**Legal**

- **Legal framework:** Yes
- **Authorizing legislation:** Law on Drugs and Medical Products, No. 07/NA (21 Dec. 2011)
- **Guidelines:** N/A

**National Regulatory Authority**

- **National Regulatory Authority present:** Yes
- **Name:** Food and Drug Department, Ministry of Health
- **Responsibilities of the NRA:** N/A

**Medical device definition**

- **Medical device defined:** Yes
- **Notes:** Medical devices are included in the definition of a medical product. Law on Drugs and Medical Products, Art. 2
- **Text:** Medical products are medical tools in the form of utensils, machines, materials in the liquid and solid form, gas and light, using for diagnosis or any similar materials to be used as prescribed by their producers and which may be used solely or in combination with other materials, for one or more time. Law on Drugs and Medical Products, Art. 3.
- **In vitro diagnostic medical device (IVD) defined:** N/A

**Medical device classification**

- **Classification:** Yes
- **Categories:** Type A, B, C, and D. Law on Drugs and Medical Products, Art. 11.
- **Classification rules:** N/A
- **Classification rules details:** N/A

**Essential principles**

- **Essential principles:** Yes
- **Details:** Medical product activities shall be carried out in compliance with the main principles in Article 5. Law on Drugs and Medical Products, Art. 31.

**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:** Yes
- **Details:** Clinical trials of medical product may only be conducted if authorized by the health sector. Law on Drugs and Medical Products, Art. 31.

**Registration and listing**

- **Registration of establishment:** Yes
- **Details:** One must obtain prior approval to the production, storage, distribution, sale, export, or import of medical devices from the Ministry of Health. Law on Drugs and Medical Products, Art. 12.
- **Listing of medical devices:** Yes
- **Details:** Medical products must be registered with the Department of Food and Drugs of the Ministry of Health. Law on Drugs and Medical Products, Art. 13.
**Import controls**

**Import controls:** Yes

**Details:** Medical products imported into Lao are subject to registration and notification with the Department of Food and Drug. The health sector inspects the importation of medical products. Law on Drugs and Medical Products, Art. 16.

**Post market controls**

**Post Market Surveillance:** N/A

**Details:** N/A

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

**Details:** N/A

**Enforcement:** Yes

**Details:** Individuals, legal entities, or organizations with “outstanding achievements” in implementing the Law on Drugs and Medical Products may receive rewards. Art. 47. Violators of the Law on Drugs and Medical Products may face penalties that include education, fines, or other criminal sanctions. Art. 48. Four state entities inspect medical products:
- Food and Drug Management Committee
- Ministry of Health
- provincial Departments of Health
- municipality Offices of Health
Law on Drugs and Medical Products, Art. 41. There are three forms of inspection:
- regular inspection
- inspection with prior notification
- emergency inspection
Law on Drugs and Medical Products, Art. 46.

**Adverse event reporting:** Yes

**Details:** The Toxicology Information Centre analyses, provides information, disseminates, and advises stakeholders on preventative measures for adverse events. Law on Drugs and Medical Products, Arts. 33-34.

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

**Details:** N/A

**Advertising:** Yes

**Details:** Medical products may only be advertised if authorized by the health sector. Advertisements must accurately convey the quality of the medical products. Law on Drugs and Medical Products, Arts. 19-20.

**Labelling:** N/A

**Details:** N/A.