Legal
Legal framework: No
Authorizing legislation: N/A
Guidelines: N/A

National Regulatory Authority
National Regulatory Authority present: No
Name: Samoa has a Medical Equipment Management Policy and Medical Equipment Donation Policy.
Responsibilities of the NRA: N/A

Medical device definition
Medical device defined: Yes
Text: Medical Equipment is defined as any instrument, apparatus or appliance, including software, whether used alone or in combination, together with any accessories necessary for correct operation, that makes physical or electrical contact with the patient, or transfers energy to or from the patient, or detects such energy transfer to or from the patient, or is intended to diagnose, treat or monitor a patient. It will typically require installation, commissioning, calibration, maintenance, repairs, user and service training, decommissioning and safe disposal. Classification of equipment includes medical, dental, laboratory and radiology.
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: N/A

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
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.