14. TURNED INITIAL APPLICATION FOR CERTIFICATE OF PRODUCT REGISTRATION FOR IN-VITRO DIAGNOSTIC DEVICES/REAGENTS (IVD)

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	LABORATORY FEE	SURCHARGE	PENALTY	LRF	TOTAL
Turned Initial (120 days after certificate's expiry date)	1 year	1,500.00	c/o NRL	10,000.00	2,000.00	15.00	13,515.00

Additional Php1,000.00 + 1% LRF if the product is for the detection of hCG (pregnancy test) which requires performance evaluation testing

***Cost does not include the performance evaluation test; cost of testing depends on the corresponding National Reference Laboratory (NRL)**

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1. Table of Contents with correct page number	Applicant
2. Notarized Application Form • Must be completely filled-up; • Model / Reference Number / Sizes / Codes must be properly identified; • Refrain from indicating the Brand name (if applicable) on the Name of the product and vice versa • For kits/sets, identify the complete contents/inclusions on the space provided for device name; • For multiple models / reference number / size / codes, an annex page may be attached; • For multiple models / reference number / size / codes; a Word copy must be submitted • Should be signed by the proper authority as indicated on the form; • Re-using forms is not acceptable since this is a legal document.	Applicant. Form may be downloaded from the FDA website.
3. License to Operate (LTO) as a Medical Device Distributor (Importer/ Exporter/ Wholesaler)/ Local Manufacturer/Trader. • Shall be valid • The principal shall be reflected on the list of sources.	Applicant
4. Government Certificate of Clearance and Free Sale/Registration approval from the country of origin issued by the Health Authority • Shall be valid • Shall be authenticated/apostilled by the territorial Philippine Consulate for Imported Product. • For products with a trade name or reference code that differs per country, submit declaration or clarification from the manufacturer/principal. The product shall be stated on the list.	Principal/Source/ Manufacturer

5. For Imported Products - 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. • Shall be valid • Shall be authenticated/apostilled by the territorial Philippine Consulate • 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 products, valid LTO of the manufacturer	Principal/Source/ Manufacturer
6. Foreign Agency Agreement / Letter of Authorization. • Shall be valid. • Shall be authenticated/apostilled by the territorial Philippine Consulate. • The product being applied must be indicated. 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, a re-issued agreement/authorization must be submitted or a notarized attestation by the Principal that the agreement/authorization is still in effect. • 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.	Applicant or Principal/Source/ Manufacturer
Technical Requirements	

7. Intended use and Directions for Use which includes the following ● 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. ● 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 - these 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.	Principal/Source/ Manufacturer

● 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. ● Intended purpose, including the following information: ○ Type of analyte or measure of the assay. ○ Whether the test is quantitative or qualitative. ○ Role of the test in the clinical use e.g. screening, diagnostic or detection, aid to diagnostic, monitoring. ○ Disease or condition that the test is intended for. ○ Type of specimen to be used e.g. serum, plasma etc. ○ The intended users (e.g. Self-testing by lay person, near- patient by trained personnel or professionals). ○ Assay type e.g. immunoassay, chemistry, cytochemistry, image analysis, immunohistochemistry. ○ The specific name of the instrument required for the assay, if any. ● Test principle. ● Specimen type. ● Conditions for collection, handling, storage and preparation of the specimen. ● Reagent description and any limitation (e.g. use with a dedicated instrument only). ● Metrological traceability of values assigned to calibrators and trueness-control materials, including identification of applicable reference materials and/or reference measurement procedures of higher order. ● Assay procedure including calculations and interpretation of results. ● Information on interfering substances that may affect the performance of the assay. ● Performance characteristics (summarized analytical and diagnostic sensitivity, specificity, reproducibility, etc.) ● Reference intervals. ● Study design(population studies, N, type of sample, matrix, dilution, target concentrations, etc.).	

8. List of all raw materials used as components of the reagents/test kit • Product part or component where the raw material is used shall be specified • Must include quantity (for solutions) and technical specifications or detailed information on physical and chemical properties of each component. • If the product contains PVC, identify the PVC plasticizer used. For kits/sets submit all raw materials and specifications used.	Principal/Source/ Manufacturer
9. Technical specifications of the Finished Product	Principal/Source/ Manufacturer

10. Analytical and clinical performance studies to support IVD performance claims:
• Specimen type (suitability, collection, storage and transport stability)
• Equivalence between specimen types
• Analytical performance characteristics
  ○ accuracy
  ○ trueness and bias
  ○ precision (repeatability and reproducibility)
• Analytical sensitivity (limit of detection, detection of variants)
• Analytical specificity (interference and cross-reactivity)
• Measuring range of the assay
• Validation of assay cut-off
• Validation of assay reading time
• Complete performance study to justify all the claims on the package insert
	Principal/Source/ Manufacturer

11. Brief description of the manufacturing procedure/flowchart which shall include the ff: • methods used in the facility • controls in the manufacture • processing • packaging • process flowchart showing an overview of production	Principal/Source/ Manufacturer

12. Risk Analysis to include the results ● Identify the risk ● Submit Failure Mode Effect Analysis	Principal/Source/ Manufacturer
13. Stability test data and results which shall include: ● shelf-life study ● in-use stability study ● shipping stability studies to justify claimed shelf life Note: - Shall be performed on at least three (3) different product lots. - For accelerated study, indicate storage conditions, duration of study and computation to justify the storage condition used.	Principal/Source/ Manufacturer
14. Labeling materials ● Immediate label ● secondary packaging ● box label ● package insert/brochure. ○ shall include blood sample collection and handling ○ performance study results and summary ○ cross reactivity and list of potential interfering substances (if applicable) ○ warnings and precautions ○ information of the manufacturer ○ revision number	Principal/Source/ Manufacturer
15. For pregnancy test kits, 15 samples of the same lot with at least nine (9) months expiration date. NOTE: For other IVD applications, samples will be submitted directly to the respective NRLs. Number of samples required will depend on the requirement of each NRL. Take note that the labeling materials for all the samples should be complete and the same.	Applicant

16. Evidence of registration fee/payment (charge slip/official receipt)	FDA Cashier
• All documents shall be submitted in English language. Documents submitted in any other foreign language not accompanied by English Translation shall be disapproved. • Submit an electronic/scanned copy (in PDF searchable format of at least 150dpi). • The soft copy shall be arranged according to the checklist of requirements. • The file name shall consist of the name of the requirement. • The electronic copy shall be contained either in one single continuous file per requirement or single continuous file for all requirements. • Bring hard copy of the assessment slip. • Submission schedule will be generated by the FDA and sent thru email to client	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME*	PERSON RESPONSIBLE
1. Client sends and 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	**Timeline starts after posting of payment**	CDRRHR Officer
	2. Pre-assessment and issuance of Order of Payment or Denial Letter.	None		Technical 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. The FDA will receive the payment from the applicant company for posting	Php1,500.00 + 1% LRF for initial with 1-year validity* Additional Php1,000.00 + 1% LRF if the product is for the detection of hCG (pregnancy test) which requires performance evaluation testing. Cost does not include the performance evaluation test; cost of testing depends on the corresponding National Reference Laboratory (NRL).		FDA Cashier
3. The applicant company receives the official receipt and sends the proof of		None	1 working day	CDRRHR Administrative

payment to cdrrhr-productregistration@fda.gov.ph through email.	4. The CDRRHR will assign the application to evaluator			Staff
.	5. The technical evaluator reviews the application. Recommends approval or disapproval.	None	80 working days**	Technical Evaluator
.	6. Endorsement of the application to NRL for performance evaluation.	None	1 working day	Technical Evaluator
.	Performance Testing	c/o NRL	**Timeline depends on the NRL Procedure**	c/o the National Reference Laboratory
	7. Review of Performance Evaluation report	None	5 working days	Technical Evaluator
.	8. Quality Assurance - Checking of recommendation of the Supervisor	None	10 working days	LRD Chief
	9. Drafting and finalization of CPR.	None	2 working days	CDRRHR Admin Staff
.	10. Final Approval /Disapproval and signature of the Director	None	2 working days	CDRRHR Director
	11. Transmittal to Records Section.	None	1 working day	CDRRHR Administrative Staff
	12. Scanning and Barcoding of CPR	None	2 working days	AFS Records Officer / Administrative Officer

	13. Queuing and endorsement to the FDA Releasing Section	None	1 working day	AFS Records Officer / Administrative Officer
	TOTAL	**PHP 1,515.00** **For HCG pregnancy test kits – additional PHP1,010.00**	**105 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.*