New Zealand
World Bank income group: High income

Legal
Legal framework: Yes

National Regulatory Authority
National Regulatory Authority present: Yes
Name: Medicines and Medical Device Safety Authority (MedSafe) http://www.medsafe.govt.nz/
Responsibilities of the NRA: N/A

Medical device definition
Medical device defined: Yes
Text: A medical device means any device instrument, apparatus, appliance or other article--
(i) is intended to be used in, or, or for human beings for a therapeutic purpose; and
(ii) does not achieve its principal intended action in or on the human body by pharmacological,
immunological, or metabolic means (but may be assisted in its function by such means); and
(b) includes material that--
(i) is intended to be used in or on human beings for a therapeutic purpose; and
(ii) does not achieve its principal intended action in or on the human body by pharmacological,
immunological, or metabolic means (but may be assisted in its function by such means); and
(c) also includes--
(i) anything that is intended to be used with a device, instrument, apparatus, appliance, article, or
material referred to in paragraph (a) or (b) to enable the device, instrument, apparatus, appliance,
article, or material to be used as its manufacturer intends; and
(ii) any device, instrument, apparatus, appliance, article, or material of a kind or belonging to a class
that is declared by regulations to be a medical device for the purposes of this act; but
(d) does not include a device, instrument, apparatus, appliance, article, or material of a kind belonging
to a class that is declared by regulations not be a medical device for the purposes of this Act.
Medicines Act 1981, Art. 3A.

In vitro diagnostic medical device (IVD) defined: Yes
Text: Any device which is- a reagent, reagent product, calibrator, control material, kit, instrument,
apparatus, equipment or system, whether used alone or in combination with other diagnostic
devices for in vitro use; and intended by the manufacturer to be used in vitro for the examination of
specimens (including blood and tissue donations) derived from the human body: solely or principally
for the purpose of giving information about a physiological or pathological state or a congenital
abnormality; or to determine safety and compatibility with a potential recipient.

Medical device classification
Classification: Yes
Categories: Class I, IIA, IIB, III, and AIMD (Active Implantable Medical Device).
Medicines (Database of Medical Devices) Regulations 2003, Art 11.
Classification rules: Yes
Classification rules details: Schedule 2 of the Medicines (Database of Medical Devices) Regulations
2003 contains particular classification rules. As a general matter, a medical device must be classified
according to its intended purpose. Art. 13.

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
WHO Western Pacific Region

Clinical investigation
Clinical investigation controls: No
Details: Medsafe does not regulate or approve clinical trials for medical devices in New Zealand, but it does request that it be informed of trials. http://www.medsafe.govt.nz/regulatory/devicesnew/13ConductingClinicalTrials.asp

Registration and listing
Registration of establishment: Yes
Details: The name of the manufacturer and the sponsor of that device must be entered into the database as well as the address of the registered office and contact information. Medicines (Database of Medical Devices) Regulations 2003, Art. 5.
Listing of medical devices: Yes
Details: The Director-General must ensure the maintenance of a database of medical devices on information including the medical device, any similar product that may in the future be treated as a medical device, and any other information relating to the use of the medical device(s). Medicines (Database of Medical Devices) Regulations 2003, Art. 4.

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

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

Inspection (QMS): N/A
Details: N/A

Enforcement: Yes
Details: The Minister may restrict the sales of medical devices if found unsafe after providing the manufacturer notice of his or her concern as well as the opportunity to supply evidence of safety. Medicines Act, Art. 38.
Fines as well as imprisonment may be imposed on individuals who do not comply with provisions of the Medicines Act. See, e.g., Art. 38 (fine and imprisonment for selling a device after receiving notice that the Minister is not assured of a device's safety).
An authorized officer may inspect, seize, and detain medical devices without warning. Medicines Act, Art. 63-64.
The Director-General may issue to any importer, manufacturer, or seller of any medicine, related product, or medical device an order to withdraw the medical device from market or to dispose/destroy the medical device. Medicines (Database of Medical Devices) Regulations 2003, Art. 50.

Adverse event reporting: Yes
Details: Medsafe receives adverse event reports of medical devices from users, healthcare professionals and industry. All reports are entered into a database and assessed for risk. Serious adverse events are investigated immediately and given priority. Outcomes of investigations may include informing professionals and consumers, recalling the product, and requesting additional user action. http://www.medsafe.govt.nz/regulatory/devicesnew/safety-monitoring.asp

Field safety corrective action monitoring: Yes
Details: All recalls must be carried out with the knowledge and the consent of the Ministry of Health. A decision for recall is made following a consultation between the company and the Ministry. New Zealand Code of Good Manufacturing Practice for Manufacture and Distribution of Therapeutic Goods, Part 5.

Advertising: Yes
Details: Medical advertisements may not be misleading, must contain the name of the advertiser, and may not bear misleading branding. Medicines Act, Arts. 56-62.
An advertisement for a medical device must include, where appropriate, an accurate description of the device, a statement of the uses of the device, a statement of appropriate precautions to be taken, and a statement of contraindications. Medicines (Database of Medical Devices) Regulations 2003, Art. 10.

Labelling: Yes
Details: A medical device may not be sold unless it is properly labelled. For medical devices, the name of the manufacturer or the name of its distributor in New Zealand. Medicines (Database of Medical Devices) Regulations 2003, Art. 12.
Every container label must be in English and legibly/durably marked. Medicines (Database of Medical Devices) Regulations 2003, Art. 17.
Every container of a medical device must also include a warning statement of its label. Medicines (Database of Medical Devices) Regulations 2003, Art. 22.

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.