Costa Rica

World Bank income group: Upper middle income

Legal

Legal framework: Yes

Authorizing legislation: General Health Law, N° 5395 https://costarica.eregulations.org/media/I-5395.pdf establishes the regulation of health products Regulations on Registration, Classification, Import, and Control of Medical Equipment and Biological Materials[hereafter DE], No. 34482-S

http://www.pgrweb.go.cr/scij/Busqueda/Normativa/Normas/nrm_texto_completo.aspx?param1=NRTC&nValor1=1&nValor2=62959&nValor3=99850&strTipM=TC


Guidelines: N/A

Notes: Medical devices are regulated as any other “equipment and biological material”

National Regulatory Authority

National Regulatory Authority present: Yes

Name: Ministerio de Salud

http://www.ministeriodesalud.go.cr/

Responsibilities of the NRA: N/A

Medical device definition

Medical device defined: Yes

Text: Medical devices are included under the definition of “equipment and biomedical material” (EMB) and regulated like all other products within that category. DE No. 34482-S, Art. 3.6.

In vitro diagnostic medical device (IVD) defined: Yes

Text: Defined separately.

DE No. 34482-S, Art. 3.15.

Medical device classification

Classification: Yes

Categories: Classes 1, 2, 3, and 4.

DE No. 34482-S, Art. 4.

Classification rules: Yes

Classification rules details: Classification rules are detailed in DE No. 34482-S, Art. 4.

Essential principles

Essential principles: Yes

Details: Any equipment or biomedical material (including medical device) may be manufactured, imported, or sold if it possesses the appropriate certificate and meets quality requirements. DE No.34482-S, Art. 5.

Conformity assessment

Conformity assessment bodies: N/A

Details: N/A

Pre-marketing / procedure: Chapter III of DE NO. 34482-S describes the Conformity Assessment Procedure.

Reliance

Reliance: Yes

Details: DE NO. 34482-S, Art. 17-18

Jurisdictions: USA

Resolucion DM-F-1518-2911

Clinical investigation

Clinical investigation controls: N/A

Details: N/A
Registration and listing
Registration of establishment: N/A
Details: N/A
Listing of medical devices: Yes
Details: Equipment and biomedical materials must be registered. DE No. 34482-S.

Import controls
Import controls: Yes
Details: Importation of equipment and biomedical material (including medical devices) requires a customs clearance by the Ministry. DE No. 34482-S, Art. 21.

Post market controls
Post Market Surveillance: Yes
Details: Registration of equipment and biomedical products requires a presentation of a monitoring program by the manufacturer. DE No. 34482-S, Art. 8.
Inspection (QMS): N/A
Details: N/A
Enforcement: Yes
Details: The Ministry may request the recall of equipment or biomedical material. If there was fault for an adverse or harmful event, then the responsible entity may be subject to civil or administrative proceedings. DE NO. 34482-S, Art. 28.
Adverse event reporting: Yes
Details: Any person responsible for equipment or biomedical material must report any adverse event to the Ministry of Health. DE No. 34482-S, Art. 26.
Field safety corrective action monitoring: N/A
Details: N/A
Advertising: N/A
Details: N/A
Labelling: Yes
Details: Labels of equipment and biomedical material must contain information on the EMB’s name, the country of origin, the name of the manufacturer, the address of the importer/distributor, etc. DE No. 34482-S, Art. 25.

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.