2. APPLICATION FOR CERTIFICATE OF MEDICAL DEVICE LISTING (CMDL)

Center/Office/Division	:	CDRRHR-LRD
Classification	:	Complex Transaction
Type of Transaction	:	**G2B - Government-to-Businesses**
Who May Avail	:	Medical Device Manufacturers/Distributors (Importer/Exporter/Wholesaler)/Trader
Fees to be Paid	:	**Php 500.00 + 1% LRF per certificate** Note: Fee is per product reflected in a single packing list or invoice. If the product is reflected on a separate packing list/invoice, an additional fee shall be required.

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
LEGAL REQUIREMENTS	
1. Duly notarized and completely filled-up scanned copy of the Application Form.	Applicant. Form may be downloaded from the FDA website.
2. Notarized letter addressed to the Director, Center for Device Regulation, Radiation Health, and Research, stating that the medical device will be used solely for the intended use (e.g., research, clinical investigation, exhibit, personal use, sample product for analysis/testing, or donated brand new medical devices) and is not intended for sale. The letter should contain the following information: a. Complete list of the devices indicating the quantity, brand and the name of the manufacturer of the product b. Declaration that the organization shall be the sole entity responsible for the medical devices and that the CDRRHR-FDA, DOH will not be held liable for any safety issue concerning the product.	Applicant company
3. Copy of Certificate of Product Notification or Certificate of Product Registration or any equivalent document attesting to the safety and effectiveness of the device issued by the regulatory agency in the country where the device will come from.	Principal/Source/Manufacturer
4. Copy of SEC or DTI registration, when applicable.	Applicant company

5. Details for Bill of Landing Number / Air Waybill; Container Numbers, Packing List Number/Invoice Number.	Principal/Source/Manufacturer
6. For donated medical device/s (brand new), a certified true copy of the deed of donation and the deed of acceptance.	Principal/Source/Manufacturer and Applicant Company
7. For research proposal, research approval from Ethics Committee and research protocol.	Applicant company
8. For clinical study, approval from the Ethics Committee and clinical study protocol.	Applicant company
9. Payment	Applicant company
• Submit an electronic/scanned copy (in PDF searchable format of at least 150 dpi) • The file name should consist of the name of the requirement.	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME*	PERSON RESPONSIBLE
1. The applicant company sends an email to FDAC Letters. The e-mail should contain the complete application requirements.**	1. Receiving officer generates a Document Tracking Number (DTN) and sends an acknowledgment email / order of payment to the client.	None		FDAC Officer
2. The applicant company receives the Order of Payment and pays the assessed fee through FDAC Cashier or any other means prescribed by FDA. (e.g. BANCNET, LANDBANK ONCOLL). The Order of Payment will only be valid for 24 hours.	2. FDA receives the payment from the applicant company for posting.	PHP 510.00 per product. Note: If the declared products for importation are reflected on different or separate	**Timeline starts after posting of payment**	FDA Cashier

		packing list/invoice, then an additional payment of PHP510.00 per invoice would be required.		
3. The applicant company receives the official receipt and sends the proof of payment to FDA Action Center (FDAC) through email.	3. FDAC forwards the application to CDRRHR.	None	1 working day	FDAC Officer
	4. CDRRHR assigns the application to evaluator	None	1 working day	CDRRHR Administrative Staff
	5. The technical evaluator reviews the application. Recommends approval or disapproval.	None	6 working days	Technical Evaluator
	6. Assigning of number and Printing of CMDL.	None	2 working days	Technical Evaluator
	7. Quality Assurance - Checking of recommendation of the Supervisor	None	5 working days	LRD Chief
	8. Final Approval/Disapproval and signature of the Director.	None	2 working days	CDRRHR Director
	9. Scanning and transmitting of CMDL to the Records Section.	None	2 working days	CDRRHR Administrative Staff

5. Pick-up of certificate	10. Queuing and endorsement to the FDA Releasing Section	None	1 working day	AFS Records Officer / Administrative Officer
	TOTAL	**PHP510.00 per product/ packing list/invoice**	**20 working days**	

**Day 1 commences upon the receipt of the proof of payment / posting of payment.*

***Refer to FDA Circular No. 2020-026 – Food and Drug Action Center (FDAC) New Normal Operational Guidelines of the Food and Drug Administration (FDA).*