CHECKLIST OF REQUIREMENTS FOR THE REGISTRATION OF AN IN VITRO DIAGNOSTIC DEVICE

REQUIREMENTS	TYPE OF APPLICATION	
	INITIAL	**RENEWAL**
1. Table of Contents (with page number)	√	√
2. Notarized Application Form from Distributor (Importer/Exporter/Wholesaler)/Local Manufacturer/Trader	√	√
3. Certificate of Brand Name Clearance (for branded products, if applicable)	√	
4. Valid License to Operate (LTO) of an IVD Distributor (Importer/ Exporter/ Wholesaler)/ Local Manufacturer/Trader	√	√
5. Valid Government Certificate of Clearance and Free Sale/Registration approval of the Product from the country of origin issued by the Health Authority and duly authenticated by the territorial Philippine Consulate for Imported Product	√	
6. Valid Government Certificate attesting to the status of the manufacturer, competency and reliability of the personnel and facilities or valid ISO Certification for Imported Product. For imported products, certificate must be and duly authenticated by the territorial Philippine Consulate	√	√
7. Copy of latest Certificate of Product Registration	N/A	√
8. Certificate of Foreign Agency Agreement between the manufacturer and trader/distributor/importer regarding the product involved duly authenticated by the territorial Philippine Consulate	√	√
9. Intended use and Directions for Use	√	
10. List of all raw materials used as components of the reagents/test kit	√	
11. Technical specifications and physical description of the Finished Product	√	
12. Process-control/Test Procedure and expected performance specification	√	
13. Brief description of the methods used in the facility and the controls in the manufacture, processing, packaging of the IVD and the process flowchart showing an overview of production	√	
14. Risk analysis with control measures	√	
15. A. For INITIAL: Stability test data and results describing the shelf life, in-use stability, and the shipping stability studies to justify claimed shelf life. The testing should be performed on at least three (3) different product lots manufactured under conditions that are essentially equivalent to routine production conditions. B. For RENEWAL: Stability test data and results describing the shelf life. The testing should be performed on at least three (3) different product lots manufactured under **REAL TIME CONDITION**.	√	√
16. A. For INITIAL: Labeling materials to be used for the product: Immediate label, secondary packaging, box label and package insert/brochure. B. For renewal, submit clear and readable commercial product label specimen of all labeling materials (outer, immediate, package insert)	√	√
17. For pregnancy test kit, 15 samples of the same lot with at least nine (9) months expiration date. For other IVD applications, samples will be submitted directly to the respective NRLs. No. of samples required will depend on the requirement of each NRL.	√	√
18. Evidence of registration fee/payment (charge slip/official receipt)	√	√

- *Application should be filed **six (6) months** prior to the expiration of the validity of the CPR.*
- *Submit an electronic/scanned copy (in PDF searchable format of at least 150dpi).*
- *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.*
- *Bring hard copy of the assessment slip***.**