Guyana

Legal
Legal framework: Yes
Authorizing legislation: Food and Drugs Act, Chapter 34:03
Guidelines: N/A

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

Medical device definition
Medical device defined: Yes
Text: Device means any instrument, apparatus or contrivance, including components, parts and accessories thereof, manufactured, sold or represented for use in the diagnosis, treatment, mitigation or prevention of a disease, disorder, abnormal state of health, or the symptoms thereof, in man or animal, or used or intended to be used for the prevention of uterine conception. Food and Drugs Act, Art 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: N/A
Details: N/A
Listing of medical devices: N/A
Details: N/A

Import controls
Import controls: Yes
Details: An inspector has the right to examine any customs entries of foods, drugs, cosmetics or devices imported into Guyana and to take samples thereof and to submit the samples to an analyst for analysis or examination. Food and Drugs Act, Art 22
Post market controls
Post Market Surveillance: N/A
Details: N/A

Inspection (QMS): Yes
Details: Food and Drugs Act, Art 21

Enforcement: Yes
Details: N/A

Adverse event reporting: N/A
Details: N/A

Field safety corrective action monitoring: Yes
Details: Forfeiture - Food and Drugs Act, Art 23

Advertising: Yes
Details: Food and Drugs Act, Art 4

Labelling: Yes
Details: Any person who labels, packages, treats, processes, sells or advertises any device in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, values, composition, merit or safety, is guilty of an offence. Food and Drugs Act, Art 18.

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.