown menu currently showing "-SELECT NAME OF CAB-".
- Name Of Registered CAB Auditor ***: A text input field.
- CAB Registration No ***: A text input field.
- Certificate Expiry Date ***: A date selection field.

On the right side, there is a sidebar titled "Application Details" with a list of steps:



- 1.0 ESTABLISHMENT DETAIL
- 2.0 PERSON RESPONSIBLE DETAILS
- 3.0 CONTACT PERSON DETAILS
- 4.0 QUALITY MANAGEMENT DETAILS (highlighted in purple)
- 5.0 ATTESTATION FOR ESTABLISHMENT

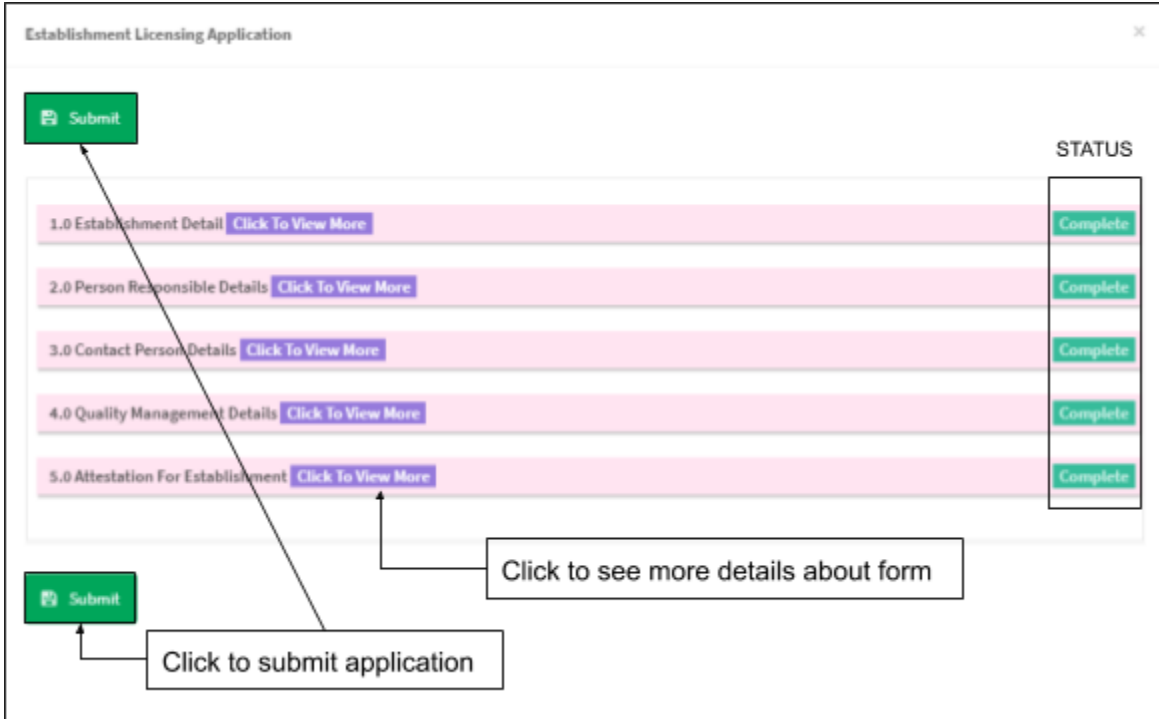
Below the sidebar is a green button labeled "PREVIEW & SUBMIT". At the bottom of the form, there are "Previous" and "Next" navigation buttons. A blue bar with the name "AHMAD" is visible above the navigation buttons.

-
- SELECT NAME OF CAB:
 - TUV SUD (MALAYSIA) SDN. BHD.
 - MEDCERT MALAYSIA SDN. BHD.
 - SQS (MALAYSIA) SDN. BHD.
 - SIRIM QAS INTERNATIONAL SDN. BHD.
 - BSI SERVICES MALAYSIA SDN. BHD.
 - DQS CERTIFICATION (M) SDN. BHD.
 - TUV RHEINLAND MALAYSIA SDN. BHD.
 - TUV NORD (M) SDN. BHD.
 - CARE CERTIFICATION INTERNATIONAL (M) SDN. BHD.
 - NQA CERTIFICATION SERVICES (M) SDN. BHD.
 - BUREAU VERITAS CERTIFICATION (M) SDN. BHD.
 - CI INTERNATIONAL CERTIFICATION SDN. BHD.
 - KGS CERTIFICATION SDN. BHD.
 - DET NORSKE VERITAS SDN. BHD.
 - PLATINUM SHAUFFMANTZ VERITAS SDN. BHD.
 - GENUINE DIAMOND SDN. BHD.
 - SYARIKAT CAB 2
 - SYARIKAT CAB 3
 - SYARIKAT CAB 4

2.5 ATTESTATION FOR ESTABLISHMENT

User cannot edit text in 'Person Responsible Name' and 'Person Responsibility Identity Card Number'. That text box automatically fill by the system. User tick all checkbox.

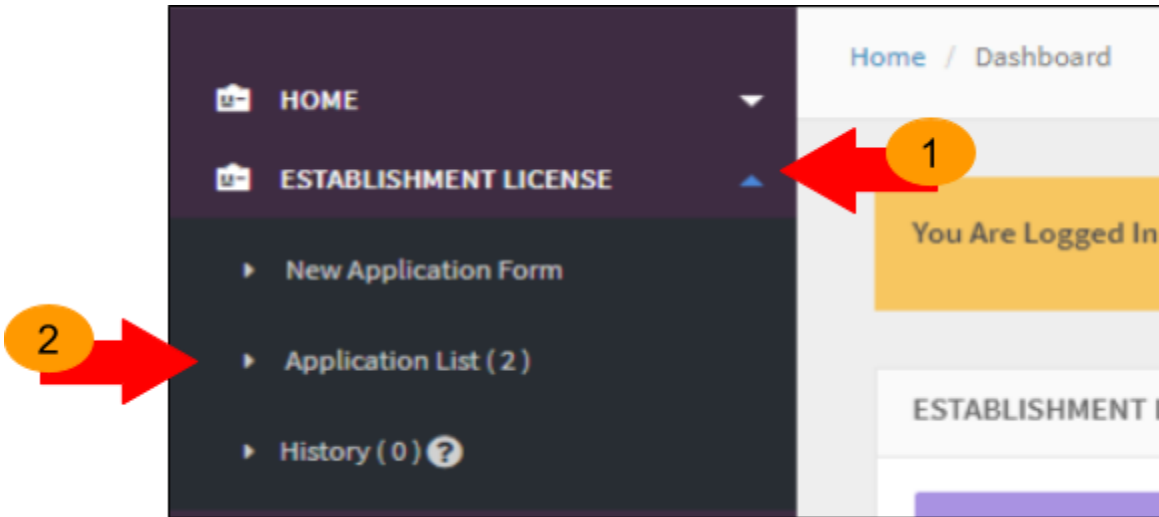
User click  to go to the previous form. Click  to preview before submitting application.

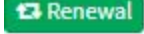


Submission only can do if all form status is **Complete**. If not, user need to complete the form. Click **Submit** to submit application.

3.0 RENEWAL APPLICATION

User go to Application List page to renew application.



The diagram below show *Application List* page. Click  to renewal application.

Establishment Licensing - All Application

[FILTER APPLICATION](#)

Showing 1-2 of 2 items.

No	Submission ID	Submitted Date	Application Type	Application Status	Role Of Establishment	Application Activeness	Action
1	EL-20171124-83	2017-11-24 03:06:19	NEW REGISTRATION	COMPLETE	MANUFACTURER	ACTIVE	View Renewal PAdvice & Receipt Amendment Minor Amendment Major Surrender
2	EL-20171124-85	2017-11-24 03:07:00	NEW REGISTRATION	PRINT LICENSE	AUTHORISED REPRESENTATIVE & IMPORTER & DISTRIBUTOR	ACTIVE	View PAdvice & Receipt

Next, user will go to 1.0 ESTABLISHMENT DETAILS page. User have to complete all

fields with (*). User click  to go to the next step.

Establishment Licensing Registration Form (SUBMISSION ID : EL-20171204-213)

All fields marked with * are mandatory

Hover at ? on field input for help

1.0 Establishment Detail

1. Type Of Establishment :- MANUFACTURER

2. Bumiputra Status *

YES NO

Copy Of Bumiputra certificate from MOF *

Upload file * Supported File Type : pdf

Uploaded Files :-

TEST.pdf

Application Details

1.0 ESTABLISHMENT DETAIL

2.0 PERSON RESPONSIBLE DETAILS

3.0 CONTACT PERSON DETAILS

4.0 QUALITY MANAGEMENT DETAILS

5.0 ATTESTATION FOR ESTABLISHMENT

PREVIEW & SUBMIT

Hu

The diagram below show 2.0 PERSON RESPONSIBLE DETAILS form. User have to complete all fields with (*).

Establishment Licensing Registration Form (SUBMISSION ID : EL-20171204-213)

All fields marked with * are mandatory

Hover at ⓘ on field input for help

2.0 Person Responsible Details

Nationality *

Malaysian Non Malaysian

NRIC/Passport No *

970706385107

Copy Of Person Responsible's Identity Card (IC) *

Upload file * Supported File Type : pdf



Uploaded Files :-

TEST.pdf

Application Details

- 1.0 ESTABLISHMENT DETAIL
- 2.0 PERSON RESPONSIBLE DETAILS
- 3.0 CONTACT PERSON DETAILS
- 4.0 QUALITY MANAGEMENT DETAILS
- 5.0 ATTESTATION FOR ESTABLISHMENT

PREVIEW & SUBMIT

User click  to go to the next step. User click  to go to the previous form.

The diagram below shows 3.0 CONTACT PERSON DETAILS form. User have to fill all fields with (*).

Establishment Licensing Registration Form (SUBMISSION ID : EL-20171206-98)

All fields marked with * are mandatory

Hover at ⓘ on field input for help

3.0 Contact Person Details

SAME AS PERSON RESPONSIBLE FOR ESTABLISHMENT *

YES NO

Nationality *

Malaysian Non Malaysian

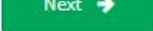
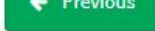
NRIC/Passport No *

970706385107

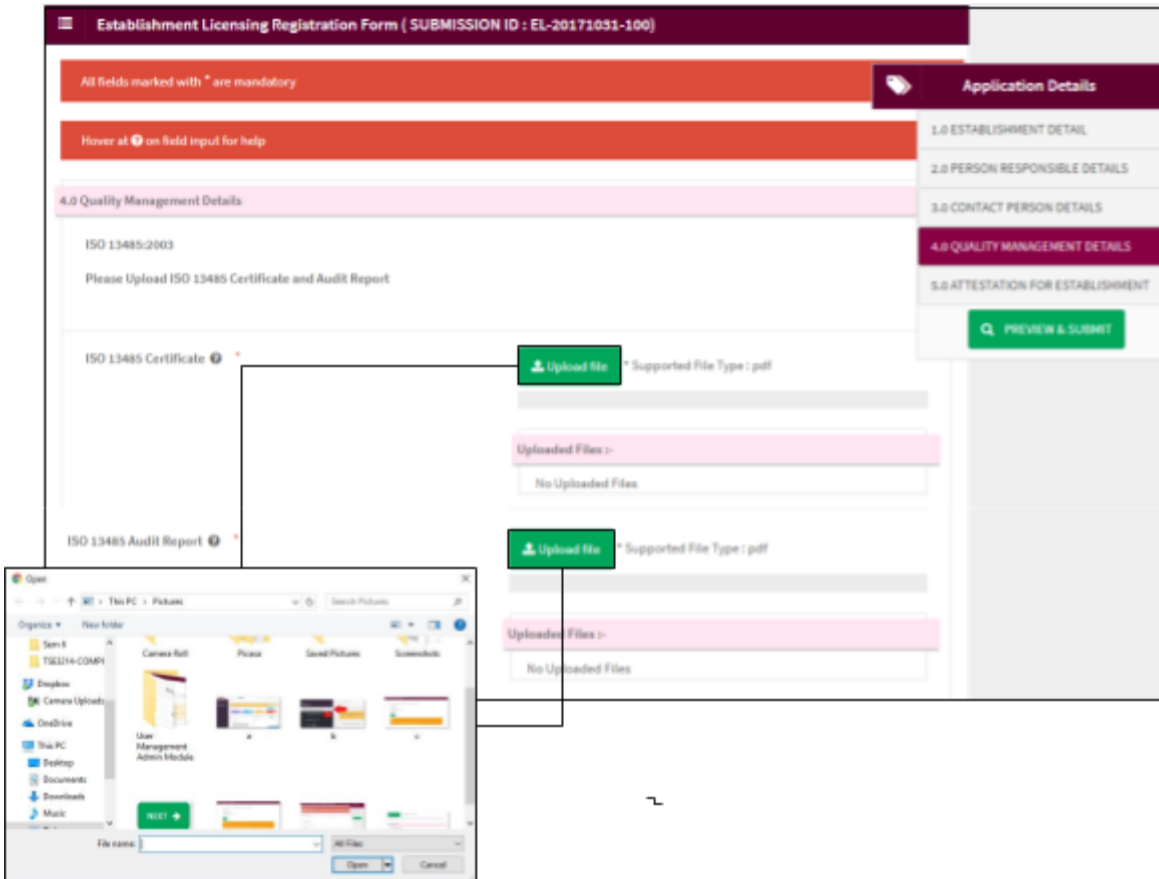
Application Details




- 1.0 ESTABLISHMENT DETAIL
- 2.0 PERSON RESPONSIBLE DETAILS
- 3.0 CONTACT PERSON DETAILS
- 4.0 QUALITY MANAGEMENT DETAILS
- 5.0 ATTESTATION FOR ESTABLISHMENT

PREVIEW & SUBMIT

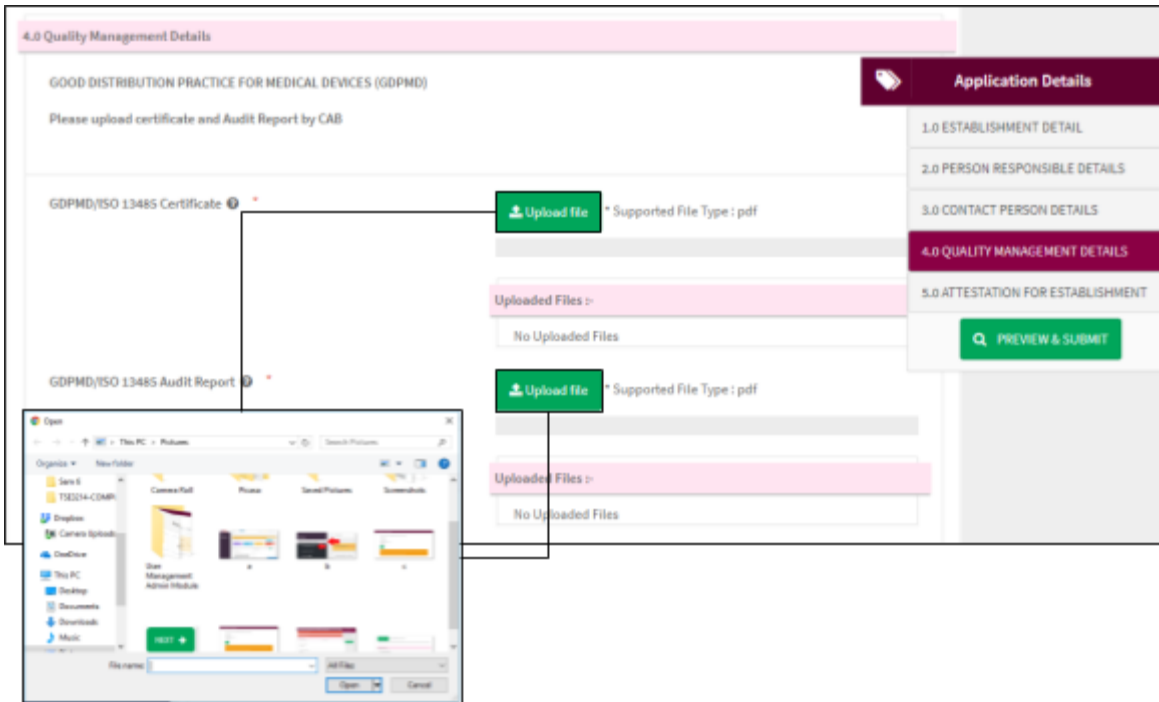
User click  to go to the next step. User click  to go to the previous form.




The diagram below shows 4.0 QUALITY MANAGEMENT DETAILS form. User have to complete all fields with (*). In this form, the user has to upload ISO 13485 Certificatej and ISO 13485 Audit Report (for manufacture application).



Click  to upload. **The file must be pdf format and size not more than 300 MB.** User click  to go to the next step. User click  to go to the previous form.

GDPMD/ISO 13485 Certificate and GDPMD/ISO 13485 Audit Report (for Authorised Representative, Distributor and Importer application).



Click  to upload. **The file must be pdf format and size not more than 300 MB.** User click  to go to the next step. User click  to go to the previous form.

User complete this field and click



to go to the next step or click





to go to the previous form.

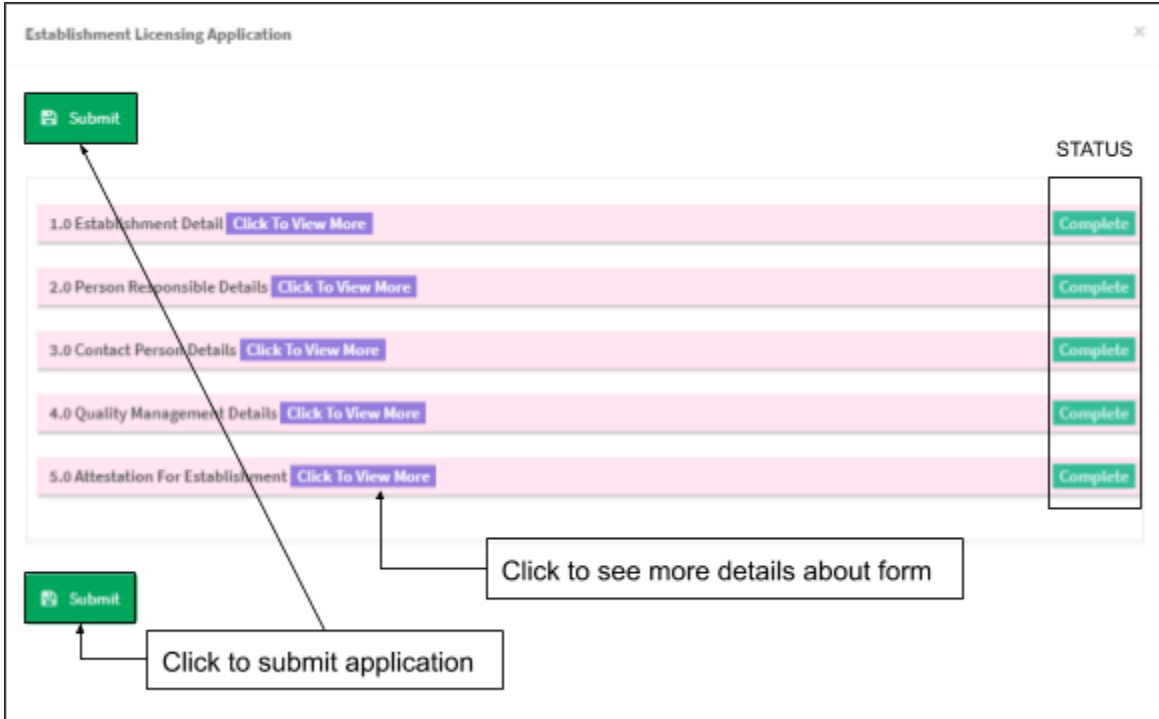
The screenshot shows a web form for establishing a license. It includes several input fields: 'Name of CAB' (a dropdown menu), 'Name Of Registered CAB Auditor', 'CAB Registration No', and 'Certificate Expiry Date'. To the right, a vertical sidebar titled 'Application Details' lists five steps: 1.0 ESTABLISHMENT DETAIL, 2.0 PERSON RESPONSIBLE DETAILS, 3.0 CONTACT PERSON DETAILS, 4.0 QUALITY MANAGEMENT DETAILS, and 5.0 ATTESTATION FOR ESTABLISHMENT. A green button labeled 'PREVIEW & SUBMIT' is located below the sidebar. At the bottom of the form, there are green buttons for 'Previous' and 'Next'.

- SELECT NAME OF CAB
- TUV SUD (MALAYSIA) SDN. BHD.
- MEDCERT MALAYSIA SDN. BHD.
- SGS (MALAYSIA) SDN. BHD.
- SIRIM QAS INTERNATIONAL SDN. BHD.
- BSI SERVICES MALAYSIA SDN. BHD.
- DQS CERTIFICATION (M) SDN. BHD.
- TUV RHEINLAND MALAYSIA SDN. BHD.
- TUV NORD (M) SDN. BHD.
- CARE CERTIFICATION INTERNATIONAL (M) SDN. BHD.
- HQA CERTIFICATION SERVICES (M) SDN. BHD.
- BUREAU VERITAS CERTIFICATION (M) SDN. BHD.
- CI INTERNATIONAL CERTIFICATION SDN. BHD.
- KGS CERTIFICATION SDN. BHD.
- DET NORSKE VERITAS SDN. BHD.
- PLATINUM SHAUFFHANTZ VERITAS SDN. BHD.
- GENUINE DIAMOND SDN. BHD.
- SYARIKAT CAB 2
- SYARIKAT CAB 3
- SYARIKAT CAB 4

The diagram below show 5.0 form. User have to fill all fields with (*).

User cannot edit text in 'Person Responsible Name' and 'Person Responsibility Identity Card Number'. That text box automatically fill by the system. User tick all checkbox.

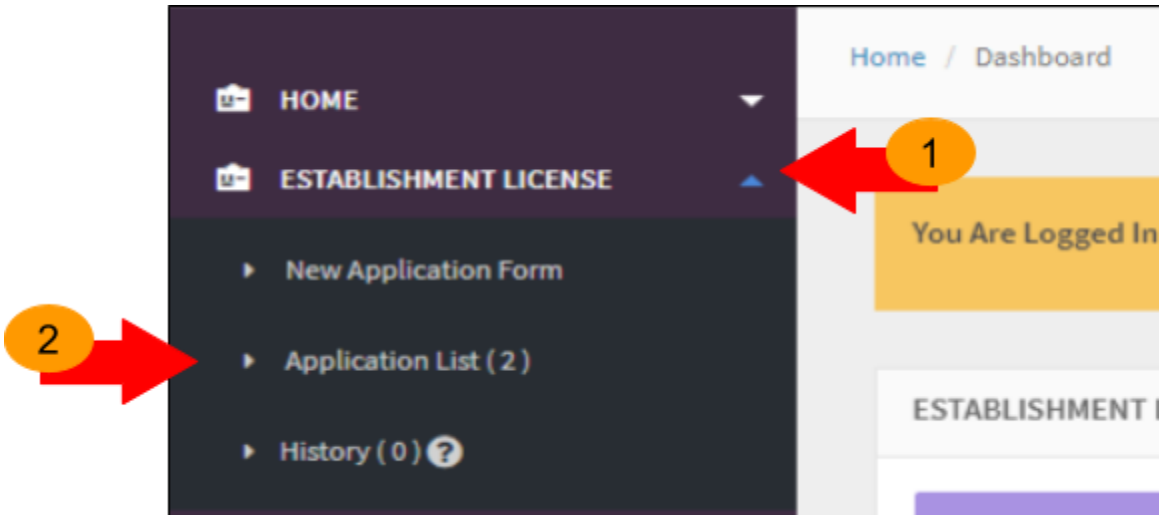
User click  to go to the previous form. Click  to preview before submitting application.



Submission only can do if all form status is **Complete**. If not, user need to complete the form. Click **Submit** to submit application.

4.0 AMENDMENT MINOR

User go to Application List page yo renew application.



The diagram below show Application List page. Click [+ Ammendment Minor](#) to make amendment minor.

The screenshot shows the 'Establishment Licensing - All Application' page. At the top left, there is a 'FILTER APPLICATION' button. Below it, it says 'Showing 1-2 of 2 items.' The table below has the following data:

No	Submission ID	Submitted Date	Application Type	Application Status	Role Of Establishment	Application Activeness	Action
1	EL-20171124-83	2017-11-24 03:06:19	NEW REGISTRATION	COMPLETE	MANUFACTURER	ACTIVE	View Renewal PAdvice & Receipt + Ammendment Minor + Ammendment Major Surrender
2	EL-20171124-85	2017-11-24 03:07:00	NEW REGISTRATION	PRINT LICENSE	AUTHORISED REPRESENTATIVE & IMPORTER & DISTRIBUTOR	ACTIVE	View PAdvice & Receipt

A red arrow points to the '+ Ammendment Minor' button in the 'Action' column of the first application row.

Next, user will go to 1.0 ESTABLISHMENT DETAILS page. In this form user make changes at :

- I. 2. Bumiputra Status
- II. 7. State hi u
- III. 8. City
- IV. 9. Postcode
- V. 10. Telephone No
- VI. 11. Fax
- VII. 12. Company Website

Establishment Licensing Registration Form (SUBMISSION ID : EL-20171205-95)

All fields marked with * are mandatory

Hover at ⓘ on field input for help

1.0 Establishment Detail

1. Type Of Establishment : - MANUFACTURER

2. Bumiputra Status *

YES NO

Copy Of Bumiputra certificate from MOF *

Upload file * Supported File Type : pdf

Uploaded Files >

No Uploaded Files

Application Details

1.0 ESTABLISHMENT DETAIL

2.0 PERSON RESPONSIBLE DETAILS

3.0 CONTACT PERSON DETAILS

4.0 QUALITY MANAGEMENT DETAILS

5.0 ATTESTATION FOR ESTABLISHMENT

PREVIEW & SUBMIT

The diagram below show 2.0 PERSON RESPONSIBLE DETAILS form. In this form user make changes at :

- I. Date of Birth

Establishment Licensing Registration Form (SUBMISSION ID : EL-20171205-95)

All fields marked with * are mandatory

Hover at ⓘ on field input for help

2.0 Person Responsible Details

Nationality *

Malaysian Non Malaysian

NRIC/Passport No *

111111111111

Copy Of Person Responsible's Identity Card (IC) *

Uploaded Files :-

TEST.pdf

Application Details

- 1.0 ESTABLISHMENT DETAIL
- 2.0 PERSON RESPONSIBLE DETAILS
- 3.0 CONTACT PERSON DETAILS
- 4.0 QUALITY MANAGEMENT DETAILS
- 5.0 ATTESTATION FOR ESTABLISHMENT

PREVIEW & SUBMIT

The diagram below shows 3.0 CONTACT PERSON DETAILS form. In this form, if user tick NO at *SAME AS PERSON RESPONSIBLE FOR ESTABLISHMENT* field, user to fill :

- I. Nationality (if user tick *Non Malaysian*, user has to upload Working Permit)
- II. Working Permit
- III. NRIC/Passport No
- IV. Full Name
- V. Place Of Birth
- VI. Date Of Birth
- VII. Designation (Designation : Letter of Authorization From Person Responsible)
- VIII. Correspondence Address
- IX. Postcode
- X. State
- XI. City
- XII. Telephone No
- XIII. Fax
- XIV. Email

Establishment Licensing Registration Form (SUBMISSION ID : EL-20171205-95)

All fields marked with * are mandatory

Hover at ⓘ on field input for help

3.0 Contact Person Details

SAME AS PERSON RESPONSIBLE FOR ESTABLISHMENT *

YES NO

Nationality *

Malaysian Non Malaysian

Working Permit

Copy Of Working Permit

Upload File * Supported File Type : pdf

Application Details

- 1.0 ESTABLISHMENT DETAIL
- 2.0 PERSON RESPONSIBLE DETAILS
- 3.0 CONTACT PERSON DETAILS
- 4.0 QUALITY MANAGEMENT DETAILS
- 5.0 ATTESTATION FOR ESTABLISHMENT

PREVIEW & SUBMIT

The diagram below shows 4.0 QUALITY MANAGEMENT DETAILS form. In this form user make changes at :

- I. ISO 13485 Certificate/GDPMD/ISO 13485 Certificate.
- II. ISO 13485 Audit Report/GDPMD/ISO 13485 Audit Report
- III. Name of C.A.B

Establishment Licensing Registration Form (SUBMISSION ID : EL-20171205-95)

All fields marked with * are mandatory

Hover at ? on field input for help

4.0 Quality Management Details

ISO 13485:2003
Please Upload ISO 13485 Certificate and Audit Report

ISO 13485 Certificate * * Supported File Type : pdf

Uploaded Files :-
TEST.pdf



ISO 13485 Audit Report * * Supported File Type : pdf

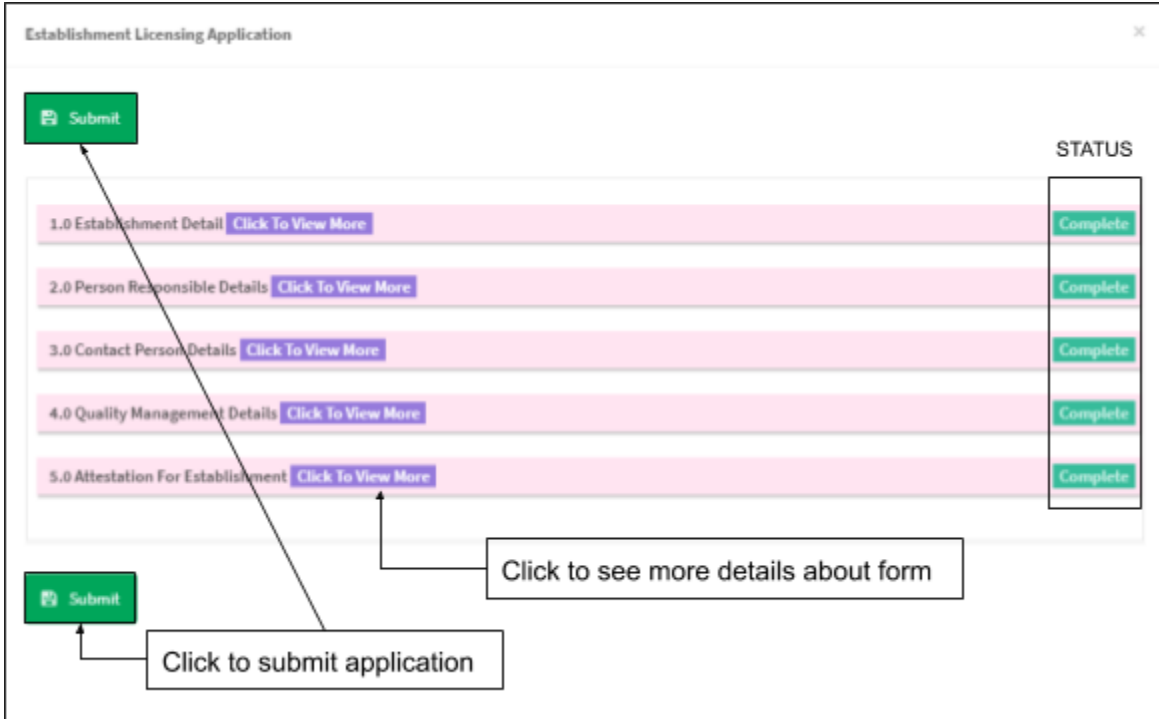
Application Details

- 1.0 ESTABLISHMENT DETAIL
- 2.0 PERSON RESPONSIBLE DETAILS
- 3.0 CONTACT PERSON DETAILS
- 4.0 QUALITY MANAGEMENT DETAILS
- 5.0 ATTESTATION FOR ESTABLISHMENT

The diagram below show 5.0 ATTESTATION FOR ESTABLISHMENT form.

User cannot edit text in 'Person Responsible Name' and 'Person Responsibility Identity Card Number'. That text box automatically fill by the system. User tick all checkbox.

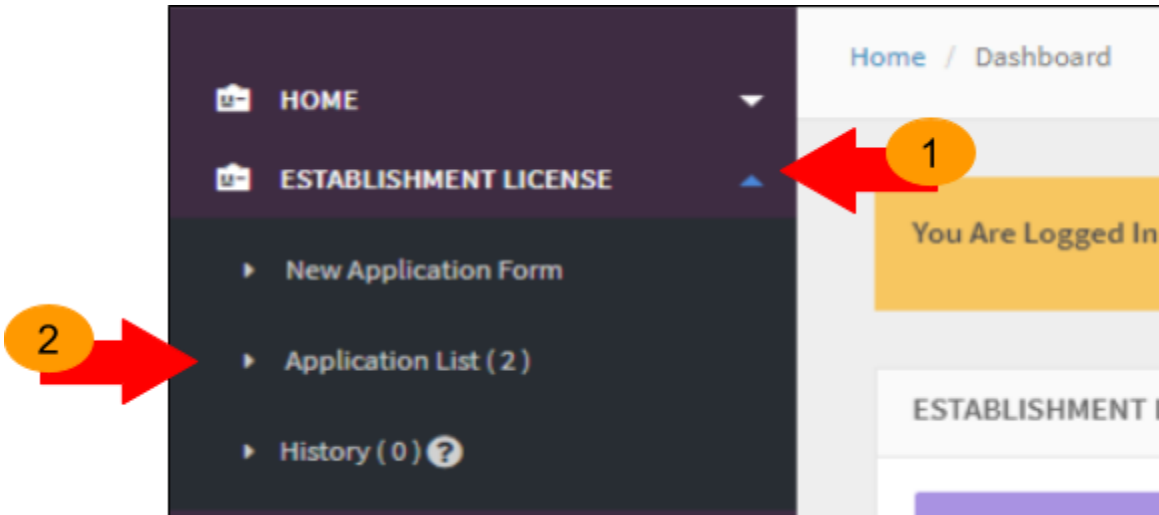
User click  to go to the previous form. Click  to preview before submitting application.



Submission only can do if all form status is **Complete**. If not, user need to complete the form. Click **Submit** to submit application.

5.0 AMENDMENT MAJOR

User go to Application List page yo renew application.



The diagram below show Application List page. Click **+ Ammendment Major** to make amendment major.

Establishment Licensing - All Application

FILTER APPLICATION

Showing 1-2 of 2 items.

No	Submission ID	Submitted Date	Application Type	Application Status	Role Of Establishment	Application Activeness	Action
1	EL-20171124-83	2017-11-24 03:06:19	NEW REGISTRATION	COMPLETE	MANUFACTURER	ACTIVE	View Renewal PAdvice & Receipt Amendment Minor + Ammendment Major Surrender
2	EL-20171124-85	2017-11-24 03:07:00	NEW REGISTRATION	PRINT LICENSE	AUTHORISED REPRESENTATIVE & IMPORTER & DISTRIBUTOR	ACTIVE	View PAdvice & Receipt

Next, user will go to 1.0 ESTABLISHMENT DETAILS page. In this form user make changes at :

- I. 2. Bumiputra Status
- II. 4. Establishment Name
- III. 5. Type Of Company
- IV. 6. Address

Establishment Licensing Registration Form (SUBMISSION ID : EL-20171207-100)

All fields marked with * are mandatory

Hover at ⓘ on field input for help

Application Details

- 1.0 ESTABLISHMENT DETAIL
- 2.0 PERSON RESPONSIBLE DETAILS
- 3.0 CONTACT PERSON DETAILS
- 4.0 QUALITY MANAGEMENT DETAILS
- 5.0 ATTESTATION FOR ESTABLISHMENT

1.0 Establishment Detail

1. Type Of Establishment :-

- AUTHORISED REPRESENTATIVE
- DISTRIBUTOR
- IMPORTER

AUTHORISED REPRESENTATIVE ⓘ *

- Download Template For Letter Of Authorisation

Uploaded Files :-

- TEST.pdf
- File Remark : AR X
- MDR A UAT PAT FAT.pdf

IMPORTER ⓘ *

The following supporting document is required :

- 1. Authorization Letter from Authorised Representative
- Download Template For Importer

Uploaded Files :-

- TEST.pdf
- File Remark : I X
- MDR A UAT PAT FAT.pdf

PREVIEW & SUBMIT

The diagram below show 2.0 PERSON RESPONSIBLE DETAILS form. In this form user can make changes at all field.

Establishment Licensing Registration Form (SUBMISSION ID : EL-20171207-100)

All fields marked with * are mandatory

Hover at ? on field input for help

2.0 Person Responsible Details

Nationality *

Malaysian Non Malaysian

New Certificate And Audit Report Need To Be Uploaded For Amendment Major

Working Permit

125456

Copy Of Working Permit

Upload File * Supported File Type : pdf

Uploaded Files >

TEST.pdf

Application Details

- 1.0 ESTABLISHMENT DETAIL
- 2.0 PERSON RESPONSIBLE DETAILS
- 3.0 CONTACT PERSON DETAILS
- 4.0 QUALITY MANAGEMENT DETAILS
- 5.0 ATTESTATION FOR ESTABLISHMENT

PREVIEW & SUBMIT

The diagram below shows 3.0 CONTACT PERSON DETAILS form. In this form, if user tick NO on *SAME AS PERSON RESPONSIBLE FOR ESTABLISHMENT* field, user need to complete all fields.

Establishment Licensing Registration Form (SUBMISSION ID : EL-20171205-95)

All fields marked with * are mandatory

Hover at ⓘ on field input for help

3.0 Contact Person Details

SAME AS PERSON RESPONSIBLE FOR ESTABLISHMENT *

YES NO

Nationality *

Malaysian Non Malaysian

Working Permit

Copy Of Working Permit

Upload file * Supported File Type: pdf

Application Details

- 1.0 ESTABLISHMENT DETAIL
- 2.0 PERSON RESPONSIBLE DETAILS
- 3.0 CONTACT PERSON DETAILS**
- 4.0 QUALITY MANAGEMENT DETAILS
- 5.0 ATTESTATION FOR ESTABLISHMENT

PREVIEW & SUBMIT

The diagram below shows 4.0 QUALITY MANAGEMENT DETAILS form. In this form user make changes at :

I. Name of CAB

Name of CAB *	CABUSER
Name Of Registered CAB Auditor *	AHMAD FADHILLAH
CAB Registration No *	CABUSER
Certificate Expiry Date *	2020-11-21


Application Details

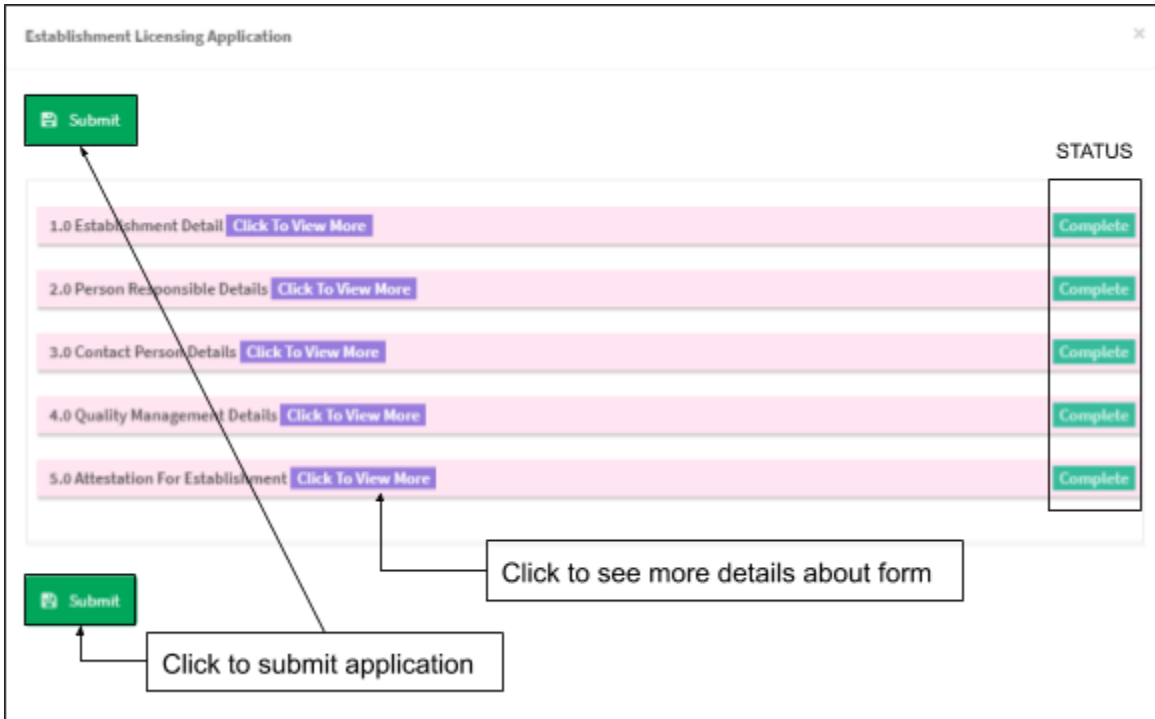
- 1.0 ESTABLISHMENT DETAIL
- 2.0 PERSON RESPONSIBLE DETAILS
- 3.0 CONTACT PERSON DETAILS
- 4.0 QUALITY MANAGEMENT DETAILS**
- 5.0 ATTESTATION FOR ESTABLISHMENT

PREVIEW & SUBMIT

The diagram below show 5.0 ATTESTATION FOR ESTABLISHMENT form.

User cannot edit text in 'Person Responsible Name' and 'Person Responsibility Identity Card Number'. That text box automatically fill by the system. User tick all checkbox.

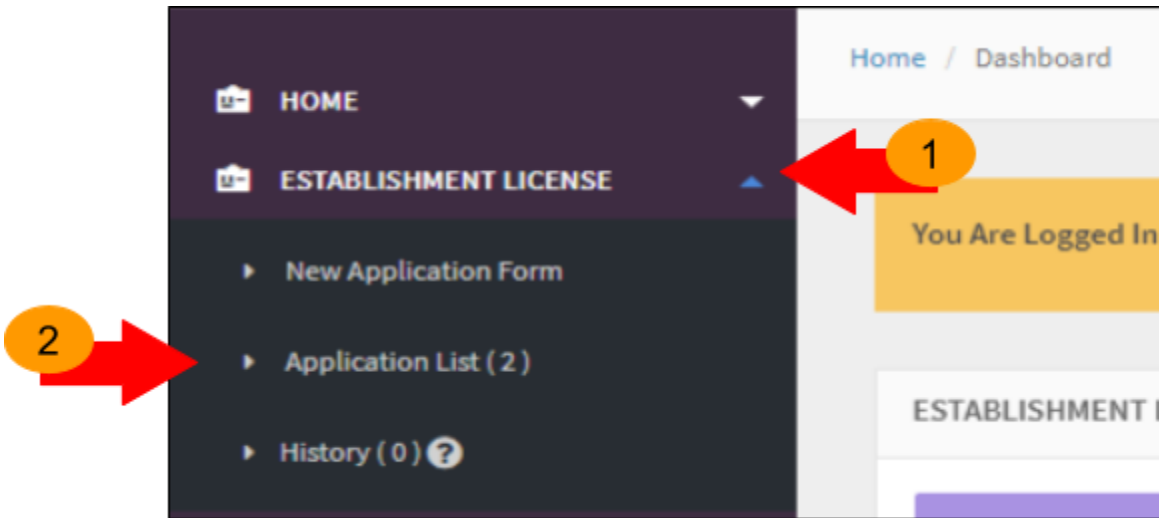
User click  to go to the previous form. Click  to preview before submitting application.



Submission only can do if all form status is **Complete**. If not, user need to complete the form. Click **Submit** to submit application.

6.0 WITHDRAWAL

User go to Application List page yo renew application.



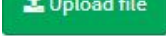
The diagram below show Application List page. Click **Withdrawal** to withdrawal application.

No	Submission ID	Submitted Date	Application Type	Application Status	Role Of Establishment	Application Activeness	Action
1	EL-20171124-85	2017-11-24 03:06:19	NEW REGISTRATION	COMPLETE	MANUFACTURER	ACTIVE	View PAdvice & Receipt
2	EL-20171124-85	2017-11-24 03:07:00	NEW REGISTRATION	COMPLETE	AUTHORISED REPRESENTATIVE & IMPORTER & DISTRIBUTOR	ACTIVE	View Renewal PAdvice & Receipt Amendment Minor Amendment Major Surrender
3	EL-20171204-213	2017-12-04 18:08:35	RENEWAL	EVALUATION	MANUFACTURER	ACTIVE	View PAdvice & Receipt Withdrawal

The diagram below show Establishment Licensing-SURRENDER APPLICATION form.

The screenshot shows a web form titled "Establishment Licensing" with a sub-header "SURRENDER APPLICATION - EL-20171124-85". The form contains the following fields and controls:

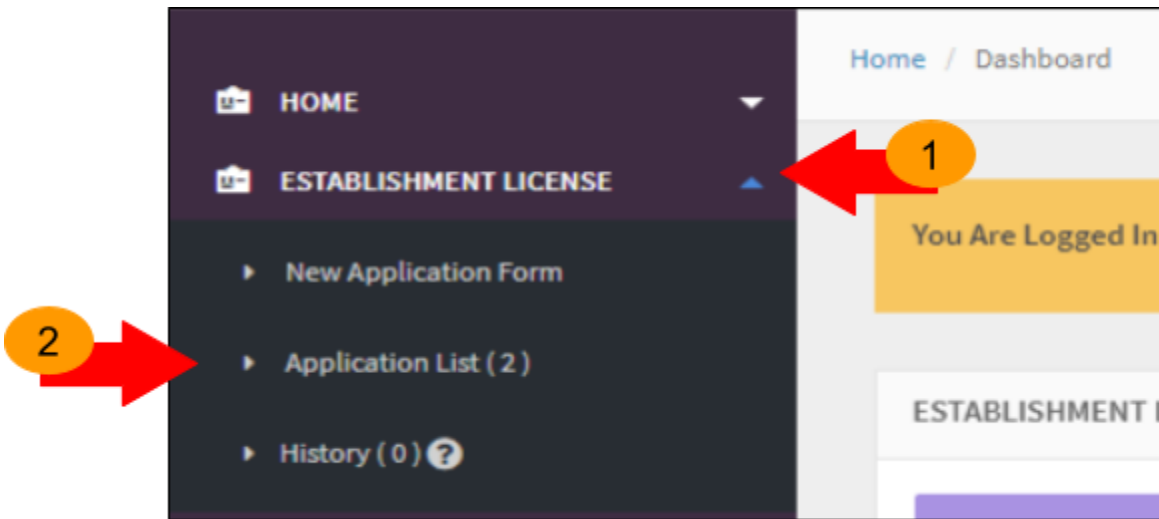
- Name Of Establishment**: DANISH AQWA
- Business Registration No**: EL_TEST
- License No**: MDA-0032-WDP10117
- Type Of License**:
 - AUTHORISED REPRESENTATIVE
 - Distributor
 - Importer
- Expire Date Of License**: 2020-11-27
- Applicant**: -Select Applicant-
- Document Of Surrender**: Includes an "Upload file" button and a text area containing "No results found."
- Reason Of Surrender**: A large text area for input.
- Submit To Surrender**: A blue button at the bottom.

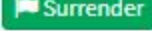
User fill *Application*, *Document Of Surrender* (click  to upload file. **The file must be pdf format and size not more than 300 MB**), and *Reason Of*

Surrender field. Next, click  to submit.

7.0 SURRENDER

User go to Application List page to renew application.



The diagram below show Application List page. Click  to surrender an application.

Establishment Licensing - All Application

[FILTER APPLICATION](#)

Showing 1-3 of 3 items.

No	Submission ID	Submitted Date	Application Type	Application Status	Role Of Establishment	Application Activeness	Action
1	EL-20171124-83	2017-11-24 03:06:19	NEW REGISTRATION	COMPLETE	MANUFACTURER	ACTIVE	View P.Advice & Receipt
2	EL-20171124-85	2017-11-24 03:07:00	NEW REGISTRATION	COMPLETE	AUTHORISED REPRESENTATIVE & IMPORTER & DISTRIBUTOR	ACTIVE	View Renewal P.Advice & Receipt Amendment Minor Amendment Major Surrender
3	EL-20171204-213	2017-12-04 18:08:35	RENEWAL	EVALUATION	MANUFACTURER	ACTIVE	View P.Advice & Receipt Withdrawal

The diagram below show Establishment Licensing-SURRENDER APPLICATION form.

Establishment Licensing

SURRENDER APPLICATION - EL-20171124-85

Name Of Establishment : DANISH AQWA

Business Registration No : EL_TEST

License No : MDA-0032-WDP10117

Type Of License

- AUTHORISED REPRESENTATIVE
- Distributor
- Importer

Expire Date Of License : 2020-11-27

Applicant : -Select Applicant-

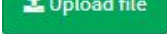
Document Of Surrender

Upload file

No results found.

Reason Of Surrender

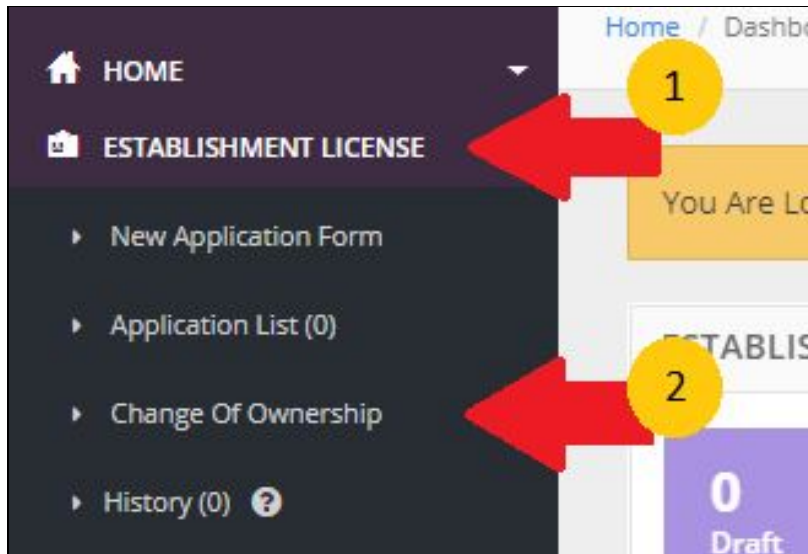
Submit To Surrender

User fill *Application*, *Document Of Surrender* (click  to upload file. **The file must be pdf format and size not more than 300 MB**), and *Reason Of*

Surrender field. Next, click  to submit.

8.0 CHANGE OF OWNERSHIP

Click on the 'ESTABLISHMENT LICENSE" at the left menu sidebar and click on the 'Change Of Ownership' to create a new form.



The diagram below show *Change of Ownership* page.

☰ Establishment License - Change Of Ownership

REGISTRATION NO :

*Please Insert Full REGISTRATION NO : Example : GA7639017-1

*Please Ensure New Authorised Representative or New Manufacturer submit the Change Ownership Registration

Search Application

No	License No	Establishment Name	Action

Search Application

User fill the 'REGISTRATION NO' text boxes and click to search the registration number. The registration number must be from other establishment user.

Establishment License - Change Of Ownership

REGISTRATION NO :

**Please Insert Full REGISTRATION NO - Example : GA7639017-1*
**Please Ensure New Authorised Representative or New Manufacturer submit the Change Ownership Registration*

Search Application

No	License No	Establishment Name	Action
1	GC6674719-28942	SI SDN BHD	View Change Of Ownership

MDR-20190516

**Click On The Title To View Details*

Section 1 : Medical Device Classification

- 1.0 Risk Type Classification **Completed**
- 1.1 Establishment Details **Completed**

Section 2 : General Information

- 2.0 General Information **Completed**

Section 3 : Medical Device Grouping

- 3.0 Medical Device Grouping **Completed**

Section 4 : CSDT

- 4.0 CSDT **Completed**

Annex A

Change of Ownership For Medical Device Registration Application Form

(In accordance with Circular Letter of Medical Device Authority No. 3 Year 2016 : Change of Ownership for Medical Device Registration)

Change Of Ownership Application is applicable for :

1. Authorised Representative
2. Local Manufacturer

who intend to transfer the ownership of the device to another Authorised Representative / Local Manufacturer

NEW AUTHORIZED REPRESENTATIVE / NEW LOCAL MANUFACTURER

Name of Establishment :
 Address :
 City : SERDANG State : SELANGOR

Establishment License Number : MDA-0001:
 Name of Contact Person : Designation : MANAGER
 Telephone No : Mobile Phone No : mail Address :

CURRENT AUTHORIZED REPRESENTATIVE / CURRENT LOCAL MANUFACTURER

Name of Establishment :
 Address :
 City : State : SELANGOR

Role : AUTHORISED REPRESENTATIVE Establishment License Number :
 Name of Person Responsible : FRAZER RODERICK JOHN Designation : MANAGING DIRECTOR

- Click **View** to view the application.
- Click **Change Of Ownership** to proceed the process change of ownership

The diagram below appear after user clicks [Change Of Ownership] button. Click



to upload file. **The file must be pdf format and size not more than 300**



MB. Next, click to submit.

+ Select file...
Supported File Type : pdf

Uploaded Files:-

No results found.

Termination Letter (Current Authorised Representative Terminated By The Foreign Manufacturer)

+ Select file...
Supported File Type : pdf

Uploaded Files:-

No results found.

DETAILS OF MEDICAL DEVICES		
No	MEDICAL DEVICE NAME	REGISTRATION NO
1	SYRINGE	GC6674719-28942

Next

After the change of ownership is submit the application will be in evaluation stage. After approval stage, applicant is required to pay for registration fee to proceed with the change of ownership. Below show the flow before change of ownership is complete.

- ✓ EVALUATION
 - ✓ VERIFICATION
 - ✓ APPROVAL
 - ✓ REGISTRATION FEE
 - ✓ PRINT CERTIFICATE
 - ✓ COMPLETE