Saint Lucia

World Bank income group: Upper middle income

Legal
Legal framework: No
Authorizing legislation: N/A
Guidelines: N/A
Notes: No formal legal regulatory framework but some level of regulation indirectly using harmonized standards from countries such as the USA and Europe for new medical equipment entering the system through the ministry of health. Organizations such as the bureau of standards monitor medical equipment standards as required.

National Regulatory Authority
National Regulatory Authority present: No
Name: N/A
Responsibilities of the NRA: N/A

Medical device definition
Medical device defined: No
Text: N/A
In vitro diagnostic medical device (IVD) defined: No
Text: N/A

Medical device classification
Classification: No
Categories: N/A
Classification rules: No
Classification rules details: N/A

Essential principles
Essential principles: No
Details: N/A

Conformity assessment
Conformity assessment bodies: No
Details: N/A
Pre-marketing / procedure: N/A

Reliance
Reliance: No
Details: N/A
Jurisdictions: No

Clinical investigation
Clinical investigation controls: No
Details: N/A

Registration and listing
Registration of establishment: No
Details: N/A
Listing of medical devices: No
Details: N/A

Import controls
Import controls: No
Details: N/A

Medical devices regulatory systems at country level
June 2015 - April 2016
Post market controls
Post Market Surveillance: No
Details: N/A
Inspection (QMS): No
Details: N/A
Enforcement: No
Details: N/A
Adverse event reporting: No
Details: N/A
Field safety corrective action monitoring: No
Details: N/A
Advertising: No
Details: N/A
Labelling: No
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.