

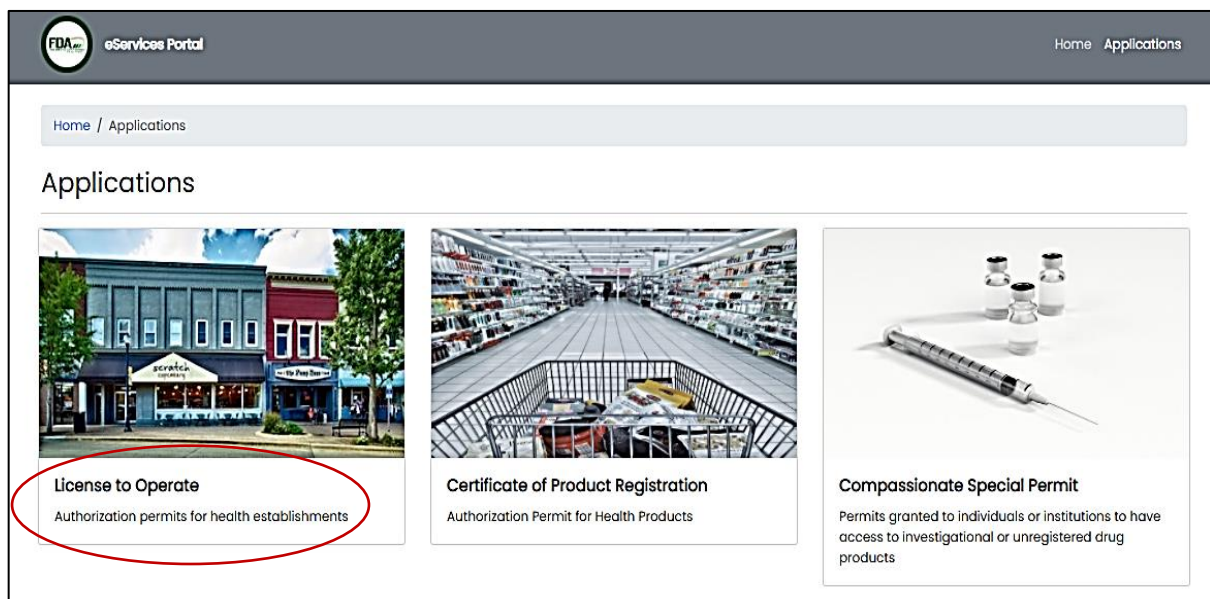
**ANNEX**  
**Procedure for the Use of the FDA eServices Portal for License to Operate (LTO) Application**

**A. Application for Initial LTO for Medical Device Distributor**

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 Medical Device and the type of Business Establishment (Distributor).



## License to Operate



### Drug

For establishments that handles drug products



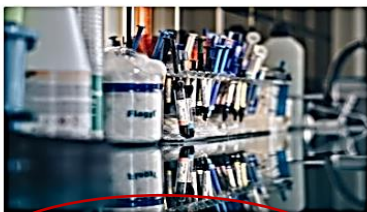
### Food

For establishments that handles food products



### Bottled Water

For establishments that handles bottled water products



### Medical Device

For establishments that handle medical device products

## Medical Device



### Application Status

Check the current status of your application



### Distributor

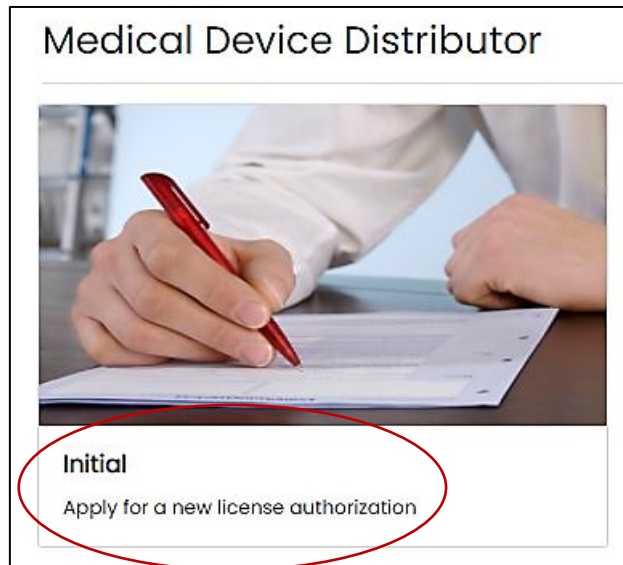
License authorization for establishment that imports and exports medical device or procure products from local establishments and distribute to other establishment on a wholesale basis.



### Trader

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

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**”.

FDA eServices Portal Home Applications

Home / Applications / License to Operate / Medical device / Distributor / Initial

### Medical Device Distributor Initial

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

#### Declaration & Undertaking

I, duly authorized officer/s or representative/s of the Establishment hereby voluntarily and categorically declare, undertake, and agree that all data and information contained and provided in the attached application, together with all other submissions, including amendments, are true and correct based on my knowledge and are based on existing records, legal documents and available information.

I, likewise declares, undertakes and agrees that:

- I. The said establishment shall be open during its business hours under the supervision of a PRC registered professional (e.g. Pharmacists) or authorized personnel at all times;
- II. The pharmacist/s and the other appropriate allied health professionals, upon and during employment in the establishment, is/are not and will not in any way be connected to, employed by or engaged with any other FDA-regulated establishment;
- III. The approved and valid license to Operate shall be displayed in a conspicuous place in the establishment visible to my customers;
- IV. The establishment will change its business name, and/or brand name in the case of products, in the event that there is a similar, same, or confusingly similar name registered with the Food and Drug Administration, or if the FDA rules later that such name is misleading, offensive, against the law, customs, public morals, public policy or otherwise violative of relevant rules and regulations;
- V. The electronic copy of the files, documents, or information submitted in relation to this application are the exact duplicate or scanned copy of the same and, any discrepancy, prejudicial contents, false claims or misrepresentation on any of the data therein shall be a ground for the disapproval of application, or if discovered post-approval shall be a ground for the appropriate sanctions including the revocation of the license or, and/or the filing of the appropriate legal action against me, the owner, its officers or the establishment whenever possible.

I agree to the declaration and undertaking  
In order to proceed with your application, you need to agree with the declaration and undertaking

**Start Application**

5. Fill-out the necessary information accurately based on establishment's activity/ies (Importer, Exporter, or Wholesaler). Make sure to properly tick the corresponding activity/ies to proceed on the next step.

The screenshot shows the 'Medical Device Distributor Initial' form. On the left, a vertical navigation menu lists steps 1 through 10. Step 2, 'General Information', is circled in red. The main form area is titled 'General Information' and contains the following fields:

- \* Type of Application: Initial
- \* Product Type: Medical Device
- \* Primary Activity: Distributor
- \* Distributor Activities:  Importer,  Exporter,  Wholesaler

At the bottom right, there are 'Back' and 'Next' buttons. The 'Next' button is highlighted in blue.

6. Indicate the Medical Device Product Line and its description. If there are two or more product lines, click on the “Add Product Line”. Choose from the drop-down button the product type (Medical Device, Equipment or Devices Used for Treating Sharps, Pathological and Infectious Waste, or Water Treatment Devices/System)

The screenshot shows the 'Medical Device Distributor Initial' form. On the left, a vertical navigation menu lists steps 1 through 10. Step 3, 'Product Line', is circled in red. The main form area is titled 'Medical Device Product Line' and contains the following fields:

- Product Line 1:
- \* Product Type: Medical Device (dropdown menu)
- \* Product Description:

Below the fields, there is a red circle around the 'Add Product Line' button. At the bottom right, there are 'Back' and 'Next' buttons. The 'Next' button is highlighted in blue.

- 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 asterisk (\*) are required to be filled-out.

The screenshot shows the 'Medical Device Distributor Initial' form. On the left, a vertical navigation menu lists steps 1 through 10. Step 4, 'Establishment Information', is circled in red. The main form area is titled 'Establishment Information' and contains several fields: '\* Name of Establishment' (text input), '\* Owner of Establishment' (text input), and '\* Tax Identification Number' (text input). Below these is the 'Contact Information' section, which includes 'Email Address' (text input, circled in red), '\* Mobile Number' (text input), and 'Landline Number' (text input). At the bottom right, there are 'Back' and 'Next' buttons.

- 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 Distributor Initial' form at the 'Office Address' step. The left navigation menu has step 5, 'Office Address', circled in red. The main form area is titled 'Office Address' and contains several fields: '\* Region' (dropdown menu), '\* Province' (dropdown menu), '\* City or Town' (dropdown menu), '\* Street Address' (text input), '\* GPS Latitude' (text input), and '\* GPS Longitude' (text input). A blue button labeled 'Get GPS Coordinates' is circled in red. At the bottom right, there are 'Back' and 'Next' buttons.

- The declared warehouse 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 warehouses provided, it shall indicate in the application with respective GPS coordinates generated on the Geo-Coding Map.

**Medical Device Distributor Initial**

1 Declaration & Undertaking

2 General Information

3 Product Line

4 Establishment Information

5 Office Address

**6 Warehouse Addresses**

7 Authorized Officer

8 Qualified Personnel

9 Documentary Requirements

10 Self-Assessment Review

**Warehouse Addresses**

Warehouse #1

\* Region

\* Province

\* City or Town

\* Street Address

The declared 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.

\* GPS Latitude

\* GPS Longitude

- 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, received result, etc.)

**Medical Device Distributor Initial**

1 Declaration & Undertaking

2 General Information

3 Product Line

4 Establishment Information

5 Office Address

6 Warehouse Addresses

**7 Authorized Officer**

8 Qualified Personnel

9 Documentary Requirements

10 Self-Assessment Review

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).

**Details of Authorized Officer**

\* First Name   
include suffix name on first name

Middle Name

\* Last Name

\* Designation   
select owner for sole proprietorships

**Government issued Identification Document**

\* Type

\* Identification Number

11. Fill-out the details of the Qualified Personnel.

**1** Declaration & Undertaking

**2** General Information

**3** Product Line

**4** Establishment Information

**5** Toll Manufacturer

**6** Office Address

**7** Warehouse Addresses

**8** Authorized Officer

**9** Qualified Personnel

### Details of the Qualified Personnel

#### Personnel Details

\* First Name

Middle Name

\* Last Name

\* Designation

\* Profession

#### Government Issued Identification Document

\* Type

\* Identification Number

[+ Add Personnel](#)

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

12. Upload the necessary documents.

**FDA** eServices Portal Home Applications

Home / Applications / License to Operate / Medical device / Distributor / Initial

### Medical Device Distributor Initial

**1** Declaration & Undertaking

**2** General Information

**3** Product Line

**4** Establishment Information

**5** Office Address

**6** Warehouse Addresses

**7** Authorized Officer

**8** Qualified Personnel

**9** Documentary Requirements

**10** Self-Assessment Review

#### Documentary Requirements

\* Proof of Business Name Registration  [File Upload](#)  
DTI Permit, SEC with Articles of Incorporation/Partnership, CDA Permit, or Government-Owned and Control Corporation (GOCC)

Business/Mayor's Permit or Barangay Clearance  [File Upload](#)  
Please upload a business/mayor's permit or barangay clearance if the declared site address is different on the proof of business name registration document.

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

13. The applicant may review all the details under the “Self-Assessment Review”.

The screenshot displays the 'eServices Portal' interface for a 'Medical Device Distributor Initial' application. The left sidebar contains a list of steps from 1 to 10, with step 10, 'Self-Assessment Review', circled in red. The main content area is titled 'Self-Assessment Review' and contains two sections: 'General Information' and 'Medical Device Product Line'. In the 'General Information' section, the following fields are visible: '\* Type of Application' (Initial), '\* Product Type' (Medical Device), '\* Primary Activity' (Distributor), and '\* Distributor Activities' (Importer checked, Exporter and Wholesaler unchecked). The 'Medical Device Product Line' section shows 'Product Line 1' with '\* Product Type' (Medical Device) and '\* Product Description' (e). An 'Add Product Line' button is located at the bottom of this section.

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

The screenshot shows the final confirmation page. At the top left, there is a reCAPTCHA widget with the text 'I'm not a robot' and a checkbox. Below this, there is a large text box containing the following text: '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.' At the bottom right, there are two buttons: a grey 'Back' button and a blue 'Confirm' button, which is circled in red.

## B. Application for Initial LTO for Medical Device Trader

Proceed as in Step No. 1 to Step No. 14 of Item A (**Application for Initial LTO for Medical Device Distributor**). Make sure to click the appropriate type of establishment under Step No. 2. However, please indicate the Toll Manufacturer details under Step 5 of the eServices Portal System.



Fill-out the Toll Manufacturer details including the address and contract validity.

**1** Declaration & Undertaking

**2** General Information

**3** Product Line

**4** Establishment Information

**5** Toll Manufacturer

**6** Office Address

**7** Warehouse Addresses

### Toll Manufacturer Details

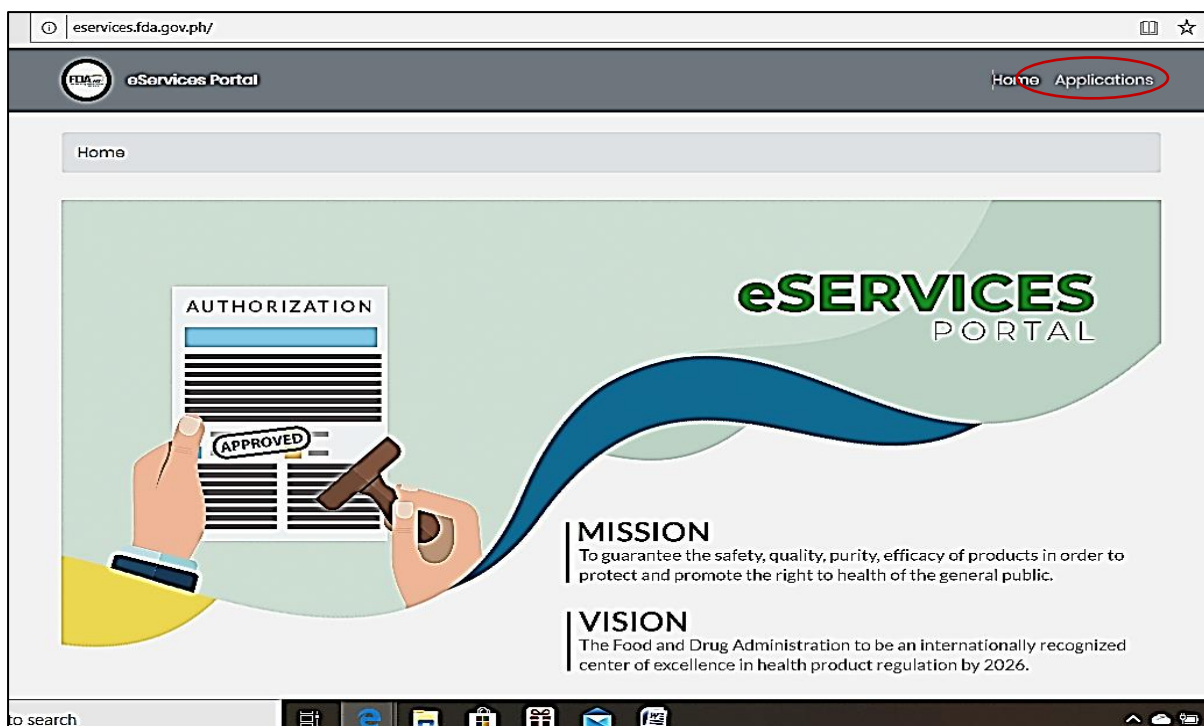
\* Name of Toll Manufacturer

\* Address

\* Contract Validity

### C. Application for Renewal of LTO for Medical Device Distributor

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 Medical Device and the type of Business Establishment (Distributor). Click on the “Renewal”.
3. Read carefully the “Declaration and Undertaking” before proceeding with application process. Make sure to check the box found below and click on “Start Application”.

4. Fill-out the required fields. The Security Code is generated by scanning the QR code in the document. If everything is in order, tick the Captcha box and click Next to proceed to Contact Information.

**1 Declaration & Undertaking**

2 General Information

3 Establishment Information

4 Office Address

5 Warehouse Addresses

6 Authorized Officer

7 Qualified Personnel

8 Documentary Requirements

9 Self-Assessment Review

**Declaration & Undertaking**

I, duly authorized officer/s or representative/s of the Establishment hereby voluntarily and categorically declare, undertake, and agree that all data and information contained and provided in the attached application, together with all other submissions, including amendments, are true and correct based on my knowledge and are based on existing records, legal documents and available information.

I, likewise declares, undertakes and agrees that:

I. The said establishment shall be open during its business hours under the supervision of a PRC registered pharmacist/s or authorized personnel at all times;

II. The registered pharmacist/s and the other appropriate allied health professionals, upon and during employment in the establishment, is/are not and will not in any way be connected to, employed by or engaged with any other FDA-regulated establishment;

I agree to the declaration and undertaking  
In order to proceed with your application, you need to agree with the declaration and undertaking

[Start Application](#)

5. Update the contact numbers if necessary. Click Next to proceed to Self-Assessment Review.

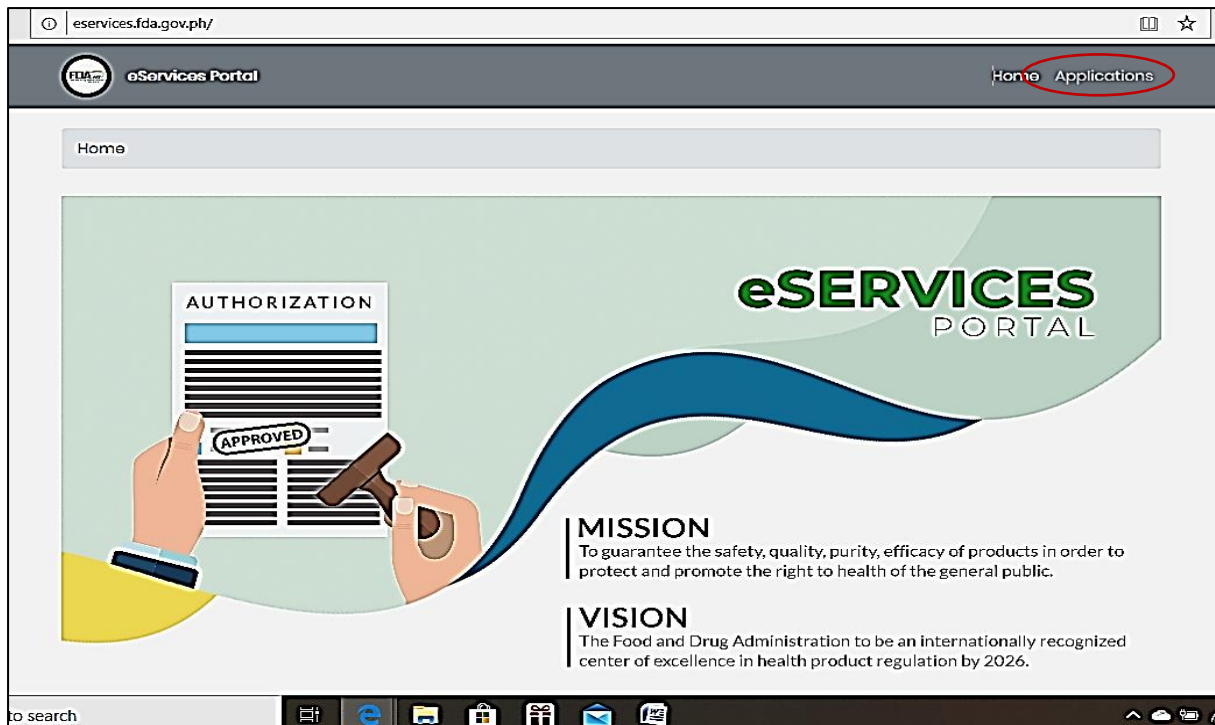
6. The applicant may review all the details under the “Self-Assessment Review”.

#### **D. Application for Renewal of LTO for Medical Device Trader**

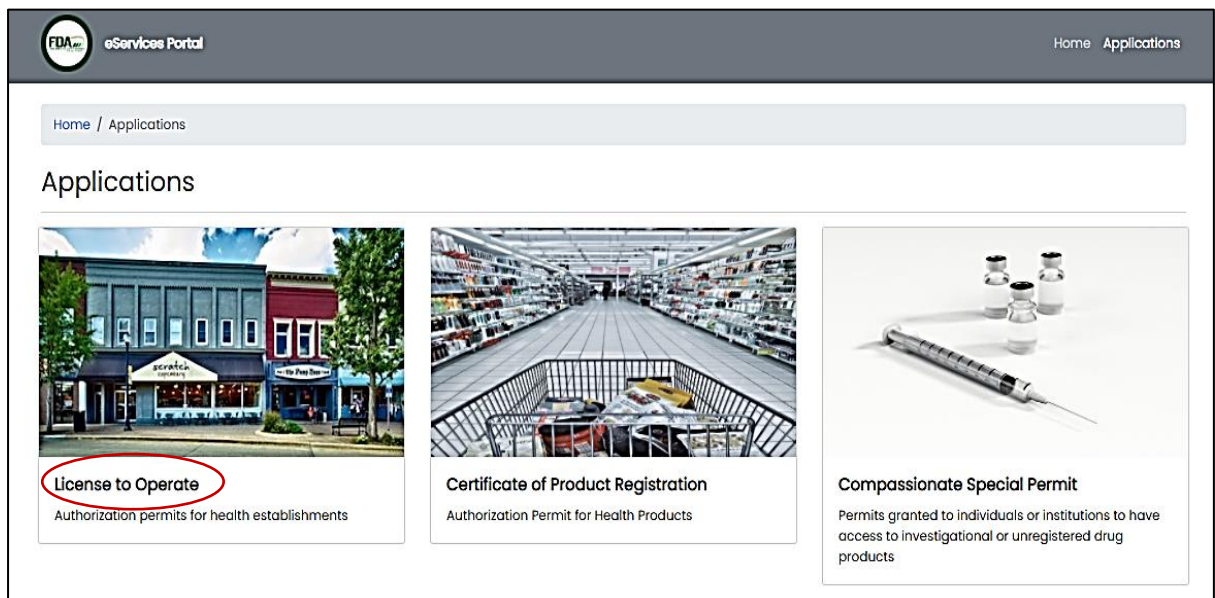
Proceed as in Step No. 1 to Step No. 6 of Item C (**Application for Renewal of LTO for Medical Device Distributor**). Make sure to click the appropriate type of establishment under Step No. 2.

## E. Application for Variation in LTO for Medical Device Distributor

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 Medical Device and the type of Business Establishment (Distributor).





### Medical Device



#### Application Status

Check the current status of your application



#### Distributor

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



#### Trader

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.

3. Click the Variation Application.



#### Variations

Apply for changes in the existing license authorization

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”.

#### 1 Declaration & Undertaking

- 2 License to Operate
- 3 Contact Information
- 4 Minor Variations
- 5 Self-Assessment Review

#### Declaration & Undertaking

I, duly authorized officer/s or representative/s of the Establishment hereby voluntarily and categorically declare, undertake, and agree that all data and information contained and provided in the attached application, together with all other submissions, including amendments, are true and correct based on my knowledge and are based on existing records, legal documents and available information.

I, likewise declares, undertakes and agrees that:

- I. The said establishment shall be open during its business hours under the supervision of a PRC registered professional (e.g. Pharmacists) or authorized personnel at all times;
- II. The pharmacist/s and the other appropriate allied health professionals, upon and during employment in the establishment, is/are not and will not in any way be connected to, employed by or engaged with any other FDA-regulated establishment;
- III. The approved and valid license to Operate shall be displayed in a conspicuous place in the establishment visible to my customers;
- IV. The establishment will change its business name, and/or brand name in the

I agree to the declaration and undertaking  
 In order to proceed with your application, you need to agree with the declaration and undertaking

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.

The screenshot shows the 'Medical Device Distributor Variations' page in the eServices Portal. The breadcrumb trail is: Home / Applications / License to Operate / Medical device / Distributor / Variations. The page title is 'Medical Device Distributor Variations'. On the left, a vertical navigation menu lists five steps: 1 Declaration & Undertaking, 2 License to Operate (highlighted with a red circle), 3 Contact Information, 4 Minor Variations, and 5 Self-Assessment Review. The main content area is titled 'License to Operate' and contains three required fields: '\* License Number', '\* Date of Validity', and '\* Security Code'. Below these fields is a note: '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. FDA-123456)'. At the bottom right, there is a reCAPTCHA widget with the text 'I'm not a robot' and a 'Next' button. A 'Back' button is also present.

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

## **F. Application for Variation in LTO for Medical Device Trader**

Proceed as in Steps one (1) to nine (9) of Item E (Application for Variation in LTO for Medical Device Distributor). Make sure to click the appropriate type of establishment under Step # 2.

## **G. Procedure for Checking of Application Status in the eServices Portal**

1. To check the status of your application, click “Application Status.
2. Enter the Reference Number and click “submit”.
3. A verification code will be sent to applicant’s registered e-mail address.
4. Enter the verification code to view the progress of your application.