



MEDICAL DEVICE CONTROL IN THE PHILIPPINES

Maria Cecilia C. Matienzo

Division Chief

Center for Device Regulation, Radiation Health and Research

Food and Drug Administration

Department of Health

Email: mccmatienzo@fda.gov.ph



TOPICS

- **Brief Overview of the FDA Structure**
- **Definition of Medical Device**
- **Different Regulatory Controls for Medical Devices**
 - **License to Operate**
 - **Certificate of Product Registration**



FDA STRUCTURE

BACKGROUND

Republic Act 3720 was enacted into law in June 1963 which is known as the Food, Drug and Cosmetic Act. The FDA then was mandated to regulate the manufacture and distribution of food, drugs and cosmetics.

Executive Order No. 175 amended RA3720. One of the additional provision is the inclusion of the regulation of medical devices in the mandated function of BFAD

Executive Order No. 102 created the Bureau of Health Devices and Technology to regulate medical devices among others, however no law was enacted to give the BHDT the authority to regulate medical devices

Republic Act No. 9711 was enacted into law in August 2009 creating the Food and Drug Administration (FDA) in the Department of Health (DOH) strengthening the regulatory authority over food, drug, cosmetics, medical devices and other health devices



Bureau of Food and Drugs (BFAD) with regulatory functions over food, drugs, medical devices, cosmetics and household hazardous substances

Bureau of Health Devices and Technology (BHDT) with regulatory functions over radiation devices and radiation facilities



**FOOD AND DRUG ADMINISTRATION (FDA)
OF THE REPUBLIC OF THE PHILIPPINES**



FDA Act created 4 Centers

**Center for Drug
Regulation and
Research (to
include
veterinary
medicine,
vaccines and
biologicals)**

**Center for Food
Regulation and
Research**

**Center for
Cosmetics
Regulation and
Research (to
include
household
hazardous/urban
substances)**

**Center for Device
Regulation,
Radiation Health,
and Research.**



CDRRHR

 **Licensing and Regulation Division**

 **Product Research and Standards Development Division**

 **Laboratory Support Division**

 **Radiation Regulation Division**



Major Functions of the CDRRHR

Regulation of the manufacture, import, export, distribution, promotion, advertisement, and sale of medical devices, radiation devices, and health-related devices

Regulation of the use of radiation devices

Health technology assessment of medical devices

Standards Formulation

Post Market Surveillance (Compliance Monitoring)



MEDICAL DEVICE DEFINITION

Medical device means any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article:

a) intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
- investigation, replacement, modification, or support of the anatomy or of a physiological process,
- supporting or sustaining life,
- control of conception,
- disinfection of medical devices,
- providing information for medical or diagnostic purposes by means of in-vitro examination of specimens derived from the human body;

and

b) which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.



What do we Regulate?

- Medical Device Product
- Medical Device Establishment (Distributor, Importer, Wholesaler, Exporter, Manufacturer)



REGULATORY CONTROLS FOR MEDICAL DEVICES

- **License to Operate**
- **Certificate of Product Registration**
- **Certificate of Exemption**



List of Medical Devices that Require Registration

A. ***Based on Memorandum Circular No. 2 series of 1992***

- 1. Absorbable Collagen Hemostatic Felt
- 2. Absorbent Cotton, sterile & non-sterile
- 3. Arterial Venous Fistula Needle Set
- 4. Bandages with Plaster of Paris
- 5. Bandage, Elastic
- 6. Band-Aid Plastic Strip Plain Pad
- 7. Bone Wax
- 8. Blood Transfusion Set
- 9. Catheters
- 10. Cervical Collar
- 11. Collagen
- 12. Condom
- 13. Contact Lenses (hard and soft and disposable)
- 14. Corset Cast
- 15. Cosmetic Puffs Cotton
- 16. Cotton Buds
- 17. Cotton Swabs
- 18. Dental Filling Ally
- 19. Disposable Needles
- 20. Disposable Skin Stapler and Staples
- 21. Disposable Tissue Measuring Device
- 22. Drainage Pouches
- 23. Duodenal Tube
- 24. Ear piercing Device
- 25. Endotracheal Tube
- 26. Exchange Transfusion Tray
- 27. Feeding Tube
- 28. Filter Set
- 29. Fluor Alloy Amalgam
- 30. Gauze, sterile and non-sterile



- 31. Humidifier Mask
- 32. Hypo-Allergenic Paper Tape
- 33. Implantable Staple
- 34. Infusion Administration Set
- 35. Intraocular Lenses
- 36. Intrauterine Device (IUD)
- 37. I.V. Catheter Needles
- 38. Ligating Clip Device
- 39. Lubricating Jelly
- 40. Lumbar Puncture Tray
- 41. Nasal Oxygen Cannula
- 42. Nebulizer with Aerosol Mask
- 43. Orthoplast Cervical Collar
- 44. Ostotomy Set
- 45. Oxygen Catheter
- 46. Oxygen Mask
- 47. Periodontal Bone Grafting Implant
- 48. Peritoneal Dialysis Administration Set
- 49. Plaster
- 50. Porcine Heart Valve
- 51. Implantable Prostheses
- 52. Rectal Catheter
- 53. Rectal Tube
- 54. Removable Skin Staple
- 55. Rotahalers
- 56. Scalp Vein Infusion Set
- 57. Scissors Skin Retractors
- 58. Skin Traction Set
- 59. Spinal Anesthesia Tray
- 60. Stomach Bag



- 61. Stomach Tube
- 62. Suction Catheter
- 63. Surgical Blades, disposable
- 64. Surgical Gloves (sterile and unsterile)
- 65. Sutures
- 66. Suturing Needles
- 67. Synthetic Cast Padding
- 68. Syringes
- 69. Thermometers
- 70. Transfusion Set
- 71. Urethral Catheter
- 72. Urinary Drainage Tube
- 73. Urine Collecting Bag
- 74. Abdominal Pads

B. Sterile Products

C. Implants

D. Invasive



Checklist for the Registration of Medical Devices

- **1. Notarized Letter of Application from Manufacturer/Trader/Distributor**
- **2. Valid License to Operate (LTO) of Manufacturer/Trader/Importer/Distributor/Wholesaler**
- **3. Government Certificate of Clearance and Free Sale/Registration approval of the product from the country of origin issued by Health Authority and duly authenticated by the territorial Philippine Consulate for Imported Product**
- **4. Government Certificate attesting to the status of the manufacturer, competency and reliability of the personnel and facilities and duly authenticated by the territorial Philippine Consulate and/or valid ISO Certification for Imported Product**
- **5. Certificate of agreement between the manufacturer and trader/distributor/importer regarding the product involved.**



- 6. Specific Use and Directions for Use.**
- 7. Copy of latest Certificate of Product Registration (CPR)**
- 8. List of Amount and technical specifications of all raw materials.**
- 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 procedure.**
- 10. Technical specification and physical description of the Finished product.**
- 11. Stability studies of the product and physical description of the Finished Product.**
- 12. Labeling materials to be used for the product: Immediate label, box label and package insert/ brochures, if available.**
- 13. Representative sample in the market or commercial presentation (at least one of each size)**
- 14 Evidence of registration/payment (charge slip/official receipt)**
- 15. Biocompatibility Study**
- 16. Clinical Study**
- 17. Risk Management**



Checklist of Licensing of Medical Device Establishments (Distributor, Importer, Wholesaler, Exporter)

- **Accomplished Notarized Petition Form/Joint Affidavit of Undertaking**
- **List of Medical Device Products to be imported/distributed**
- **Copies of Pharmacist's Board of Registration Certificate, PRC ID, Valid PTR, ID Picture, Duties and Responsibilities, Certificate of attendance of the owner or pharmacist to a BFAD Seminar on Licensing of establishments**
- **Location plan and floor plan with dimensions**
- **If corporation, registration certificate with SEC and articles of incorporation or partnership**
- **If single proprietor, certificate of Business Name Registration with Bureau of Trade Regulation and Consumer Protection**
- **Contract of lease for the space of the office and storage to be occupied or any proof of ownership**



For importers:

- FAA duly authenticated by the Philippine Consular Office
- ISO/GMP of Manufacturer

For wholesalers/exporters:

- Valid contract with BFAD licensed supplier/manufacturer
- Certification that products to be sold are registered with BFAD
- LTO of local distributor/manufacturer

To be presented during inspection of establishment

- Copies of applicable laws
- Batch distribution record, product recall procedure



CERTIFICATE OF EXEMPTION

LTO

- **Letter of Intent**
- **Complete Product Line**
- **Brochure of the Products**

CPR:

- **Letter of Intent**
- **Intended use of the Product**



CERTIFICATES ISSUED FOR IMPORT/EXPORT

For Importation: Certificate of Non-Radiation

For Exportation: Certificate of Freesale

**** For registrable medical device products, it should be registered to be able us to issue the Free Sale Certificate**



TIMELINES

LTO

- **90 DAYS**

CPR:

- **180 DAYS**

COE

- **30 DAYS**



THANK YOU
VERY MUCH