El Salvador

Legal

Legal framework: Yes

Authorizing legislation: Decreto No. 1008: Ley de Medicamentos, 2012
http://www.asamblea.gob.sv/eparlamento/indice-legislativo/buscador-de-documentos-legislativos/ley-de-medicamentos
Decreto No. 245: Reglamento General de la Ley de Medicamentos


National Regulatory Authority

National Regulatory Authority present: Yes

Name: Direccion Nacional de Medicamentos
http://www.medicamentos.gob.sv/index.php/

Responsibilities of the NRA: N/A

Medical device definition

Medical device defined: Yes

Text: Medical devices are regulated under the term medical supply (insumo médico). Medical supply or medical device, article, instrument, apparatus or device, including parts components or accessories, sold or recommended for use in: 1. Diagnosis, curative or palliative treatment or prevention of a disease or disorder or abnormal physical state in a human symptoms. 2. Restoration, correction or modification of physiological function or body structure in a human. 3. Diagnosis of a human pregnancy. 4. Humans care during pregnancy, birth or during the same including newborn care

The difference between a specialty pharmaceutical and medical supply is that the medical device does not achieve its purpose for which it is used through an chemical action in the body or is biotransformed during use. Guia de registro y tramites post registro de insumos medicos p. 2.

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

Text: N/A

Medical device classification

Classification: N/A

Categories: N/A

Classification rules: N/A

Classification rules details: N/A

Essential principles

Essential principles: N/A

Details: N/A

Conformity assessment

Conformity assessment bodies: N/A

Details: N/A

Pre-marketing / procedure: N/A

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: Reglamento General de la Ley de Medicamentos, Titulo V.
Listing of medical devices: Yes
Details: Medical devices are registered as a medical supply. They must meet established requirements to be registered. Reglamento General de la Ley de Medicamentos, Art. 23-26.

Import controls
Import controls: Yes
Details: Registration of an imported medical device requires the inclusion of a free sales certificate in the application. Manual. Reglamento General de la Ley de Medicamentos, Titulo IV

Post market controls
Post Market Surveillance: N/A
Details: N/A
Inspection (QMS): Yes
Details: It is the responsibility of the inspection and control unit to periodically supervise the activities of authorized establishments. Reglamento General de la Ley de Medicamentos, Titulo VII.
Enforcement: N/A
Details: N/A
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: 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.