Sierra Leone

World Bank income group: **Low income**

**Legal**

**Legal framework:** Yes

**Authorizing legislation:** The Pharmacy and Drugs Act, No 58 of 13th December 2001


**Guidelines:** Guidelines for conducting clinical trials of medicines, food supplements, vaccines and medical devices in Sierra Leone.

Guidelines for registration of medical devices.

Guidelines for licensing of manufacturing industries.


**National Regulatory Authority**

**National Regulatory Authority present:** Yes

**Name:** The Pharmacy Board of Sierra Leone, Ministry of Health and Sanitation.

http://www.pharmacyboard.gov.sl/

**Responsibilities of the NRA:** “Ensuring that appropriate and workable regulatory guidelines are implemented in order to achieve the highest practicable standards of the practice of pharmacy by professionals and of safety, efficacy and quality of all drugs, medical devices, cosmetics and nutritional agents (collectively termed ‘products’) locally manufactured, imported, exported, distributed, sold or used to ensure the protection of the public health as envisaged by the Pharmacy and Drugs Act”.

**Medical device definition**

**Medical device defined:** Yes

**Text:** Medical device means any instrument, apparatus including components, parts and accessories of it, or medical consumables manufactured, sold or represented for use in the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or the symptoms of it in man or animal. A medical device can be: (a) Condom (b) Glove (Surgical/Examination) (c) Test-Kit (d) Needle and syringe (e) Insecticide Treated Net (ITN) etc. Guidelines for the registration of medical devices’.

**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:** Yes

**Details:** See Guidelines for Conducting Clinical Trials of Medicines, Food Supplements, Vaccines and Medical Devices in Sierra Leone.
Registration and listing
Registration of establishment: Yes
Details: Manufacturers must apply for a license to manufacture a product. Guidelines for Licensing of Manufacturing Industries, Art. 3
Listing of medical devices: Yes
Details: See Guidelines for the Registration of Medical Devices, Art 2.1

Import controls
Import controls: N/A
Details: N/A

Post market controls
Post Market Surveillance: N/A
Details: N/A

Inspection (QMS): Yes
Details: Manufacturers are required to have and report on their quality management system. Guidelines for Licensing of Manufacturing Industries, Art. 3.1.8.

Enforcement: N/A
Details: N/A

Adverse event reporting: Yes
Details: See Guide for Detecting and Reporting Adverse Drug Reactions.

Field safety corrective action monitoring: Yes
Details: Manufacturers shall have arrangements and recording system for handling of complaints, distribution of products and product recall, when necessary. Guidelines for Licensing of Manufacturing Industries, Art. 3.1.10

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.