


---

# **Administrative Measures for Clinical Use of Medical Devices (Order No. 8 of National Health Commission)**

Issued on: February 4, 2021 Source: Department of Legal Affairs

## **National Health Commission of the People's Republic of China Order**

No. 8

 The Administrative Measures for Clinical Use of Medical Devices, which was reviewed and adopted at the 2<sup>nd</sup> commission affairs meeting on December 4, 2020, is hereby promulgated. It shall come into force as of March 1, 2021.

Director Ma Xiaowei

January 12, 2021

---

# Administrative Measures for Clinical Use of Medical Devices

## Chapter I General Provisions

Article 1 In order to strengthen the management of clinical use of medical devices and ensure the safety and effectiveness of clinical use of medical devices, the Measures is hereby formulated in accordance with the *Regulations on the Supervision and Administration of Medical Devices*, *Regulations on the Administration of Medical Institutions* and other laws and regulations.

Article 2 The Measures is applicable to the supervision and management of clinical use of medical devices in various medical institutions at all levels.

The Measures is not applicable to the management of clinical trials of medical devices.

Article 3 The National Health Commission is responsible for the supervision and administration of clinical use of medical devices.

The local health authorities at or above the county level shall be responsible for the supervision and administration of the clinical use of medical devices within their respective administrative regions.

Article 4 The main principal of a medical institution shall be the first person responsible for the clinical use and management of medical devices in the institution.

Medical institutions shall establish and improve their own management system for clinical use of medical devices to ensure the rational use of medical devices.

Article 5 Local health authorities and medical institutions at or above the county level shall, in accordance with the relevant provisions of state government, establish an emergency support mechanism for medical devices to ensure the demand for emergency treatment in emergencies.

Article 6 Medical institutions shall, in accordance with the classified catalogue of medical devices issued by state government, implement classified management of medical devices.

Article 7 Health authorities shall constantly improve the clinical use of artificial-intelligence medical devices, and encourage medical institutions to strengthen the training of clinical use of artificial-intelligence medical devices.

---

**It is the end of preview.  
Should you need the full text,  
please sign in and place an order**