Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION
Filinvest Corporate City
Alabang, City of Muntinlupa

Food and Drug Administration PHILIPPINES

QWP-CDRRHR/LRD-02 Annex 02
Rev. No. 04

CHECKLIST OF REQUIREMENTS FOR CERTIFICATE OF PRODUCT REGISTRATION OF MEDICAL DEVICES

1. Table of Contents (with page number)
2. Notarized Application Form from Distributor (Importer/ Exporter/ Wholesaler)/ Local Manufacturer/Trader
3. Valid License to Operate (LTO) of Distributor (Importer/ Exporter/ Wholesaler)/ Local Manufacturer/Trader
4. Valid Government Certificate of Clearance and Free Sale/Registration approval from the country of origin issued by the Health Authority and duly authenticated by the territorial Philippine Consulate for Imported Product
5. 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
6. Valid Certificate of Foreign Agency Agreement between the manufacturer and trader / distributor / importer regarding the product involved duly authenticated by the territorial Philippine Consulate
7. Specific Use and Directions/Instruction for use
8. List of all raw materials used as component of the product. Must include quantity and technical specifications or detailed information on physical and chemical properties of each component
9. Brief description of the methods used, the facilities and control in the manufacture, processing, and packaging of the product. For sterile products, include sterilization standard parameters, sterilization procedures, validation protocol and results of latest sterilization revalidation with sterility tests. If the sterilization of the device is contracted out, submit copy of valid ISO Certificate of the contracted sterilizing company.
10. Technical specifications and physical description of the Finished Product. Submit also the following: (a) Functionality/performance test data and results conducted on the finished product; (b) Test data and results of the Biocompatibility test of the device being registered; (c) Risk analysis with control measures, if applicable
11. Stability study of the product duly signed by the person who conducted the studies to justify claimed expiration date. For accelerated study, submit computation to justify the storage condition used. If no expiration, submit justification from the manufacturer why the device has no expiration.
12. Labeling materials for all the sizes/reference codes to be used for the product: Immediate label, secondary packaging, box label and package insert/brochure, whichever is applicable
13. Representative sample (as needed) and clear colored photo of the actual commercial product sample without its packaging
14. Evidence of registration fee/payment (charge slip/official receipt)

- *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.*
- *Bring hard copy of the assessment slip*