Ecuador

World Bank income group: Upper middle income

Legal

Legal framework: Yes

Authorizing legislation:
- Health Code of 1971
- Executive Decree No. 1583, RO/Sup 349, June 18, 2001, 2
- Reglamento y Control Sanitario de Dispositivos Medicos y Dentales (2009)
- Reglamento Para El Registro y Control Sanitario de Dispositivos Médicos; reactivos Bioquimicos y Diagnostico; y, Productos Dentales (2013)
- Ministerial Agreement No. 0000230, 30 May 2007 (Ley No. 2000-12)

Guidelines: N/A

National Regulatory Authority

National Regulatory Authority present: Yes

Name: Agencia Nacional de Regulación, Control y Vigilancia Sanitaria

NOTE: The National Institute of Hygiene and Tropical Medicine oversees registration of medical devices. Reglamento (2013), Art. 3.

Responsibilities of the NRA: Protect the health of the population through the regulation and control of the quality, safety, efficacy and safety of products for human use and consumption as well as the hygienic conditions of the establishments subject to sanitary surveillance and control in the field of action.

Medical device definition

Medical device defined: Yes

Text: Medical devices are articles, instruments, apparatus, appliances and mechanical inventions, including their components, parts or accessories, manufactured, sold or recommended for use in diagnosis, cure or palliative, preventing a disease, disorder or abnormal physical state or its symptoms to replace or modify the anatomy or a physiological process or control. It includes amalgams, varnishes, sealants and dental products similar and are:

1. Medical devices transient use: intended for continuous use for less than 60 minutes.
2. Medical devices for short-term, continuous use for a period of up to 30 days.

Reglamento (2013), Art. 2.

In vitro diagnostic medical device (IVD) defined: Yes

Text: Defined Separately. Regulation and Sanitary Control of Medical and Dental Devices, Art. 2

Medical device classification

Classification: Yes

Categories: I, II, III, and IV

Classification rules: Yes

Classification rules details: Medical devices are classified according to use and level of risk. Reglamento (2009), Art. 16.

Diagnostic products are classified separately. Reglamento (2009), Art. 23.

Essential principles

Essential principles: N/A

Details: N/A

Conformity assessment

Conformity assessment bodies: N/A

Details: N/A

Pre-marketing / procedure: Yes - Chapter III of Reglamento (2009)

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: Yes  
Details: Providers and authorized representatives must be registered. Ministerial Agreement No. 230, Art. 1

Listing of medical devices: Yes  
Details: Medical devices must be registered for production, storage, transportation, marketing and consumption. Health Law, Art. 100.  
Database available at http://www.controlsanitario.gob.ec/base-de-datos/

**Import controls**

Import controls: Yes  
Details: Products to be imported need to be registered in advance, prior to import. Executive Decree No. 1583, Art. 53, 64.

**Post market controls**

Post Market Surveillance: N/A  
Details: N/A

Inspection (QMS): Yes  
Details: Authorities must conduct periodic inspections to verify compliance. Executive Decree No. 1583, Art. 27

Enforcement: Yes  
Details: The National Health Authority must verify the quality, efficacy, and safety of products that have been approved for registration. At least two inspections must be undertaken during the registration period. Reglamento, Art 27.  
Failure to comply with provisions of the Health Law may result in punishment under the law. See, e.g., Health Law, Art 100 (penalties under law for not complying with registration requirements).

Adverse event reporting: N/A  
Details: N/A

Field safety corrective action monitoring: N/A  
Details: N/A

Advertising: Yes  
Details: All publicity is subject to control and approval by the health authority. Health Law, Art. 164.

Labelling: Yes  
Details: Labels must be in Spanish or contain other languages so long as it includes Spanish. Information on the name of the product, brand name, contents of the packaging, etc. must be included on the label. Reglamento (2009), Art. 14.  
Any change to the labelling of a registered product must require the product to be registered again. Health Law, Art. 109.

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.