Legal
Legal framework: Yes
Authorizing legislation: Andorra doesn’t have a specific regulation on medical devices. The General Health Law (1989) gives general provisions on medicines and ‘other health products’ Chapter 6: Medicines and other health products (Art. 39-45) Law can be retrieved at: https://www.mindbank.info/item/3233
Guidelines: N/A

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

Medical device definition
Medical device defined: N/A
Text: N/A
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: Yes
Details: Marketing authorizations from other countries can be recognized. General Health Law, Art. 40.
Jurisdictions: N/A

Clinical investigation
Clinical investigation controls: N/A
Details: N/A

Registration and listing
Registration of establishment: Yes
Details: Manufacturers must be authorised to operate. General Health Law, Art. 39, 46.
Listing of medical devices: N/A
Details: N/A

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: Any breach to the regulations will result in administrative sanctions. General Health Law, Art. 60.

Adverse event reporting: Yes
Details: Importers, manufacturers and health professionals have an obligation to communicate the harmful effects caused by medicines and other health products, when it might result in any hazard to patient health. General Health Law, Art. 44.

Field safety corrective action monitoring: N/A
Details: N/A

Advertising: Yes
Details: Advertising of drugs and other health products aimed at professionals and the public may be subject to an administrative authorization scheme. General Health Law, Art. 45.

Labelling: Yes
Details: The labelling and presentation of health products will be regulated by the government. General Health Law, Art. 42.