Philippines

Legal
Legal framework: Yes

National Regulatory Authority
National Regulatory Authority present: Yes
Name: Bureau of Health Devices and Technology (BHDT), Department of Health http://www.doh.gov.ph/bhdt.html
Responsibilities of the NRA: The BHDT:
- Develops plans, policies, programs, and strategies for regulating health and health-related devices and technology
- Formulates rules, regulations and standards for licensing and accreditation of health and health-related devices and technology
- Conducts licensing and accreditation of health and health-related devices and technology.
- Provides technical consultative and advisory services to and develops capability of field offices on licensing and enforcement of laws, rules and regulations pertaining to health and health-related devices and technology.
- Monitors, evaluates and ensures compliance of manufacturers, distributors, advertisers and retailers of health and health-related devices and technology to health rules and regulations and standards of quality.
- Advises the Secretary and the Undersecretary of Health on matters pertaining to regulation of health and health-related devices and technology.
http://www.doh.gov.ph/bhdt.html

Medical device definition
Medical device defined: Yes
Text: Medical devices are not defined; rather, the Food, Drug and Cosmetics Act purports to regulate “devices” generally. Defined as instrument, apparatus, or contrivances, including their components, parts, and accessories, intended (1) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animals; or (2) to affect the structure or any function of the body of man or animals.
In vitro diagnostic medical device (IVD) defined: N/A
Text: N/A

Medical device classification
Classification: N/A
Categories: N/A
Classification rules: N/A
Classification rules details: N/A

Essential principles
Essential principles: N/A
Details: N/A

Conformity assessment
Conformity assessment bodies: N/A
Details: N/A
Pre-marketing / procedure: N/A

Reliance
Reliance: N/A
Details: N/A
Jurisdictions: N/A
Clinical investigation
Clinical investigation controls: N/A
Details: N/A

Registration and listing
Registration of establishment: N/A
Details: N/A
Listing of medical devices: Yes
Details: Only certain classes of devices must be registered prior to sale, distribution, and use. FDA Memorandum Circular No. 2014-005 (25 Feb. 2014)

Import controls
Import controls: Yes
Details: The Commissioner of Customs may take random samples of shipments of devices. Food, Drug, and Cosmetics Act, § 30. If the device is found not to meet requirements, then the Commissioner of Customs may cause them to be destroyed or to reliable the devices. Id.

Post market controls
Post Market Surveillance: N/A
Details: N/A
Inspection (QMS): Yes
Details: Officers or employees may inspect where devices are manufactured, processed, packed, or held. Food, Drug, and Cosmetics Act, § 27, 30.
Enforcement: N/A
Details: N/A
Adverse event reporting: N/A
Details: N/A
Field safety corrective action monitoring: N/A
Details: N/A
Advertising: Yes
Details: False representations and misbranding are prohibited. Food, Drug, and Cosmetic Act, §§ 11, 19.
Labelling: N/A
Details: False and misleading labelling is prohibited. Food, Drug, and Cosmetic Act, § 19.

Limitations: these data reflect a limited view and do not capture what may currently occur within Member States or how they implemented the data. Complete verification of the data may not be immediately possible and inaccuracies may linger. Mis-categorization or non-capture of a country’s regulatory framework is possible due to translation and interpretation.