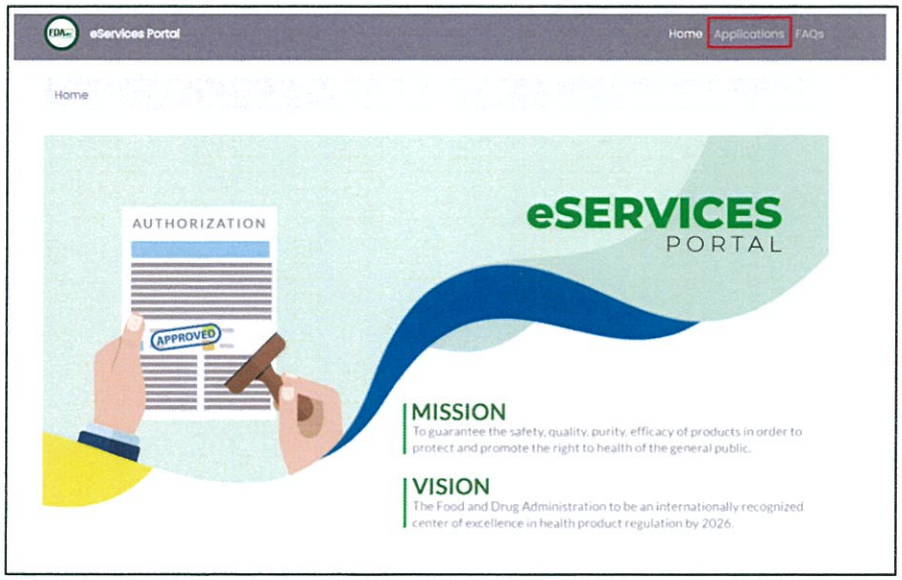
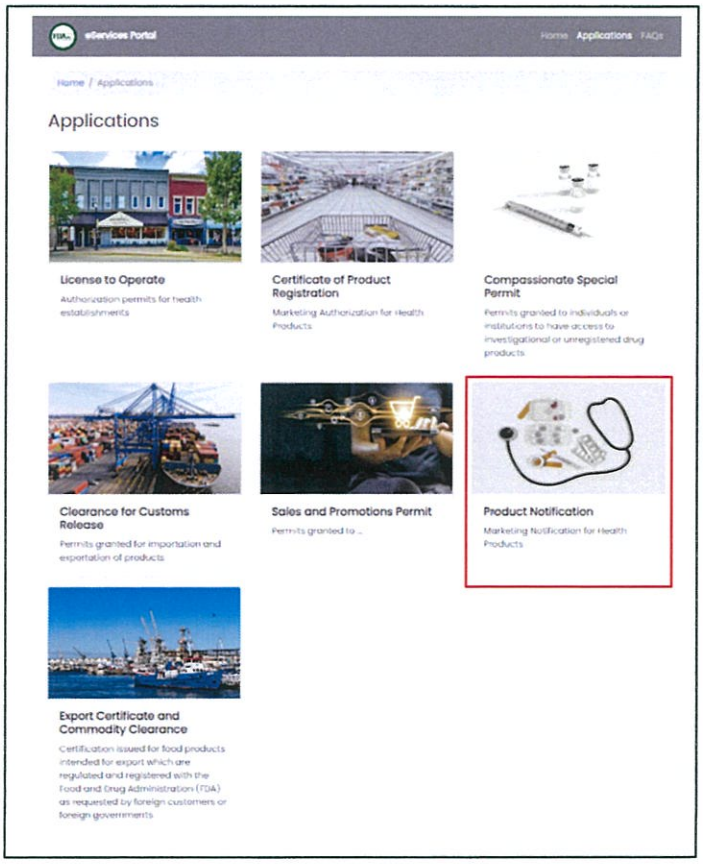
ANNEX A

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

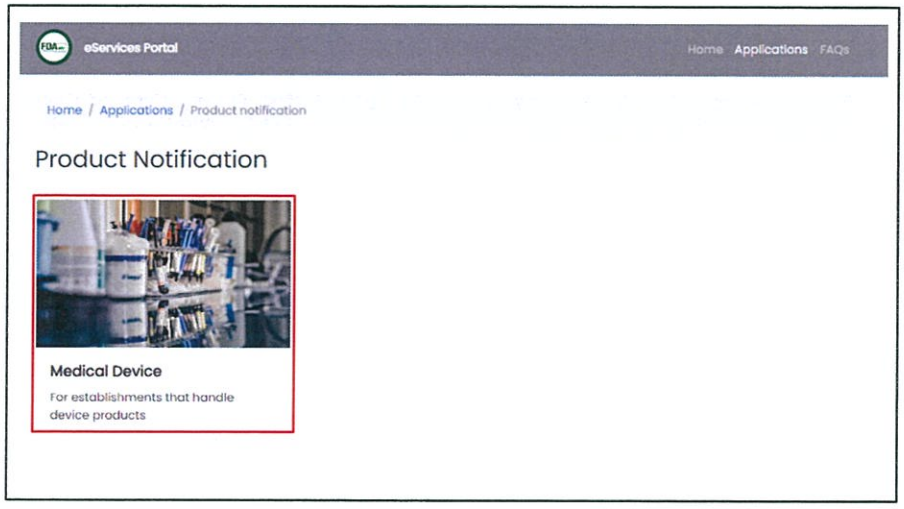
1. To start the application, access the online portal through http://eservices.fda.gov.ph/ and click "Applications" found on the upper right corner of the eServices landing page.



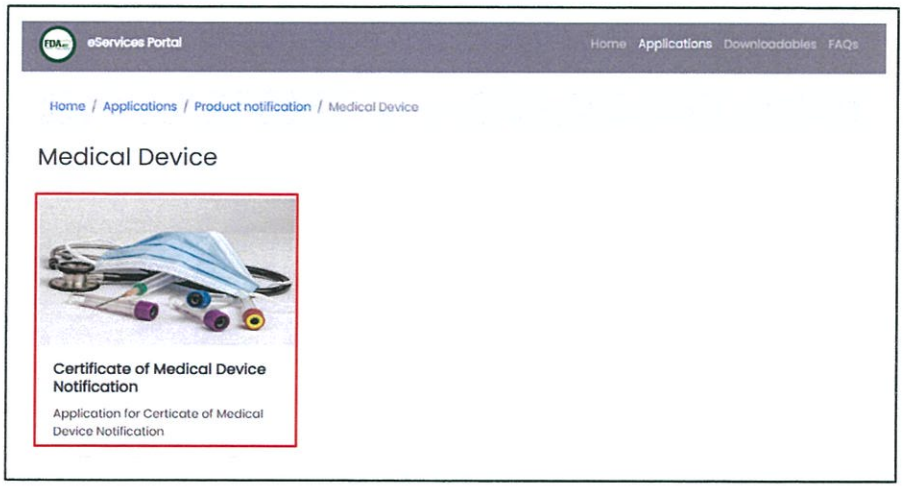
2. Click Product Notification.



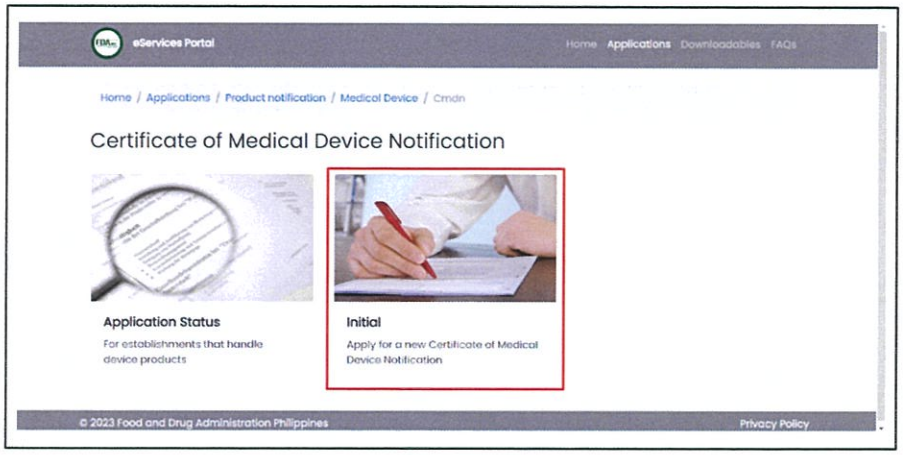
3. Click Medical Device.



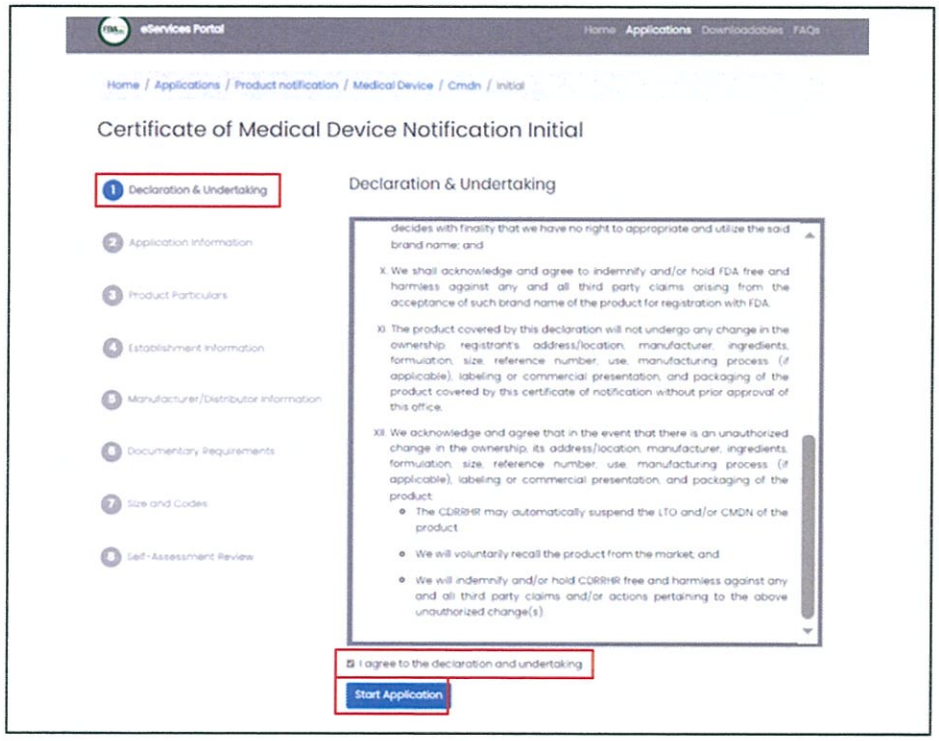
4. Click Certificate of Medical Device Notification.



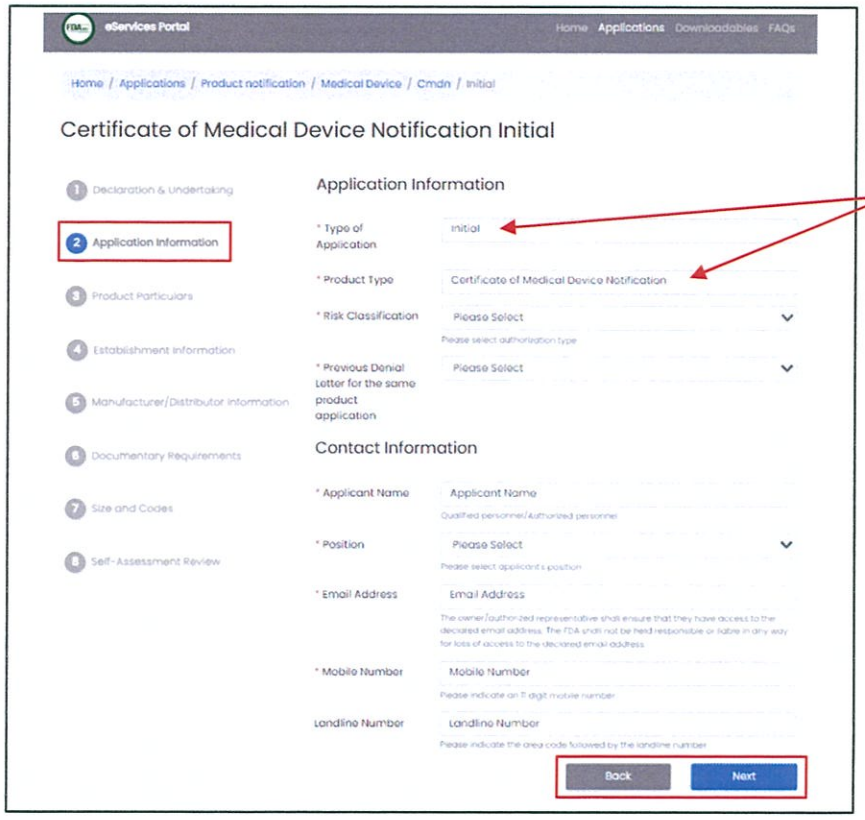
5. Click Initial.



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".

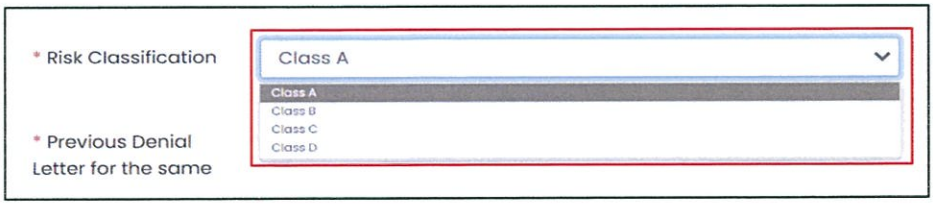


7. Fill out the necessary information accurately based on the application information and contact information. Click "Next" to go to the next page. Click "Back" to return to the previous page.



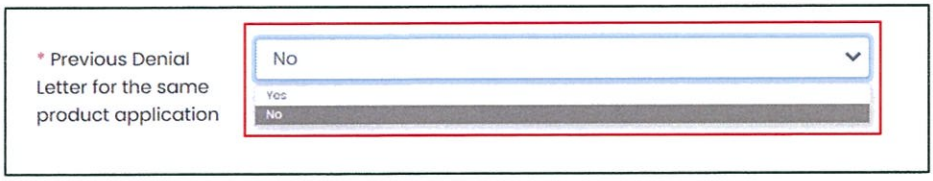
The following information cannot be changed.

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

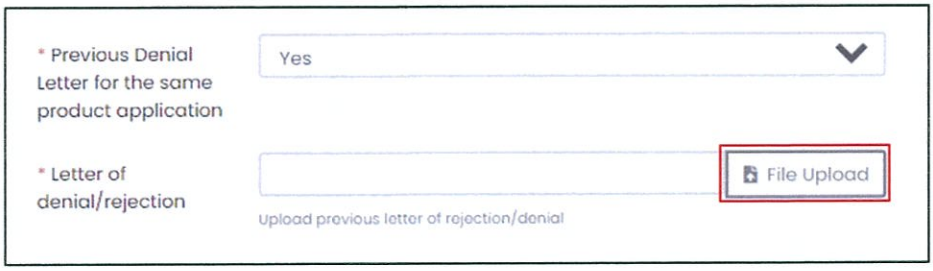


b. Specify whether there is/are previous denial letter/s received for the same product application.

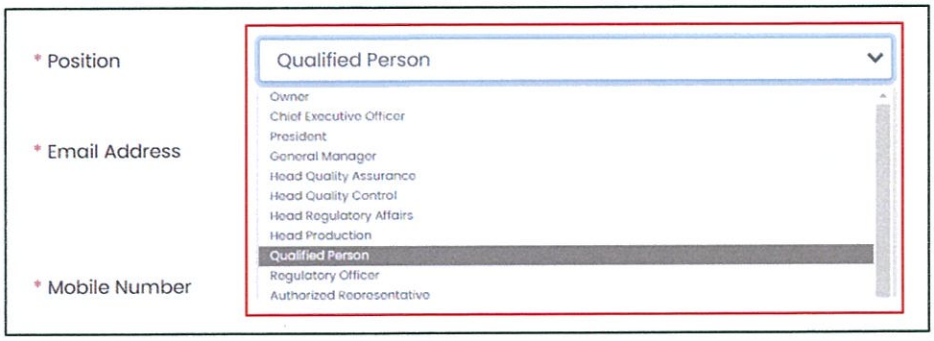
i. If there is no denial letter received, Choose "No".



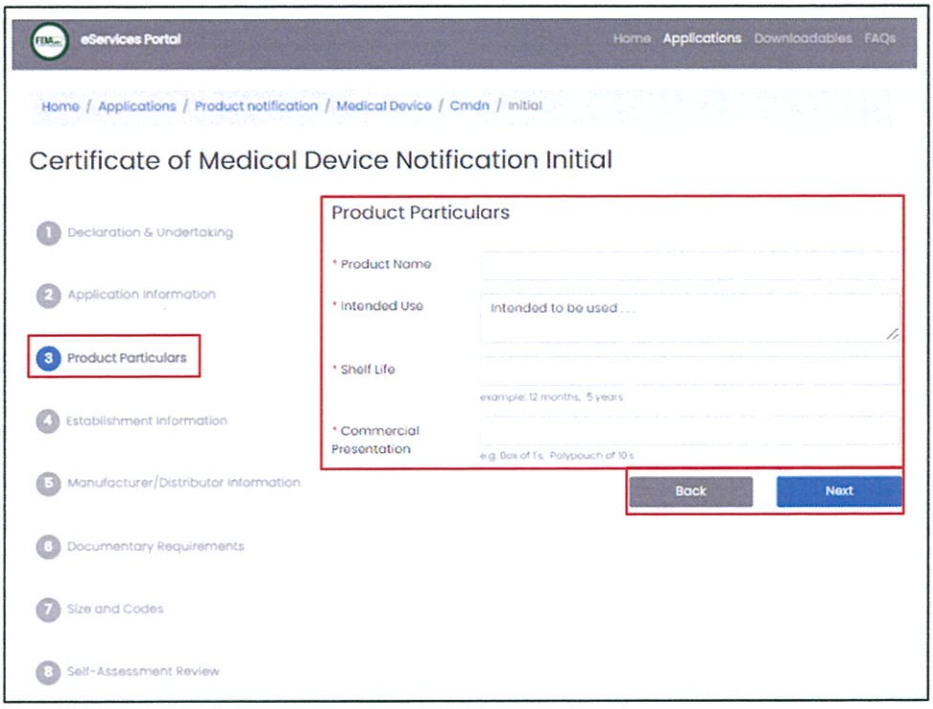
ii. If there is a previous application with a denial letter, choose "Yes" and click "File Upload" to upload the PDF file of the letter of denial.



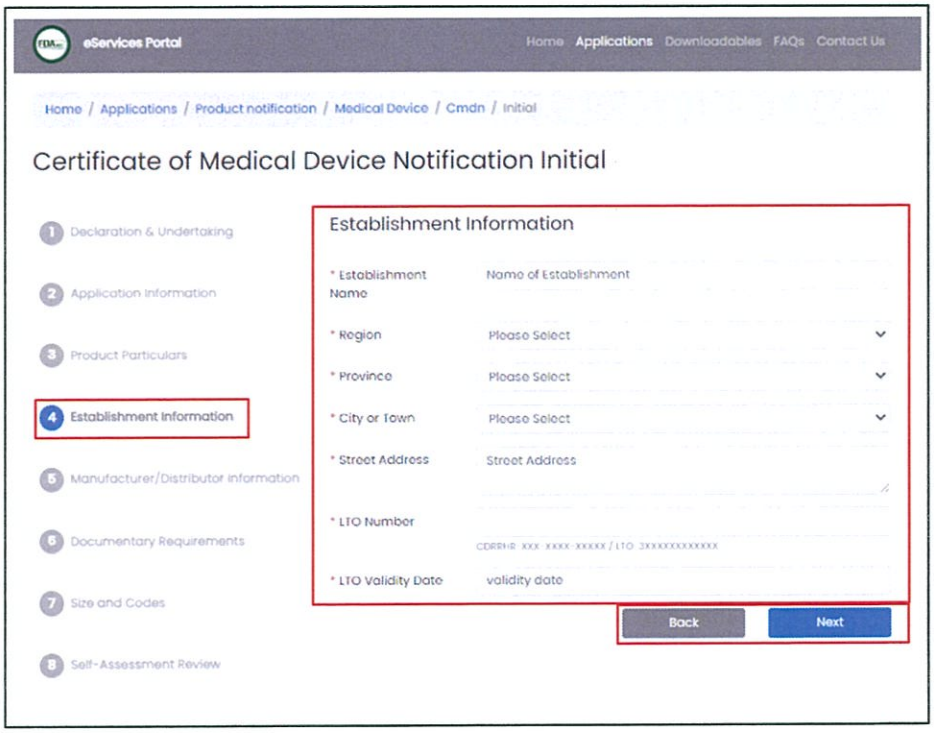
c. For the "Contact Information", choose from the selection the applicant's position in the company/establishment.



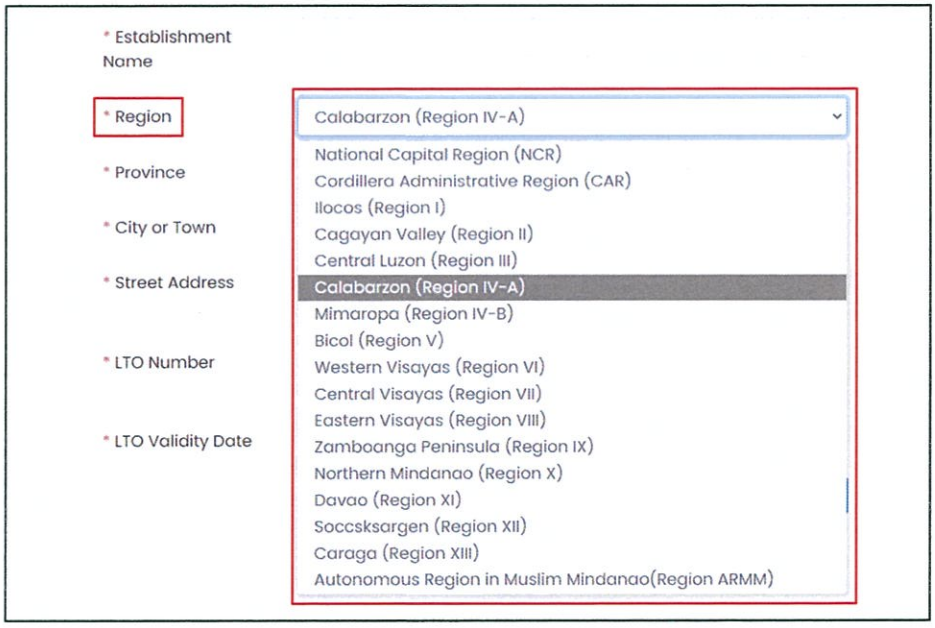
8. Fill out the necessary information accurately based on the product particulars. Click "Next" to go to the next page. Click "Back" to return to the previous page.

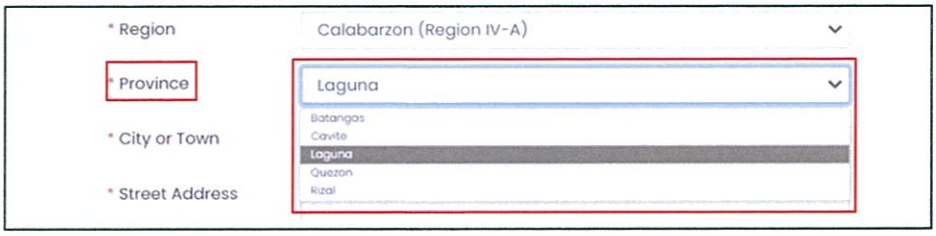


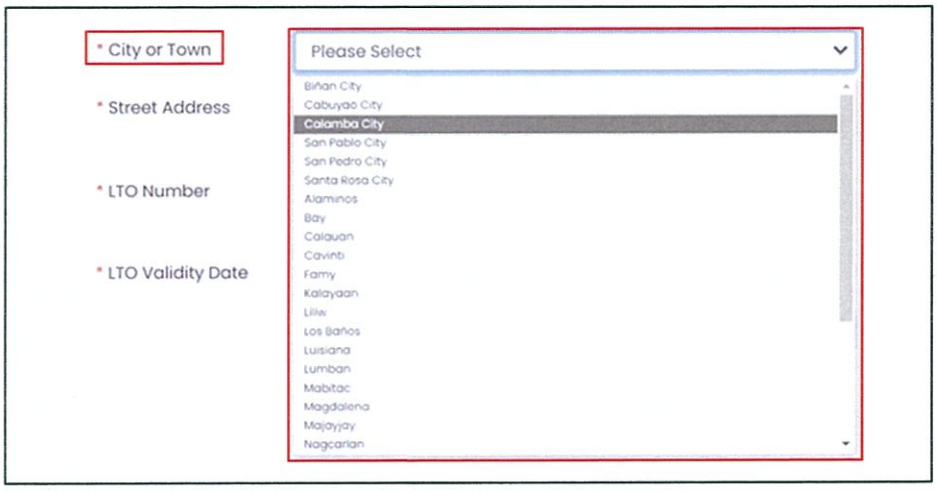
9. Fill out the necessary information accurately based on the client/establishment information. Click "Next" to go to the next page. Click "Back" to return to the previous page.



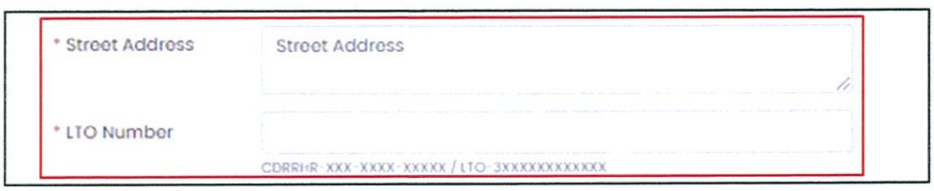
a. Select the region, province, city or town where the establishment is located.



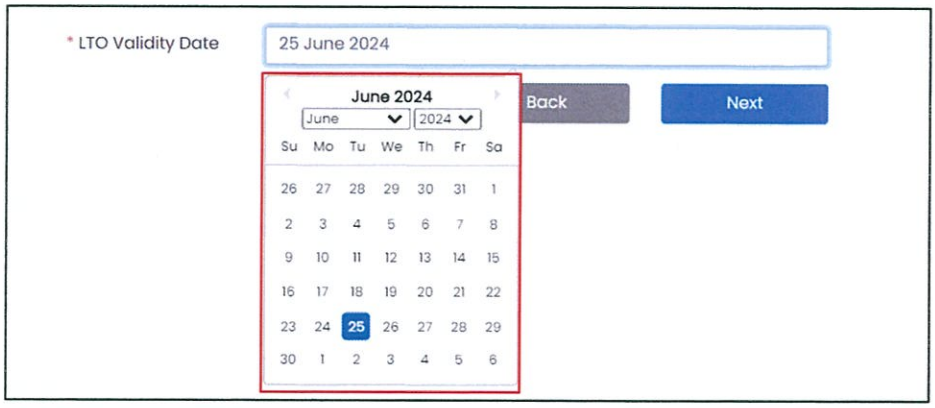




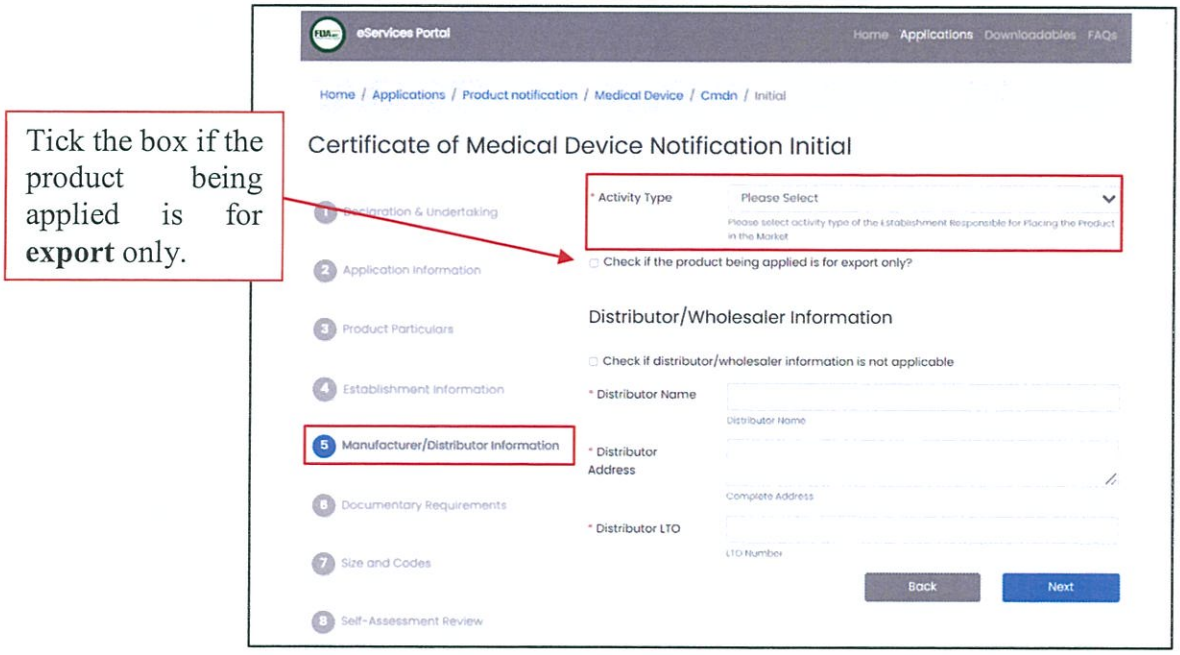
b. Fill out the necessary information accurately based on the street address and the LTO Number.



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

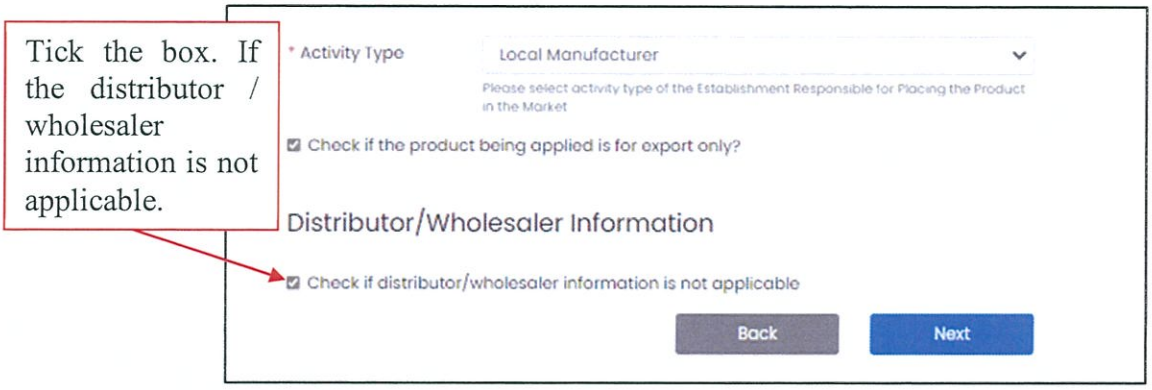


10. Select the type of activity in which their establishment is engaged in.

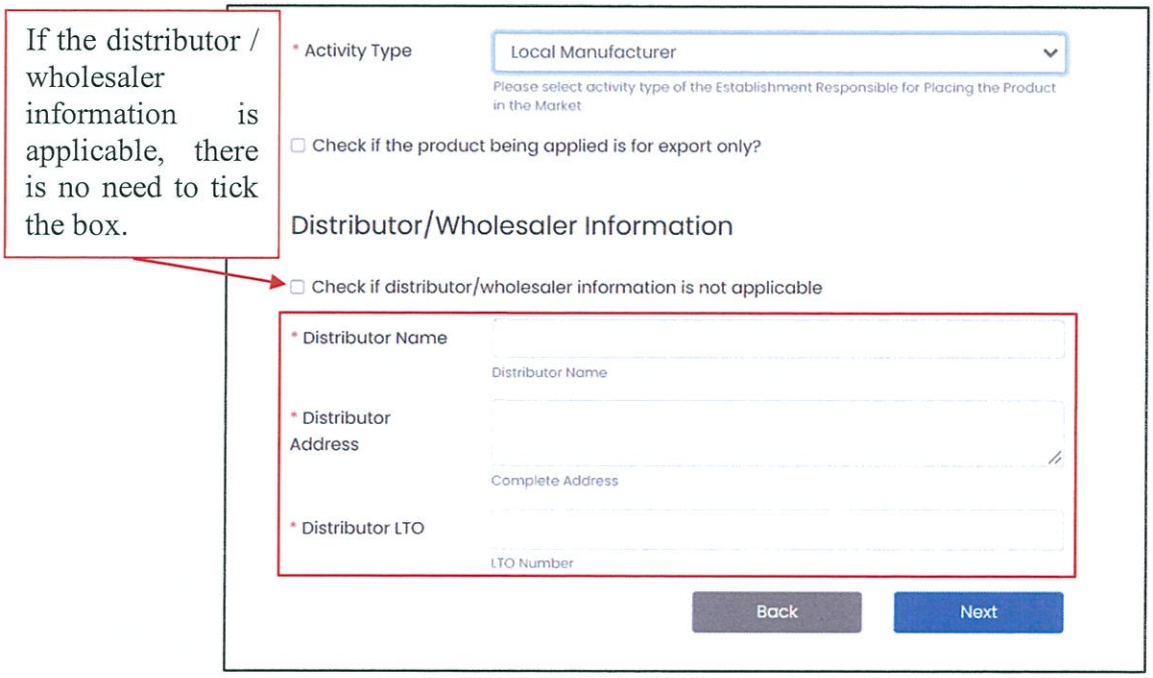


a. The "Distributor/Wholesaler Information" is common to all establishment options. Choose whether this information is applicable or not.

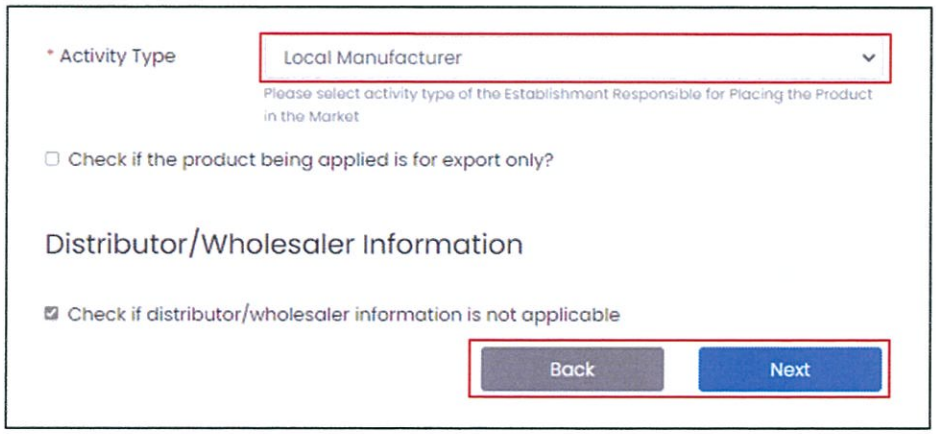
i. If the distributor / wholesaler information is not applicable, tick the box "Check if distributor / wholesaler information is not applicable".



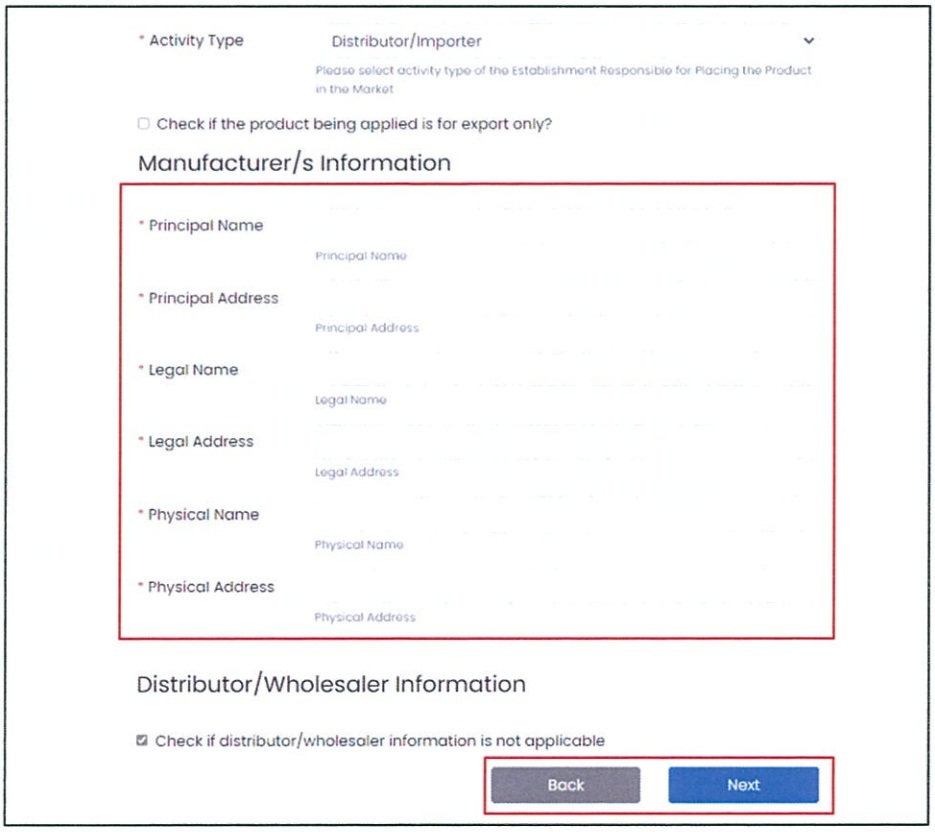
ii. If the distributor / wholesaler information is applicable, there is no need to place a check on the box "Check if distributor / wholesaler information is not applicable". Fill out the necessary information based on the distributor / wholesaler information.



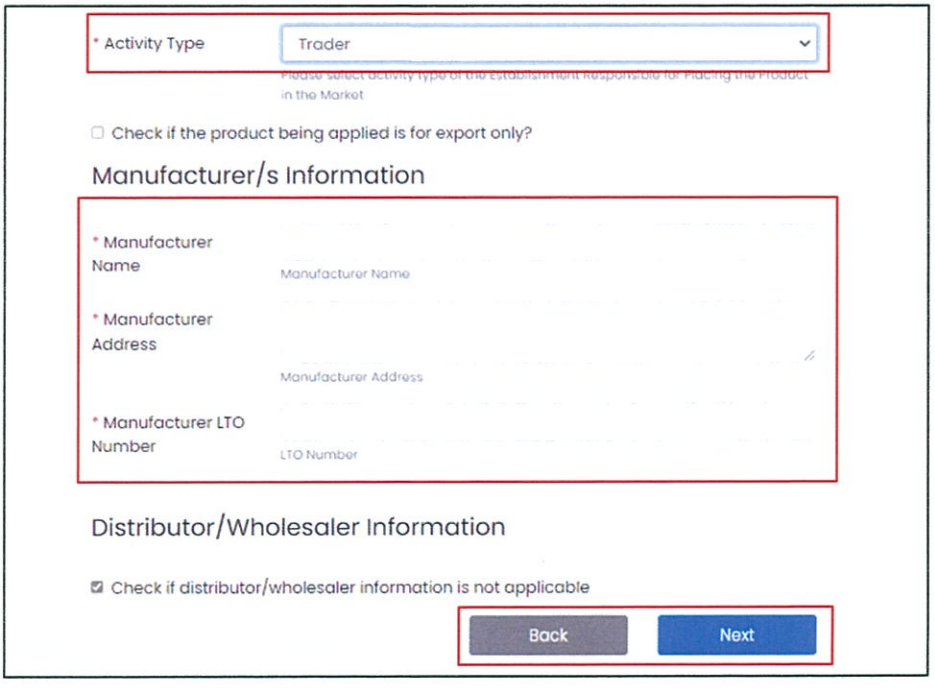
b. If the activity "Local Manufacturer" is selected, the only information required is the activity type "local manufacturer". Click "Next" to go to the next page. Click "Back" to return to the previous page.



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.

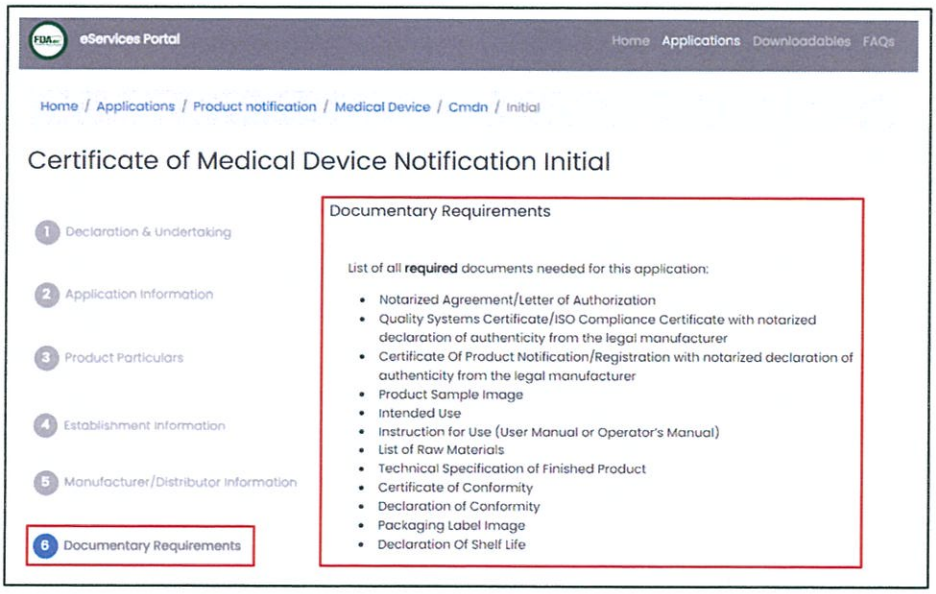


d. If the activity "Trader" is selected, fill out the necessary information accurately based on the manufacturer/s information. Click "Next" to go to the next page. Click "Back" to return to the previous page.

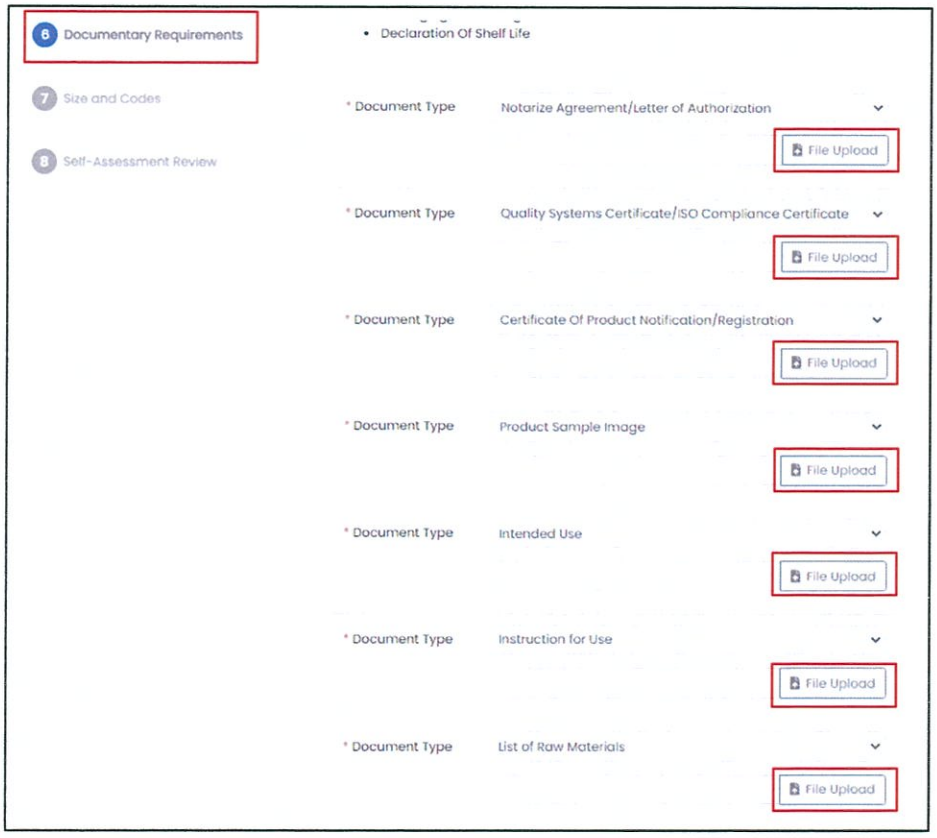


11. Submit the required documents needed for the application.

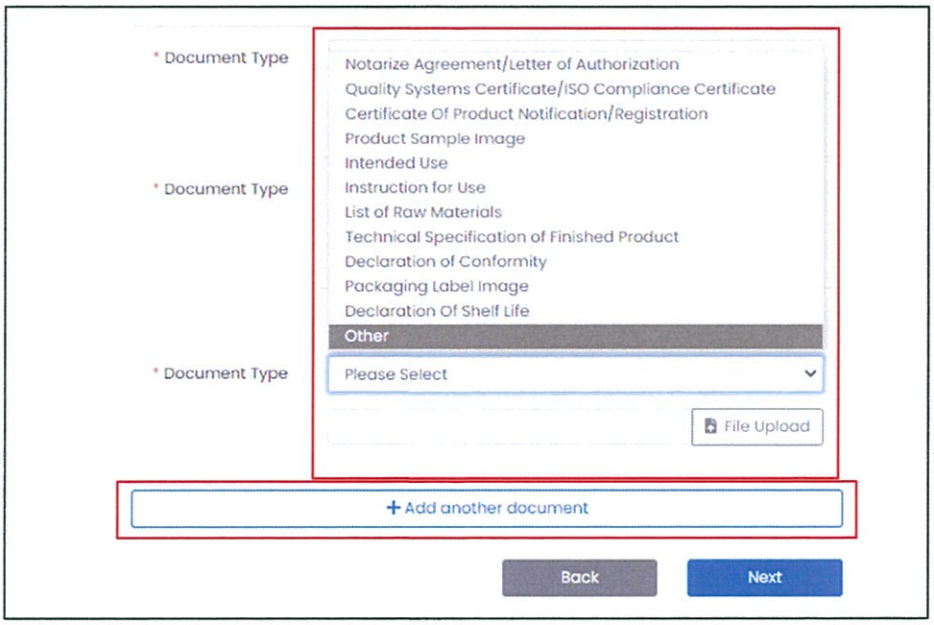
    a. The applicant will find a thorough list of application requirements in the upper section of the web page.



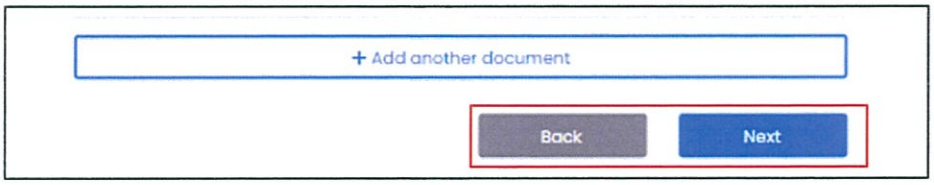
    b. Upload the required documents by clicking the "File Upload" button accessible for each type of document in the lower section of the webpage. The file to be uploaded should be named according to the type of documentary requirement and should be in searchable PDF format, 150 DPI and not exceed two (2)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



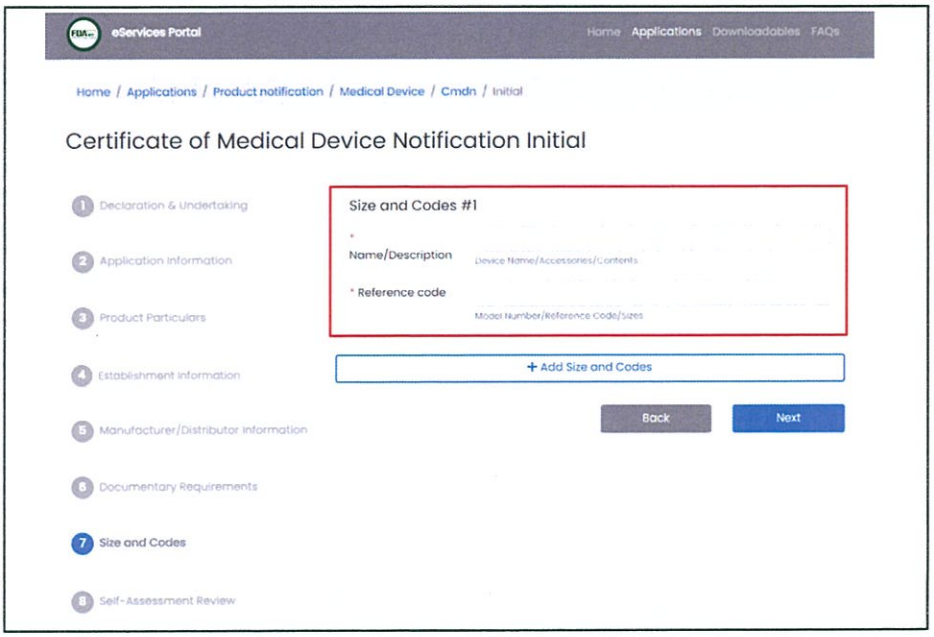
c. If necessary, additional documents may be included by clicking the "+ Add another document" option at the bottom of the web page. The applicant has the option of selecting the type of document to upload.



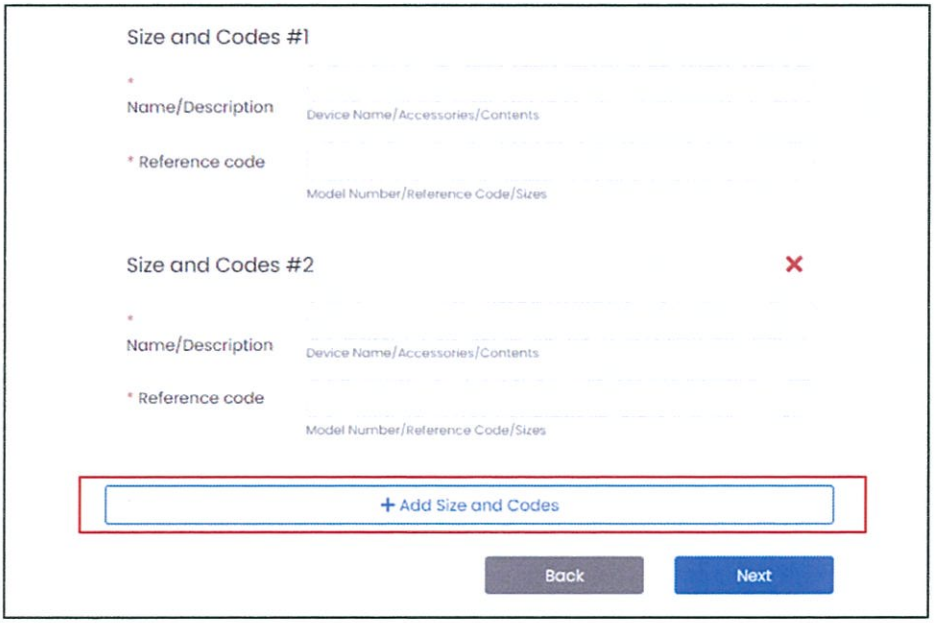
d. After all the documentary requirements have been uploaded, click "Next" to go to the next page or click "Back" to return to the previous page.



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.

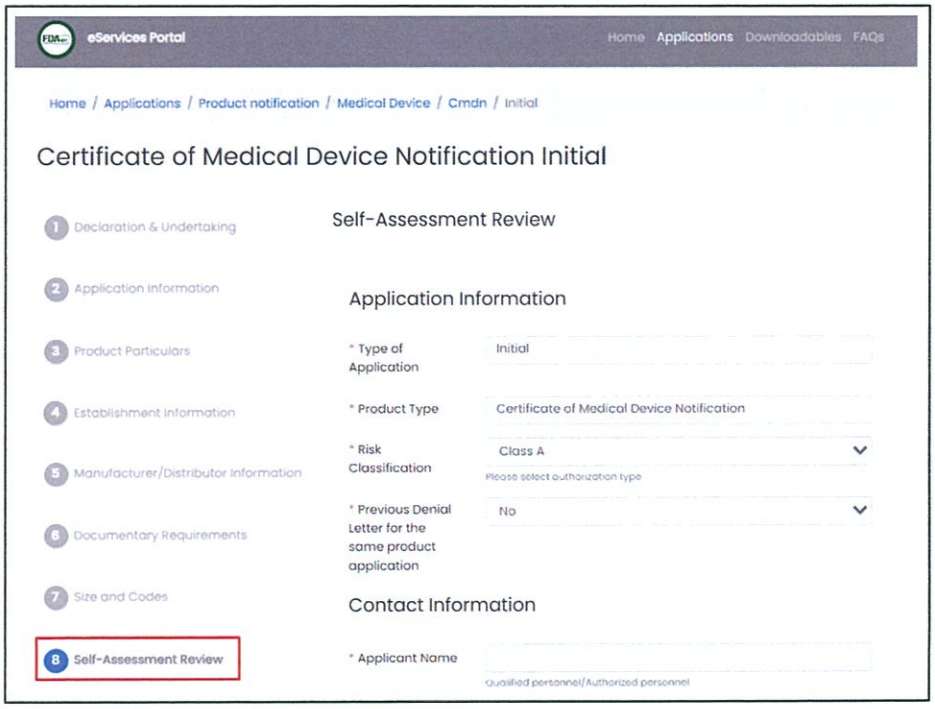


a. Additional sizes and codes may be included by clicking the "+ Add Size and Codes" option at the bottom of the web page.

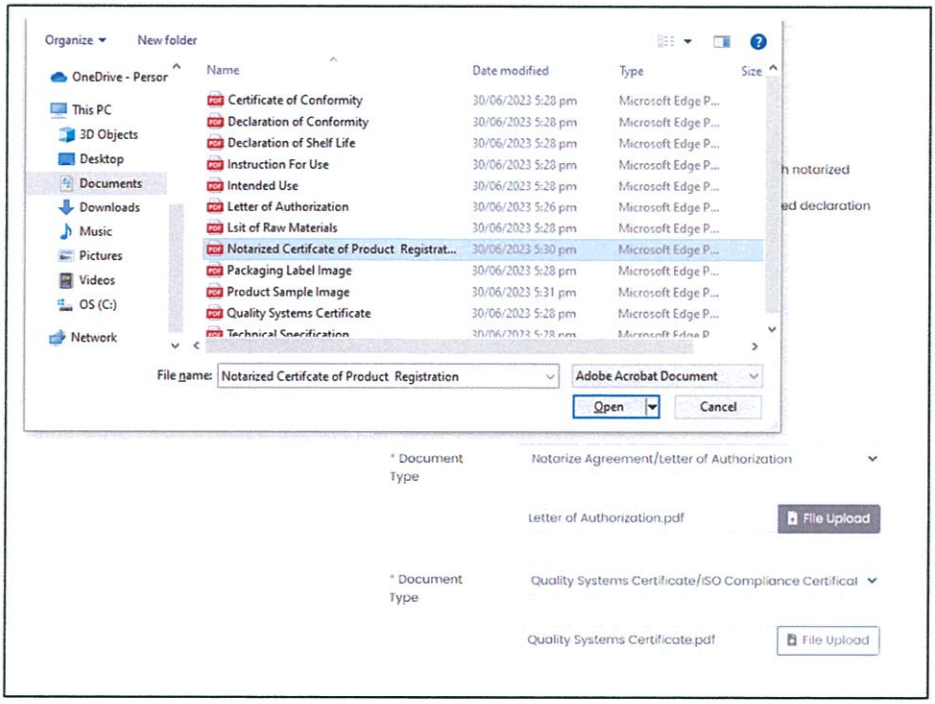


b. After all the information on sizes and codes have been provided, click "Next" to go to the next page or click "Back" to return to the previous page.

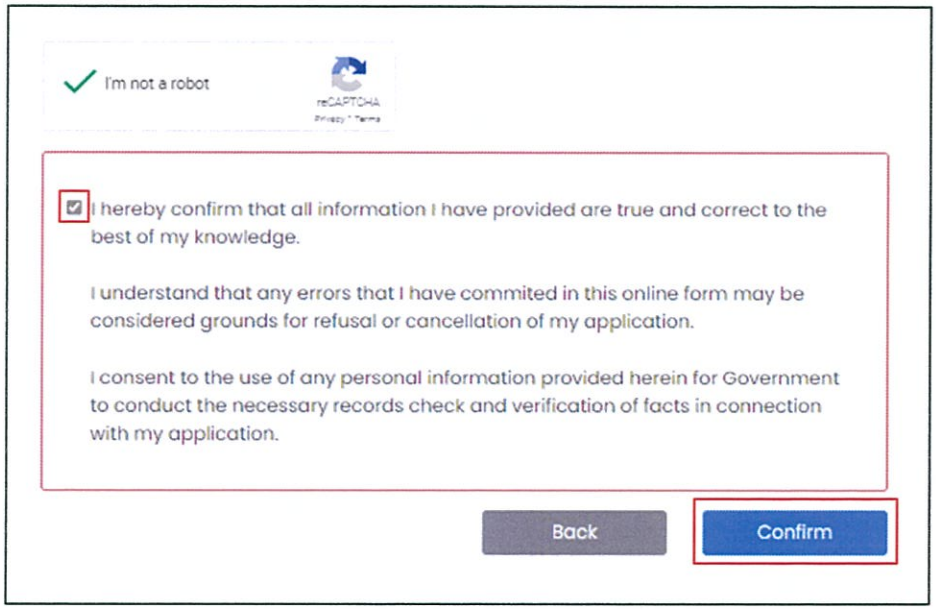
13. The "Self-Assessment Review" page allows the applicant to go through all of the information from the preceding pages and make necessary changes.



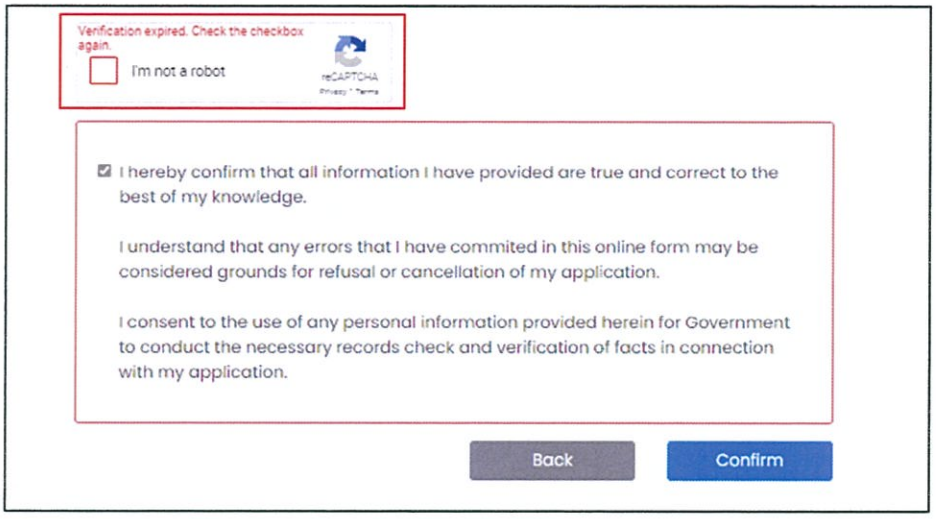
a. Under the "Documentary Requirements" portion, the applicant can replace the uploaded PDF File by clicking the "File Upload" option and choosing the correct PDF file.



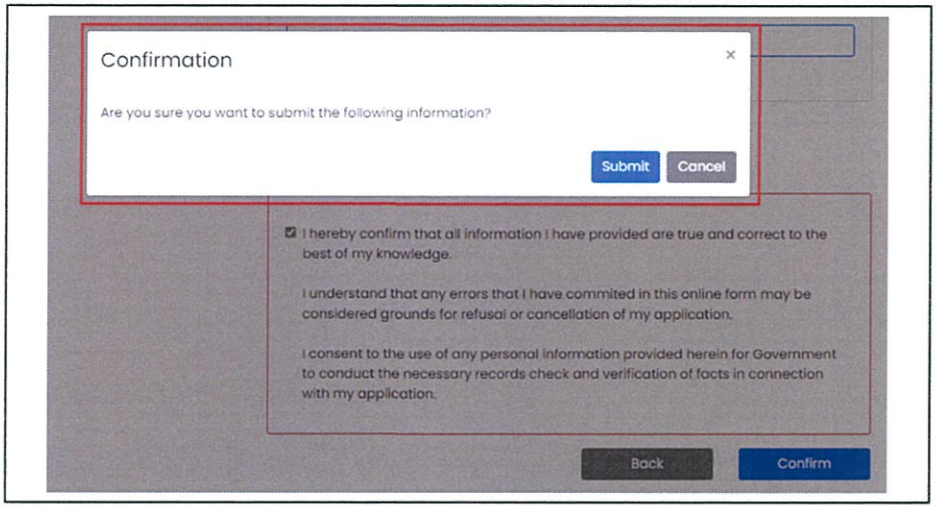
b. Once all of the information and requirements have been confirmed, check the "I'm not a robot" and tick the "Confirmation and Consent" tab at the bottom of the page and click "Confirm".



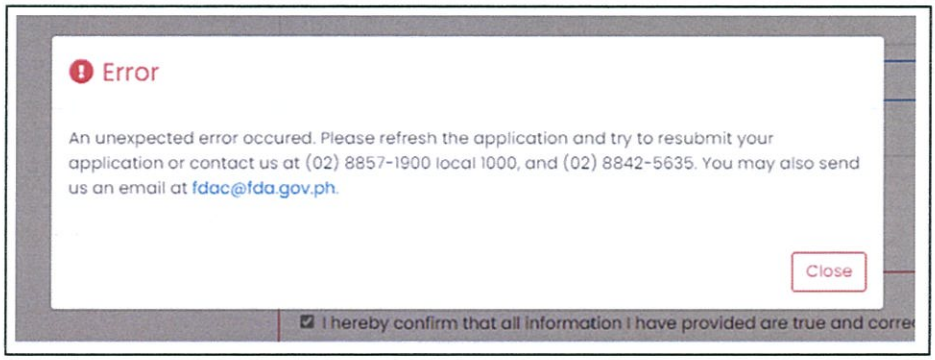
c. The applicant should immediately click the "Confirm" button to avoid expiry of the verification.



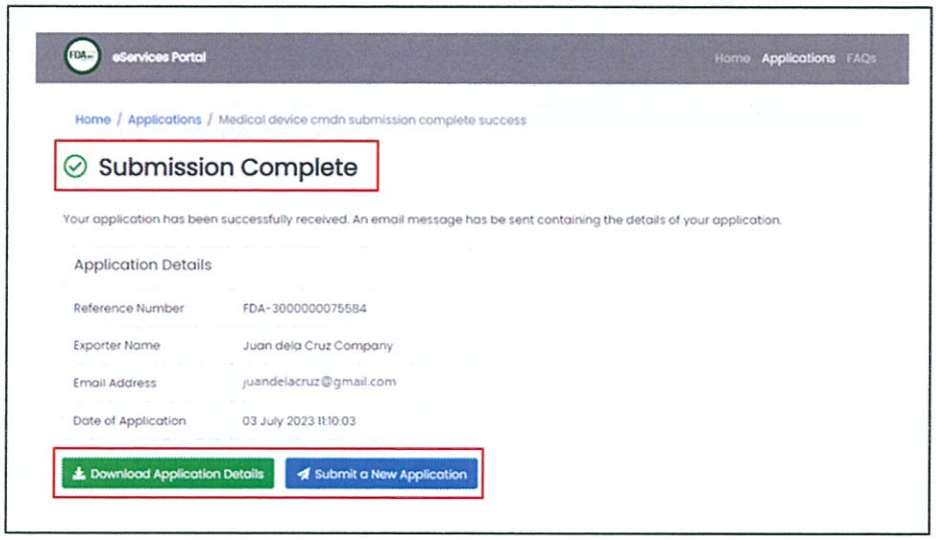
d. After clicking the "Confirm" button, the applicant will be asked for confirmation on the submission of the provided information. Click "Submit" if there are no more corrections.



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.



14. 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.



15. 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.