Legal
Legal framework: Yes
Notes: The Ministry of Health is responsible for all public health issues. An act of parliament was passed to establish an Inspectorate Authority, but it has not yet been implemented. When implemented, several agencies will merge to form the Rwanda Inspectorate and Competition Authority (NICA). See Law N° 61/2013 of 23/08/2013 on the establishment of NICA.

National Regulatory Authority
National Regulatory Authority present: N/A
Name: N/A
Responsibilities of the NRA: N/A

Medical device definition
Medical device defined: Yes
Text: Medical device: any device used in the medical field for the purpose of diagnosis, testing, cure, surgery or health protection. Law 47/2012, Art. 2.7.
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: Yes
Details: Medical devices must meet quality standards and be manufactured in compliance with relevant principles of their manufacture. Law N°47/2012, Art. 21.

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: Any activity related to the manufacture, storing, import or export, sale, packaging, distribution, supply, transport medical devices, must be registered. A licence to operate must be granted. Law N°47/2012, Art. 3-4
Listing of medical devices: Yes
Details: No person shall market a pharmaceutical product or a medical device on the Rwandan market unless such a product or device is registered. Law N°47/2012, Art. 26.
**Import controls**
*Import controls:* Yes  
*Details:* No person shall import and export medical devices unless they are granted a license to do so. Law N°47/2012, Art. 34.

**Post market controls**
*Post Market Surveillance:* N/A  
*Details:* N/A  
*Inspection (QMS):* Yes  
*Details:* Establishments and products are subject to inspection. Law N° 47/2012, Art. 44-45  
*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:* Yes  
*Details:* No person shall label, pack, treat, sell, distribute or advertise any medical device in a manner that is false, misleading or is likely to create an erroneous impression regarding its performance, design, use, intended use, value or quality. Law 47/2012, Art. 24.  
*Labelling:* Yes  
*Details:* No person shall label, pack, treat, sell, distribute or advertise any medical device in a manner that is false, misleading or is likely to create an erroneous impression regarding its performance, design, use, intended use, value or quality. Law 47/2012, Art. 24.