



CHINA'S MEDTECH INDUSTRY - MARKET OUTLOOK AND TRENDS

Accurate as of August 2022

Outlook of China's medtech industry

- **With an annual growth rate of around 20% since 2015**, China's medtech industry has consistently outpaced its GDP growth in recent years.
- Due to COVID-19, there was a demand surge for medical devices such as surgical masks and test kits, resulting in an **industry revenue high of RMB 800 billion in 2020**.
- It is estimated that by 2030, China will be the **world's 2nd largest medical devices market** after USA.
- As of 2019, **medical equipment made up nearly 57%** of the market, followed by high-value consumables (20%), low-value consumables (11%) and in-vitro diagnostic devices (IVDs) (11%).

Market Size of Medical Devices in China, 2019



Source: Deloitte

Outlook of China's medtech industry

Today, China accounts for around 20% of the global medtech market, and is expected to continue this upwards growth trajectory in the future, driven by a number of key factors:



An ageing population resulting in an increasing prevalence of chronic diseases



Proliferation of more healthcare clinics and hospitals



Income growth leading to more healthcare spending per capita



New policies to encourage medical device development

China is emerging as an essential player in the medtech industry. With its distinctive regulatory and competitive environment, foreign firms interested in expanding to China will need to consider how to position themselves competitively in the market.

Medtech industry trends in China



Biomedical sector is undergoing progressive reforms

China is moving towards a more innovation-friendly regulatory environment, with policies and procedures such as:

- Developing fast-track channels to accelerate innovation and approval of medical devices
- Accepting overseas clinical trial data used in clinical evaluation for pre-market registration of medical devices
- Approved Market Authorisation Holder pilots for both medical devices and drugs
- Increasing support and opportunities for foreign companies



Shifts in business model & areas of growth

Chinese medtech leaders are expected to accelerate product development and scaling, through collaborations like strategic partnerships, investment in products or companies through licensing or merger and acquisition, and venture investments and incubators. Areas of growth include, but are not limited to:

- Cardiovascular health
- Orthopedics
- Ophthalmology
- Cerebrovascular health
- Robotics and digital health



Opportunities for Singapore companies

- Entities like Contract Research Organisations and Contract Development & Manufacturing companies are increasingly relevant partners for quick access to China market
- More China companies will be keen to license medtech solutions and treatments from foreign players

Understanding China's regulatory processes

Disclaimer: This section is intended as a generic guidance only

An introduction to China's government agency, **National Medical Product Administration (NMPA or 国家药品监督管理局)**, and the approval process for medical products sold in China.

Note: *The regulatory pathways can vary across devices and it is essential for your company to verify the most up-to-date provisions and guidelines published by NMPA before commencing any registration activities. You may also consider consulting third party professional advisors who can advise on the application process relevant to your medical device(s).*

Knowing China's regulatory body for medical devices

- **NMPA is the main regulatory and administrative body that supervises the safety, registration and standards management of drugs, including Traditional Chinese Medicine and ethno-medicines, medical devices, and cosmetics.**
- NMPA is also responsible for most of the relevant pre-market approvals and post-marketing activities.

Determining classification of medical devices

	Device Examples	Risk Level	Initial Registration	Requirement on Manufacturers	Requirement on Distributors
Class III Devices with the highest level of risk, subject to the strictest controls for their safety and efficacy	Ventilators, Implants, Test Kits	High	Registration with NMPA	Production License (clinical trial required)	Distribution License
Class II Devices with a moderate level of risk, requiring greater control to ensure their safety and efficacy	Blood Pressure Monitors, ECG Machines	Medium	Registration with NMPA (provincial level)	Production License (clinical trial required)	Record Filing with NMPA
Class I Devices with the lowest level of risk, requiring only routine administration for their safety and efficacy	Examination Gloves, Goggles	Low	Record Filing with NMPA	Record Filing with NMPA	None

Source: State Council Website, National Medical Products Administration

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Key steps in the NMPA application process

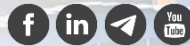
- Determine the classification of your medical device in China using NMPA's Medical Device Classification Catalog (医疗器械分类目录) and Rules for Classification of Medical Devices (医疗器械分类规则). Class II and III device manufacturers should also identify predicates and determine the clinical data requirements for your medical device at an earlier stage as the duration of the application process can vary.
- Appoint an legal agent located in China to coordinate your NMPA device registration.
- Provide proof of approval from home country using documents such as Certificate of Free Sale (CFS) or Certificate to Foreign Government (CFG). Manufacturers should also submit notarised certificates or documents to show manufacturer's qualification. Examples of such documents include ISO 13485, establishment registration from Food & Drug Administration or manufacturing license.
- Prepare product technical requirement document. Look for applicable Technical Review Guidelines (注册技术审查指导原则) on Center for Medical Device Evaluation (医疗器械技术审评中心) of NMPA's website and include details of the testing(s) that will be conducted in China. Compile application dossier.
- **For Class I devices:** Prepare technical documentation for Class I submission and provide the required information to NMPA. Class I devices are subject to administrative review only. When the submission is accepted, NMPA will issue a record filing certificate.
- **For Class II and III devices:** In-country testing with NMPA-authorized test centres will be required. Check the latest Catalogue of Medical Devices Exempted from Clinical Trials (免于临床评价医疗器械目录) on NMPA's website before conducting any clinical trials. Prepare application dossier including test reports, agent authorisation letter, CFS/CFG, clinical data, clinical evaluation report, and any other technical documents that can support the submission. A full application review (i.e. technical and administration evaluation) will be conducted. Note that novel and high-risk products may be subject to a NMPA's expert panel meeting, and NMPA may also conduct on-site inspections of the quality management system. When the submission is accepted, NMPA will issue a registration certificate that is valid for five years.

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To find out more about China's medtech industry,
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