Colombia

World Bank income group: Upper middle income

Legal

Legal framework: Yes


Guidelines: N/A

National Regulatory Authority

National Regulatory Authority present: Yes


Responsibilities of the NRA: N/A

Medical device definition

Medical device defined: Yes

Text: A medical device for human use is any instrument, apparatus, machine, software, or other biomedical equipment similar or related article, whether used alone or in combination, including their components, parts, accessories and software necessary for its proper application intended by the manufacturer for use in:
   a) diagnosis, prevention, monitoring, treatment or alleviation of disease;
   b) diagnosis, prevention, monitoring, treatment, alleviation or compensation for an injury or handicap;
   c) investigation, replacement, modification or support the anatomical structure or physiological process;
   d) diagnosis of pregnancy and conception control;
   e) care during pregnancy, birth or thereafter, including newborn care;
   f) products for disinfection and/or sterilization of medical devices,
Medical devices for human use shall not exercise as main action by pharmacological, immunological, or metabolic means.
Decreto 4725, 2005, Art. 2.

In vitro diagnostic medical device (IVD) defined: Yes


Medical device classification

Classification: Yes

Categories: Class I, IIA, IIB, and III.
Decreto 4725, 2005, Art. 5.

Classification rules: Yes

Classification rules details: Decreto 4725, 2005, Arts. 6-7.

Essential principles

Essential principles: Yes

Details: Medical devices must meet the requirements safety and performance established by the manufacturer that apply to them according to the intended purpose. Decreto 4725, 2005, Art. 4.

Conformity assessment

Conformity assessment bodies: N/A

Details: N/A

Pre-marketing / procedure: All importers and establishments must meet conformity requirements. Decreto 4725, 2005, Art. 10.

Reliance

Reliance: Yes

Details: For class I, IIA, and IIB devices
Decreto 3275, 2009

Jurisdictions: EU, USA, Canada, Japan, Australia, Decreto 3275, 2009
Clinical investigation

**Clinical investigation controls:** N/A
**Details:** N/A

Registration and listing

**Registration of establishment:** Yes
**Details:** Before entering the market the manufacturer must submit INVIMA request for inspection visit to certify compliance of good manufacturing practices of medical devices: the documentation must include: a) Name of the owner or legal representative of the establishment; b) Name or business name and address of the establishment; c) Certificate of incorporation and legal representation of the establishment or certificate commercial for natural person, issued by the Chamber of Commerce, which must have a date less than thirty (30) days expedition; d) Testing and quality assurance of the product and the manufacturing process; e) Organizational manufacturer establishment; f) Architectural plans manufacturer distribution facility; g) List of equipment that is available. Decreto 4725, 2005, Art 13.

**Listing of medical devices:** Yes
**Details:** Devices require sanitary registration issued by Invima. Class I and IIa devices may be registered through an automatic sanitary registry, given their compliance with essential requirements. Decreto 4725, 2005, Arts. 16-17.

Import controls

**Import controls:** Yes
**Details:** All importers must meet storage and packaging requirements established by the Ministry of Social Protection. Decreto 4725, 2005, Art. 10.
Importers must also receive an import registration. Decreto 4725, 2005, Art. 23.

Post market controls

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

**Inspection (QMS):** Yes
**Details:** There must be evidence of the manufacturer’s quality system for registration of a device. Decreto 4725, 2005, Art. 12, Art 13; Art. 65

**Enforcement:** Yes
**Details:** Decreto 4725, 2005, Arts. 71- 85.

**Adverse event reporting:** Yes
**Details:** Establishments, manufacturers, holders of valid health records and marketing permits, users, or any other person with knowledge of any adverse event or of any inadequacy must notify the regional health directorates as well as INVIMA. The directorates of health must in turn take any necessary actions. Decreto 4725, 2005, Arts. 59-60.
INVIMA must conduct periodic visits or when convenient to ensure compliance with conditions under law of establishments and importers. Decreto 4725, 2005, Art. 66.

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

**Advertising:** Yes
**Details:** Colombia prescribes false advertising. The nature of advertisement differs based on the classification of the device. Decreto 4725, 2005, Art. 58.

**Labelling:** Yes
**Details:** Labels should have information to identify and safely use the medical device. Decreto 4725, 2005, Art. 53. Further, labels should be in Castilian. Id. Art. 54, 57 (for imported devices).

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.