



FDA CIRCULAR  
No. 2022-007

09 SEP 2022

SUBJECT : Guidelines on the Use of the Food and Drug Administration eServices Portal System for License to Operate (LTO) Application of Retailers of Medical Devices

## I. RATIONALE

The Food and Drug Administration (FDA) through Republic Act (RA) No. 9711, otherwise known as the “*Food and Drug Administration Act of 2009*” is mandated to develop and issue standards and appropriate authorizations that would cover establishments, facilities, and health products under its jurisdiction.

RA No. 11032, otherwise known as the “*Ease of Doing Business and Efficient Government Service Delivery Act of 2018*”, mandates all government agencies to simplify and expedite documentary requirements and procedures for business and non-business-related transactions. Such efforts are also compliant with the provisions of RA 8792 or the “*Electronic Commerce Act of 2000*” that promotes the universal use of electronic transactions in government services.

This is also in line with the initiatives embodied in Administrative Order (A.O.) No. 2020-0017 of the Department of Health entitled, “*Revised Guidelines on the Unified Licensing Requirements and Procedures of the Food and Drug Administration Repealing Administrative Order No. 2016-0003*”. The objective of AO 2020-0017 is to reengineer and streamline FDA’s processes, specifically, on the issuance of License to Operate (LTO) for FDA regulated establishments including all Retailers of Medical Devices through a web-based application platform.

On 07 October 2021, the FDA issued FDA Circular (FC) No. 2021-021 entitled, “*Guidelines on the Licensing of Retailers of Medical Devices in the Philippines*”. This issuance seeks to provide technical guidance to Medical Device Retailers with regard to regulatory compliance in forms of licensing requirements and qualification criteria of the establishments’ qualified personnel. Such guideline shall be construed as part of the eServices Portal procedures which shall be discussed in this FDA Circular.

In this light, the FDA eServices Portal System has been developed to provide a streamlined online platform for FDA Authorization applications. Through this Circular, the FDA eServices Portal has also been updated to include LTO applications of Retailers of Medical Devices.



## **II. OBJECTIVE**

The objective of this Circular is to provide guidelines on the use of the FDA eServices Portal System for the LTO application of Retailers of Medical Devices.

## **III. SCOPE**

This Circular shall cover the following LTO applications:

### **A. Types of Establishments:**

1. Retail stores for medical devices;
2. Clinics that sell products classified as medical devices except those that are covered by the DOH One Stop Shop Licensing System;
3. Sellers of products classified as medical device through online shopping website and social media platforms with physical office;
4. TV shopping companies that sell or offer to sell medical device directly to the general public;
5. Optical shops;
6. Drug outlets, such as drugstores, and retail outlets for non-prescription drugs (RONPD) that also sell or offer to sell medical devices.

### **B. Types of LTO application:**

1. Initial;
2. Renewal; and
3. Variation

## **IV. DEFINITION OF TERMS**

The terms used in this Circular shall have the same definition as prescribed in RA 9711 and its Implementing Rules and Regulations (IRR), AO No. 2020-0017, FDA Circular (FC) No. 2021-021 on the Guidelines on the Licensing of Retailers of Medical Devices in the Philippines, and other applicable laws and regulations.

## **V. GENERAL GUIDELINES**

The Guidelines on the eServices application for LTO of the establishments enumerated under Section III.A of this FDA Circular shall be expounded herein. Whereas, the technical requirements and other guidelines relative to the licensing of establishments in accordance with their compliance with the FDA regulations shall also be provided in AO 2020-0017 and FC No. 2021-021.

In addition, qualification requirements for Optometrists relative to licensing of Optical Shops shall be expounded in this FDA Circular.

By applying for an FDA LTO, the establishment understands and abides by the rules and regulations set forth by the Agency. The establishment shall have the ultimate

responsibility as to their compliance with national and/or international standards of safety, quality, purity, and efficacy of health products they provide to the consumers and the general public.

#### A. Application Process

1. The application shall be filed online through the eServices Portal website ([eservices.fda.gov.ph](http://eservices.fda.gov.ph)). The creation of account and password is no longer a requirement to obtain access to the eServices Portal.
2. The applicant is expected to agree with the “**Declaration and Undertaking**” in order to continue with the application. Such conveys a binding agreement of the applicant company with the FDA to provide accurate information, affirm primary responsibility over the products, and comply with all the rules and regulations set forth during and after the application process. Any misrepresentation of the information in this application shall be subjected to administrative and criminal liabilities, provided by R.A. 9711, which includes, but not limited to suspension, cancellation, or revocation of the LTO.
3. In filling-out the fields in the eApplication form, the applicant shall be assisted with written warnings/pop-ups/reminders before proceeding to the next step to ensure accuracy of the information being provided. The establishment applying for LTO shall ensure that the declared information in the eApplication form is consistent with the uploaded supporting documents, i.e., establishment name and owner, establishment’s address, and others.
4. The declared e-mail address under the Contact Information is **unalterable**. Hence, the applicant shall be responsible in making sure that the e-mail address is within the scope and access of the Authorized Person/s, Qualified Personnel, and/or owner of the establishment. The FDA shall not be held liable in any way for loss of access to the declared e-mail address.

In the event that the company wishes to change the declared e-mail address during the initial application, the applicant may send a request addressed to the FDA – Food and Drug Action Center at [fdac.pacd@fda.gov.ph](mailto:fdac.pacd@fda.gov.ph).

The Company Authorized Officer or Qualified Personnel shall comply with the regulatory and technical requirements of the FDA.

- a. The **Authorized Person** refers to the owner, President, Chief Executive Officers (CEO) or its equivalent, or any organic or full-time employee representing the establishment in an authorized or official capacity; and
  - b. The **Qualified Person** refers to an organic or full-time employee of the establishment who possesses technical competence related to the establishment’s activities and health products by virtue of his profession, training, or experience. The Qualified Person may also be the duly Authorized Person of the establishment.
5. Variation and renewal applications shall be applied separately. If the retailer of medical devices is due for renewal, but is expected to apply for changes in

information that need to be reflected in the system or registry, then a renewal application shall first be submitted and approved by the FDA prior to the application for variation.

The clients shall be informed that the LTO to be issued upon renewal shall reflect the previous information and the updating shall be done through filing of a separate variation. In addition, the clients cannot apply for a renewal of application if not within three (3) months prior to the validity date of the LTO.

6. For any variation, the establishment shall be required to file for a new notification.
7. For applications filed through the FDA eServices Portal System, there shall be a change in the format of LTO number as such;  
Old: 300000XXXXXX  
New: CDRRHR-(Region)-(Activity)- (Sequence Number)
8. Documents required to be uploaded in the eApplication form shall be in portable document file (PDF), with no more than 2 megabytes (MB) file size.
9. Once the eApplication Form is completed, applicants can review the duly filled out form in the Self-Assessment Review. By agreeing to the terms and conditions, the applicant shall confirm to the correctness of information provided and data privacy terms.
10. The Application Summary shall be automatically sent to the applicant's registered e-mail address to indicate the successful submission of the application in the eServices Portal.
11. Applications filed after the prescribed working/office hours or during weekends and holidays shall be considered filed on the next working day.
12. The status of the application can be monitored at eServices website by validating through the reference code to be sent to the registered e-mail address used for the application.

*(The step-by-step procedures in the eServices Portal for the LTO application of Retailers of Medical Devices are attached as Annexes in this issuance)*

#### **B. Qualified Person for Retailers of Ophthalmic Lenses and Similar Devices**

1. Optical Shop shall have one (1) Optometrist based on RA 8050 otherwise known as the "Revised Optometry Law of 1995" and one (1) Qualified Person pursuant to AO 2020-0017 per branch/establishment. In the event that the establishment during its application with the FDA registered the same Optometrist and Qualified Person, then it shall be understood that the same person shall act on both roles as defined by this issuance.
2. The Optometrist and Qualified Person per branch/establishment shall always be available during operating hours. They may operate or work in more than one

(1) optical shop/clinic provided that their schedules shall not overlap with respective operating hours of other branches/establishments.

3. Section V.B.2 of FC No. 2021-021 is hereby amended to read as follows:

For Optical Shop that retail ophthalmic lenses, prisms, contact lenses, and their accessories and solutions, low vision aids, and similar appliances and devices, wherein dispensing is governed by RA 8050 otherwise known as the "Revised Optometry Law of 1995", there shall be one (1) Qualified Person per branch/establishment. The Qualified Person can be a registered professional or graduate of allied health course including but not limited to Optometry, Doctor of Medicine, Pharmacy or other courses relevant to the medical devices being handled.

## **VI. SPECIFIC GUIDELINES**

### **A. Application Requirements**

Based on AO No. 2020-0017, the requirements that follow must be submitted:

#### 1. Initial Application

##### a. Accomplished eApplication form with Declaration and Undertaking

- i. Location Plan;
- ii. Global Positioning System (GPS) Coordinates; and
- iii. Name of Qualified Person, depending on the type of health product establishment

##### b. Proof of Business Name Registration

- i. For Single Proprietorship, Certificate of Business Registration issued by the Department of Trade and Industry (DTI).
- ii. For Corporation, Partnership and other Juridical Person, the Certificate of Registration issued by the Security and Exchange Commission (SEC) and Articles of Incorporation.
- iii. For Government owned and Controlled Corporation, the law creating the establishment, if with original charter, or its Certificate of Registration issued by the SEC and articles of Incorporation, if without original charter.
- iv. For Cooperatives, proof of Business Name Registration issued by the Cooperative Development Authority.

##### c. Payment of Fees based on the latest FDA issuance

- d. Business Permit (e.g., LGU/Mayor's Permit, Barangay Business Clearance/Permit) - if the business establishment address is different from the business name registration address.

- e. For Trader, latest audited Financial Statement with Balance Sheet (in pdf) shall be submitted. This is to verify the capitalization of establishment to their corresponding application fee.

2. Renewal Application

- a. Accomplished e-Application Form with Declaration of Undertaking; and
- b. Payment of Fees based on the latest FDA issuance

3. Variation Application

- a. Accomplished e-Application Form with Declaration of Undertaking;
- b. Documentary requirements depending on the variation of circumstances of the establishment or the product; and

<b>Type of Variation</b>	<b>Document Requirement</b>
Transfer of Location of Offices <ul style="list-style-type: none"> <li>• Physical transfer of the office of the establishment</li> </ul>	Proof of business address reflecting the new office location: <ol style="list-style-type: none"> <li>1. For Single Proprietorship: Business Permit/Mayor's Permit or Barangay Business Permit/Clearance reflecting the new office location;</li> <li>2. For Securities and Exchange Commission (SEC)-registered establishments:               <ol style="list-style-type: none"> <li>a. Amended Articles of Incorporation (if transferred from one city/municipality/province; or</li> <li>b. Updated General Information Sheet (GIS) from SEC (if transferred within the same city/municipality/province)</li> </ol> </li> <li>3. If the establishment address is different from the address indicated in the SEC registration, provide LGU/Mayor's Permit or Barangay Business Permit/Clearance reflecting the new office location</li> </ol>
Transfer/addition of Warehouse <ul style="list-style-type: none"> <li>• Physical transfer and addition of warehouse of the establishment</li> </ul>	Mayor's Permit or Barangay Business Permit/Clearance reflecting the new warehouse location

<p>Change of Ownership</p> <ul style="list-style-type: none"> <li>Change in ownership of the licensed establishment</li> </ul>	<ol style="list-style-type: none"> <li>Business name registration reflecting new ownership</li> <li>Any proof on the transfer of ownership such as any of the following: <ol style="list-style-type: none"> <li>Deed of sale or assignment or transfer of rights/ownership;</li> <li>Memorandum of Agreement; or</li> <li>Notarized Affidavit of the owner, proprietor, Chairman or Chief Executive Officer (CEO) of the establishment validating the transfer</li> </ol> </li> </ol>
<p>Change of Business Name</p> <ul style="list-style-type: none"> <li>Change only in the business name of the establishment</li> </ul>	Business name registration reflecting the new business name
<p>Zonal Change in Address</p> <ul style="list-style-type: none"> <li>Change of the name/number of the street/building without physical transfer of the establishment</li> </ul>	<ol style="list-style-type: none"> <li>Certificate of Zonal Change</li> <li>Certification from Local Government Unit (LGU) (City/Municipality) stating no physical transfer of the establishment</li> </ol>
<p>Change of Qualified Person</p> <ul style="list-style-type: none"> <li>Change in the identified qualified person initially registered with the FDA</li> </ul>	<ol style="list-style-type: none"> <li>Name of the new Qualified Person</li> <li>Valid Professional Regulation Commission (PRC) ID</li> <li>Signed Letter of Resignation duly noted by the former employer, if previously connected with another pharmacy/establishment</li> </ol>
<p>Change of Authorized Person</p> <ul style="list-style-type: none"> <li>Change of authorized person initially registered with the FDA</li> </ul>	<ol style="list-style-type: none"> <li>Name of the new Authorized Person</li> <li>Valid Government ID</li> <li>Updated contact details</li> </ol>

c. Payment of Fees based on the latest FDA issuance.

### B. Qualification and Credential Requirements of the Qualified Person

Qualification	Training Requirements
<p>Registered professionals or graduates in the field of allied health profession including but not limited to the following:</p> <ul style="list-style-type: none"> <li>Nurse</li> <li>Dentist</li> <li>Pharmacist</li> <li>Optometrist</li> <li>Medical Technologist</li> <li>Radiologic Technologist</li> <li>Medical Doctor</li> <li>Physical Therapist</li> <li>Computer Science Graduate</li> <li>Chemist</li> <li>Engineering Professions, to include but not limited to the following:</li> </ul>	<ol style="list-style-type: none"> <li>PRC ID for professions with Board/Licensure Exam or Diploma for professions without Board/Licensure Exam</li> <li>Certificate of Attendance to seminars, trainings, learning and development activities on medical device safety, quality and use given by the academe, industry, organization, professional organization, National Regulatory Authorities, international organization (World Health Organization, International Organization for Standardization, among others)</li> </ol>

<ul style="list-style-type: none"> <li>- Electronic Engineer</li> <li>- Electrical Engineer</li> <li>- Mechanical Engineer</li> <li>- Chemical Engineer</li> <li>- Computer Engineer</li> <li>- Manufacturing Engineer</li> <li>- Sanitary Engineer</li> <li>- Environmental Engineer</li> </ul> <ul style="list-style-type: none"> <li>• Other allied science courses relevant to the device to be distributed and imported.</li> </ul>	
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**C. Pre-assessment**

1. An FDA evaluator/assessor shall conduct a pre-assessment on the submitted application and documentary requirements with regards to their completeness and correctness. Applications with incomplete or incorrect data entries and document submissions shall not be accepted and the application shall automatically be aborted.
2. The Pre-assessment of applications shall be done within the prescribed working days and office hours of the FDA.
3. The FDA shall inform the applicant through the registered email address of the result of the pre-assessment. If the application passed the pre-assessment step, the applicant shall receive the Order of Payment with Reference Number through email indicating the fees to be paid. However, if the application did not pass the pre-assessment step, the FDA shall notify the reason/s for non-acceptance e.g., deficiency/ies found and prompt the applicant to apply again through the eServices Portal.

**D. Payment of Fees**

1. The payment of the total application fee as indicated in the Order of Payment (OP) shall be done in any of these payment channels:
  - a. Landbank Over-the-Counter payment using the FDA Clearing Account Number based on FDA Memorandum Circular No. 2013-046 through this link, <https://bit.ly/36ChH4X>

Please input the following information on the Oncoll Payment Slip:

- i. Account Number (for FDA Devices Clearing Account) – 0392-2220-30
- ii. Reference No. 1 – Account Code (reflected in the Order of Payment)
- iii. Reference No. 2 – Company Name



iv. Merchant Name – Food and Drug Administration

b. BANCNET online (<https://bit.ly/3uB8PEL>)

c. LBP Online Payment Link.Biz Portal based on FDA Advisory No. 2021-0246 (<https://bit.ly/3DmdPRv>)

2. The clients shall always indicate the reference number reflected in the OP when paying through FDA available online payment channels. Otherwise, when transacting through over-the-counter payment method, the print-out OP shall be endorsed to Cashier Officer for the processing of payment. Clients will be informed of other available channels of payment through an FDA issuance.
3. Once the payment is made, the payment channel -LBP or Bancnet (except for OTC at FDAC) shall send a transaction report to FDA which usually takes a minimum of two (2) days. Upon receipt of the report, the Cashier Section shall check the details and post the payment in the eServices Portal if payment is made in full. Posting of payment may take a maximum of two (2) days, depending on the volume of paid applications received.
4. Incomplete payment (amount paid is less than that of OP amount) will not be posted until the full amount as indicated in OP is settled. As such, applications with incomplete or unsettled payments shall be aborted.
5. Applicants shall receive a system-generated message through the registered e-mail address on the status of the payment made once posted or need further settlement. If full payment is made, the e-mail shall contain Acknowledgment Receipt, otherwise, a notification on payment deficiency.

#### **E. Approval of Application**

1. The veracity of the application and compliance with all relevant FDA requirements and standards shall be checked.
2. The applications with complete documentary requirements and payment, shall receive an Acknowledgement Receipt from FDA, containing the employees' number/code who received the application, reference number, agency logo, the date and time of application, payment, and the statement of completeness of the documents submitted. An application is considered filed once the applicant receives the Acknowledgement Receipt.
3. If the application is approved, the FDA shall send the LTO to the registered e-mail address of the applicant. If the application is disapproved, the FDA shall inform the applicant through its registered e-mail address of the reason for such action on the application.

#### **F. Disapproval of Application**

1. **For emphasis, the grounds for disapproval of LTO application shall be any of the following, as stated in A.O No. 2020-0017:**

- a. the documentary requirements submitted show that the establishment does not meet the required technical requirements and/or appropriate standards;
- b. absence of physical office upon inspection;
- c. the applicant made misrepresentations, false entries, withhold relevant data contrary to the provisions of the law or appropriate standards;
- d. the owner has violated any of the terms and conditions of its license; and
- e. such other analogous grounds or causes as determined by the FDA.

The disapproval of an application is without prejudice to re-application. However, disapproval shall mean outright forfeiture of payment.

#### **G. Release of LTO**

1. The applicant shall receive the LTO in their registered e-mail address and may also be accessed through the FDA eServices Portal.
2. Upon receipt of the LTO, the establishment shall print the LTO on a standard A4 size (21 cm x 29.7 cm) paper, on full-colored page and in portrait orientation. It shall be positioned on the most conspicuous place within the business establishment.
3. A QR Code verifier shall be included in the LTO as basis of legitimacy of the document.
4. For Variation, the applied variation shall automatically be reflected on the LTO. An updated LTO shall be provided to the registered e-mail address of the applicant.

#### **VII. SEPARABILITY CLAUSE**

The provisions of this FDA Circular are hereby declared separable and in the event of any such provision/s is/are declared invalid or unenforceable, the validity of enforceability of the remaining portions or provisions which are not affected, shall remain in full force and in effect.

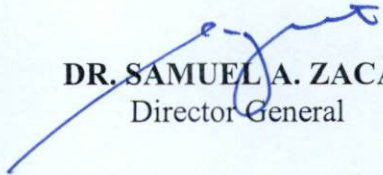
#### **VIII. REPEALING CLAUSE**

FDA Advisory No. 2021-2634 entitled, "Pilot Implementation of Food and Drug Administration eServices Portal System for License to Operate Application of Retailers of Medical Devices within the National Capital Region", FC No. 2021-021 (V.B.2), and other issuances, rules, and regulations on the LTO applications of Retailers of Medical Devices through the eServices Portal System which are found to

be inconsistent with the provisions of this FDA Circular are hereby repealed accordingly.

**IX. EFFECTIVITY**

This FDA Circular shall take effect fifteen (15) days following its publication in a newspaper of general circulation and upon filing with the University of the Philippines – Office of the National Administrative Register (UP-ONAR). The provisions stipulated in this FDA Circular shall remain in effect unless otherwise revoked or repealed.

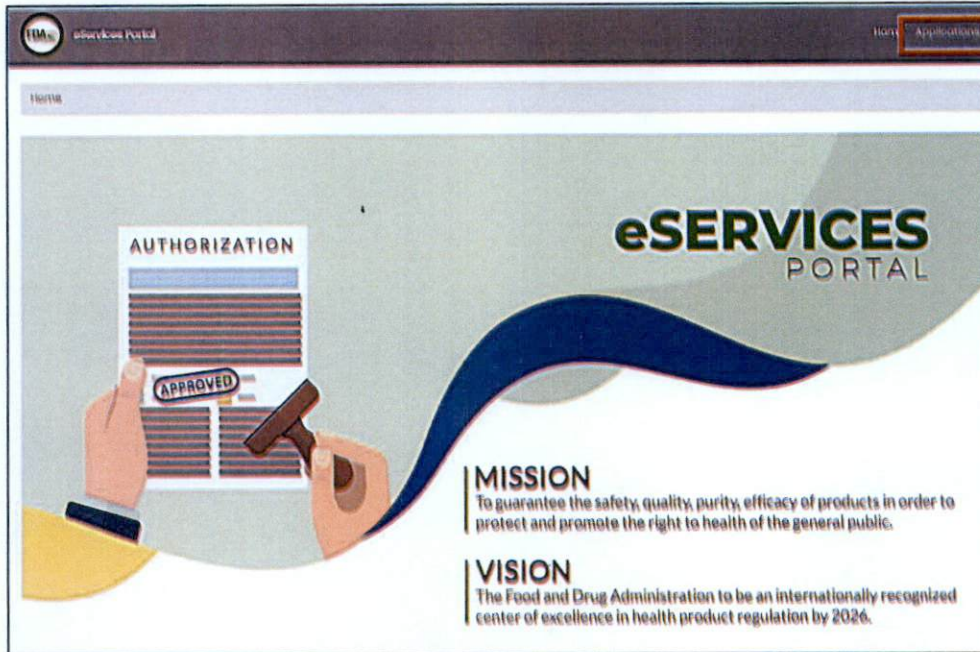


**DR. SAMUEL A. ZACATE**  
Director General

## ANNEX A


### Procedure for the Use of the FDA eServices Portal System for License to Operate (LTO) Application of Medical Device Retailers (INITIAL)

1. Access the online portal through [eservices.fda.gov.ph](http://eservices.fda.gov.ph) and click “Applications” found on the upper right corner of the eServices landing page.



2. Click the License to Operate for Device and the type of health product (Medical Device) and Business Establishment (Retailer).





[Home](#) / [Applications Portal](#)
[Home](#) / [Applications](#)


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[Home](#) / [Applications](#) / [License to Operate](#)


## License to Operate




**Bottled Water**  
For establishments that handle bottled water products




**Drug**  
For establishments that handle drug products



**Food**  
For establishments that handle food products




**Device**  
For establishments that handle device products


[Home](#) / [Applications Portal](#)
[Home](#) / [Applications](#)


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## Device



**Medical Device**  
For establishments that handle Medical Device products




**Health Related Device**  
For establishments that handle Health Related Device products


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[Home](#) / [Applications](#) / [License to Operate](#) / [Device](#) / [Medical](#)


## Medical Device




**Application Status**  
Check the current status of your application



**Distributor**  
License authorization for establishment that imports and exports medical device or procure products from local establishments and distribute to other establishment on a wholesale basis

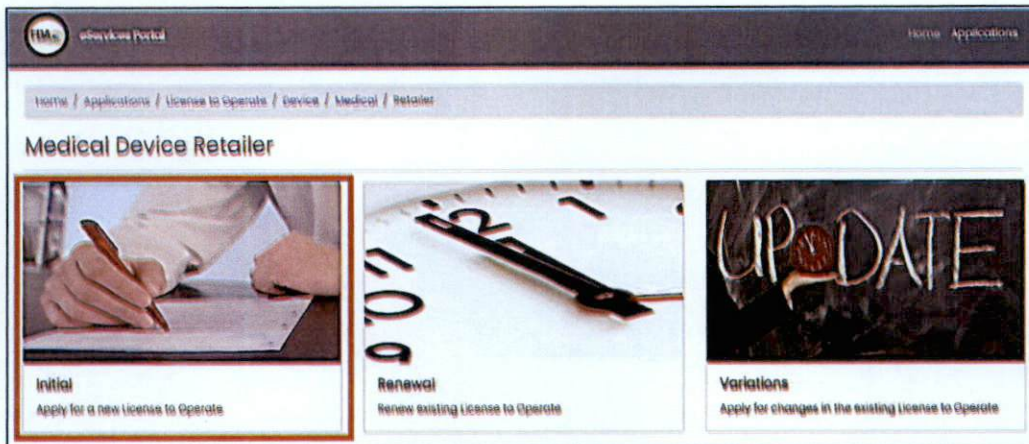


**Trader**  
License authorization for establishments that import or export raw materials, active ingredients and/or finished products to own use and wholesale distribution to other establishments or outlets but subcontracts the manufacture of such product to a licensed manufacturer

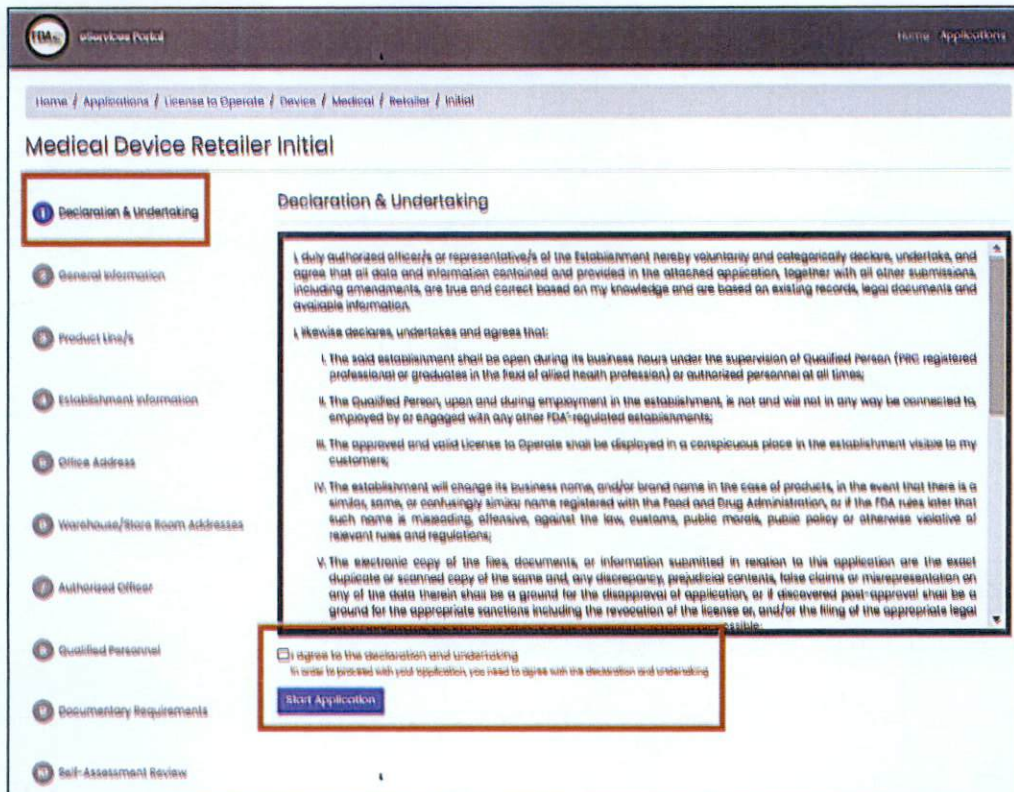


**Retailer**  
License authorization for establishments that sells or offers to sell medical devices directly to the general public

3. Click the Initial Application.



4. Read carefully the “**Declaration and Undertaking**” before proceeding with the application process. Make sure to check the box found below and click on “**Start Application**”.



5. Fill out the necessary information accurately based on establishment’s activity/ies. Make sure to properly tick the corresponding activity/ies before proceeding onto the next step.

Home / Applications / License to Operate / Device / Medical / Retailer / Initial

### Medical Device Retailer Initial

1 Declaration & Undertaking

**2 General Information**

3 Product Line/s

4 Establishment Information

5 Office Address

6 Warehouse/Store Room Address/s

7 Authorized Officer

8 Qualified Personnel

9 Documentary Requirements

10 Self-Assessment Review

**General Information**

Type of Application: Initial

Product Type: Medical Device

Primary Activity: Retailer

**Retailer Activities**

Retail stores for medical devices

Clinics that sell products classified as medical devices except those that are covered by the DCI One Stop Shop Licensing System

Sellers using online shopping website and/or social media platforms

Website Link #1

Website Link:

[Add Website Link](#)

TV shopping companies that sell or offer to sell medical device directly to the general public

Operator of medical device vending machine

Optical shop

Drug outlets, such as drugstores, or boticas, and retail outlets for non-prescription drugs (NPNP) that also sell or offer to sell medical devices

[Back](#) [Next](#)

When ticking this particular activity, make sure to include all the website/social media platform links of your business.

Home / Applications / License to Operate / Device / Medical / Retailer / Initial

### Medical Device Retailer Initial

1 Declaration & Undertaking

**2 General Information**

3 Product Line/s

4 Establishment Information

5 Office Address

6 Warehouse/Store Room Address/s

7 Authorized Officer

8 Qualified Personnel

9 Documentary Requirements

10 Self-Assessment Review

**General Information**

Type of Application: Initial

Product Type: Medical Device

Primary Activity: Retailer

**Retailer Activities**

Retail stores for medical devices

Clinics that sell products classified as medical devices except those that are covered by the DCI One Stop Shop Licensing System

Sellers using online shopping website and/or social media platforms

TV shopping companies that sell or offer to sell medical device directly to the general public

Operator of medical device vending machine

Vending Machine Location:

Vending Machine Address:

Optical shop

Drug outlets, such as drugstores, or boticas, and retail outlets for non-prescription drugs (NPNP) that also sell or offer to sell medical devices

[Back](#) [Next](#)

Kindly indicate the location of the vending machine. If the establishment has two or more vending machines, they may opt to apply for a separate LTO.

6. Indicate the Medical Device Product Line and its description. If there are two or more product lines, click on the “Add Product Line”.

IDA services Portal Home Applications

Home / Applications / License to Operate / Device / Medical / Retailer / Initial

### Medical Device Retailer Initial

- 1 Declaration & Undertaking
- 2 General Information
- 3 Product Line/s
- 4 Establishment Information
- 5 Office Address
- 6 Warehouse/Store Room Addresses
- 7 Authorized Officer
- 8 Qualified Personnel
- 9 Documentary Requirements
- 10 Self-Assessment Review

#### Product Line/s

Product Line #1

\* Product Type:

\* Product Description:

+ Add Product Line

7. The e-mail address shall be official and the applicant shall make sure that it is within the scope and access of the Authorized Representative/s.

Please take note that all the fields marked with asterisks (\*) are required to be filled out.

IDA services Portal Home Applications

Home / Applications / License to Operate / Device / Medical / Retailer / Initial

### Medical Device Retailer Initial

- 1 Declaration & Undertaking
- 2 General Information
- 3 Product Line/s
- 4 Establishment Information
- 5 Office Address
- 6 Warehouse/Store Room Addresses
- 7 Authorized Officer
- 8 Qualified Personnel
- 9 Documentary Requirements
- 10 Self-Assessment Review

#### Establishment Information

\* Name of Establishment:   
Business Name shall be the same name in the S.S. (Sole Proprietorship/Original Owner). Please ensure correctness of the declared Business Name as this will be the same name to be reflected in the License to Operate.

\* Owner of Establishment:   
For S.S./PCA registered establishments, the name of the corporation/cooperative must be used as the owner.

\* Tax Identification Number:

#### Contact Information

\* Email Address:   
The owner/authorized representative shall ensure that they have access to the declared email address. The IHA shall not be held responsible or liable in any way for loss of access to the declared email address.

\* Mobile Number:   
Please indicate an 8 digit mobile number.

Landline Number:   
Please indicate the area code followed by the landline number.



- Click the **“Get GPS Coordinates”** to determine the exact location of the Office Address. Pin accurately the location on the map.

The screenshot shows the 'Medical Device Retailer Initial' application form, Step 5: Office Address. The left sidebar contains a navigation menu with steps 1 through 10. Step 5, 'Office Address', is highlighted with a red box. The main form area has the following fields:

- Region: Please Select
- Province: Please Select
- City or Town: Please Select
- Street Address: Street Address
- GPS Latitude: GPS Latitude
- GPS Longitude: GPS Longitude

Below these fields is a button labeled 'Get GPS Coordinates' which is highlighted with a red box. At the bottom of the form are 'Back' and 'Next' buttons.

- The declared store room address shall be the same address indicated in the SEC/DTI/CDA permit. Otherwise, the declared address must be consistent with the one indicated in the business permit.

If there are two or more store room addresses provided, it shall indicate in the application with respective GPS coordinates generated on the Geo-Coding Map.

The screenshot shows the 'Medical Device Retailer Initial' application form, Step 6: Warehouse/Store Room Addresses. The left sidebar contains a navigation menu with steps 1 through 10. Step 6, 'Warehouse/Store Room Addresses', is highlighted with a red box. The main form area has the following fields:

- Storage #1
- Region: Please Select
- Province: Please Select
- City or Town: Please Select
- Street Address: Street Address
- GPS Latitude: GPS Latitude
- GPS Longitude: GPS Longitude

Below these fields is a button labeled 'Get GPS Coordinates' which is highlighted with a red box. At the bottom of the form is a button labeled 'Add Warehouse/Store Room Address' which is also highlighted with a red box. 'Back' and 'Next' buttons are also visible.

- The declared name of the Authorized Officer is understood to be the one transacting with the FDA and shall only have the authority to transact on behalf of the establishment (i.e., follow-ups, received result, etc.).

The screenshot shows the 'Medical Device Retailer Initial' form at the FDA eDevice Portal. The navigation bar includes 'Home / Applications / License to Operate / Device / Medical / Retailer / Initial'. The left sidebar lists steps 1 through 10, with 'Authorized Officer' (step 7) highlighted with a red box. The main content area features a warning message: 'The declared name of the authorized officer is understood to be the one transacting with FDA and shall only have the authority to transact on behalf of the establishment (i.e. follow-ups, receives result)'. Below this is the 'Details of Authorized Officer' section, which includes input fields for First Name, Middle Name, and Last Name; a dropdown for Designation; a 'Government Issued Identification Document' section with dropdowns for Type and an input for Identification Number; and 'Back' and 'Next' buttons.

- Fill out the details of the Qualified Personnel.

The screenshot shows the 'Medical Device Retailer Initial' form at the FDA eDevice Portal. The navigation bar includes 'Home / Applications / License to Operate / Device / Medical / Retailer / Initial'. The left sidebar lists steps 1 through 10, with 'Qualified Personnel' (step 8) highlighted with a red box. The main content area features the 'Details of the Qualified Personnel' section, which includes a 'Personnel Details' subsection with input fields for First Name, Middle Name, and Last Name; dropdowns for Profession and Designation; a 'Government issued Identification Document' section with dropdowns for Type and an input for Identification Number; and an 'Add Personnel' button. 'Back' and 'Next' buttons are also present.


12. Upload the necessary documents.

The screenshot shows the 'Medical Device Retailer Initial' application page. On the left is a vertical navigation menu with 11 steps: 1. Declaration & Undertaking, 2. General Information, 3. Product Line/s, 4. Establishment Information, 5. Office Address, 6. Warehouse/Store Room Addresses, 7. Authorized Officer, 8. Qualified Personnel, 9. **Documentary Requirements** (highlighted with a red box), 10. Self-Assessment Review, and 11. Self-Assessment Review. The main content area is titled 'Documentary Requirements' and contains two upload fields: '1 Proof of Business Name Registration' and 'Business/Mayor's Permit or Barangay Clearance', each with a 'File Upload' button. Below these fields are 'Back' and 'Next' buttons.

13. The applicant may review all the details of the applications in the “Self-Assessment Review”.

The screenshot shows the 'Medical Device Retailer Initial' application page at the 'Self-Assessment Review' step. The left navigation menu is identical to the previous screenshot, but step 9 'Documentary Requirements' is no longer highlighted, and step 10 'Self-Assessment Review' is highlighted with a red box. The main content area is titled 'Self-Assessment Review' and is divided into two sections: 'General Information' and 'Retailer Activities'. The 'General Information' section includes dropdown menus for '1 Type of Application' (set to 'Initial'), '1 Product Type' (set to 'Medical Device'), and '1 Primary Activity' (set to 'Retailer'). The 'Retailer Activities' section contains several checkboxes, with the first one 'Clinics that sell products classified as medical devices except those that are covered by the DDM One Stop Shop Licensing System' being checked. Below this is the 'Product Line/s' section, which includes a dropdown for '1 Product Type' (set to 'Medical Device') and a text field for '1 Product Description' containing the number '11'.

14. After the self-assessment review, the applicant shall confirm the correctness of the data and uploaded documents and click on “**Confirm**” to submit the application.

I'm not a robot   
reCAPTCHA  
Privacy & Terms

I hereby confirm that all information I have provided are true and correct to the best of my knowledge.

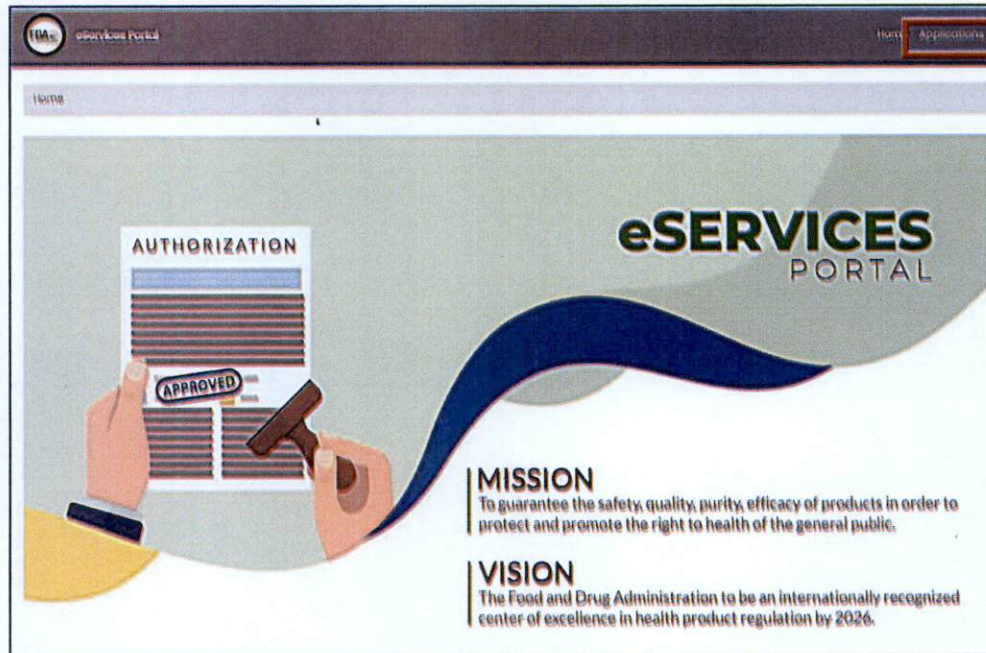
I understand that any errors that I have committed in this online form may be considered grounds for refusal or cancellation of my application.

I consent to the use of any personal information provided herein for Government to conduct the necessary records check and verification of facts in connection with my application.

## ANNEX B

### Procedure for the Use of the FDA eServices Portal System for License to Operate (LTO) Application of Medical Device Retailers (RENEWAL)

1. Access the online portal through [eservices.fda.gov.ph](http://eservices.fda.gov.ph) and click “Applications” found on the upper right corner of the eServices landing page.



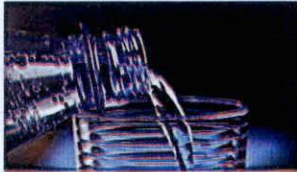
2. Click the License to Operate for Device and the type of health product (Medical Device) and Business Establishment (Retailer).





Home / Applications / License to Operate

### License to Operate



#### Bottled Water

For establishments that handle bottled water products



#### Drug

For establishments that handle drug products



#### Food

For establishments that handle food products



#### Device

For establishments that handle device products



Home / Applications / License to Operate / Device

### Device



#### Medical Device

For establishments that handle Medical Device products



#### Health Related Device

For establishments that handle Health Related Device products



Home / Applications / License to Operate / Device / Medical

### Medical Device



#### Application Status

Check the current status of your application



#### Distributor

License authorization for establishment that imports and exports medical device or procure products from local establishments and distribute to other establishment on a wholesale basis



#### Trader

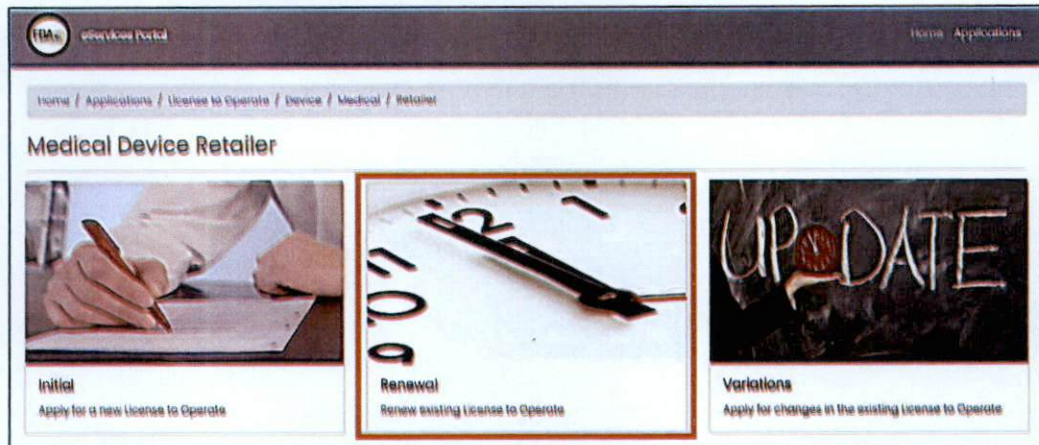
License authorization for establishments that import or export raw materials, active ingredients and/or finished products to own use and wholesale distribution to other establishments or outlets but subcontract the manufacture of such product to a licensed manufacturer



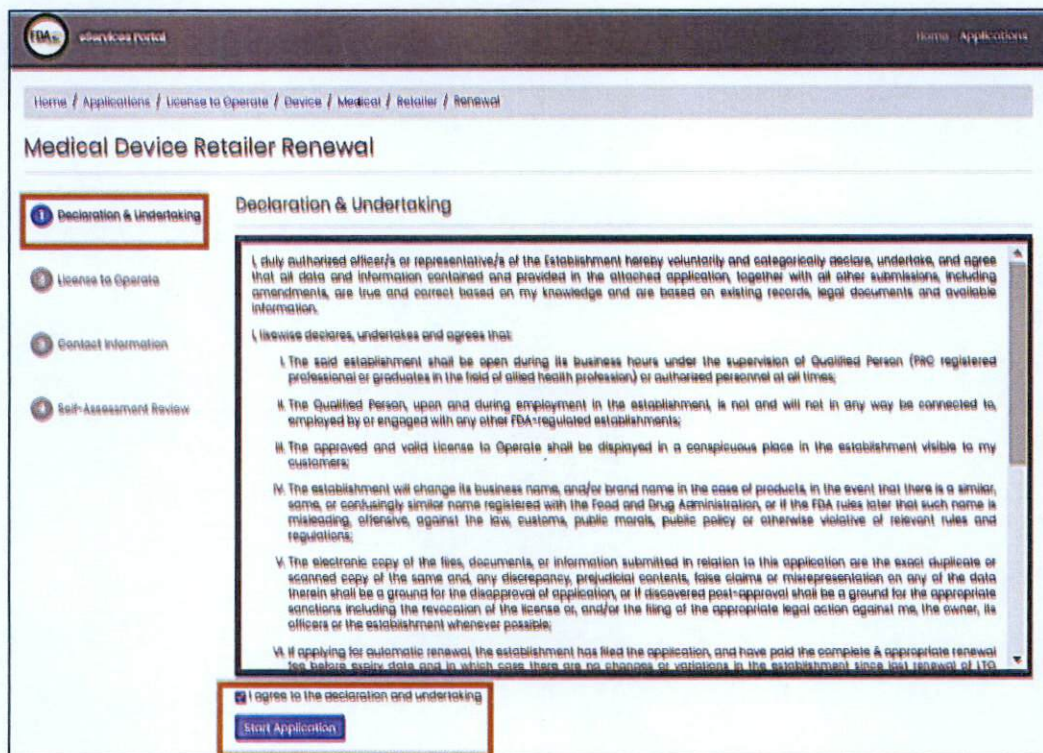
#### Retailer

License authorization for establishments that sells or offers to sell medical device directly to the general public

3. Click the Renewal Application.



4. Read carefully the “Declaration and Undertaking” before proceeding with the application process. Make sure to check the box found below and click on “Start Application”.



5. Fill out the necessary details such as the valid License Number, its date of validity, and security code.

The security code is generated by scanning the QR code found in the document. If everything is in order, tick the Captcha box and click “Next” to proceed to Contact Information.

Home / Applications / License to Operate / Device / Medical / Retailer / Renewal

## Medical Device Retailer Renewal

1 Declaration & Undertaking

2 **License to Operate**

3 Contact Information

4 Self-Assessment Review


### License to Operate

> License Number

> Date of Validity

> Security Code

Please scan the QR Code in the document. For previously issued LTO, enter the sequence number located at the bottom right corner of the document (e.g. LTO-123456).

I'm not a robot 

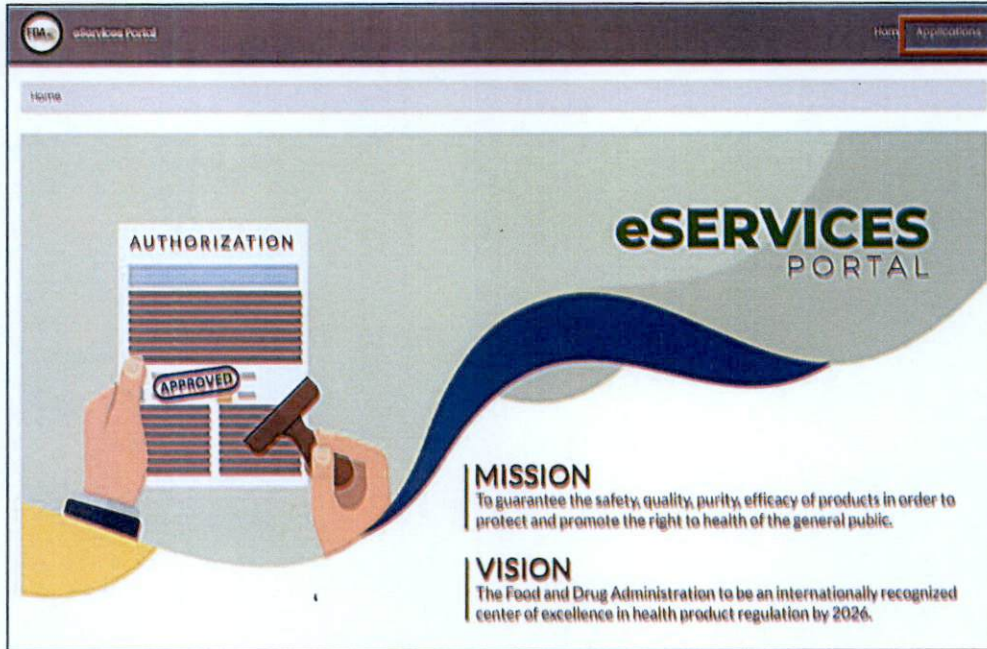
6. Update the contact number if necessary. Click “Next” to proceed to “Self-Assessment Review”.
7. The applicant may review all the details of the applications in the “Self-Assessment Review”.



## ANNEX C

### Procedure for the Use of the FDA eServices Portal System for License to Operate (LTO) Application of Medical Device Retailers (VARIATION)

1. Access the online portal through [eservices.fda.gov.ph](http://eservices.fda.gov.ph) and click “Applications” found on the upper right corner of the eServices landing page.




2. Click the License to Operate for Device and the type of health product (Medical Device) and Business Establishment (Retailer).




Home Applications

Home / Applications / Licenses to Operate


### Licenses to Operate




**Bottled Water**  
For establishments that handle bottled water products



**Drug**  
For establishments that handle drug products



**Food**  
For establishments that handle food products



**Device**  
For establishments that handle device products

Home Applications

Home / Applications / Licenses to Operate / Device

### Device



**Medical Device**  
For establishments that handle Medical Device products




**Health Related Device**  
For establishments that handle Health Related Device products


Home Applications

Home / Applications / Licenses to Operate / Device / Medical


### Medical Device




**Application Status**  
Check the current status of your application



**Distributor**  
License authorization for establishment that imports and exports medical device or procure products from local establishments and distribute to other establishment on a wholesale basis

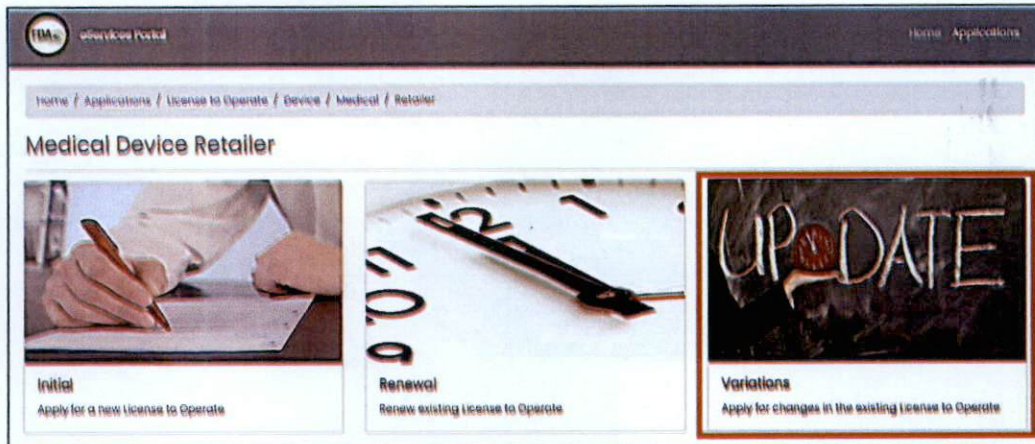


**Trader**  
License authorization for establishments that import or export raw materials, active ingredients and/or finished products to own use and wholesale distribution to other establishments or outlets but subcontract the manufacture of such product to a licensed manufacturer

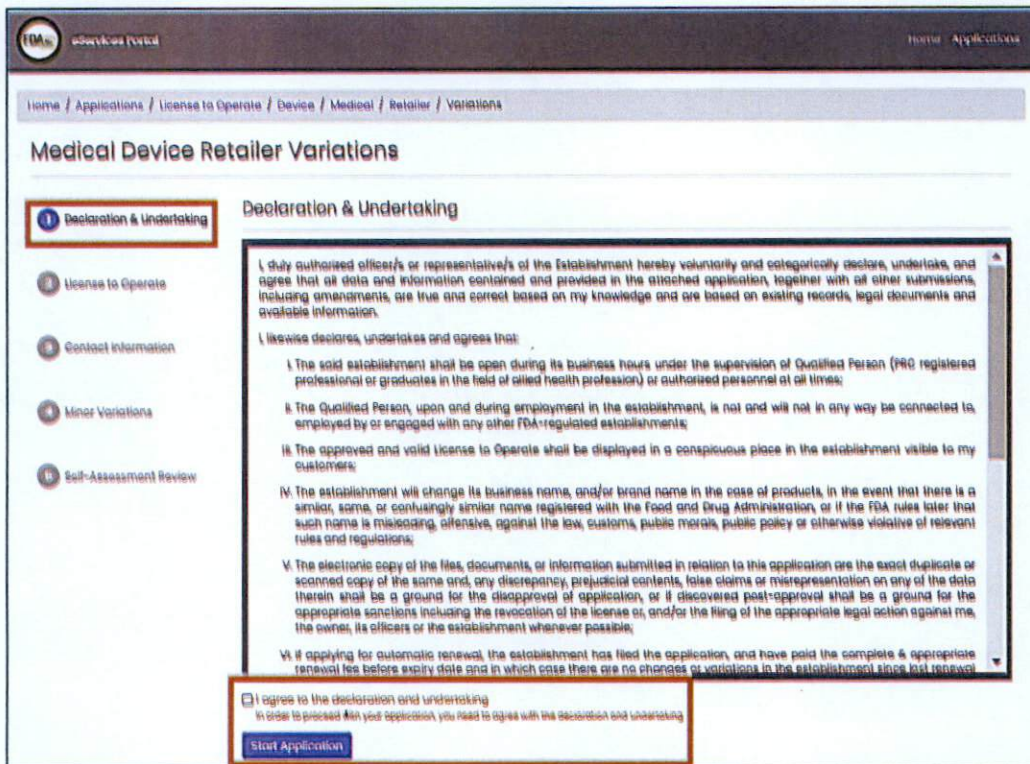


**Retailer**  
License authorization for establishments that sells or offers to sell medical device directly to the general public

3. Click the Variation Application.



4. Read carefully the “Declaration and Undertaking” before proceeding with the application process. Make sure to check the box found below and click on “Start Application”.



5. Provide the existing LTO Number, Validity Date, and Security Code (by scanning the QR Code from the given document). Please ensure the correctness of the data given to proceed with the change in licensing authorization.

Home Applications

Home / Applications / License to Operate / Device / Medical / Retailer / Variations

## Medical Device Retailer Variations

1 Declaration & Undertaking

**2 License to Operate**

3 Contact Information

4 Minor Variations

5 Self-Assessment Review


### License to Operate

License Number

Date of Validity

Security Code

Please enter the QR Code in the document, or previously issued LTO, enter the sequence number located at the bottom right corner of the document (e.g. 10A-10349).

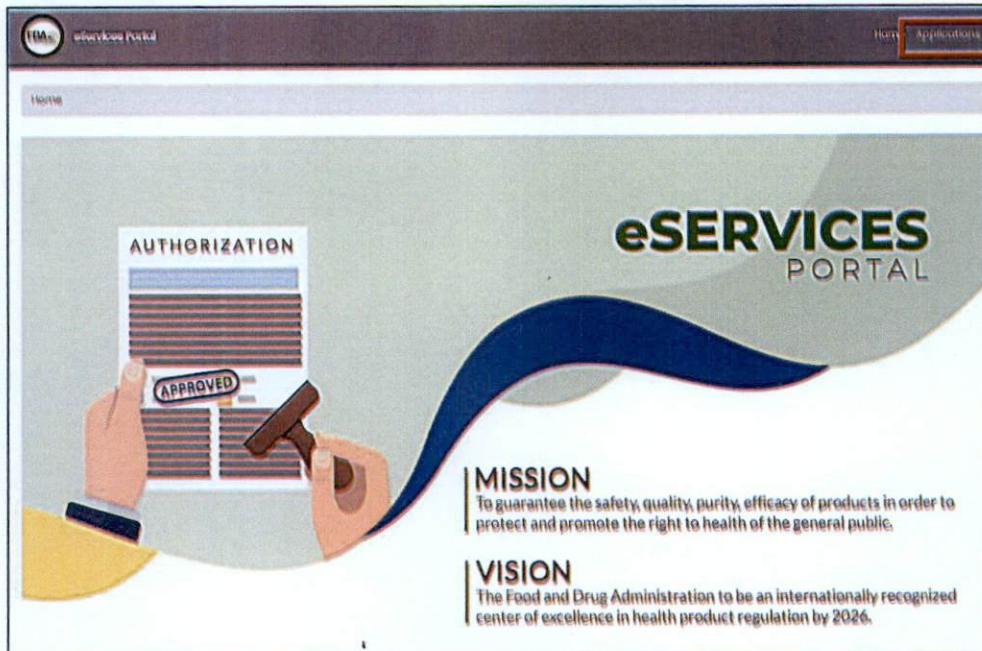
I'm not a robot 

6. Provide an updated contact information if applicable.
7. Key in the required fields. To upload the documents, click the File Upload. Fill out the necessary variations (ex. Transfer of Location of Offices, Change of Retailer Activity/ies, additional store room/warehouse address, and expansion of office establishments, change of business name, qualified person, or authorized person).
8. User may review if all the details are correct in the “**Self-Assessment Review**”.
9. Once reviewed, the User shall confirm the correctness of the data given and click on “**Confirm**” to submit the application.

## ANNEX D

### Procedure for Checking of Application Status in the eServices Portal System

1. Access the online portal through [eservices.fda.gov.ph](http://eservices.fda.gov.ph) and click “Applications” found on the upper right corner of the eServices landing page.



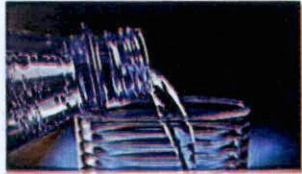
2. Click the License to Operate for Device and the type of health product (Medical Device).




Home Applications

Home / Applications / License to Operate


## License to Operate




**Bottled Water**  
For establishments that handle bottled water products



**Drug**  
For establishments that handle drug products



**Food**  
For establishments that handle food products



**Device**  
For establishments that handle device products

Home Applications

Home / Applications / License to Operate / Device

## Device



**Medical Device**  
For establishments that handle Medical Device products



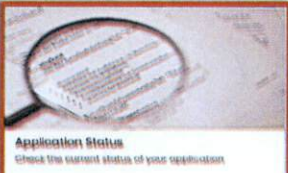
**Health Related Device**  
For establishments that handle Health Related Device products

3. To check the status of the application, click “**Application Status**”.

Home Applications

Home / Applications / License to Operate / Medical / Medical Device


## Medical Device



**Application Status**  
Check the current status of your application



**Distributor**  
License substitutions for establishments that transport and receive medical devices to practice premises from local distributors and distribute to other establishments on a wholesale basis



**Retailer**  
License substitutions for establishments that request or request non-emergency, device ingredients transfer substitutions to other establishments or outside local jurisdictions the manufacture of such product to a licensed manufacturer



**Retailer**  
License substitutions for establishments that sell or offer to sell medical device directly to the general public

4. Enter the Reference Number and click on **“Submit”**.

The screenshot shows a web browser window with the following elements:

- Header:** Includes a logo on the left and the text "Home Applications" on the right.
- Breadcrumb:** "Home / Applications / License to Operate / Device / Medical / Status".
- Section Header:** "Application Status".
- Progress Indicators:** Three numbered steps: "1 Reference Number", "2 Verification Code", and "3 Application Status". The first step is highlighted.
- Form Area (highlighted with a red box):**
  - Instruction: "Enter the reference number indicated in your application."
  - Label: "Reference Number" with a small asterisk.
  - Input field: A text box containing "Reference Number" and an example "e.g. 104-1000000000".
  - Button: A blue "Submit" button.

5. A verification code will be sent to applicant's registered e-mail address.
6. Enter the verification code to view the progress.

## ANNEX E

### References

- *Food and Drug Administration (2009). An Act Strengthening and Rationalizing the Regulatory Capacity of the Bureau of Food and Drugs (BFAD) by Establishing Adequate Testing Laboratories, and Field Offices, Upgrading its Equipment, Augmenting its Human Resource Complement, Giving Authority to Retain its Income, Renaming it the Food and Drug Administration (FDA), Amending Certain Sections of Republic Act No. 3720, as Amended, and Appropriating Funds Thereof. Republic Act No. 9711. 15. <http://spsissuances.da.gov.ph/attachments/article/31/RA9711.pdf>*
- *Anti-Red Tape Authority. (2018). An Act Promoting Ease of Doing Business and Efficient Delivery of Government Services, Amending for the Purpose Republic Act No. 9485, Otherwise Known as the Anti-Red Tape Act of 2007, and for other Purposes. Republic Act No. 11032. 16. [https://arta.gov.ph/wpcontent/uploads/2020/07/RA.11032\\_Certified\\_True\\_Copy.pdf](https://arta.gov.ph/wpcontent/uploads/2020/07/RA.11032_Certified_True_Copy.pdf)*
- *Food and Drug Administration. (2020). Revised Guidelines on the Unified Licensing Requirements and Procedures of the Food and Drug Administration Repealing Administrative Order No. 2016-0003. Administrative Order No. 2020-0017. 9. <https://www.fda.gov.ph/wp-content/uploads/2020/05/Administrative-Order-No.2020-0017.pdf>*
- *Food and Drug Administration. (2021). Guidelines on the Licensing of Retailers of Medical Devices in the Philippines. FDA Circular No. 2021-021. 6. <https://www.fda.gov.ph/wp-content/uploads/2021/10/FDA-Circular-No.2021-021.pdf>*