Legal
Legal framework: Yes
Guidelines: N/A

National Regulatory Authority
National Regulatory Authority present: Yes
Name: Direccion General de Regulacion Sanitaria
http://www.dgrs.gob.hn/default.aspx
Responsibilities of the NRA: Acuerdo No. 6, Art. 72; 99; 103

Medical device definition
Medical device defined: Yes
Notes: Medical devices are included in the definition of “medical devices and equipment.”
Text: Medical devices and equipment is a tool, apparatus, implement, machine, or other similar article that used by itself or in combination with an accessory for proper function is used in prevention, cure, rehabilitation and investigation of health. Acuerdo No. 6, Art. 2.
In vitro diagnostic medical device (IVD) defined: N/A
Text: N/A

Medical device classification
Classification: Yes
Categories: Class A, B, and C.
Acuerdo No. 6, Art. 97.
Classification rules: Yes
Classification rules details: Classification rules are detailed in Acuerdo No. 6, Art. 98 et seq.

Essential principles
Essential principles: Yes
Details: N/A

Conformity assessment
Conformity assessment bodies: N/A
Details: N/A
Pre-marketing / procedure: All medical devices and equipment must comply with norms. Acuerdo No. 6, Art. 104; Chapter VII.

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: All establishments that function within Honduras must register with theDireccion General de Regulacion Sanitaria. Acuerdo No. 6, Art. 127.
Listing of medical devices: Yes
Details: All medical devices must be registered in accordance with Acuerdo No. 6, § 3 before they may be imported, transported, distributed, commercialized, etc. in Honduras. Acuerdo No. 6, Art. 140.
## Import controls

**Import controls:** Yes  
**Details:** To register an imported medical device, one must present a certificate of free trade or a declaration of quality assurance. Acuerdo No. 6, Art. 152.

## Post market controls

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

**Inspection (QMS):** Yes  
**Details:** The Sanitary Authority shall carry out inspections of medical device and equipment establishments and apply corrective measures, if necessary. Acuerdo No. 6, Art. 103

**Enforcement:** Yes  
**Details:** Violations of Acuerdo No. 6 may result in sanctions, penalties, etc. Acuerdo No. 6, Ch. IX.

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

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

**Advertising:** N/A  
**Details:** N/A

**Labelling:** Yes  
**Details:** Any product in the national market must comply with labelling requirements. Acuerdo No. 6, Chapter VI.

---

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.