7. RENEWAL APPLICATION OF MEDICAL DEVICES FOR ALL CLASSIFICATIONS (CMDN FOR CLASS A AND CMDR FOR CLASS B, C, & D)

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	:	**Php5,000.00 + 1% LRF for renewal with 5-year validity (Php 5,050.00) per product** **Late Renewal Fees (as per FDA Circular 2011-004)**

Timeline (after expiry date of certificate)	Validity of certificate (in years)	Fee	Surcharge	Penalty	LRF	Total
a. First month (10% penalty)	5	5,000.00	10,000.00	500.00	50.00	15,550.00
b. 1st day of the second month (20% penalty)	5	5,000.00	10,000.00	1,000.00	50.00	16,050.00
c. 1st day of the third month (30% penalty)	5	5,000.00	10,000.00	1,500.00	50.00	16,550.00
d. 1st day of the fourth month (40% penalty)	5	5,000.00	10,000.00	2,000.00	50.00	17,050.00

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1. Notarized Application Form ● Must be completely and accurately filled-up; ● Model / Reference Number / Sizes / Codes must be properly identified; ● For kits/sets, identify the complete contents/inclusions on the space provided for device name; ● LTO must be valid. However, if it is for renewal, submit proof of renewal application including the payment; ● For multiple CPR scheme, an annex page may be attached. However, the product name and model / reference number / size / code must be specified to which CPR it belongs to; ● For multiple models / reference number / size / codes, an annex page must be attached; ● For multiple models / reference number / size / codes, a Word copy must be submitted ● The Product Registration Number must be indicated (DVR/MDR/CMDN/CMDR); ● Should be signed by the proper authority as indicated on the form; ● Re-using forms is not acceptable.	Applicant. Form may be downloaded from the FDA website.
2. Payment	FDA Cashier

3. 1 Copy of Notarized Agreement / Letter of Authorization. • Must be valid; • The product being applied for 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 local agreements, it must be notarized locally, with passport ID page and record of arrival in the Philippines of the signatory/ies, and must be signed by both parties; • The issuing party and the local market authorization holder must bear their approved name and address as indicated in the CPR; • For open-dated agreements/authorizations, if the certificate is beyond the 5-year period, a certificate to confirm that the agreement is still valid must be submitted; • 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 locally manufactured medical devices with exclusive distributors, the agreement should be duly notarized. • For locally manufactured medical devices with toll manufacturer, agreement between the trader and the manufacturer should be duly notarized. For Imported Medical Devices - valid 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. • 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 where the product will be sourced from; • The product being applied must be indicated in the scope. • For locally manufactured medical devices, a valid LTO of the manufacturer must be submitted, a copy of valid ISO 13485 is also encouraged.	Principal/Source/Manufacturer

4. Colored picture of the device from all sides. However, the CDRRHR may require a representative sample or commercial presentation for verification purposes. • Must be removed from its packaging for clear visualization of the device.	Principal/Source/Manufacturer
5. Clear and complete colored pictures of label from all sides of the packaging (loose label or artworks of all layers of packaging) • Immediate label, secondary packaging, box label and package insert/brochure, whichever is applicable; • All the approved product model / reference number / sizes / codes must be submitted, indicating both the international and mandatory labeling requirements; • For any additional product claim/s on the label, submit studies or tests to support the claim/s; • For imported products, if the brand name is the product's local brand, submit a declaration from the manufacturer allowing use of the brand name and its corresponding IPO approval; • If the CE marking is reflected on the label, submit valid certificate supporting the placement of the CE mark; • Labels must be legible even after when zoom in; • Actual commercial labels must be submitted. Artworks are not acceptable since this is already for renewal; • Primary packaging must be identified. • All documents must be submitted in English language. • 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.	Principal/Source/Manufacturer
• Submit Table of Contents with correct page number.	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME*	PERSON RESPONSIBLE
1. Client sends an email containing the PDF of their application to fdac.letters@fda.gov.ph following the correct schedule.	1. Receiving officer generates a Document Tracking Number (DTN) and sends an acknowledgment email / order of payment to the client.	None	**Timeline starts after posting of payment**	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.	PHP5,050.00		FDA Cashier
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		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	10 Working days**	Technical Evaluator

	6. Quality Assurance - Checking of recommendation of the Supervisor	None	4 working days	LRD Chief
	7. Drafting and finalization of CPR.		1 working day	Technical Evaluator
	8. Final Approval/Disapproval and signature of the Director.	None	1 working day	CDRRHR Director
	9. Assigning of number and printing of CMDN/CMDR.	None	1 working day	CDRRHR Administrative Staff
	10. Transmittal of CMDN/CMDR to the Records Section.	None	1 working day	CDRRHR Administrative Staff
4. Pick-up of Certificate	11. Queuing and endorsement to the FDA Releasing Section.	None	1 working day	AFS Records Officer / Administrative Officer
	TOTAL	**PHP 5,050.00**	**20 working Days*** **	

**Day 1 commences upon the receipt of the proof of payment / posting of payment.*
***Timeline provided is for applications that are complete and correct with no Notice of Deficiencies issued.*
****Service is covered under Republic Act No. 3720 Section 21 as amended by Executive Order No. 175 Section 13.*