Albania
World Bank income group: Upper middle income

Legal
Legal framework: Yes
Notes: The National Policy for Management of Medical Devices document provides all Medical Device regulation information, including the definition of a device, the assignment of a NRA and its responsibilities, and the regulatory steps for a device to enter the Albanian market.

National Regulatory Authority
National Regulatory Authority present: Yes
Name: National Agency for Drugs and Medical Devices (AKBPM) http://akbpm.gov.al/
Responsibilities of the NRA: AKBPM responsibilities include: registration of medical devices, inspections, reporting of adverse events.
Law No. 89/2014

Medical device definition
Medical device defined: Yes
Text: Medical device means any instrument, apparatus, material or any other means usable alone or in combination and the intended action in or on the human body performs assisted by pharmacological, immunological or metabolic:
a) for the diagnosis, prevention, monitoring treatment or alleviation of disease;
b) for the diagnosis, monitoring, treatment, mitigation or compensation of an injury or disability;
c) investigation, replacement or modification of the anatomy or of a physiological process;
d) to control conception
Law No. 89/2014 On Medical Devices, Art. 4.
In vitro diagnostic medical device (IVD) defined: Yes
Text: Included, Defined Separately - Medical equipment in vitro diagnostic is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, which is used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue, derived from the body, in order to provide information: a) with respect to a physiological or pathologival condition; b) associated with a congenital anomaly; c) to determine the safety and compatibility with a potential recipient; d) to monitor therapeutic measures.
Law No. 89/2014 on Medical Devices, Art. 4.

Medical device classification
Classification: Yes
Categories: Classes I, IIA, IIB, and III
Law No. 89/2014 on Medical Devices, Art. 9.
Classification rules: Yes
Classification rules details: N/A

Essential principles
Essential principles: Yes
Details: Law No. 89/2014 on Medical Devices, Art. 7.

Conformity assessment
Conformity assessment bodies: Yes
Details: YES
Law No. 89/2014 on Medical Devices, Art. 4. Law 10489/2011
Pre-marketing / procedure: If CE marked, product can bypass the conformity assessment procedure.
If no CE marking, then need a full conformity assessment procedure.
Law No. 89/2014 on Medical Devices, Art. 10.
Reliance
Reliance: Yes
Details: N/A
Jurisdictions: EU

Clinical investigation
Clinical investigation controls: Yes
Details: Clinical investigations verify the efficiency and safety of devices as well as any side effects. The Minister of Health authorizes clinical investigations in Albania. Law No. 89/2014, Art. 11.

Registration and listing
Registration of establishment: Yes
Details: One infers that medical equipment manufacturers within Albania must register their activity as well as the representatives of foreign manufacturers. Law No. 89/2014, Art. 13.
Listing of medical devices: Yes
Details: All medical devices placed on the Albanian market must be recorded in the national register held by the Drug Control and Medical Devices Agency. Law No. 89/2014, Art. 13.

Import controls
Import controls: Yes
Details: It is prohibited to import devices that damage and endanger human health. Law No. 89/2014, Art. 5. Importers must hold legal authority for wholesale import of medical equipment. Law No. 89/2014, Art. 22

Post market controls
Post Market Surveillance: N/A
Details: N/A
Inspection (QMS): Yes
Details: An inspector for medical devices carries out the inspection of the manufacturer’s quality assurance system. It may require all necessary information form the manufacturer or the holder of marketing authorization to get access to technical documentation. It may order tests, sampling, proper labelling, or withdrawal of the product from market. Law No. 89/2014, Art. 27.
Enforcement: Yes
Details: Violations of provisions of Law No. 89/2014 result in penalties (they are administrative, not criminal, offenses) Law No. 89/2014 Art. 30.
Adverse event reporting: Yes
Details: Adverse events must be reported to the AKBMP by physical and legal entities that place a device on the market or into service. The AKBMP then takes steps to notify the manufacturer or its authorized representative. Law No. 89/2014, Art. 26.
Field safety corrective action monitoring: Yes
Details: Law No. 89/2014 On Medical Devices ,Art 26
Advertising: Yes
Details: Punitive damages are available for mis-labelling of medical devices.
Labelling: Yes
Details: Any medical equipment placed on the market and put into service must be labelled in Albania. Law No. 89/2014, Art. 20.

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.