Legal
Legal framework: Yes
Guidelines: N/A

National Regulatory Authority
National Regulatory Authority present: Yes
Name: Directorate General of Pharmaceutical and Medical Devices, The Ministry of Health of the Republic of Indonesia
http://www.binfar.depkes.go.id/

Medical device definition
Medical device defined: Yes
Text: Medical devices are the instruments, apparatuses, machines and/or implants that do not contain drugs used to prevent, diagnose, cure and relieve diseases, treat sick people, recover health of human beings, and/or form the structure and correct body function. Regulation Regarding Medical Devices, Art. 1
Medical devices may also contain drugs that do not reach the main work at or inside the human body through pharmacology, immunology or metabolism processes, but may support the desired function of the Medical Device in such way. Regulation Regarding Medical Devices, Art. 2.
Further, a Medical Device, based on the purpose of use as meant by the producer, may be used individually or in combination for human beings with one or several objectives as follows:
  a. diagnose, prevention, monitoring, treatment, or reduction of diseases;
  b. diagnose, monitoring, treatment, reduction of compensation of sick condition;
  c. investigation, replacement, modification, supporting the anatomy physiological process;
  d. support or maintain life;
  e. obstruct fertilization;
  f. disinfection of Medical Devices;
  g. provide information for medical purposes or diagnosis through the in vitro test on the specimen of human body.
Regulation Regarding Medical Devices, Art. 3.

In vitro diagnostic medical device (IVD) defined: N/A

Medical device classification
Classification: Yes
Categories: Class I, IIa, IIb, and III
Regulation Regarding Medical Devices, Art. 14.
Classification rules: Yes
Classification rules details: Classification is risk-based into four categories. Regulation Regarding Medical Devices, Appendix, I.A.

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

Conformity assessment
Conformity assessment bodies: N/A
Details: N/A
Pre-marketing / procedure: Medical devices that obtain a marketing license must:
- show safety and efficacy by conducting clinical tests and/or with other evidence
- demonstrate quality through GMP (shown through a production certificate for imported devices) and compliance with requirements
Regulations Regarding Medical Devices, Art. 9.
Reliance
Reliance: N/A
Details: N/A
Jurisdictions: N/A

Clinical investigation
Clinical investigation controls: Yes
Details: Medical devices that receive a marketing license must prove safety and efficacy by conducting clinical tests. Regulations Regarding Medical Devices, Art. 9.

Registration and listing
Registration of establishment: N/A
Details: N/A
Listing of medical devices: N/A
Details: N/A

Import controls
Import controls: Yes
Details: Medical devices that are imported (or used or marketed) within Indonesia must have a marketing license, which is provided by the Director General. Regulation Regarding Medical Devices, Arts. 5, 32-34.

Post market controls
Post Market Surveillance: N/A
Details: N/A
Inspection (QMS): N/A
Details: N/A
Enforcement: Yes
Details: Both administrative and criminal sanctions are available for violations of provision of the Regulation Regarding Medical Devices, Arts. 55-56.
Adverse event reporting: Yes
Details: The company that possesses a marketing license should submit a report on adverse events once a year. Regulations Regarding Medical Devices, Art. 25.
Field safety corrective action monitoring: N/A
Details: N/A
Advertising: Yes
Details: Advertisements may not be misleading. The Minister evaluates advertisements after they have aired/been disseminated to the public. Regulations Regarding Medical Devices, Arts. 28-29.
Labelling: Yes
Details: Labels may be in the form of pictures, colours, writing, or a combination thereof. The label must contain at minimum:
- product name and/or trade name
- named and address of the company
- main components
- intended use and instructions for use in Indonesian
- warnings in Indonesian
- expiration date
- batch or lot number
- marketing license number
Regulation Regarding Medical Devices, Arts. 26.

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.