**Legal**

**Legal framework:** Yes  
**Authorizing legislation:** Pharmaceutical Law (19 March 1998) (as amended) http://www.zva.gov.lv/?id=355&top=333&large=  
The Cabinet of Ministers regulation No.891 “Medical devices for human clinical trial procedure” (21 September 2010)  
Regulation No. 581 (2 August 2005)  
"Procedures for Registration, Conformity Assessment, Distribution, Operation and Technical Supervision of Medical Devices"  
http://www.ttc.lv/export/sites/default/docs/LRTA/MK_Noteikumi/Cab._Reg._No._581_-_Registration_etc._of_Medical_Devices.doc  

**National Regulatory Authority**

**National Regulatory Authority present:** Yes  
**Name:** State Agencies of Medicines http://www.zva.gov.lv/?setlang=en  
**Responsibilities of the NRA:** The Agency, with regard to medical devices, must:  
- perform conformity assessment and registration  
- establish and update the register of medical devices  
- issue permits for the performance of clinical investigations  
- supervise the safety and use of medical devices  
- create and maintain a database on observed adverse reactions caused by medical devices  
Pharmaceutical Law, para. 10.

**Medical device definition**

**Medical device defined:** Yes  
**Text:** Medical devices understands instruments, apparatus, materials or other objects which are used alone or in combination with any other devices, including the software necessary for the parties to use the device as intended by the manufacturer for the diagnosis, prevention, monitoring, treatment or alleviation of disease, diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap, investigation, replacement or modification of the person’s body structure or physiological process, control of conception, and that the intended effects on individuals do not reach by pharmacological, immunological and metabolic means, but which such funds can help. Subjects who are not medical devices and are specifically intended by the manufacturer for use with a medical device, ensuring that the device is used according to the device manufacturer their intended purpose within the meaning of this provision should be considered as medical devices.  
Regulation No. 581, Art. 22.  
**In vitro diagnostic medical device (IVD) defined:** Yes  
**Text:** Defined separately. Regulation No. 581, Art. 63.

**Medical device classification**

**Classification:** Yes  
**Categories:** Medical devices are classified by risk into class I, IIa, IIb, and III. IVDs are classified into list A, list B, and into other categories. Pharmaceutical law, para. 4.  
**Classification rules:** Yes  
**Classification rules details:** Medical devices are classified in accordance with these Regulations Annex 1. Regulation No. 581, Art. 4.

**Essential principles**

**Essential principles:** Yes  
**Details:** Only medical devices that meet essential requirements can be placed on the market. Regulation No. 581, Art. 20.

**Conformity assessment**

**Conformity assessment bodies:** Yes  
**Details:** Conformity assessment bodies must be accredited pursuant to Latvian standards or EU ones. Regulation No. 581,Art. 3  
**Pre-marketing / procedure:** To register devices that are not CE-marked, the Agency will receive the application, and the authorized representative of the manufacturer will be entitled to register and distribute the device. On request of the Agency, the manufacturer will also supply samples of the devices. Pharmaceutical Law, para. 102.

**Reliance**

**Reliance:** Yes  
**Details:** N/A  
**Jurisdictions:** EU. Regulation No. 581, Art. 3, 9, 10.
**Clinical investigation**

**Clinical investigation controls:** Yes  
**Details:** Clinical trials are regulated pursuant to Regulation No. 891. The manufacturer must obtain authorization of the Agency prior. Id.Art. 26.

**Registration and listing**

**Registration of establishment:** Yes  
**Details:** The Agency shall maintain a registry of medical devices (LATMED) that stores information on producers, distributors, incidents, as well as any other information the Agency is obliged to acquire and store. This database is separately from the EUDAMED registry. Pharmaceutical Law, para. 88.  
**Listing of medical devices:** Yes  
**Details:** A manufacturer or the authorised representative thereof shall, in accordance with the notification procedure, send the Agency (by post or electronically to the official electronic mail address of the Agency) the information (notification) regarding manufacturer of the device and certifications of the conformity assessment procedures of the device (declaration of conformity and CE certificate) in relation to the placing on the market of Class IIb and Class III medical devices and medical devices of List A, List B and in vitro diagnostic medical devices for self-testing in the territory of the Republic of Latvia.  
In order to place Class I and Class IIa medical devices on the market in the territory of the Republic of Latvia, they shall be labelled with CE marking. It is not necessary to notify regarding Class I and Class IIa medical devices and other (rest) in vitro diagnostic devices.  
[31 March 2009]  
Regulation No. 581. Art. 19, 20.1

**Import controls**

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

**Post market controls**

**Post Market Surveillance:** Yes  
**Details:** Under Pharmaceutical Law paras 159 - 170, medical devices are categorized into three “security groups,” and, based on the group, manufacturers are required to have different vigilance systems in place.  
Manufacturers and their authorized representatives must have a vigilance system and report to the Agency any incidents that may cause harm to a patient, user, or third-part. Pharmaceutical Law, para. 188. Further, manufacturers must follow timing guidelines on transmitting investigative information to the Agency. Id. paras. 202-04.  
**Inspection (QMS):** Yes  
**Details:** The decision regarding suspension of the activity of the subject of pharmaceutical and veterinary pharmaceutical activity, if the laws and regulations governing the field of pharmacy and veterinary pharmacy have been violated, in conformity with their competence, shall be taken by the manager of the Health Inspectorate of Latvia, deputy managers thereof, managers of territorial divisions of the Health Inspectorate of Latvia and deputy managers thereof or by the State chief food and veterinary inspector of the Food and Veterinary Service, senior inspectors and inspectors of the Food and Veterinary Service. Pharmaceutical Law section 65 http:/ /www.zva.gov.lv/?id=355&top=333&large=  
**Enforcement:** N/A  
**Details:** N/A  
**Adverse event reporting:** Yes  
**Details:** A manufacturer is responsible for necessary investigation actions after an adverse event and must submit an report to the Agency within 30 days. Regulation No. 581, Art. 202  
**Field safety corrective action monitoring:** N/A  
**Details:** N/A  
**Advertising:** N/A  
**Details:** N/A  
**Labelling:** Yes  
**Details:** The label must include the manufacturer’s name and address as well as information about the device. Law on Pharmaceuticals, para. 43.