Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA CIRCULAR
No. 2021-014

24 JUN 2021

SUBJECT : **Guidelines for the Use of the Food and Drug Administration (FDA) eServices Portal System for License to Operate (LTO) Application of Traders and Distributors including Wholesalers, Importers, and Exporters of Medical Devices, Equipment or Devices Used for Treating Sharps, Pathological and Infectious Waste and Water Treatment Devices/Systems**

I. BACKGROUND

Streamlining of License to Operate (LTO) application procedures is one of the key infrastructures that the Food and Drug Administration (FDA) is undertaking. This is in line with the initiatives embodied in the Administrative Order (A.O.) No. 2020-0017 of the Department of Health (DOH) 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 re-engineer and streamline FDA's processes, specifically, on the issuance of LTO through a web-based application platform.

Further, Republic Act (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 transaction in the government services.

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 Traders and Distributors including Wholesalers, Importers, and Exporters of medical devices, equipment or devices used for treating sharps, pathological and infectious waste, and water treatment devices/systems.

II. OBJECTIVE

The objective of this Circular is to provide the guidelines on the FDA eServices Portal System in applying for LTO applications of Traders and Distributors including Wholesalers, Importers, and Exporters of medical devices, equipment or devices used for treating sharps, pathological and infectious waste, and water treatment devices/systems.

III. SCOPE

This FDA Circular shall cover the following LTO applications:

A. Types of Establishments:

1. Traders; and
2. Distributors (Wholesalers/Importers/Exporters)

B. Types of Health Product:

1. Medical Devices; and
2. Health-related devices;
   i. Equipment or Devices used for Treating Sharps, Pathological and Infectious Waste; and
   ii. Water Treatment Devices/Systems

C. 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, and other applicable laws and regulations.

V. GUIDELINES

A. The **General** and **Specific Guidelines** on the application for LTO as indicated in AO No. 2020-0017 shall be adopted and 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 to national and/or international standards of safety, quality, purity, and efficacy of health products they provide to the consumers and the general public.

B. 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. Proof of Income (in pdf, 2MB maximum file size) such as the latest audited Financial Statement with Balance Sheet (in pdf) shall be submitted. This is to verify the capitalization of the establishment to their corresponding application fees. For newly established companies that have no financial statement yet, Statement/Certification of Initial Capitalization must be submitted.

d. Payment of Fees based on the latest FDA issuance

e. 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.

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

Type of Variation	**Document Requirement**
Transfer of Location of Offices • Physical transfer of the office of the establishment	Proof of business address reflecting the new office location: 1. For Single Proprietorship:

	Business Permit/Mayor's Permit or Barangay Business Permit/Clearance reflecting the new office location; 2. For Securities and Exchange Commission (SEC)-registered establishments: a. Amended Articles of Incorporation (if transferred from one city/municipality/province; or b. Updated General Information Sheet (GIS) from SEC (if transferred within the same city/municipality/province) 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 new office location
Change of Distributor Activity • Additional/deletion or change in activity that the distributor is currently engaged	Contract Agreement showing change in activity
Transfer/addition of Warehouse • Physical transfer and addition of warehouse of the establishment	Mayor's Permit or Barangay Business Permit/Clearance reflecting new warehouse location
Change of Ownership • Change in ownership of the licensed establishment	1. Business name registration reflecting new ownership 2. Any proof on the transfer of ownership such as any of the following: a. Deed of sale or assignment or transfer of rights/ownership; b. Memorandum of Agreement; or c. Notarized Affidavit of the owner, proprietor, Chairman or Chief Executive Officer (CEO) of the establishment validating the transfer
Change of Business Name • Change only in the business name of the establishment	Business name registration reflecting new business name
Zonal Change in Address • Change of the name/number of the street/building without physical transfer of the establishment	1. Certificate of Zonal Change 2. Certification from Local Government Unit (LGU) (City/Municipality) stating no physical transfer of the establishment
Change of Qualified Person • Change in the identified qualified person initially registered with the FDA	1. Name of new Qualified Person 2. Valid Professional Regulation Commission (PRC) ID

	3. Signed Letter of Resignation duly noted by the former employer, if previously connected with another pharmacy/establishment
Change of Authorized Person • Change of authorized person initially registered with the FDA	1. Name of new Authorized Person 2. Valid Government ID 3. Updated contact details

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

C. Qualification and Credential Requirements of the Qualified Person

Qualification	Training Requirements
For Medical Devices • Registered professional or graduates in the field of allied health profession: Pharmacy, Nursing, Medical Technology, Dentistry, Radiologic Technology, Medicine, Physical Therapy, and other allied science courses relevant the device to be distributed • Engineering profession (includes the following course but not limited to EE, ECE, ME, CoE, CHE, SE), Computer Science, and Chemistry **For Health-Related Devices** Graduate of engineering courses preferably chemical, sanitary, civil or mechanical or other science courses relevant to the device to be distributed	a. PRC ID for professions with Board/Licensure Exam or Diploma for profession without Board/Licensure Exam b. Certificate of Attendance to seminars, training, learning and development activities on medical device safety and quality given by the academe, industry, organization, professional organization, National Regulatory Authorities, international organization like the WHO and ISO

D. Application Process

1. The application shall be filed online through the eServices Portal website (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 read and 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 false 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-up the fields in the eApplication form, the applicant will 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.

   The Company Authorized Officer or Qualified Personnel shall have the responsibility to comply with the regulatory and technical requirements of the FDA wherein:

   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. A Qualified Person has the responsibility to comply with the technical requirements of FDA or discuss/clarify matters with the FDA when submitting technical requirements or engage the FDA Officials when conducting inspection or post-market surveillance activities. The Qualified Person may also be the duly Authorized Person of the establishment.

5. All Traders and Distributors including Wholesalers, Importers, and Exporters shall submit a notification of sources immediately after the approval of the LTO.

6. Variation and renewal applications must be applied separately. If a Medical Device Establishment 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 must first be submitted.

   The clients should be informed that the LTO to be issued upon renewal will reflect the previous information and the updating should be done through filing of a separate variation. In addition, the clients cannot apply for a renewal of application if not within ninety (90) days before the expiration date of the LTO.

7. For any variation, the establishment is required to file for a new notification.

8. 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)**

9. 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.

10. 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 confirms to the correctness of information provided and data privacy terms.

11. The Application Summary shall be automatically sent to the applicant's registered email address to indicate the successful submission of the application in the eServices Portal.

12. Applications filed after the prescribed working/office hours or during weekends and holidays shall be considered filed on the next working day.

13. The status of the application can be monitored at eServices website by validating thru the e-mail address used for the application.

14. Establishments with existing LTO applications via ePortal may opt to apply to the eServices Portal for a new fee. The previous payment will be forfeited as the filed applications are already in-process.

(The step-by-step procedure in the eServices Portal is attached as Annex in this issuance)

E. Pre-assessment

1. An FDA evaluator/assessor shall conduct a pre-assessment on the submitted application and documentary requirements with regards to their completeness. Applications with incomplete document submissions shall not be accepted and the application will not proceed to the next step of the process.

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.

F. Payment of Fees

1. The payment of the total application fee as indicated in the Order of Payment (OP) maybe done through Over-the-counter (OTC) payment at FDAC, On-coll payment at Land Bank of the Philippines (LBP) branches, or online payment thru Bancnet (including LBP bills payment), based on the existing FDA issuances. The clients should 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 should be endorsed to Cashier Officer for the processing of payment. Clients will be informed of other available channels of payment through an FDA issuance.

2. Once the payment is made, the payment channel -LBP or Bancnet (except for OTC at FDAC) will send a transaction report to FDA which usually takes a minimum of two (2) days. Upon receipt of the report, the Cashier Section checks the details and posts 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.

3. 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 will not proceed to the next step of the process.

4. Applicants will receive a system-generated message through the registered email address on the status of the payment made once posted or need further settlement. If full payment is made, the e-mail will contain Acknowledgment Receipt, otherwise, a notification on payment deficiency.

G. 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.

H. Disapproval of Application

1. **For emphasis, the grounds for disapproval of LTO application may 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, without permission or approval from FDA;

   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.

I. 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 establishments 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 establishments.

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.

VI. SEPARABILITY CLAUSE

If any part or term of provision of this Circular shall be declared invalid or unenforceable, the validity or enforceability of the remaining portion or provision should not be affected, and this Circular shall be construed as it did not contain the invalid or unenforceable part, term or provision.

VII. REPEALING CLAUSE

Issuances, rules and regulations on the LTO applications for Traders, and Distributors including Wholesalers, Importers, and Exporters of medical devices, equipment/devices used for treating sharps, pathological and infectious waste, and water treatment devices/systems found inconsistent with the provisions of this Circular are hereby amended or repealed accordingly.

VIII. EFFECTIVITY

This Circular shall be effective immediately.

ROLANDO ENRIQUE D. DOMINGO, MD
Director General

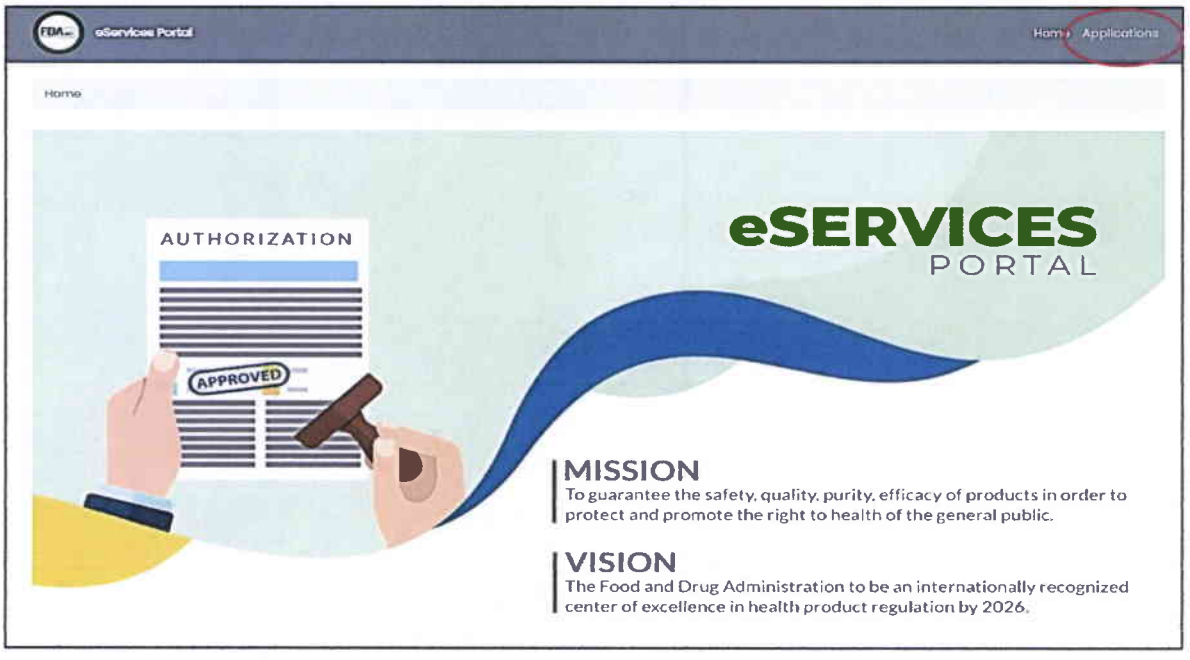
DTN: 20200928104025

ANNEX A

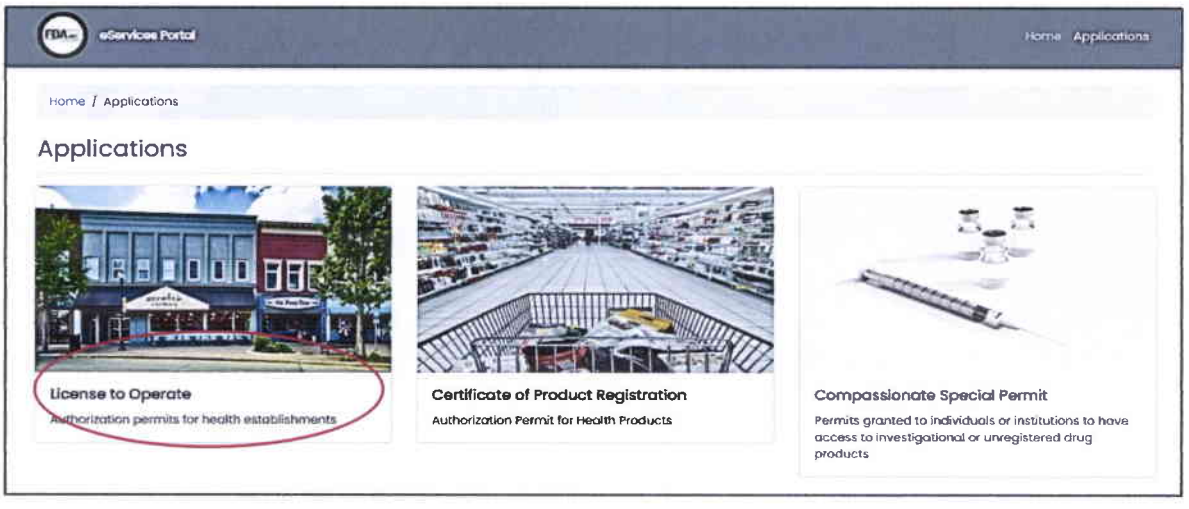
Procedure for the Use of the FDA eServices Portal for License to Operate (LTO) Application of Traders and Distributors including Wholesalers, Importers, and Exporters of Medical Devices

A. APPLICATION FOR INITIAL LTO OF MEDICAL DEVICE DISTRIBUTOR

1. Access the online portal through 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 (Distributor).



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

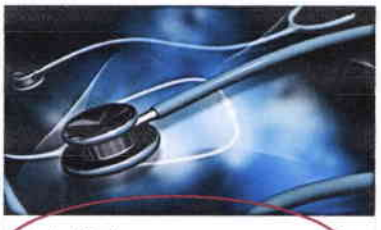
Device

For establishments that handle device products

FDA eServices Portal Home Applications

Home / Applications / License to Operate / Device

Device



Medical Device

For establishments that handle Medical Device

Health Related Device

For establishments that handle Health-Related Device products

FDA eServices Portal Home Applications

Home / Applications / License to Operate / Medical device

Medical Device

Application Status

Check the current status of your application

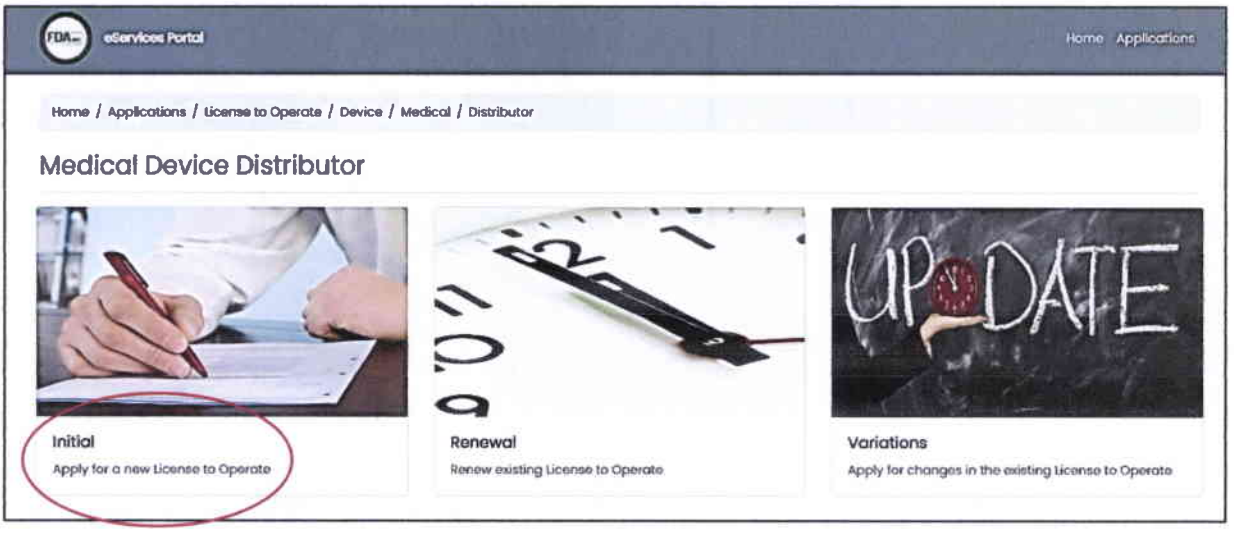
Distributor

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.

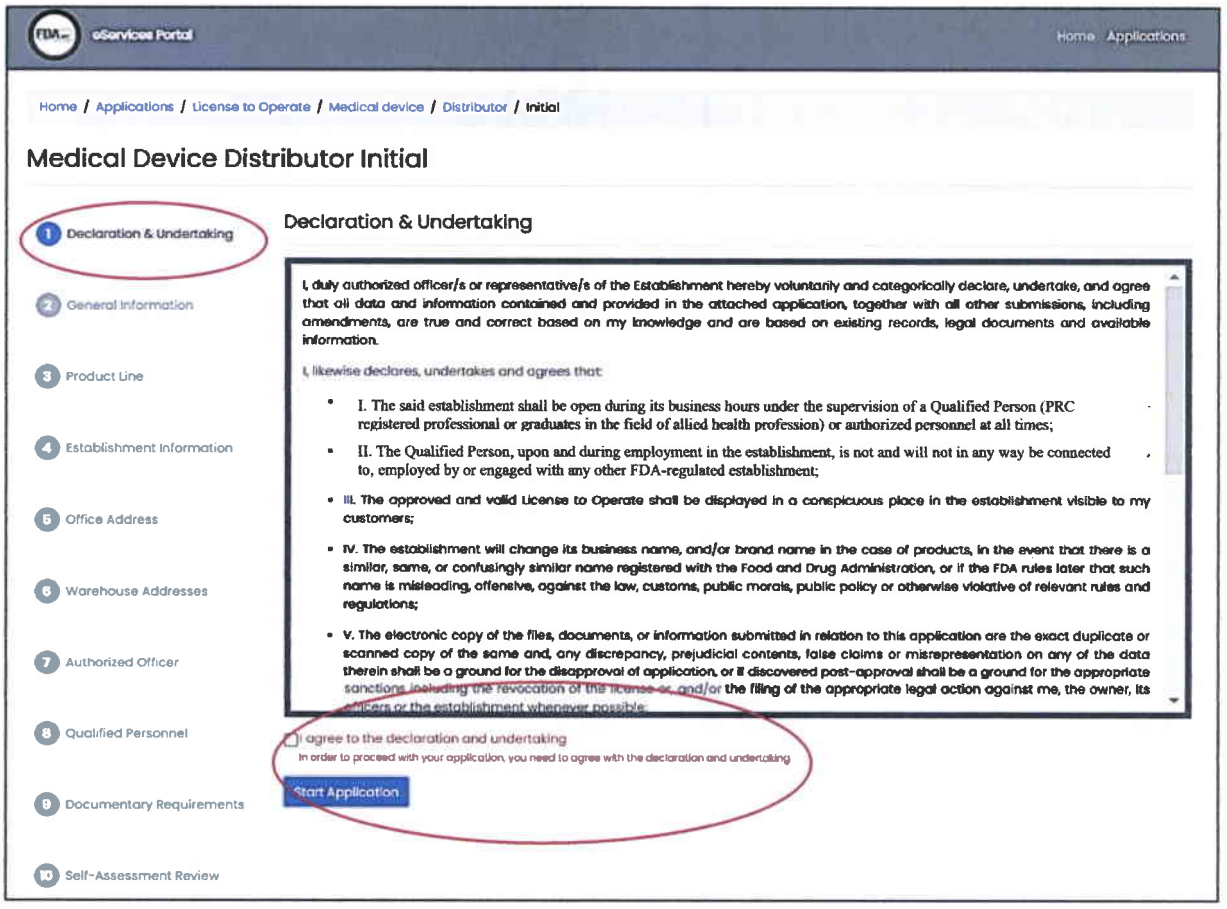
Trader

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

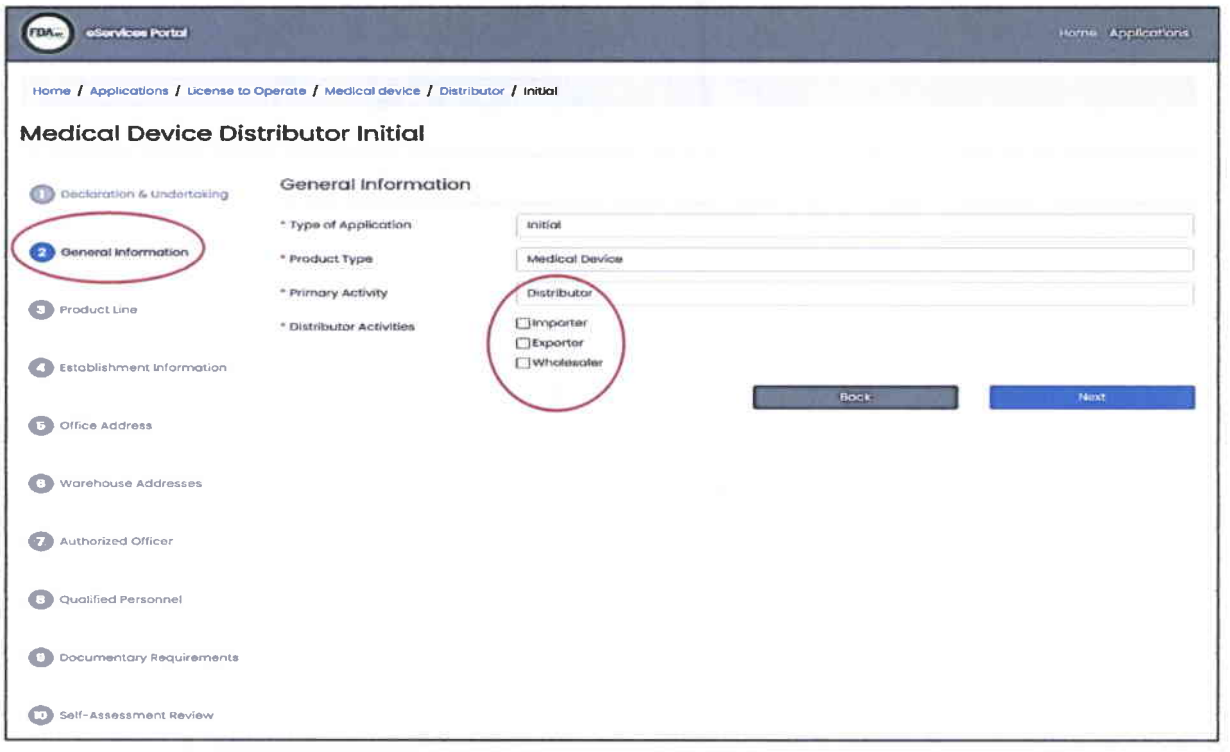
3. Click the Initial Application.



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"**.



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 before proceeding on the next step.



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