Nicaragua

World Bank income group: Lower middle income

Legal

Legal framework: Yes

Authorizing legislation: Decreto No. 001-2003 “Reglamento de la Ley General de Salud”
Ministerial Resolution No. 402-2015
http://www.minsa.gob.ni/index.php/repository/Descargas-MINSA/Direcci%C3%B3n-General-de-Regulaci%C3%B3n-Sanitaria/Dispositivos-M%C3%A9dicos/Resoluci%C3%B3n-C3%3An-Ministerial-No.-402-2015/

Ministerial Resolution 144-2011
http://www.minsa.gob.ni/index.php/repository/Descargas-MINSA/Direcci%C3%B3n-General-de-Regulaci%C3%B3n-Sanitaria/Dispositivos-M%C3%A9dicos/Resoluci%C3%B3n-Ministerial-144-2011/

Guidelines: Norma Para El Registro de Dispositivos Médicos (April 2011) http://www.minsa.gob.ni/index.php/repository/Descargas-MINSA/Direcci%C3%B3n-General-de-Regulaci%C3%B3n-Sanitaria/Dispositivos-M%C3%A9dicos/Normativa-064%E2%80%9CNorma-para-elRegistro-de-dispositivos-m%C3%A9dicos%E2%80%9D/ 
Procedimiento para la Autorizaction de Facturas de Importacion de Dispositivos Médicos http://www.minsa.gob.ni/index.php/repository/Descargas-MINSA/Direcci%C3%B3n-General-de-Regulaci%C3%B3n-Sanitaria/Dispositivos-M%C3%A9dicos/Procedimiento-para-la-autorizaci%C3%B3n-de-facturas-de-importacion-de-dispositivos-m%C3%A9dicos-%E2%80%93-Anexo-II/.

National Regulatory Authority

National Regulatory Authority present: Yes

Name: Direccióan General de Regulacióan Sanitaria, Ministerio de Salud (MINSA) http://www.minsa.gob.ni/index.php/component/search/?searchword=dispositivos%20medicos&searchphrase=all&Itemid=435

Responsibilities of the NRA: N/A

Medical device definition

Medical device defined: Yes

Text: A medical device is any instrument, implement, machine, device, implant material, or another similar item or related, used alone or in combination, including accessories and software necessary for its proper application intended by the manufacturer for use with human beings for the diagnosis, prevention, monitoring, treatment and relief of disease, injury, or disability. They are also used in research, replacement, or modification of anatomy, physiological processes, and the control of conception. Norma, p. 9.

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

Text: N/A

Medical device classification

Classification: Yes

Categories: Class I, II, III, and IV.

Classification rules: Yes

Classification rules details: Classification rules are detailed in Norma, pp. 20-31.

Essential principles

Essential principles: Yes

Details: Note: medical devices must meet ISO standards. Norma, p. 20.

Conformity assessment

Conformity assessment bodies: N/A

Details: N/A


Reliance

Reliance: Yes

Details: N/A

Jurisdictions: USA, EU, Norma p. 19.
Clinical investigation
Clinical investigation controls: N/A
Details: N/A

Registration and listing
Registration of establishment: Yes
Details: All establishments that manufacture, import and/or distribute medical devices must be registered with the Direccion de Registro. Norma, p. 17.
Listing of medical devices: Yes
Details: All medical devices must be registered. Norma, p. 16.

Import controls
Import controls: Yes
Details: Importers must comply with the requirements (such as establishment registration, etc.) under law, detailed in Norma

Post market controls
Post Market Surveillance: N/A
Details: N/A
Inspection (QMS): N/A
Details: N/A
Enforcement: Yes
Details: The NRA may cancel or suspend licenses in cases of adverse events, be they reported in Nicaragua or by the FDA, etc. Norma, 17-18.
Adverse event reporting: Yes
Details: The Direccion de Regulacion Sanitaria has a system of control and vigilance for medical devices. Norma, p. 18.
Field safety corrective action monitoring: N/A
Details: N/A
Advertising: N/A
Details: N/A
Labelling: N/A
Details: N/A

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.