IMDRF International Medical Device Regulators Forum

Medical Devices Regulation update in China

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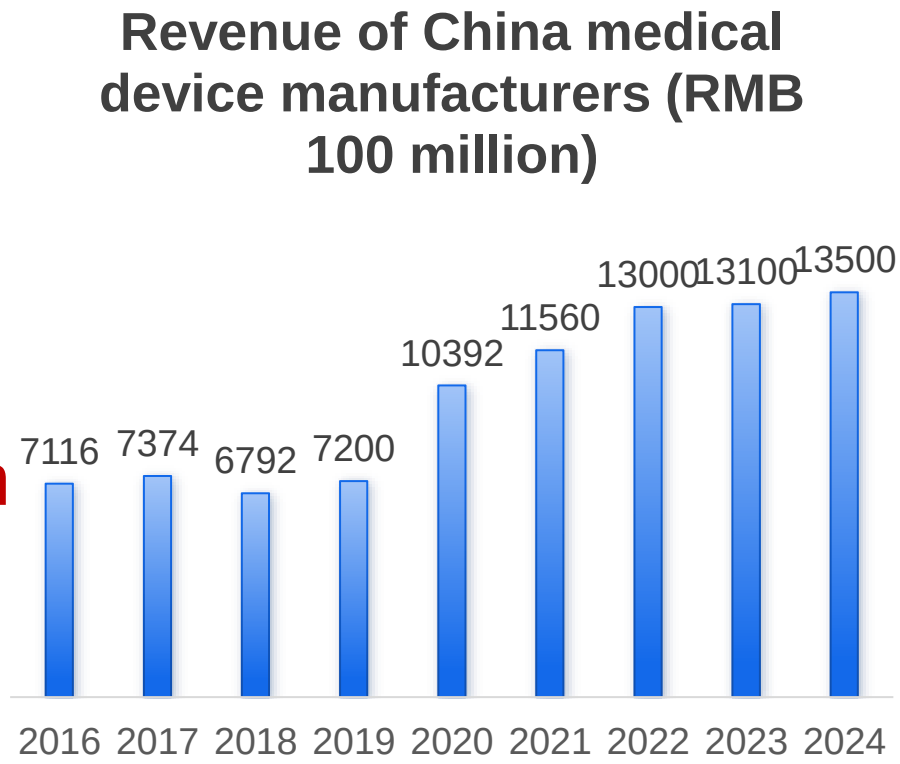
15 September 2025

1.China's Medical Device Industry Market: - Key Development Data (As of 2024)

According to industry operation monitoring data,

- China's medical device industry achieved a r evenue of 1.35 trillion yuan in 2024, sustainin g the sound momentum of steady growth witn essed in recent years.

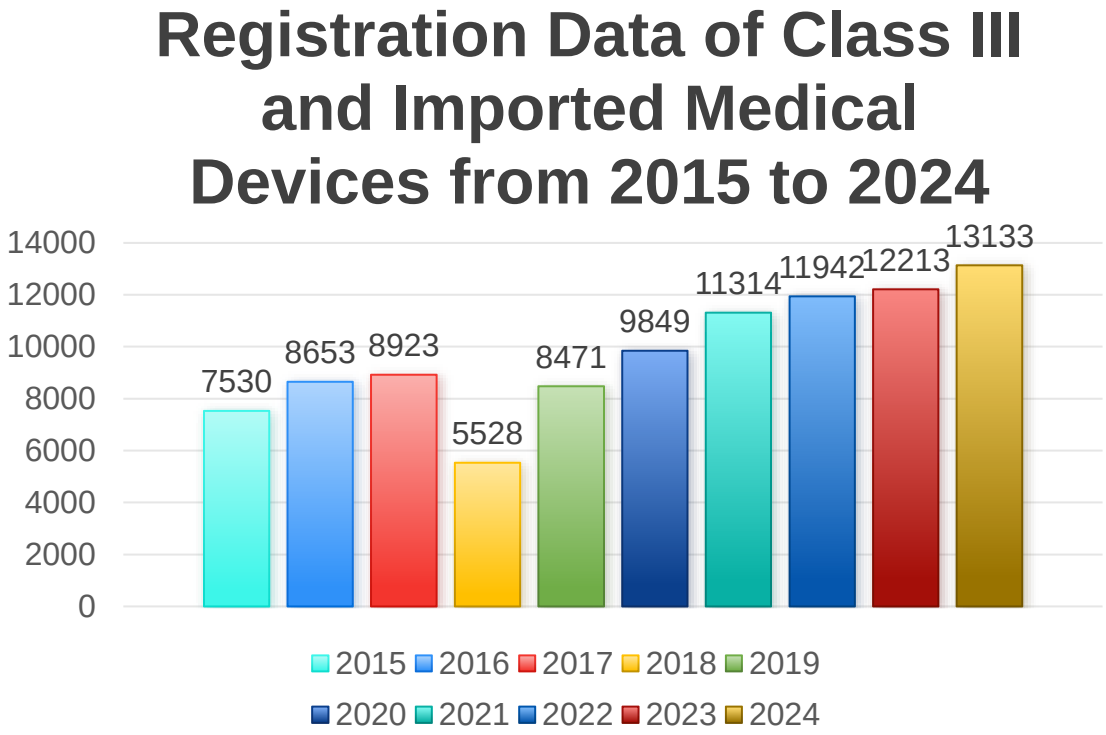


Effective medical device registration products continue to increase

- 25686 of Class III Registration Certificate
- 122413 of Class II Registration Certificate
- Number of 184329 filed in the first category

untill 30th August , 2025

Registration of domestic Class III and imported medical devices approved by NMPA



- In 2024, NMPA approved a total of 13,133 medical device registrations.
- This figure marked a 7.5% year - on - year growth compared to 2023, indicating a steady upward trend in the approval of medical devices in China.

2. On December 30, 2024, China government issued the Guidelines on Comprehensively Deepening Pharmaceutical and Medical Devices Opinions on Regulatory Reform to Promote High-quality Development of Pharmaceutical Industry

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首页 > 国务院公报 > 2025年第2号

字号：默认 大 超大 | 打印 |

国务院办公厅关于全面深化药品医疗器械监管改革促进医药产业高质量发展的意见

国办发〔2024〕53号

各省、自治区、直辖市人民政府，国务院各部委、各直属机构：

为深入贯彻落实习近平总书记关于药品医疗器械监管和医药产业发展的重要指示批示精神，全面深化药品医疗器械监管改革，促进医药产业高质量发展，经国务院同意，现提出以下意见。

一、总体要求

以习近平新时代中国特色社会主义思想为指导，全面贯彻党的二十大和二十届二中、三中全会精神，坚持科学化、法治化、国际化、现代化的监管发展道路，统筹高质量发展和高水平安全，深化药品医疗器械监管全过程改革，加快构建药品医疗器械领域全国统一大市场，打造具有全球竞争力的创新生态，推动我国从制药大国向制药强国跨越，更好满足人民群众对高质量药品医疗器械的需求。

General Requirements for Drug and Medical devices Supervision to Promote the High-Quality Development of the Pharmaceutical Industry (with a Focus on Phased Goals)

01

December 30, 2024

As we mentioned just now, China has officially issued the Opinions on

Comprehensively Deepening the Regulatory Reform of Pharmaceuticals and Medical Devices

to Promote the High-Quality Development of the Pharmaceutical Industry

(hereinafter referred to as the "Opinions").

02

Aim

Efforts will be stepped up to accelerate the development of a unified national market for pharmaceuticals and medical devices, with a focus on breaking down regional barriers, standardizing market rules, and optimizing resource allocation across the sector. Concurrently, work will be intensified to foster a world-competitive innovation ecosystem—this includes strengthening support for core technology research, improving the transformation mechanism of scientific and technological achievements, and creating a policy environment that encourages enterprises to take the lead in innovation.

03

By 2027

A notable progress has been achieved in the refinement of laws and regulations governing the supervision of pharmaceuticals and medical devices in China. Meanwhile, the regulatory system, mechanisms, and approaches have been further optimized to be more aligned with the demands of pharmaceutical innovation and the high-quality development of the sector, laying a solid institutional foundation for industrial advancement.

04

By 2035

The quality, safety, effectiveness and accessibility of pharmaceuticals and medical devices in China have been fully secured, providing a solid guarantee for safeguarding public health and meeting the people's growing demand for high-quality medical and health services.

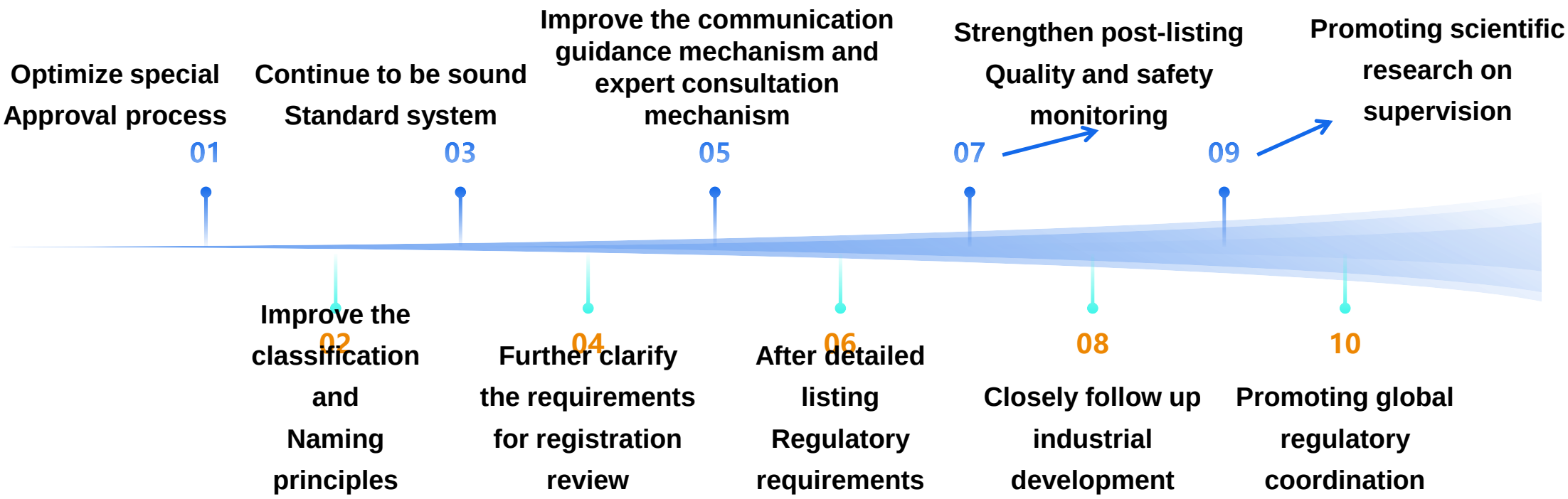
3.Continue to encourage the innovation and development of the medical device industry

Announcement of NMPA on Issuing Measures to Optimize the Whole Life Cycle Supervision and Support the Innovation and Development of High-end Medical Devices (No.63 of 2025)

Continue to encourage the innovation and development of the medical device industry

- Medical robots, high-end medical imaging equipment, artificial intelligence medical devices and new biomaterial medical devices are the key areas to shape the new productivity of medical devices. In order to promote the High-quality Development of the Pharmaceutical Industry , improve the examination and approval mechanism, strengthen the supervision of the whole life cycle, and fully support the major innovation of high-end medical devices.
- To promote the application of more new technologies, new materials, new processes and new methods in the field of health care, better meet the health needs of the people, and enhance the international competitiveness of high-end medical devices in China, NMPA has put forward ten supporting measures.

3.Continue to encourage the innovation and development of the medical device industry



Continue to encourage the innovation and development of the medical device industry

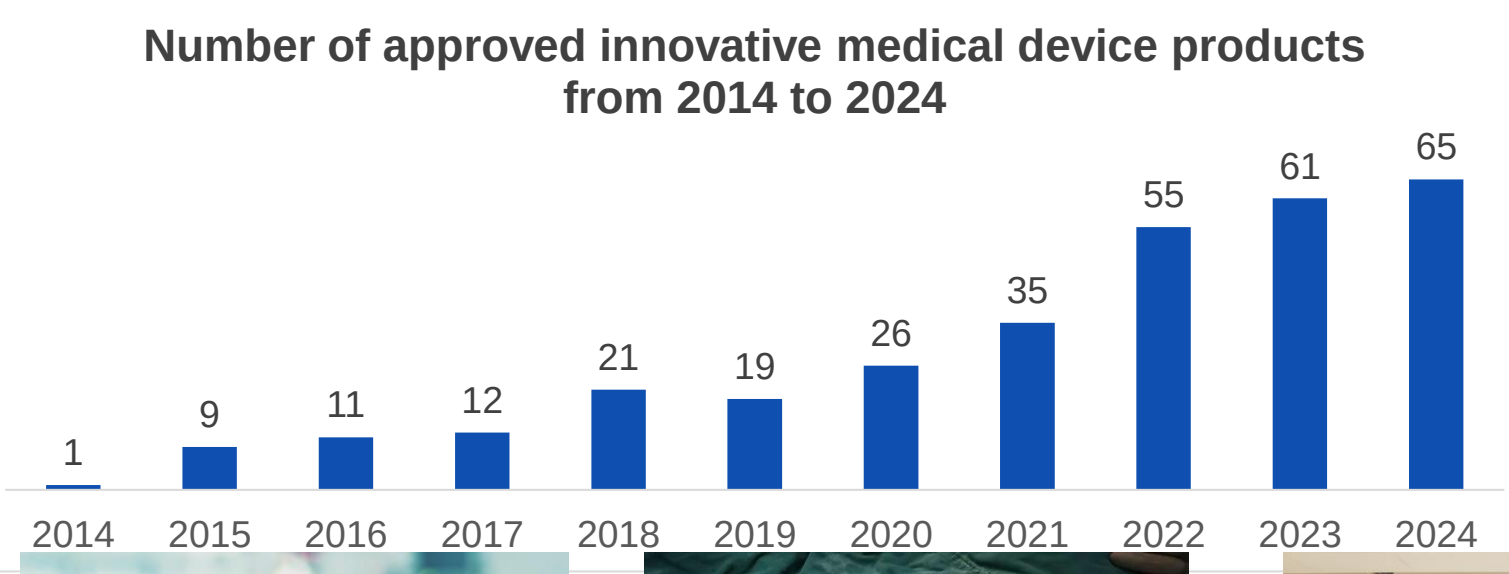
Brain-computer interface Medical Devices

Seven national departments jointly issued the Opinions on the Implementation of Promoting the Innovation and Development of Brain-Computer Interface Industry, giving priority to the registration guidance of key products such as implantable brain-computer medical devices.

Focus on supporting the research and development of two-way closed-loop implantable brain-computer interface medical devices with continuous acquisition of time axis, semi-invasive or fully invasive.

We will actively promote the formulation of key points for the review of invasive brain-computer interface medical devices, provide comprehensive pre-service and communication guidance for key products, and speed up the progress of product listing.

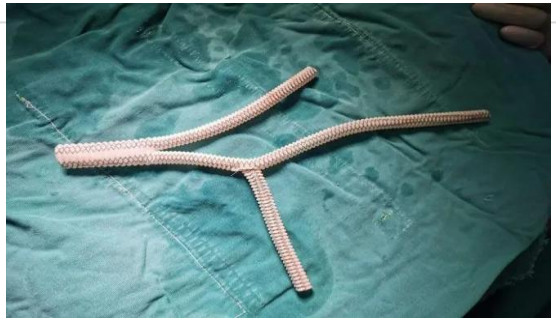
Continue to encourage the innovation and development of the medical device industry



In 2025 untill now, 52 innovative medical devices have been approved. As of August 30, 2025, NMPA has approved 368 innovative medical devices and given priority to 153 medical devices.

The number of innovative products has increased year by year.

Implantable left ventricular assist system



Artificial blood vessel

Proton therapy system

Endoscopic surgical robot

Improve the registration management requirements of medical devices.

Extend the scope of exemption from clinical evaluation

01

List of Medical Devices Exempted from Clinical Evaluation (2025)

28 new items of medical devices exempted from clinical evaluation were added, and the expression of relevant information of 40 original items was revised. After the revision, a total of 1047 medical device products were exempted from clinical evaluation.

Improve the registration management requirements of medical devices.

Extend the scope of exemption from clinical evaluation

02

List of IVD exempted from clinical trials (2025)

Fifty-five new items of IVD exempted from clinical trials were added. A total of 445 in IVD products were exempted from clinical trials after the revision.

4.Standards of Medical Devices

- As of now, China has established **296 national standards and 1,727 industrial standards**, which comprehensively covers all professional and technical domains of medical devices nationwide.

- A key focus of this framework's advancement lies in elevating three critical pillars: scope of coverage, systemic integration, and—most notably—**international alignment**. Through targeted efforts to align with global benchmarks, the consistency between China's medical device standards and international standards has now surpassed 90%.

Accelerating Progress in Global Cutting-Edge Technology Domains for Medical Devices

Since 2024, efforts to advance standards for cutting-edge medical device technologies have achieved notable progress, with a focus on brain-computer interface (BCI) applications. Specifically, three industrial standards for BCI-enabled medical devices have successfully secured approval and been initiated through an expedited procedure— a move designed to fast-track the alignment of domestic technical specifications with global frontier practices.

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Accelerating Progress in Global Cutting-Edge Technology Domains for Medical Devices

The three standards in question are as follows:

1. Medical Devices Utilizing Brain-Computer Interface Technology – Terminology
2. Medical Devices Utilizing Brain-Computer Interface Technology – Implantable Neural Stimulators with Closed-Loop Function – Test Methods for Sensing and Response Performance
3. Medical Devices Utilizing Brain-Computer Interface Technology – Quality Requirements and Evaluation Methods for EEG Datasets Used in Artificial Intelligence Algorithms

Accelerating Progress in Global Cutting-Edge Technology Domains for Medical Devices

- Among these key milestones in BCI medical device standardization, a critical update is set to take effect imminently: the industrial standard *Medical Devices Utilizing Brain-Computer Interface Technology – Terminology* has been officially slated for release **within this week**.

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Thanks for watching!