
The Regulation of Medical Devices Recall Administration

(Decree No.29 of CFDA)

The Regulation of Medical Devices Recall Administration has been approved in the conference held by China Food and Drug Administration on January 5, 2017, it is to be issued by now and implemented on May 1, 2017.

Secretary: Bi Jingquan

January 25, 2017

The Regulation of Medical Devices Recall Administration

Chapter 1 General Guideline

Article 1 For better supervision, controlling defective products, eliminating potential safety hazard, ensuring the safety and effectiveness of medical devices and to guarantee people's health and well-being, this legislation is drafted in accordance with Regulations for the Supervision and Administration of Medical Devices.

Article 2 This regulation is applied to recall, supervision and administration of medical devices in the People's Republic of China.

Article 3 The definition of medical devices recall refers to the actions taken by manufacturers to eliminate the defects of sold devices, such as warning, checking, repairing, relabeling, refining and improving instructions, updating software, replacing, recalling and destroying of a certain category, model or batch.

The definition of medical device manufacturers mentioned above refers to the registrants or filers, and the agents in China designated by overseas manufacturers of imported medical devices.

Article 4 The range of defective products of medical devices includes:

- (I) Products with unreasonable risks that may endanger human health and life safety;

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- (II) Products that fail to comply with compulsory standards, registered or filed technical requirements for products;
 - (III) Products that fail to comply with relevant regulations on quality management of production and circulation for medical devices, with the possibility of unreasonable risks;
 - (IV) Other products that need to be recalled.

Article 5 The major force of controlling and eliminating defective products are the manufacturers of medical devices, therefore they shall positively recall the defective products.

Article 6 Under this regulation, the manufacturers of medical devices shall establish and perfect their recalling management system, collect the related information regarding the safety of medical devices and investigate, evaluate possible defective products to recall these defective medical devices promptly.

The agents in China designated by overseas manufacturers of imported medical devices shall inform China Food and Drug Administration of the relevant information on medical devices recall only implemented overseas. If recall within China is involved, the designated agents in China shall organize and implement in accordance with this regulation.

The operating enterprises and users of medical devices shall positively coordinate the manufacturers of medical devices to investigate and evaluate the defective products, actively coordinate manufacturers to fulfill the obligation of recall, timely convey and give feedback of recall information of medical devices in accordance with recall program, control and withdraw defective products.

Article 7 On condition that enterprises that run business with or make use of the medical devices discover the medical devices they possess may be defective products, the usage and marketing of these products shall be suspended immediately. They shall inform the manufacturers and suppliers of these certain products, and report to the Food and Drug Administration and Supervision Department of province, autonomous region or municipality directly under the central government; medical organizations that use these devices can also report to the health administration of the province, autonomous region or municipality directly under the central government.

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