Certificate of Product Registration/Notification

1. INITIAL APPLICATION FOR CERTIFICATE OF MEDICAL DEVICE NOTIFICATION (CMDN)

Center/Office/Division	:	CDRRHR-LRD
Classification	:	Highly Technical
Type of Transaction	:	**G2B - Government-to-Businesses**
Who May Avail	:	Medical Device Manufacturers/Distributors (Importer/Exporter/Wholesaler)/Trader
Fees to be Paid	:	**Php7,500.00 + 1% LRF for initial with 5-year validity for Class A medical devices** **Php3,000.00 + 1% LRF for initial with 2-year validity for Class B, C, D medical devices not included in FDA Circular 2020-001-A**

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
LEGAL REQUIREMENTS	
1. 1 copy of Notarized Agreement / Letter of Authorization. ● Must be valid; ● The product being applied must be indicated. ● For imported medical devices, with notarized declaration from the legal manufacturer or product owner attesting that the authorization / agreement is true and correct. ● For imported medical devices but the agreements are signed in the Philippines, it must be notarized locally, with passport ID page and record of arrival and departure of the principal to and from the Philippines of the signatory/ies, and must be signed by both parties. ● For open-dated agreements/authorizations, if the certificate is beyond the 5-year period from the document's issuance, a re-issued agreement/authorization or a notarized attestation by the Principal that the agreement/authorization is still in effect must be submitted. ● For locally manufactured medical devices with an exclusive distributor, the agreement should be duly notarized. ● For locally manufactured medical devices with a toll manufacturer, the agreement between the	Principal/Source/Manufacturer

trader and the manufacturer should be duly notarized.	
2. For Imported Medical Devices - 1 copy of government-issued certificate attesting to the status of the Manufacturer with regard to the competence and reliability of the personnel and facilities, a Quality Systems Certificate of approval, or a compliance certificate for ISO 13485. ● Must be valid ● Copy of the certificate shall be accompanied by a notarized declaration from the legal manufacturer or product owner attesting that the certificate is true and correct. ● For products that are manufactured in multiple sites or toll manufacturers, identify or highlight the product source. ● The product being applied must be indicated in the scope. ● For locally manufactured products, submit the valid LTO of the manufacturer	Principal/Source/Manufacturer
3. For imported medical devices, 1 copy of Certificate of Product Notification, Certificate of Product Registration, or any equivalent document attesting to the safety and effectiveness of the device issued by the manufacturer (Self-Declaration), regulatory agency or accredited notified body in the country of origin. ● Must be valid ● The copy of the certificate shall be accompanied by a notarized declaration from the legal manufacturer or product owner attesting that the certificate is true and correct. Authenticated or apostilled document can be accepted if the document is authenticated or apostilled prior to September 2020.	Principal/Source/Manufacturer
4. 1 Clear colored picture of the actual commercial product sample of the device for all sides without its packaging. An actual representative sample or commercial presentation can be required by the CDRRHR for verification purposes. ● Picture should not pixelate when the view is increased in size	Principal/Source/Manufacturer

TECHNICAL REQUIREMENTS	
5. Device Description consisting of the following: a. Intended use – this should include the specific use of the product being applied. If the product is part of the system, the specific use of the product as part of the system should be indicated and not the intended use of the system. b. Instruction for use – this is the detailed instruction for use for the users of the medical device. The instruction should be clear enough to guide its users. c. List of raw materials – this should include all the raw materials as a component of the medical device itself. d. Technical specification of the finished product – This should include the technical specification of the finished products (physical, chemical, mechanical, electrical, etc.). This may in the form of Certificate of Analysis or Test certificate. For locally manufactured, the hierarchy of product standards shall apply.	Principal/Source/Manufacturer
6. 1 copy of Certificate of Conformity (issued by the government agency, or its equivalent, dealing with metrology) on the aspect of manufacture relating to metrology for devices with measuring functions, if applicable i.e. Thermometer, Weighing Scale, etc.	Principal/Source/Manufacturer
7. Declaration of Conformity with product standards (self-declaration by the manufacturer) with list of product standards. • These are the standards used during the design, development, manufacture, testing of the medical devices. • The following standards shall be considered: Philippine National Standards (PNS), international standards (ISO, IEC), other International Standard Bodies recognized by the DOH and other equivalent national standards (of these international standards).	Manufacturer

8. Clear and complete colored pictures of label from all sides of the packaging (loose label or artworks of all layers of packaging) for all codes included in the application. ● Immediate label, secondary packaging, box label and package insert/brochure, whichever is applicable. ● For any additional product claims on the label, submit studies or tests supporting the claims. ● For imported products, if the brand name is the product's local brand, declaration from the manufacturer allowing use of the brand name and IPO approval of the said brand name. ● For local manufactured products, IPO approval of the brand name ● If the CE marking is reflected on the label, submit a valid certificate supporting the placement of the CE mark. ● Pictures and text of the label should be clear and will not be pixelated when the view is increased in size. ● Lot No., Batch No., Serial No., whichever is applicable should be reflected. ● Expiration date, reference codes/sizes/variants/model whichever is applicable should be reflected. ● Storage condition, sterilization method should be reflected if applicable. ● Importer and distributor's name and address should be reflected in the label of the product together with the Product Notification Number ● Suggested Retail Price (SRP) in Philippine peso Note: The above requirements shall be superseded upon the approval of Administrative Order for the labeling requirements of medical devices.	Principal/Source/ Manufacturer
9. Declaration of shelf life.	Manufacturer
10. Payment	FDA Cashier
● All documents must be submitted in the English language. Documents submitted in any other foreign language not accompanied by a notarized English translation for legal documents and an English translation for technical documents shall be disapproved. ● Documents should be 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 will request for the user account through email.	1. FDA issues user account	None		FDAC Officer
2. The authorized representative of the applicant company fills out the online form/e-notification through the portal (eportal.fda.gov.ph). Uploads all the documents indicated on the checklist.	2. The CDRRHR assigns the application to the evaluator for pre-assessment. Applications filed from 5:00 PM and beyond will be decked for pre-assessment the next working day (8:00 AM).	None		CDRRHR Administrative Staff
3. If all the requirements are deemed complete, 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 5 working days.	3. Pre-assessment the application. The Client will receive either Order of Payment or Letter of Denial	None		CDRRHR Evaluator
4. The applicant company receives the official receipt.	4. FDA receives the payments from the applicant company.	Php 7,575.00 or Php 3,030.00	**Timeline starts after posting of payment**	FDA Cashier
	5. Posting of payment and automatic decking of the application to CDRRHR.	None		FDA Cashier
	7. Evaluation of application.	None	10 working days	
	8. Quality Assurance - Checking of recommendation of the Supervisor	None	10 working days	LRD Chief

	9. Final Approval/Disapproval with e-signature of the Director.	None	5 working days	CDRRHR Director
	TOTAL	**PHP 7,575.00 or Php 3,030.00**	**25 working days****	

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

***Service is covered under Republic Act No. 3720 Section 21 as amended by Executive Order No. 175 Section 13.*