**Legal**

**Legal framework:** Yes

**Authorizing legislation:** Regulations for the Supervision and Administration of Medical Devices [hereafter Regulations] [http://eng.sfda.gov.cn/WS03/CL0767/61641.html](http://eng.sfda.gov.cn/WS03/CL0767/61641.html)


The Description and Labelling of Medical Device Regulations, Administrative Order No. 6 (30 July 2014) [http://www.sda.gov.cn/WS01/CL0053/103758.html](http://www.sda.gov.cn/WS01/CL0053/103758.html)


**Guidelines:** N/A

**National Regulatory Authority**

**National Regulatory Authority present:** Yes

**Name:** China Food and Drug Administration [http://www.sfda.gov.cn/WS01/CL0001/](http://www.sfda.gov.cn/WS01/CL0001/)

**Responsibilities of the NRA:** The drug regulatory authority is responsible for the supervision and administration of medical devices. Regulations, Art. 4.

**Medical device definition**

**Medical device defined:** Yes

**Text:** A medical device is any instrument, apparatus, appliance, material, or other article whether used alone or in combination, including the software necessary for its proper application. It does not achieve its principal action in or on the human body by means of pharmacology, immunology or metabolism, but which may be assisted in its function by such means; the use of which is to achieve the following intended objectives:

1. Diagnosis, prevention, monitoring, treatment or alleviation of disease;
2. Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap conditions;
3. Investigation, replacement or modification for anatomy or a physiological process;
4. Control of conception.

Regulations, Art. 3.

**In vitro diagnostic medical device (IVD) defined:** Yes

**Text:** Defined Separately - Administrative Order No. 5 (30 July 2014), Art. 1.

**Medical device classification**

**Classification:** Yes

**Categories:** Class I, II, and III.

**Classification rules:** Yes

**Classification rules details:** Regulations Art. 5 details classification:

Class I Medical Devices are those for which safety and effectiveness can be ensured through routine administration;

Class II Medical Devices are those for which further control is required to ensure their safety and effectiveness

Class III Medical Devices are those which are implanted into the human body, or used for life support or sustenance, or pose potential risk to the human body and thus must be strictly controlled in respect to safety and effectiveness.

More specific classification rules are detailed in Order No. 15.

**Essential principles**

**Essential principles:** Yes

**Details:** An applicant or person filing an application for registration or for filing, shall follow the basic requirements of safe and effective medical devices, to ensure that the development process specifications, and all data is true, complete and traceable.

Administrative Order No. 4, Art. 11

**Conformity assessment**

**Conformity assessment bodies:** N/A

**Details:** N/A
**Pre-marketing / procedure:** Clinical trials of new medical devices, defined as the kind of brand new product varieties which have not been recognized domestically, in classes II or III can only be conducted after approval by the relevant authority. Regulations, Art. 7.

A clinical evaluation must be conducted for class II and III medical devices before they are placed on the market. Regulations, Art. 8. Class I devices do not require a clinical evaluation. Administrative Order No. 4, Art. 22.

**Reliance**

Reliance: N/A

Details: N/A

Jurisdictions: N/A

**Clinical investigation**

Clinical investigation controls: Yes

Details: Clinical trials are regulated pursuant to Order No.5 (17 Jan. 2004).

**Registration and listing**

Registration of establishment: Yes

Details: Manufacturers of medical devices must file a record with the appropriate governmental body, depending on the risk classification of the manufactured devices. Regulations, Art. 20. Distributors of class II and/or III devices must also file a record with the appropriate drug regulatory authority. Id. Art 24.

Listing of medical devices: Yes

Details: All classes of medical devices must be registered with the government. They must receive a certificate of registration. Regulations, Art. 8.

**Import controls**

Import controls: Yes

Details: The agent of a device that is imported into China for the first time must submit instructions for use, quality standards, testing methods, other relevant information, product samples, and marketing authorization certificates. The drug regulatory authority inspect and approves the device and issues an import product registration certificate before customs. Regulations, Art. 11.

**Post market controls**

Post Market Surveillance: N/A

Details: N/A

Inspection (QMS): Yes

Details: Drug regulatory authorities of county governments (and higher governments) must appoint device monitors who supervise and inspect medical device enterprises within their regions. Those monitors may take product samples. Regulations, Art. 29.

Enforcement: Yes

Details: The drug regulatory authority of county-level governments may detain devices. And the authority of provincial-level government and above may revoke registration certificates of medical devices, meaning those devices may not be manufactured, distributed, or used. Regulations, Arts. 31-32. Municipality-level authorities may order correction of any violations. Id. Art. 33. Violations may result in fines and/or criminal penalties. Regulations, Arts. 35-46.

Adverse event reporting: Yes


Field safety corrective action monitoring: N/A

Details: N/A

Advertising: Yes

Details: Advertisements must be reviewed and approved by the drug regulatory authority of provincial governments and above before publication, broadcast, circulation, or posting. Regulations, Art. 34.

Labelling: Yes

Details: Labels must comply with relevant standards or provisions in China. Regulations, Art. 16. Medical device instructions and labels must be in Chinese. Labelling specifications can be found in Administrative Order No. 6 Art. 9.

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.