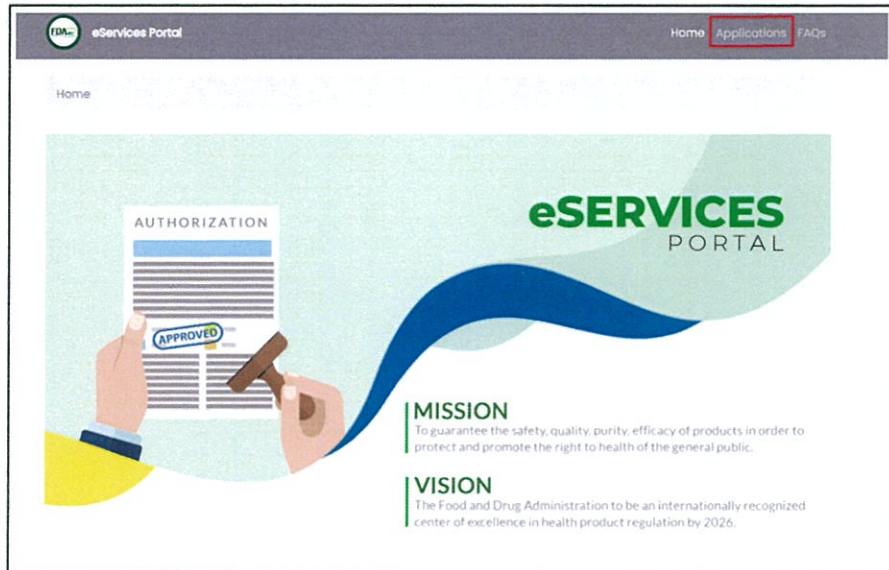


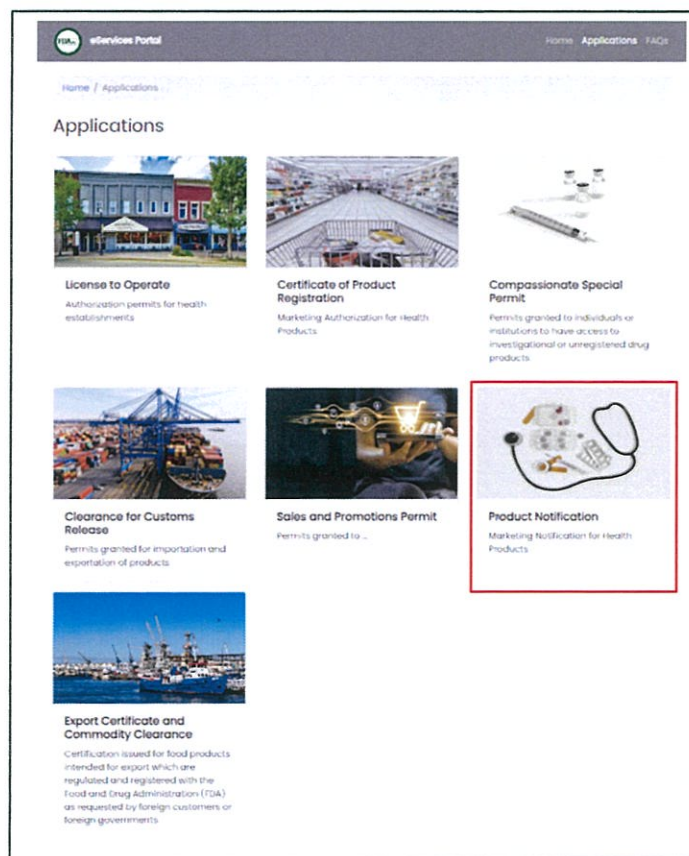
ANNEX A

Procedure for the Use of the FDA eServices Portal System for the Initial Application of Certificate of Medical Device Notification

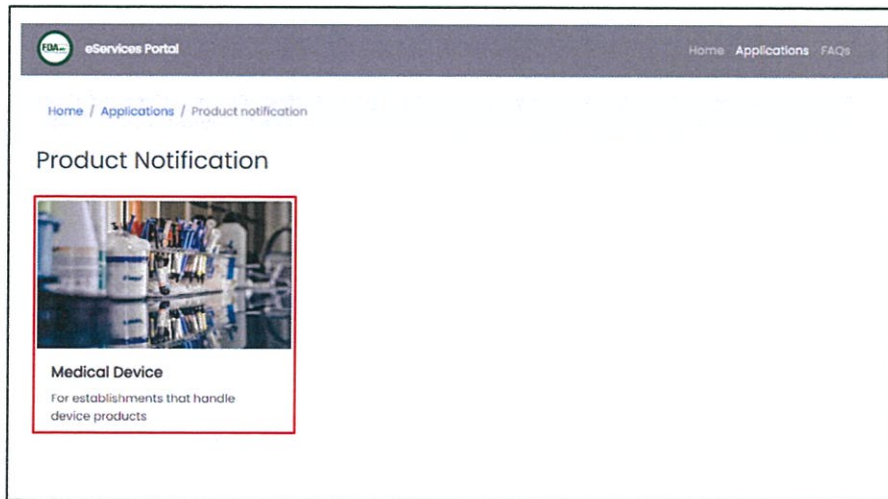
1. To start the application, access the online portal through <http://eservices.fda.gov.ph/> and click “Applications” found on the upper right corner of the eServices landing page.



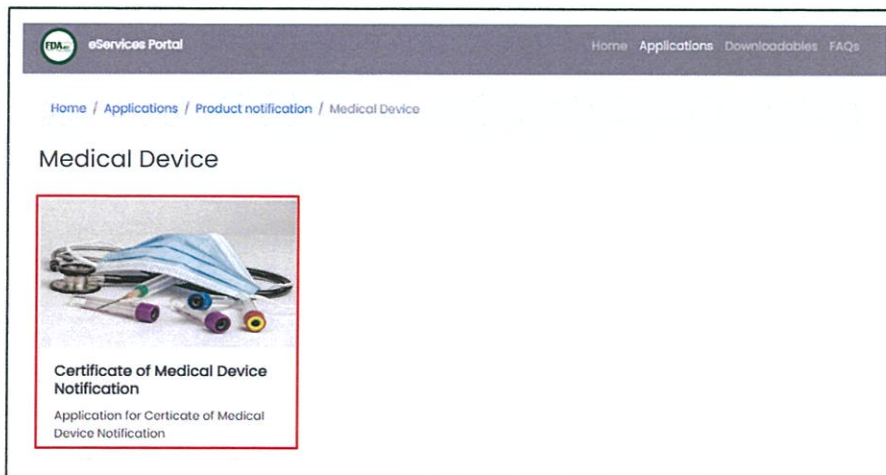
2. Click Product Notification.



3. Click Medical Device.



4. Click Certificate of Medical Device Notification.



5. Click Initial.



6. Read carefully the “Declaration and Undertaking” before proceeding with the application process. Make sure to check the box “I agree to the declaration and undertaking” found below the page and click on “Start Application”.

The screenshot shows the 'Declaration & Undertaking' step of the application process. The page title is 'Certificate of Medical Device Notification Initial'. A sidebar on the left lists the steps: 1 Declaration & Undertaking, 2 Application Information, 3 Product Particulars, 4 Establishment Information, 5 Manufacturer/Distributor Information, 6 Documentary Requirements, 7 Size and Codes, and 8 Self-Assessment Review. The main content area contains a scrollable text box with the following text: 'decides with finality that we have no right to appropriate and utilize the said brand name; and', 'X. We shall acknowledge and agree to indemnify and/or hold FDA free and harmless against any and all third party claims arising from the acceptance of such brand name of the product for registration with FDA.', 'XI. The product covered by this declaration will not undergo any change in the ownership, registrant's address/location, manufacturer, ingredients, formulation, size, reference number, use, manufacturing process (if applicable), labeling or commercial presentation, and packaging of the product covered by this certificate of notification without prior approval of this office.', and 'XII. We acknowledge and agree that in the event that there is an unauthorized change in the ownership, its address/location, manufacturer, ingredients, formulation, size, reference number, use, manufacturing process (if applicable), labeling or commercial presentation, and packaging of the product:'. Below the text box, there is a checkbox labeled 'I agree to the declaration and undertaking' and a 'Start Application' button.

7. Fill out the necessary information accurately based on the application information and contact information. Click “Next” to go to the next page. Click “Back” to return to the previous page.

The screenshot shows the 'Application Information' step of the application process. The page title is 'Certificate of Medical Device Notification Initial'. A sidebar on the left lists the steps: 1 Declaration & Undertaking, 2 Application Information, 3 Product Particulars, 4 Establishment Information, 5 Manufacturer/Distributor Information, 6 Documentary Requirements, 7 Size and Codes, and 8 Self-Assessment Review. The main content area contains form fields for 'Application Information' and 'Contact Information'. The 'Application Information' section includes fields for Type of Application (Initial), Product Type (Certificate of Medical Device Notification), Risk Classification (Please Select), and Previous Denial Letter for the same product application (Please Select). The 'Contact Information' section includes fields for Applicant Name, Position (Please Select), Email Address, Mobile Number, and Landline Number. At the bottom, there are 'Back' and 'Next' buttons.

The following information cannot be changed.

- a. Select the risk classification of the product being applied.

* Risk Classification

Class A

* Previous Denial Letter for the same

Class A
Class B
Class C
Class D

This screenshot shows a form field for 'Risk Classification' with a dropdown menu open. The selected option is 'Class A'. Below the dropdown, a list of options is visible: 'Class A', 'Class B', 'Class C', and 'Class D'. To the left of the dropdown, there is a label '* Risk Classification' and another label '* Previous Denial Letter for the same'.

- b. Specify whether there is/are previous denial letter/s received for the same product application.

- i. If there is no denial letter received, Choose “No”.

* Previous Denial Letter for the same product application

No

Yes
No

This screenshot shows a form field for 'Previous Denial Letter for the same product application' with a dropdown menu open. The selected option is 'No'. Below the dropdown, a list of options is visible: 'Yes' and 'No'. To the left of the dropdown, there is a label '* Previous Denial Letter for the same product application'.

- ii. If there is a previous application with a denial letter, choose “Yes” and click “File Upload” to upload the PDF file of the letter of denial.

* Previous Denial Letter for the same product application

Yes

* Letter of denial/rejection

File Upload

Upload previous letter of rejection/denial

This screenshot shows a form with two fields. The first field is 'Previous Denial Letter for the same product application' with a dropdown menu open and 'Yes' selected. The second field is 'Letter of denial/rejection' with a 'File Upload' button next to it. Below the second field, there is a label 'Upload previous letter of rejection/denial'.

- c. For the “Contact Information”, choose from the selection the applicant’s position in the company/establishment.

* Position

Qualified Person

* Email Address

Owner
Chief Executive Officer
President
General Manager
Head Quality Assurance
Head Quality Control
Head Regulatory Affairs
Head Production
Qualified Person
Regulatory Officer
Authorized Representative

* Mobile Number

This screenshot shows a form field for 'Position' with a dropdown menu open. The selected option is 'Qualified Person'. Below the dropdown, a list of options is visible: 'Owner', 'Chief Executive Officer', 'President', 'General Manager', 'Head Quality Assurance', 'Head Quality Control', 'Head Regulatory Affairs', 'Head Production', 'Qualified Person', 'Regulatory Officer', and 'Authorized Representative'. To the left of the dropdown, there are labels '* Position', '* Email Address', and '* Mobile Number'.

- Fill out the necessary information accurately based on the product particulars. Click “Next” to go to the next page. Click “Back” to return to the previous page.

The screenshot shows the 'eServices Portal' interface for a 'Certificate of Medical Device Notification Initial'. The breadcrumb trail is 'Home / Applications / Product notification / Medical Device / Cmdn / Initial'. The form is divided into eight steps, with 'Product Particulars' (step 3) highlighted in a red box. The 'Product Particulars' section contains the following fields:

- * Product Name: [Text input field]
- * Intended Use: [Text input field with value 'Intended to be used ...']
- * Shelf Life: [Text input field with example 'example: 12 months, 5 years']
- * Commercial Presentation: [Text input field with example 'e.g. Box of 1s, Polybouch of 10s']

At the bottom right of the form, there are 'Back' and 'Next' buttons.

- Fill out the necessary information accurately based on the client/establishment information. Click “Next” to go to the next page. Click “Back” to return to the previous page.

The screenshot shows the 'eServices Portal' interface for a 'Certificate of Medical Device Notification Initial'. The breadcrumb trail is 'Home / Applications / Product notification / Medical Device / Cmdn / Initial'. The form is divided into eight steps, with 'Establishment Information' (step 4) highlighted in a red box. The 'Establishment Information' section contains the following fields:

- * Establishment Name: [Text input field with value 'Name of Establishment']
- * Region: [Dropdown menu with value 'Please Select']
- * Province: [Dropdown menu with value 'Please Select']
- * City or Town: [Dropdown menu with value 'Please Select']
- * Street Address: [Text input field with value 'Street Address']
- * LTO Number: [Text input field with example 'CDSE# xxx-xxxx-xxxxx/LTO-xxxxxxxxxxxxxx']
- * LTO Validity Date: [Text input field with value 'validity date']

At the bottom right of the form, there are 'Back' and 'Next' buttons.

- a. Select the region, province, city or town where the establishment is located.

* Establishment Name

* Region: Calabarzon (Region IV-A)

* Province

* City or Town

* Street Address

* LTO Number

* LTO Validity Date

Calabarzon (Region IV-A)
National Capital Region (NCR)
Cordillera Administrative Region (CAR)
Ilocos (Region I)
Cagayan Valley (Region II)
Central Luzon (Region III)
Calabarzon (Region IV-A)
Mimaropa (Region IV-B)
Bicol (Region V)
Western Visayas (Region VI)
Central Visayas (Region VII)
Eastern Visayas (Region VIII)
Zamboanga Peninsula (Region IX)
Northern Mindanao (Region X)
Davao (Region XI)
Soccsksargen (Region XII)
Caraga (Region XIII)
Autonomous Region in Muslim Mindanao (Region ARMM)

* Region: Calabarzon (Region IV-A)

* Province: Laguna

* City or Town

* Street Address

Laguna
Batangas
Cavite
Laguna
Quezon
Rizal

* City or Town: Please Select

* Street Address

* LTO Number

* LTO Validity Date

Please Select
Biran City
Cabuyao City
Calamba City
San Pablo City
San Pedro City
Santa Rosa City
Alaminos
Bay
Calauan
Cavinti
Famy
Kalayaan
Liliw
Los Baños
Luisiana
Lumban
Mablat
Magdalena
Majayay
Nagcarlan

- b. Fill out the necessary information accurately based on the street address and the LTO Number.

* Street Address: Street Address

* LTO Number

CDRRHR-XXX-XXXX-XXXX / LTO-XXXXXXXXXXXX

c. A calendar can be used to input the LTO validity date.

The screenshot shows a form field labeled "LTO Validity Date" with the value "25 June 2024". Below the input field is a calendar widget for June 2024. The calendar shows the days of the week (Su, Mo, Tu, We, Th, Fr, Sa) and the dates from 1 to 30. The date 25 is highlighted in blue. There are "Back" and "Next" buttons to the right of the calendar.

10. Select the type of activity in which their establishment is engaged in.

The screenshot shows the "Certificate of Medical Device Notification Initial" form. On the left is a vertical navigation menu with steps 1 through 8. Step 5, "Manufacturer/Distributor Information", is highlighted with a red box. A red arrow points from a text box to the "Activity Type" dropdown menu. The text box contains the instruction: "Tick the box if the product being applied is for export only." The "Activity Type" dropdown is currently set to "Please Select". Below it is a checkbox labeled "Check if the product being applied is for export only?". Under the "Distributor/Wholesaler Information" section, there is a checkbox labeled "Check if distributor/wholesaler information is not applicable". Below this are input fields for "Distributor Name", "Distributor Address", and "Distributor LTO". There are "Back" and "Next" buttons at the bottom right.

a. The "Distributor/Wholesaler Information" is common to all establishment options. Choose whether this information is applicable or not.

i. If the distributor / wholesaler information is not applicable, tick the box "Check if distributor / wholesaler information is not applicable".

The screenshot shows a close-up of the "Distributor/Wholesaler Information" section. The "Activity Type" dropdown is set to "Local Manufacturer". The checkbox "Check if the product being applied is for export only?" is ticked. The checkbox "Check if distributor/wholesaler information is not applicable" is also ticked. A red arrow points from a text box to this checkbox. The text box contains the instruction: "Tick the box. If the distributor / wholesaler information is not applicable." There are "Back" and "Next" buttons at the bottom.

- ii. If the distributor / wholesaler information is applicable, there is no need to place a check on the box “Check if distributor / wholesaler information is not applicable”. Fill out the necessary information based on the distributor / wholesaler information.

If the distributor / wholesaler information is applicable, there is no need to tick the box.

* Activity Type Local Manufacturer
Please select activity type of the Establishment Responsible for Placing the Product in the Market

Check if the product being applied is for export only?

Distributor/Wholesaler Information

Check if distributor/wholesaler information is not applicable

* Distributor Name
Distributor Name

* Distributor Address
Complete Address

* Distributor LTO
LTO Number

Back Next

- b. If the activity “Local Manufacturer” is selected, the only information required is the activity type “local manufacturer”. Click “Next” to go to the next page. Click “Back” to return to the previous page.

* Activity Type Local Manufacturer
Please select activity type of the Establishment Responsible for Placing the Product in the Market

Check if the product being applied is for export only?

Distributor/Wholesaler Information

Check if distributor/wholesaler information is not applicable

Back Next

- c. If the activity “Distributor / Importer” is selected, fill out the necessary information accurately based on the manufacturer/s information. Click “Next” to go to the next page. Click “Back” to return to the previous page.

* Activity Type **Distributor/Importer**
Please select activity type of the Establishment Responsible for Placing the Product in the Market

Check if the product being applied is for export only?

Manufacturer/s Information

* Principal Name
Principal Name

* Principal Address
Principal Address

* Legal Name
Legal Name

* Legal Address
Legal Address

* Physical Name
Physical Name

* Physical Address
Physical Address

Distributor/Wholesaler Information

Check if distributor/wholesaler information is not applicable

Back **Next**

- d. If the activity “Trader” is selected, fill out the necessary information accurately based on the manufacturer/s information. Click “Next” to go to the next page. Click “Back” to return to the previous page.

* Activity Type **Trader**
Please select activity type of the Establishment Responsible for Placing the Product in the Market

Check if the product being applied is for export only?

Manufacturer/s Information

* Manufacturer Name
Manufacturer Name

* Manufacturer Address
Manufacturer Address

* Manufacturer LTO Number
LTO Number

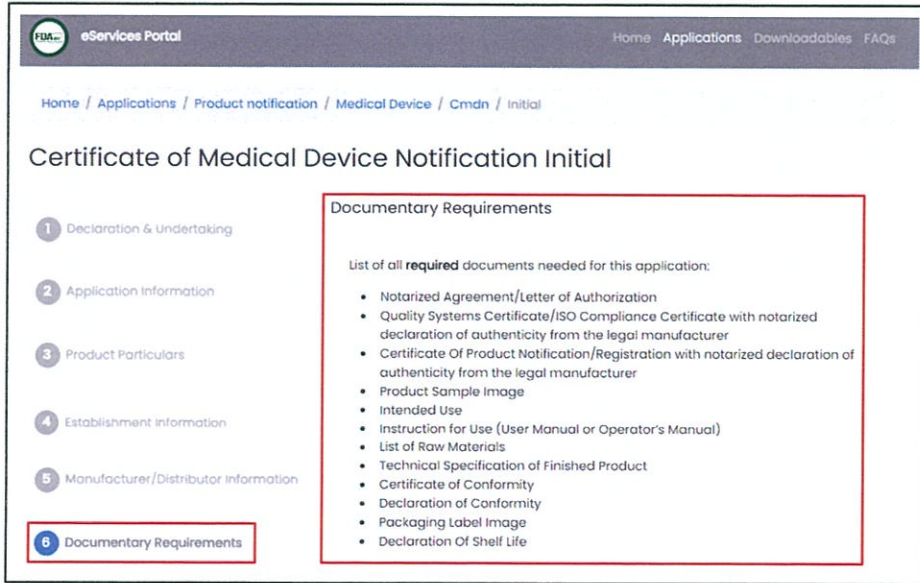
Distributor/Wholesaler Information

Check if distributor/wholesaler information is not applicable

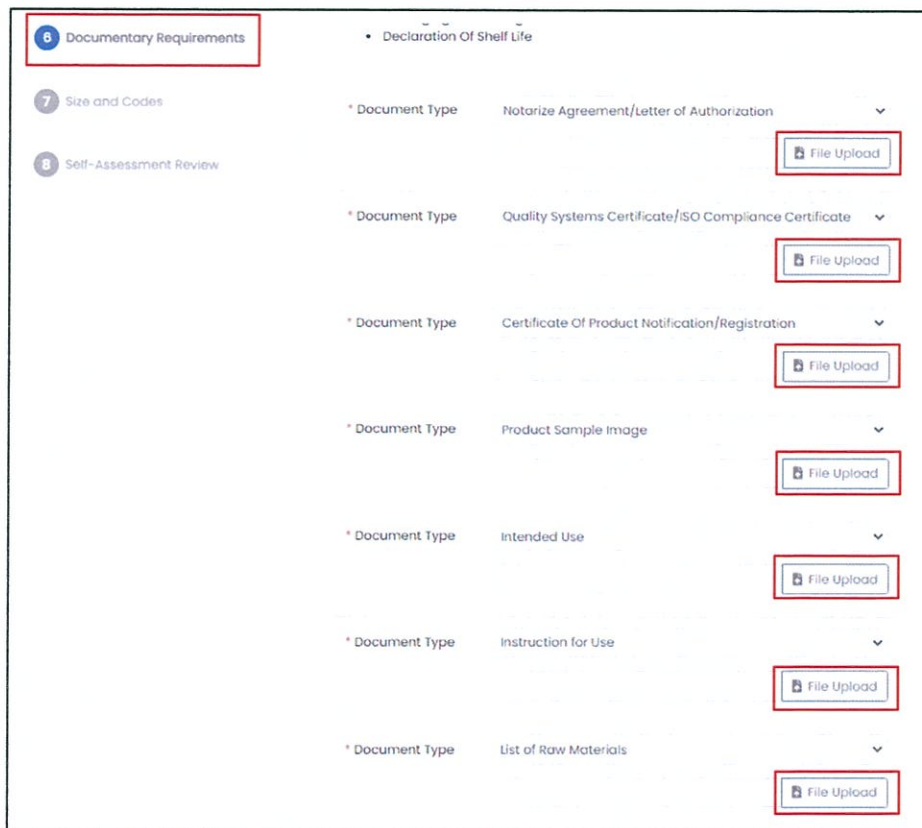
Back **Next**

11. Submit the required documents needed for the application.

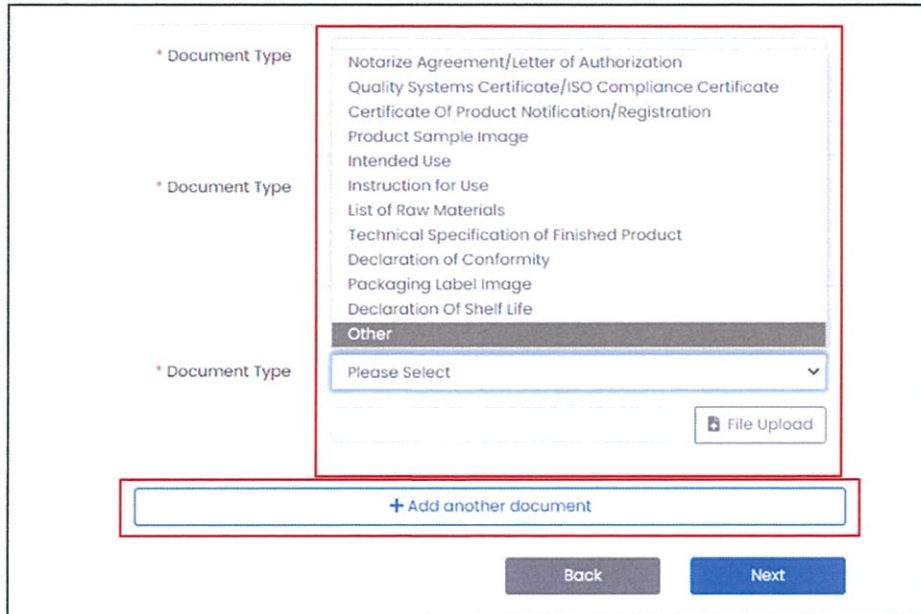
- a. The applicant will find a thorough list of application requirements in the upper section of the web page.



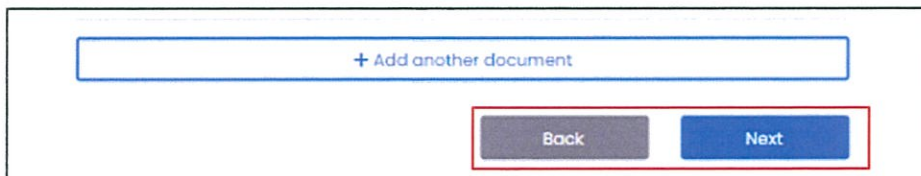
- b. Upload the required documents by clicking the "File Upload" button accessible for each type of document in the lower section of the webpage. The file to be uploaded should be named according to the type of documentary requirement and should be in searchable PDF format, 150 DPI and not exceed two (2) MB.



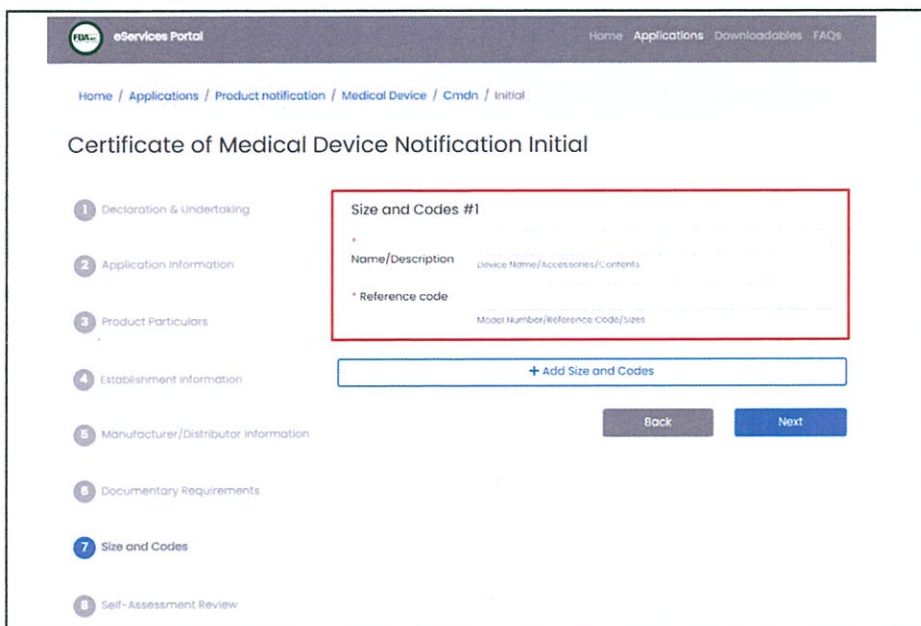
- c. If necessary, additional documents may be included by clicking the "+ Add another document" option at the bottom of the web page. The applicant has the option of selecting the type of document to upload.



- d. After all the documentary requirements have been uploaded, click "Next" to go to the next page or click "Back" to return to the previous page.



- 12. Fill out the necessary information accurately based on the size and code of the medical device. The size and code portion should be filled up per item. Indicate the name of the item and its corresponding reference code or model whichever is applicable.



- a. Additional sizes and codes may be included by clicking the "+ Add Size and Codes" option at the bottom of the web page.

The screenshot shows a web form titled "Size and Codes #1" and "Size and Codes #2". Each section has a "Name/Description" field (placeholder: "Device Name/Accessories/Contents") and a "Reference code" field (placeholder: "Model Number/Reference Code/Sizes"). A red "X" is visible next to the "Size and Codes #2" section. At the bottom, a button labeled "+ Add Size and Codes" is highlighted with a red box. Below the button are "Back" and "Next" buttons.

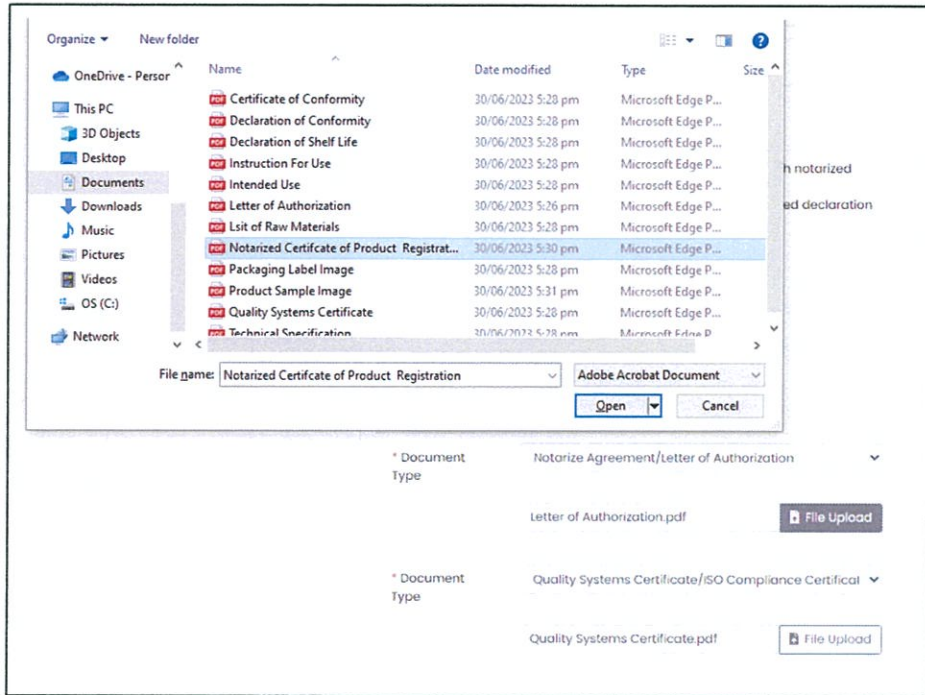
- b. After all the information on sizes and codes have been provided, click "Next" to go to the next page or click "Back" to return to the previous page.

This is a close-up of the bottom of the form. It shows the "+ Add Size and Codes" button, the "Back" button, and the "Next" button. The "Back" and "Next" buttons are highlighted with a red box.

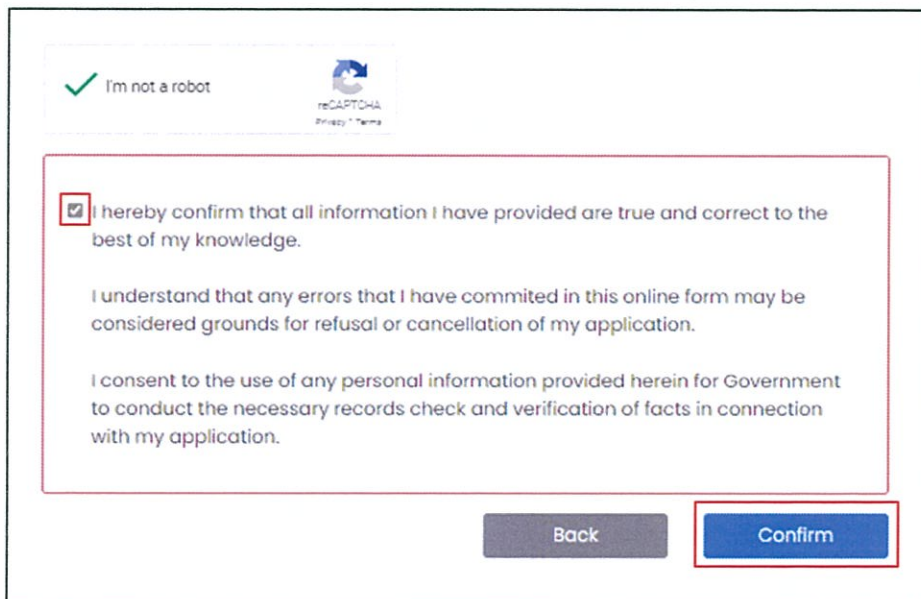
- 13. The "Self-Assessment Review" page allows the applicant to go through all of the information from the preceding pages and make necessary changes.

The screenshot shows the "eServices Portal" interface. The breadcrumb trail is "Home / Applications / Product notification / Medical Device / Cmdn / Initial". The main heading is "Certificate of Medical Device Notification Initial". On the left, a vertical list of steps is shown, with step 8 "Self-Assessment Review" highlighted with a red box. The main content area is titled "Self-Assessment Review" and contains sections for "Application Information" and "Contact Information". The "Application Information" section includes fields for "Type of Application" (Initial), "Product Type" (Certificate of Medical Device Notification), "Risk Classification" (Class A), and "Previous Denial Letter for the same product application" (No). The "Contact Information" section includes a field for "Applicant Name" (qualified personnel/authorized personnel).

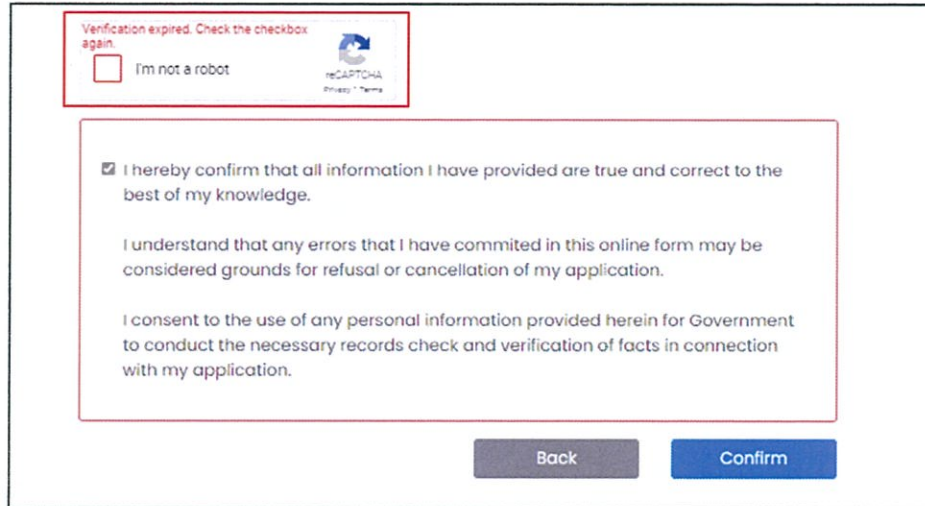
- a. Under the “Documentary Requirements” portion, the applicant can replace the uploaded PDF File by clicking the “File Upload” option and choosing the correct PDF file.



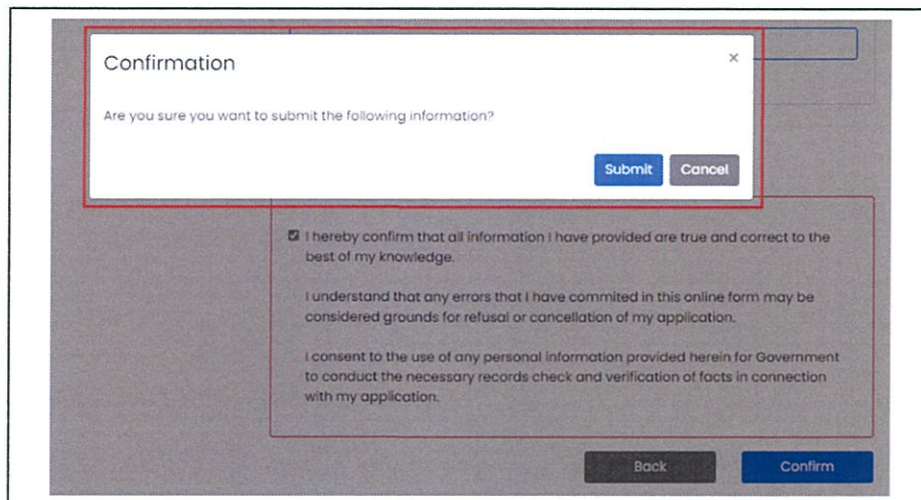
- b. Once all of the information and requirements have been confirmed, check the "I'm not a robot" and tick the "Confirmation and Consent" tab at the bottom of the page and click “Confirm”.



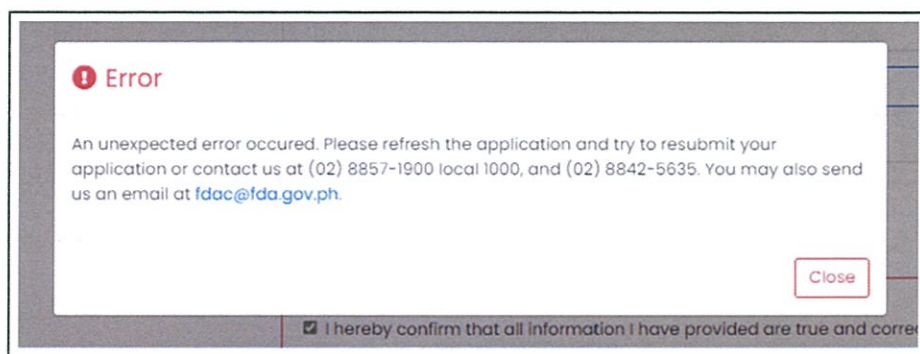
- c. The applicant should immediately click the “Confirm” button to avoid expiry of the verification.



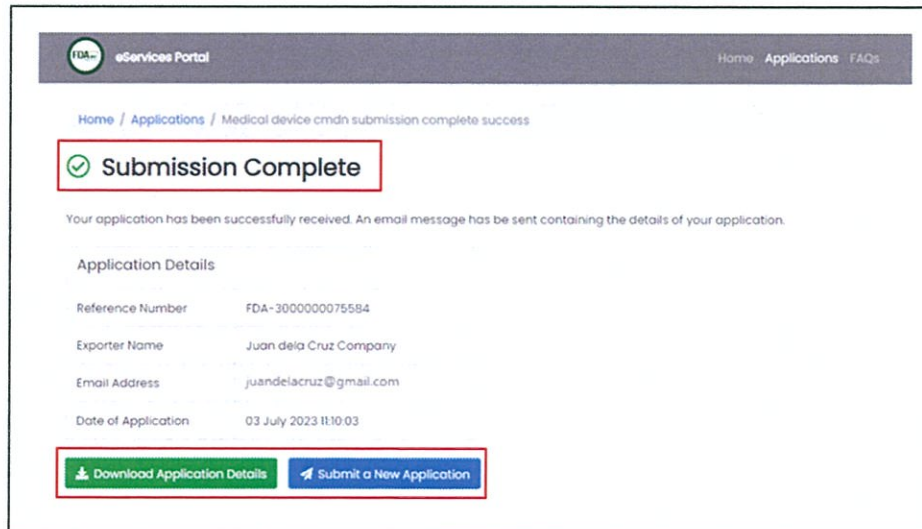
- d. After clicking the “Confirm” button, the applicant will be asked for confirmation on the submission of the provided information. Click “Submit” if there are no more corrections.



- e. Should an error warning appears, double-check the provided information and resubmit the application. If the error warning continues to appear, contact the FDA through the contact information provided in the error warning.



- Once the application is successfully submitted, a “Submission Complete” message will be posted showing the application details. The applicant may download the application details by clicking the “Download Application Details” tab at the bottom of the page. Click the “Submit a New Application” tab to start a new application.



- A generated email will be sent by the FDA to the applicant’s email account in response to the filed application. The generated email contains instructions regarding the Order of Payment.

