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## **Regulation on the Supervision and Administration of Medical Devices (2021 Revision)**

**Document Number :** Order No. 739 of the State Council of the People's Republic of China

**Area of Law :** [Import and Export of Medical Devices, Drugs, and Medicine Materials](#)

**Level of Authority :** [Administrative Regulations](#)

**Date issued :** 02-09-2021

**Effective Date :** 06-01-2021

**Issuing Authority :** [State Council](#)

Order of the State Council of the People's Republic of China (No. 739)

The [Regulation on the Supervision and Administration of Medical Devices](#) , as revised and adopted at the 119th executive meeting of the State Council on February 21, 2020, is hereby issued and shall come into force on June 1, 2021.

Premier: Li Keqiang

February 9, 2021

[Regulation on the Supervision and Administration of Medical Devices](#)

(Issued by Order No. 276 of the State Council of the People's Republic of China on January 4, 2000, revised and adopted at the 39th executive meeting of the State Council on February 12, 2014, revised in accordance with the [Decision of the State Council to Amend the Regulation on the Supervision and Administration of Medical Devices](#) on May 4, 2017, and revised and adopted at the 119th executive meeting of the State Council on December 21, 2020)

### **Chapter I General Provisions**

**Article 1** This Regulation is developed for the purposes of ensuring the safety and effectiveness of medical devices, guaranteeing human health and life safety and promoting the development of the medical device industry.

**Article 2** Whoever engages in the research and development, production, distribution or use of medical devices as well as the supervision and administration thereof within the territory of the People's Republic of China shall abide by this Regulation.

**Article 3** The medical products administration of the State Council shall be responsible for the supervision and administration of medical devices nationwide.

The relevant departments of the State Council shall be responsible for the supervision and

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administration related to medical devices within their respective functions.

**Article 4** The local people's governments at or above the county level shall strengthen the leadership over the supervision and administration of medical devices within their respective administrative regions, organize and coordinate the supervision and administration of medical devices and the emergency response work within their respective administrative regions, strengthen the building of medical device supervision and administration capabilities, and provide guarantees for the safety of medical devices.

The medical products administrations of the local people's governments at or above the county level shall be responsible for the supervision and administration of medical devices within their respective administrative regions. The relevant departments of the local people's governments at or above the county level shall be responsible for the supervision and administration related to medical devices within their respective functions.

**Article 5** Medical device supervision and administration shall follow the principles of risk management, management and control in the whole process, scientific regulation and co-governance by the whole society.

**Article 6** The state shall conduct the classification administration of medical devices according to their risk levels.

“Medical devices of Class I” means the medical devices with low risks, whose safety and effectiveness can be ensured through routine administration.

“Medical devices of Class II” means the medical devices with moderate risks, which shall be strictly controlled and administered to ensure their safety and effectiveness.

“Medical devices of Class III” means the medical devices with relatively high risks, which shall be strictly controlled and administered through special measures to ensure their safety and effectiveness. The evaluation of the risk levels of medical devices shall take consideration of the expected objectives, structural features, use methods and other factors of medical devices.

The medical products administration of the State Council shall be responsible for developing the classification rules for and the classified catalogues of medical devices, and, according to the information on the production, distribution and use of medical devices, analyzing and evaluating in a timely manner the risk changes of medical devices and adjusting the classification rules and classified catalogues; and shall develop and adjust the classification rules and classified catalogues, fully listen to the opinions of medical device registrants, recordation entities, production and

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