9. TURNED INITIAL APPLICATION FOR CERTIFICATE OF MEDICAL DEVICE REGISTRATION (CMDR) FOR CLASS 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	:	

APPLICATION	VALIDITY	FEE	SURCHARGE	PENALTY	LRF	TOTAL
Turned Initial (120 days after certificate's expiry date)	5	7,500.00	10,000.00	2,000.00	75.00	19,575.00

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1. Notarized Application Form ● Must be completely and correctly filled-up and signed ● Must use the latest form prescribed by the CDRRHR for the type of application ● Must submit one application form with attachment reflecting all the product codes being applied. Furthermore, the grouping of medical device family should be clearly specified. Only one condition should be considered in the multiple CPR application. ● Must be unedited, non-tampered; and must reflect the correct brand name, medical device name, and device risk-classification.	Applicant. Form may be downloaded from the FDA website.

2. 1 Copy of Notarized Agreement / Letter of Authorization. a. Must be valid; i. For imported medical devices, with notarized declaration from the legal manufacturer or product owner attesting that the authorization / agreement is true and correct. ii. 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 exclusive distributors, the agreement should be duly notarized. ● For locally manufactured medical devices with a toll manufacturer, the agreement between the trader and the manufacturer should be duly notarized.	Principal/Source/ Manufacturer
3. 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

4. For imported medical devices, 1 copy of Certificate of Product Registration, CE Certificate or any equivalent document attesting to the safety and effectiveness of the device issued by 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. • USA FDA 510K and PMA (Post Market Approval), Online registry from the Singapore HAS, and EC Full Quality Assurance and Design Verification Certificate	Principal/Source/ Manufacturer
5. Clear colored picture of the actual commercial product sample of the device for all sides without its packaging, for all the codes included in the application. An actual representative sample or commercial presentation can be required by the CDRRHR for verification purposes. ● Pictures should not be pixelated when the view is increased in size.	Applicant or Principal/Source/ Manufacturer
Technical Requirements	
6. Executive Summary. The executive summary shall include the following information: ● an overview, e.g., introductory descriptive information on the medical device, the intended uses and indications for use of the medical device, any novel features and a synopsis of the content of the CSDT; ● the commercial marketing history; ● the list of regulatory approvals or marketing clearances obtained; ● the status of any pending request for market clearance; and ● the important safety/performance related information.	Applicant or Principal/Source/ Manufacturer
7. Relevant essential principles and method/s used to demonstrate conformity. ● Must be completely filled-up.	Principal/Source/ Manufacturer
8. Device description with the following information: ● Intended use- this refers to the use for which the medical device is intended, for which it is suited according to the data supplied by the product owner in the instructions as well as the functional capability of the medical device. - 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.	Principal/Source/ Manufacturer

● Indications of use- this is a general description of the disease or condition that the medical device will diagnose, treat, prevent, cure or mitigate and includes a description of the target patient population for which the medical device is intended. ● Instruction for use- this are all necessary information from the product owner including the procedures, methods, frequency, duration, quantity and preparation to be followed for sale use of the medical device, instructions needed to use the medical device in a safe manner shall, to the extent possible, be included on the medical device itself and/or its packaging by other formats/forms. - This is the detailed instruction for use for the users of the medical device. The instruction should be clear enough to guide its users. ● Contraindications- This is a general description of the disease or condition and the patient population for which the medical device should not be used for the purpose of diagnosing, treating, curing or mitigating. Contraindications are conditions under which the medical device should not be used because the risk of use clearly outweighs any possible benefit. ● Warnings-This is the specific hazard alert information that a user needs to know before using the medical device. ● Precautions-This alerts the user to exercise special care necessary for the safe and effective use of the medical device. They may include actions to be taken to avoid effects on patients/users that may not be potentially life threatening or result in serious injury, but about which the user should be aware. Precautions may also alert the user to adverse effects on the medical device of use or misuse and the care necessary to avoid such effects. ● Potential adverse effects- These are potential undesirable and serious outcomes (death, injury, or serious adverse events) to the patient/user, or side effects from the use of the medical device, under normal conditions. ● Alternative therapy (practices and procedures) (if applicable) - This is a description of any alternative practices or procedures for diagnosing, treating, curing or mitigating the disease or condition for which the	

medical device is intended. ● Raw Materials or formulation. A description of the materials or formulation of the device and their physical properties to the extent necessary to demonstrate conformity with the relevant Essential Principles. The information shall include complete chemical, biological and physical characterization of the materials of the device. ● Should have a List of all raw materials used as a component of the product (specify for which product part or component the raw material is used). ● Must include quantity (for solutions) and technical specifications or detailed information on physical and chemical properties of each component. ● If the device contains PVC, identify the PVC plasticizer used. ● For kits/sets: submit the raw materials used with specifications of all components in the kit/set. ● Other Relevant Specifications to include the following: j.1 The functional characteristics and technical performance specifications of the device including, as relevant: accuracy, sensitivity, specificity of measuring and diagnostic medical devices, reliability, and other factors j.2 Other specifications including chemical, physical, electrical, mechanical, biological, software, sterility, stability, storage and transport, and packaging. ● May submit Certificate of Analysis or Test Certificate with finished product specification. ● For Stability, submit functionality and packaging/integrity test study of the product duly signed by the person who conducted the studies to justify the claimed expiration date. ● For accelerated study, submit computation to justify the storage conditions used. ● If the product has no expiration, submit justification from the manufacturer why the device has no expiration. ● Submit in-use stability study, as applicable. (e.g. contact lens solution, disinfectant) ● Identify the product's storage condition. ● For products with special storage conditions, submit transport stability study. ● For packaging, clarify the type of packaging used. i.e. blister pack, carton box, etc.	

● For medical devices with animal tissue origin, submit Certificate of Compliance with ISO 22442 - Medical devices utilizing animal tissues and their derivatives issued by Government Authority or notified body. ● Other Descriptive Information to demonstrate conformity with the relevant Essential Principles (e.g. biocompatibility category for the finished medical device)	
9. Summary of Design Verification and Validation Documents: The validation documents shall consist of the following: a. Declaration/Certificates of Conformity to the product standards issued by the manufacturer b. Summaries or reports of tests and evaluation based on other standards, manufacturer methods and tests, or alternative ways of demonstrating compliance, such as a listing of and conclusions drawn from published reports that concern the safety and performance of aspects of the medical device with reference to the Essential Principles; c. Data summaries or tests reports and evaluations covering the following appropriate test reports, whichever is applicable: ● Engineering test, including software validation studies, if applicable ● Laboratory test ● Biocompatibility test/biological evaluation ● Animal Test ● Simulated Use d. Clinical evidence - Implantable devices - Newly introduced devices - Devices incorporating new materials coming into contact with the patient - Existing materials applied in a body part not previously exposed to that material, and for which no prior chemical experience exists - An existing device that is modified and the modification might affect the safety and effectiveness - All other medical devices under Class D	Principal/Source/ Manufacturer

● Clinical evidence of the effectiveness may comprise of medical device-related investigations conducted domestically or other countries, or it may be derived from relevant publications in peer-reviewed scientific literature. ● The documented evidence submitted should include the objectives, methodology and results presented in context, clearly and meaningfully. ● The conclusions on the outcome of the clinical studies should be preceded by a discussion in context with the published literature. For Class D medical devices: A bibliography of all published reports dealing with the use, safety, and effectiveness of the device. ● Submit the most recent published reports for the medical device	
10. Clear and complete colored pictures of label from all sides of the packaging (loose label or artworks of all layers of packaging): a. Immediate label, secondary packaging, box label and package insert/brochure, whichever is applicable. b. For any additional product claims on the label, submit studies or tests supporting the claims. c. 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. d. For local manufactured products, IPO approval of the said brand name e. If the CE marking is reflected on the label, submit a valid certificate supporting the placement of the CE mark. f. Pictures and text of the label should be clear and will not be pixelated when the view is increase in size g. Lot No., Batch No., Serial No., whichever is applicable should be reflected h. Expiration date, reference codes/sizes/variants/model whichever is applicable should be reflected i. 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 Registration Number. ● Suggested Retail Price (SRP) in Philippine peso. The above requirements shall be superseded upon the approval of Administrative Order for the labeling requirements for medical devices.	Applicant or Principal/Source/ Manufacturer

11. Risk assessment which consists of risk analysis, evaluation and reduction measures. j. Identify the risk k. Submit Failure Mode Effect Analysis (FMEA) / Risk Benefit Analysis l. Evaluation of the effectiveness of control measures	Principal/Source/ Manufacturer
12. Physical Manufacturer information: m. Manufacturing process, including quality assurance measures. This should include the manufacturing methods and procedures, manufacturing environment or conditions, facilities and controls. The information may be presented in the form of a process flow chart showing an overview of production, controls, assembly, final product testing, and packaging of finished medical device. n. A brief summary of the sterilization method should be included. ● Include sterilization standard parameters, sterilization procedures, validation protocol and results of latest sterilization revalidation. ● If the sterilization of the device is contracted out, submit copy of valid ISO Certificate of the contracted sterilizing company. ● For non-sterile devices: a) submit Non-sterile declaration from the manufacturer; b) If the device is required to be sterilized prior to use, submit recommended sterilization guidelines from the manufacturer.	Principal/Source/ Manufacturer
● Documentary requirements must be arranged according to the CSDT format. ● Submit an electronic/scanned copy (in PDF searchable format of at least 150 dpi) ● The soft copy should be arranged according to the checklist of requirements. The file name should consist of the name of the requirement. The electronic copy should be contained either in one single continuous file per requirement or single continuous file for all requirements. ● Provide table of contents with page number	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME*	PERSON RESPONSIBLE
1. Client sends an email containing the PDF file of their application to cdrrhr-productregistration@fda.gov.ph following the correct schedule of application.	1. Receiving officer sends an acknowledgment email to the client and decks the application to the evaluator for pre-assessment.	None		CDRRHR officer
	2. Pre-assessment and issuance of Order of Payment or Denial Letter.	None	10 working days	CDRRHR Evaluator
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 3 working days.	3. FDA receives the payment from the applicant company for posting	PHP7,575.00	**Timeline starts after posting of payment**	FDA Cashier
3. The applicant company receives the official receipt and sends the proof of payment to cdrrhr-productregistration@fda.gov.ph through email.	4. CDRRHR assigns the application to evaluator	None	2 working days	CDRRHR Administrative Staff
	5. The technical evaluator reviews the application. Recommends approval or disapproval.	None	83 working days**	Technical Evaluator
	6. Quality Assurance - Checking of recommendation of the Supervisor	None	10 working days	LRD Chief
	7. Drafting and finalization of CPR.	None	3 working days	Technical Evaluator

	8. Final Approval/Disapproval and E- Signature	None	5 working days	CDRRHR Director
	9. Assigning of number and printing of CMDR.	None	3 working days	CDRRHR Administrative Staff
	10. Scanning, barcoding, and transmitting of CMDR to the Records Section.	None	3 working days	CDRRHR Administrative Staff
	11. Queuing and endorsement to the FDA Releasing Section	None	1 working day	AFS Records Officer/ Administrative Officer
	TOTAL	**PHP 7,575.00**	**110 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.*