XVI. LICENSE TO OPERATE – INITIAL APPLICATION FOR MEDICAL DEVICE TRADERS AND DISTRIBUTORS (IMPORTER, EXPORTER, WHOLESALER)

Center/Office/Division	:	Center for Device Regulation, Radiation and Health Research (CDRRHR)
Classification	:	Complex
Type of Transaction	:	G2B – Government to Business
Who May Avail	:	All Medical Device Traders and Distributors (Importer, Exporter, Wholesaler)
Fees to be Paid	:	**Medical Device Trader:** 20 million and below – Php 3,000 + 1% LRF Over 20 million but below 50 million – Php 5,000 + 1% LRF 50 million and above – Php 7,000 + 1% LRF **Medical Device Distributors (Importer, Exporter, Wholesaler) :** Php 4,000 + 1% LRF **Administrative Order 50 s. 2001** *Revised 2001 Schedule of Fees and Charges for the Corresponding Services Rendered by the Bureau of Food and Drugs* **FDA Circular No. 2011-003** *Collection of Legal Research Fee Imposed by Republic Act No. 3870, as amended by PD 200 and further Amended by PD 1856*

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1)Basic Requirements based on the Administrative Order No. 2020-0017:	FDA website (www.fda.gov.ph)

Accomplished e-Application Form as prescribed by FDA regulations. ● Location plan and Global Positioning System (GPS) coordinates to be filled in the e-Application Form ● Name of the Qualified Person depending on the type of health product establishment Self-Declaration in the e-Application Form	FDA eServices (www.fda.gov.ph)
2) Proof of Business Registration Any one of the following shall be submitted as proof of business name registration (in pdf): ● For single proprietorship, the Certificate of Business Registration issued by the Department of Trade and Industry (DTI) (1 Scanned copy PDF) ● For Corporation, Partnership and other Juridical Person, the Certificate of Registration issued by the Securities and Exchange Commission (SEC) and Articles of Incorporation (1 Scanned copy PDF) ● For Cooperative, the Certificate of Registration issued by the Cooperative Authority and Articles of Cooperation (1 Scanned copy PDF) ● For Government-Owned or Controlled Corporation, the law creating the establishment, if with original charter, or its Certificate of Registration issued by the Securities and Exchange Commission (SEC) and Articles of Incorporation, if without original charter (1 Scanned copy PDF) When a business or establishment address is different from the business name registration address, the applicant shall submit a copy of the Business Permit (e.g., Mayor's Permit).	
3) Proof of income (for Trader) - Latest Audited Financial Statement with Balance Sheet or Duly notarized Statement/Certification of Initial Capitalization.	
4) Payment of fees as prescribed by current FDA regulations (AO 50 s. 2001).	
5) Refer to FROO Inspection Agenda of this Citizen's charter for the documents that will be presented to the FDA inspectors during inspection	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Access the online application portal through http://eservices.fda.gov.ph and click **"Applications"** found on the upper right corner of the system.		None	0	Qualified person
2. Selects the product category (Medical Device) and the type of business establishment (Medical Device Trader, Medical Device Distributor) before clicking "**Initial"** Application		None	0	Qualified Person
3. Reads the **"Declaration and Undertaking "**before proceeding with the application process. Check the box *"I agree to the Declaration and Undertaking"* and click on **"Start Application".**		None	0	Qualified Person
4. Fills-out all necessary information. All fields mark with asterisk (*) are required to be filled-out.		None	0	Qualified Person
5. Uploads the required documents as indicated on the Checklist of Requirements in pdf format.		None	0	Qualified Person
6. Reviews the duly filled out form in the **Self-Assessment Review**. Once reviewed, click on **"Confirm"** to submit the application.	1. Conducts pre-assessment on the submitted application and documentary requirements with regards to completeness and correctness. If the application passed the pre-assessment step, the applicant shall receive the	None	0	Qualified Person FDA Evaluator (Center/Licensing and Registration)

	Order of Payment with Reference Number via email. If not, the FDA shall notify the client the reason/s for non-acceptance and prompt the applicant to apply again through the eServices Portal.			
7. Prints the Order of Payment form with Reference Number sent through the declared e-mail address		None	0	Qualified Person
8. Pays the application fee through existing payment channels	2. Posts payment in eServices Portal System for confirmed payments. This will prompt automatic decking of application to respective Center. **LBP OnColl Payment: 5 wd** **Other Payment Channels: 2 wd** **Note**: Acknowledgement Receipt will automatically be sent to the client once payment is posted and will signify the	See above table	0	Qualified Person FDA Cashier Administrative and Finance Service (AFS)

	start of processing time of the application.			
9. Receives Acknowledgement Receipt through email	3. Checks and quality assurance of the documents provided	None	11 working days	Technical Officer of Center
	4. Finalizes decision on the LTO application If application is approved, the FDA shall send the LTO to the registered email address of the applicant. If application is disapproved, the FDA shall inform the applicant through its registered email address of the reason for such action on the application.	None	3 working days	Center Director
10. Receives notification and prints LTO if application is approved				Qualified Person
TOTAL:			**14 working days**	