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沙利文

# 2025 Blue Book on the Current Status and Trends of Global Expansion of Chinese Medical Devices

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# Preface

In the trend of globalization, global expansion has become an inevitable trend for the medical device industry. As a global expert in applied safety science, UL Solutions is honored to contribute to the “2025 Blue Book on the Current Status and Trends of Global Expansion of Chinese Medical Devices” and share our insights and commitment to the development of the industry.

Global expansion is not only a strategic choice for medical device companies to enter new markets, but also a key mission to improve global healthcare and promote human well-being. However, this journey brings many challenges. Companies must deal with different regulatory standards across countries and regions, challenges in market access, cultural differences, and technical requirements. The main issue is how to find direction in a complex international environment and achieve the shift from product export to brand trust, which every company expanding globally must face.

This book provides a detailed look into every stage of global expansion: from regulatory understanding to market strategy, from quality control to brand building. It offers practical and comprehensive guidance for companies going global. The content brings together the experience and knowledge of many industry experts, aiming to support Chinese medical device companies in growing steadily in the international market and shifting from product exporters to influential global brands.

UL Solutions remains committed to providing complete quality and safety solutions for medical device companies. We look forward to working closely with companies across the industry to jointly promote the global expansion of Chinese medical device sector and bring high-quality Chinese medical devices to patients around the world.

—— Regional VP, China & Hong Kong, UL Solutions

David Wu

Amid profound changes in the global healthcare landscape, Chinese medical device companies are accelerating their global expansion with innovation as the driving force. In recent years, Chinese medical devices have achieved both greater scale and higher quality in the international markets, thanks to technological breakthroughs, cost advantages, and supportive government policies. Export volumes have continued to grow, while product lines are moving toward higher-end and more diversified offerings. However, the road to global expansion is not without challenges. Chinese companies must navigate through complex international regulations, intense global competition, localization difficulties, and geopolitical risks.These challenges are significant hurdles that companies must overcome to break through growth bottlenecks and advance their global expansion. In this context, the “2025 Blue Book on the Current Status and Trends of Global Expansion of Chinese Medical Device” was launched, aiming to provide a clear globalization roadmap for Chinese medical device companies.

This Blue Book outlines the key drivers, strategic pathways, and regional opportunities behind Chinese medical device global expansion. It delivers in-depth insights into key sectors such as medical equipment, high-value consumables, and in vitro diagnostics, and explains entry requirements and market strategies in core regions including the U.S., EU, and Southeast Asia. With detailed data, representative case studies, and forward-looking perspectives, the Blue Book not only maps out the development logic of the global medical device industry, but also offers full-cycle solutions, from R&D and regulatory compliance to distribution channel building. Notably, it tracks evolving global regulatory trends and provides forward-looking guidance on critical topics such as MDR, FDA certification, and data security, helping companies build robust risk control systems and achieve stable global expansion.

In this globalization process, expert legal support plays a vital role. As a leading provider of legal services in China’s healthcare and pharmaceutical industry, AllBright Law Offices actively contributed to the writing of this Blue Book, offering deep industry expertise and legal insights. AllBright’s contribution reflects the value of legal frameworks in supporting industry globalization and provides Chinese enterprises with a solid legal foundation for their global strategies.

Looking ahead, Chinese medical device companies must aim high by seizing technological and market opportunities, while also staying grounded by building comprehensive risk prevention systems. We hope this Blue Book will serve as a practical guide for industry players and, together with all stakeholders, help “Innovative Manufacturing in China” shine even brighter on the global healthcare stage.

——Pharmaceutical and Healthcare Committee, Shanghai AllBright Law Offices

# Catalogue

## Chapter 1 Overview of Chinese Medical Device Global Expansion

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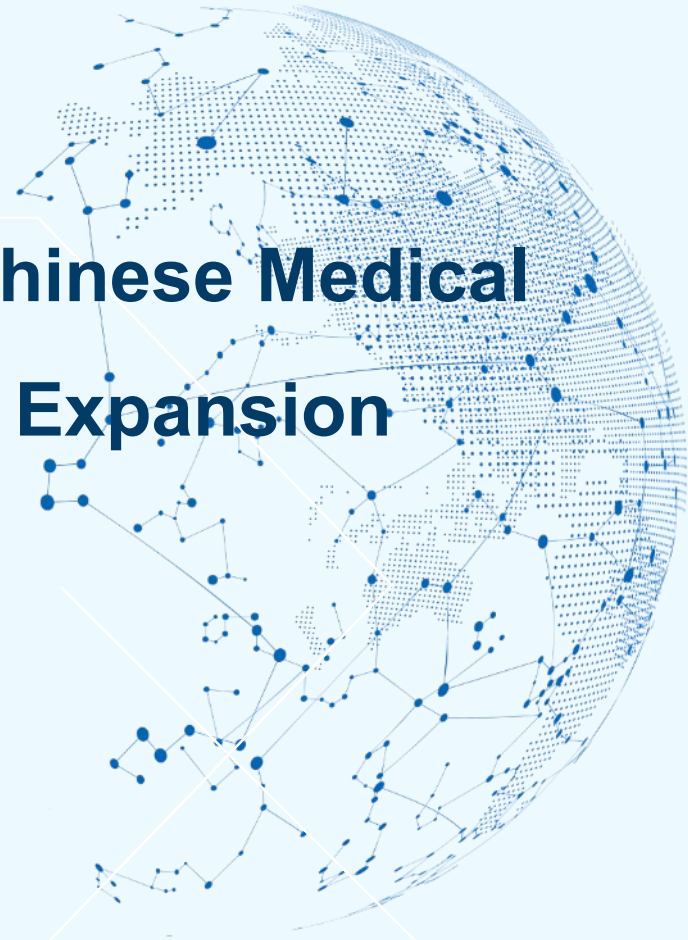
# Chapter 1

# Overview of Chinese Medical Device Global Expansion



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# Overview of Chinese Medical Device Industry

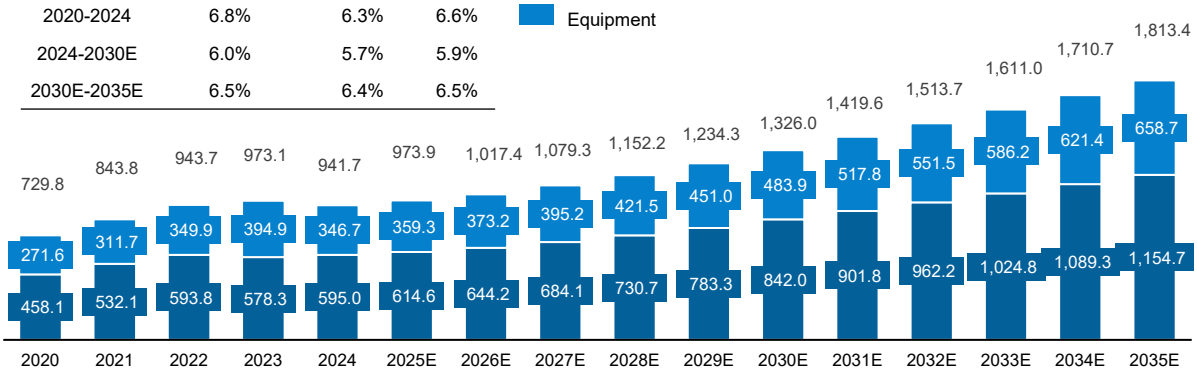
**Driven by the accelerating aging population, rising healthcare demand, and continuous technological innovation, the medical device market in China and worldwide is experiencing steady growth and is expected to demonstrate greater potential in the coming years.**

## Market Size of Global and Chinese Medical Device Industry

China's medical device industry has maintained steady growth, driven by advancements in technology, a rapidly aging population, a rising number of people with chronic diseases, and increasing healthcare demand. According to Frost & Sullivan's analysis, the overall market size in China grew from 729.8 billion RMB in 2020 to 941.7 billion RMB in 2024, with a compound annual growth rate (CAGR) of 6.6%. The Chinese medical device industry is projected to reach 1,813.4 billion RMB by 2035.

**Fig. China Medical Device Market Size and Forecast, 2020–2035E**

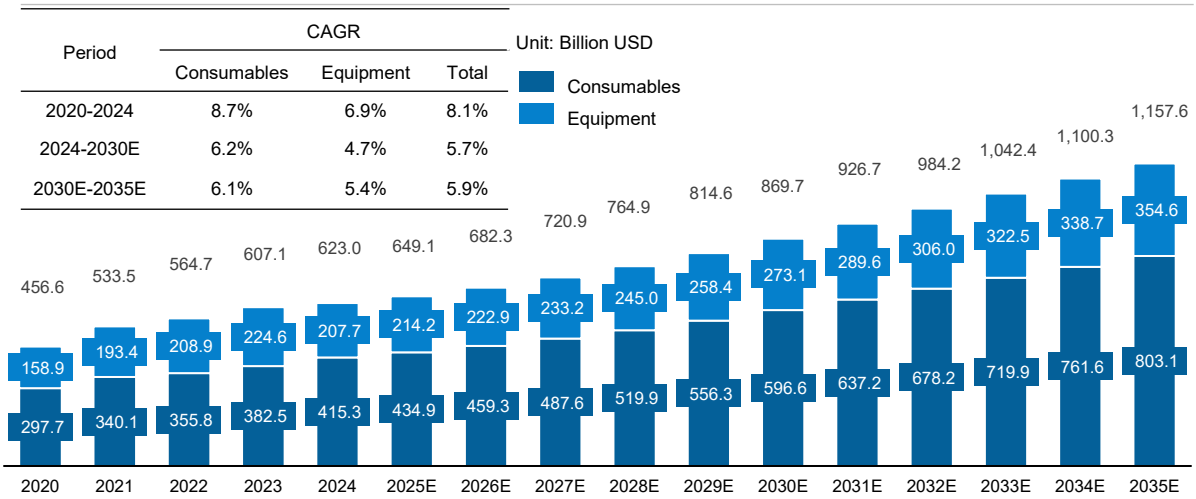
| Period | CAGR | | |
|---|---|---|---|
| | Consumables | Equipment | Total |
| 2020-2024 | 6.8% | 6.3% | 6.6% |
| 2024-2030E | 6.0% | 5.7% | 5.9% |
| 2030E-2035E | 6.5% | 6.4% | 6.5% |




The global medical device market has shown steady growth in recent years. North America remains the largest single market, while the Asian market has seen rapid expansion especially in China. In the coming years, driven by factors such as an aging population and the growing demand for chronic disease management, global market demand is expected to continue rising steadily. According to Frost & Sullivan's data, the overall global medical device market size grew from $456.6 billion USD in 2020 to $623.0 billion USD in 2024, with a CAGR of 8.1%. It is projected to reach $1,157.6 billion USD by 2035.

**Fig. Global Medical Device Market Size and Forecast, 2020–2035E**

| Period | CAGR | | |
|---|---|---|---|
| | Consumables | Equipment | Total |
| 2020-2024 | 8.7% | 6.9% | 8.1% |
| 2024-2030E | 6.2% | 4.7% | 5.7% |
| 2030E-2035E | 6.1% | 5.4% | 5.9% |




Source: IMF, World Bank, Frost & Sullivan Analysis.





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# ■ Drivers of Chinese Medical Device Global Expansion – Internal Factors

The Chinese medical device industry has a large number of companies and high production capacity, but low profit margins result in low per-unit output efficiency. With ongoing price pressure under volume-based procurement policies, companies are accelerating their global expansion to seek new growth opportunities.

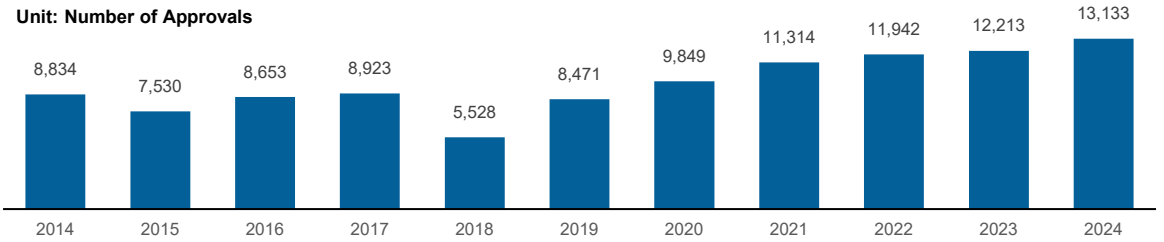
## Numerous Chinese Manufacturers with Large Capacity but Low Output per Company

According to data from the Information Center of the National Medical Products Administration, there were ***32,313*** medical device manufacturing companies in China by the end of 2023.

Most of them focus on low-value consumables with low technical barriers, intense competition, and thin profit margins. Although China files a large number of medical device patents, the share of high-value patents is low, limiting improvements in per-company productivity. According to Frost & Sullivan's analysis, the Chinese medical device market reached 973.1 billion RMB in 2023. Based on this, the average output value per company was only ***30 million RMB***.

Meanwhile, market demand declined significantly, especially for devices related to pandemic prevention, slowing the overall growth of the industry. According to data released by the National Bureau of Statistics, total revenue of large-scale pharmaceutical manufacturing enterprises was ***2,520.57 billion RMB*** in 2023, down 3.7% from 2022.

**Fig. Medical Device Registration Approvals by the National Medical Products Administration, 2014–2024**




## Centralized Procurement Brings Pricing Pressure

Since the State Council issued the Reform Plan for the Control of High-Value Medical Supplies in 2019, Anhui and Jiangsu provinces were the first to pilot volume-based procurement (VBP) of high-value consumables. By December 2024, five rounds of national-level VBP for high-value consumables had been launched, focusing on segments such as cardiovascular intervention and orthopedics, resulting in substantial price reductions. Currently, VBP covers most major categories of medical devices, with an emphasis on products with high clinical demand and large market scale. It is being broadly implemented across high-value consumables, low-value consumables, and in vitro diagnostic reagents, putting considerable pressure on industry development.

**Fig. Changes in Varieties and Unit Prices of Products under National Centralized Procurement**

| Date | Product Category | Average Price Before Procurement | Average Price After Procurement |
|---|---|---|---|
| Oct 2020 | Coronary Stents | 13,000 RMB | 700 RMB |
| Jun 2021 | Artificial Joints | Hip Joint: 35,000 RMB<br>Knee Joint: 32,000 RMB | Hip Joint: 7,000 RMB<br>Knee Joint: 5,000 RMB |
| Jul 2022 | Orthopedic Spinal Implants | 33,000–60,000 RMB | 3,250 RMB |
| Sep 2022 | Coronary Stents | 13,000 RMB | 770 RMB |
| Sep 2023 | Intraocular Lenses | 27,000–60,000 RMB | 2,900 RMB |
| | Sports Medicine Products | 5,500 RMB | 1,430 RMB |
| Nov 2024 | Cochlear Implants | 200,000 RMB | 50,000 RMB |
| | Peripheral Vascular Stents | 10,000–45,000 RMB | less than 6,000 RMB |

Source: Public Information, Frost & Sullivan Analysis.





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# ■ Drivers of Chinese Medical Device Global Expansion – Internal Factors

China's medical device R&D and innovation capabilities have continued to grow. The global pandemic has objectively accelerated the global recognition of Chinese medical device brands. In response, companies have expanded their overseas distribution channels and strengthened brand development. Their global expansion is advancing in both scale and quality.

**Fig. Winning Bids for Eight Categories of Medical Device in 2023**

| Device Type | Device Type | Total Winning Quantity |
|---|---|---|
| Endoscopes | 24.36 billion RMB | ~60,000 |
| Ultrasound Imaging Machines | 22.99 billion RMB | ~18,000 |
| Patient Monitoring Devices | 2.67 billion RMB | ~54,000 |
| Ventilators | 4.84 billion RMB | ~32,000 |
| External Defibrillators | 0.89 billion RMB | ~39,000 |
| Anesthesia Machines | 1.94 billion RMB | ~5,900 |
| Hemodialysis/Peritoneal Dialysis Machines | 3.05 billion RMB | ~14,000 |
| Surgical Assistance Systems | 3.84 billion RMB | ~490 |

Public hospitals in China typically procure medical equipment through a tendering process to reduce purchase costs and help lower overall healthcare expenses.

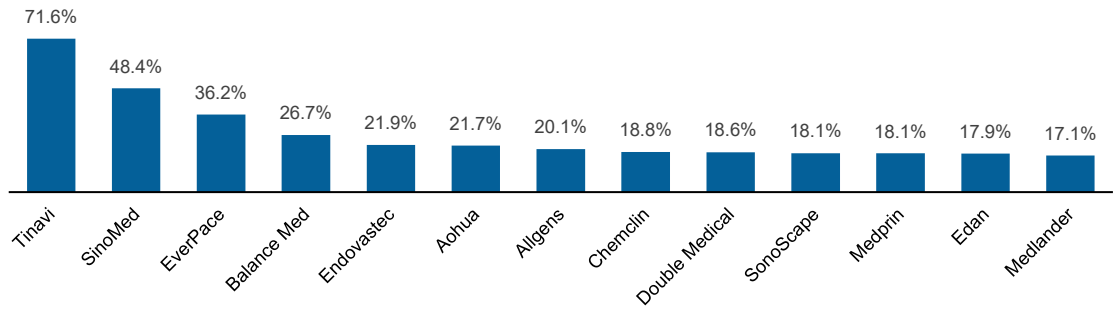
According to an analysis of 2023 bidding data for eight categories of medical equipment:endoscopes, ultrasound imaging systems, patient monitors, ventilators, external defibrillators, anesthesia machines, hemodialysis/peritoneal dialysis equipment, and surgical assistance systems, the total successful bidding contract value reached 43.39 billion RMB, with over 150,000 units winning bids.

## Steady Growth in Chinese Medical Device R&D and Innovation Capacity

The 14th Five-Year Plan calls for accelerating independent innovation in high-end medical equipment and supporting domestic manufacturers in overcoming technological barriers, with strong policy support for innovation in China's medical device industry.

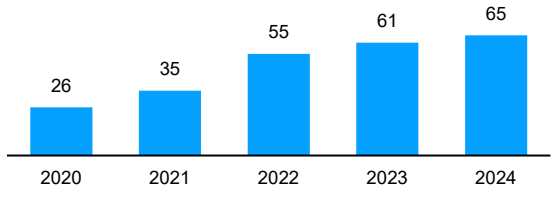
In recent years, leading Chinese medical device companies have steadily increased the proportion of revenue allocated to R&D, approaching the level of their international counterparts. Technology-intensive companies have further increased investment to promote industry-wide technological progress and enhance the competitiveness of Chinese-made medical devices. For example, Tinavi, which focuses on orthopedic surgical robots and related technologies, reported in its 2023 annual report that R&D investment accounted for 71.6% of its revenue. The company holds 328 valid patents.

**Fig. Proportion of R&D Investment as Revenue for Selected Companies, 2023**




From 2018 to 2023, the National Medical Products Administration (NMPA) approved a total of 217 innovative medical device products for market entry. In 2024, the NMPA approved 65 such products, showing a year-on-year increase. The top five categories of innovative devices approved in 2024 were active surgical instruments, passive implantable devices, active implantable devices, medical software, and devices for neurological and vascular surgery, as well as medical imaging equipment, all representing high-end segments of the medical device sector.

**Fig. Number of Approved Innovative Medical Devices in China, 2020–2024**




Source: Public Information, Frost & Sullivan Analysis.





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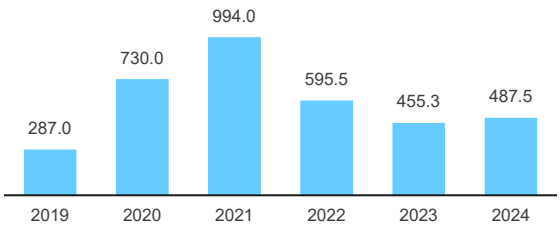
# ■ Drivers of Chinese Medical Device Global Expansion – Internal Factors

National policies continue to support the global expansion of innovative medical devices. Leading companies, by drawing on hands-on experience from early internationalization efforts, have developed replicable models for global expansion, effectively lowering market entry barriers and compliance risks.

## Pandemic Strengthened Overseas Channels and Brand Awareness

**Fig. Chinese Medical Device Export Value, 2019–2024**

Unit: Hundred Million USD




Source: China Chamber of Commerce of Medicines & Health Products Imports & Exports

In the early stage of the pandemic, global shortages of medical protective supplies led to China's large-scale exports of masks, ventilators, and IVD test kits, quickly establishing broad overseas market channels. During this period, the export value of Chinese medical devices increased rapidly.

Amid the impact of pandemic, IVD companies expanded their global business rapidly, building strong channel resources and brand influence. Although export volumes gradually returned to normal levels in the post-pandemic period, Chinese companies successfully leveraged the channel advantages and supply chain capabilities developed during the pandemic to secure long-term orders. This has accelerated the independent global expansion of mid- to high-end products and further strengthened their international competitiveness and brand image.

## Chinese Policies Support Global Expansion of Innovative Devices

**Belt and Road Initiative:** Through a combination of policy measures and the Belt and Road Initiative (BRI), China has established a comprehensive support system for the global expansion of its medical device industry. The government has set up dedicated funding pools, providing export credits and loan guarantees to reduce financial pressure on companies. It has also promoted free trade agreement negotiations to lower tariff barriers and reduce export costs. The BRI supports market development in participating countries, helping Chinese medical device companies achieve sustainable growth globally and enhance the international presence of domestically produced devices.

**14th Five-Year Plan:** Under the 14th Five-Year Plan, China has strengthened systematic support for the global expansion of medical devices. The National Medical Products Administration (NMPA) has introduced measures in three areas: regulatory systems, approval processes, and international alignment. ① Improving review mechanisms, strengthening standard-setting and intellectual property protection, and building a compliant regulatory environment; ② Speeding up the review and approval of major innovations and urgently needed clinical products, with customized, full-process guidance for individual enterprises ("delicated policy for every enterprise, and all time guildance"); ③ Expanding the scope of Free Sales Certificates, allowing products that comply with GMP standards to be exported even if they are not approved for domestic sale. Aligned with the National Development and Reform Commission's strategy to "accelerate the upgrading of biopharmaceuticals and medical devices," these measures create a full-chain support system covering R&D, regulatory approval, and international certification, providing strong policy support for global expansion.

**Export Tax Rebate:** China supports the global expansion of high-tech products such as medical devices by optimizing export tax rebate policies, promoting the "zero-tariff" policy of the Hainan Free Trade Port, and introducing the "25 Measures" policy package. Companies like If-Health have benefited from efficient local tax services, receiving fee reductions for U.S. FDA small business certification, saving around 114,000 annually RMB. These measures help reduce compliance costs and lower the threshold for going global. By combining streamlined tax rebates, reduced tax burdens, and free trade port incentives, China is systematically improving the global competitiveness of its medical device industry and supporting its move up the high-end value chain.

Source: Public Information, Frost & Sullivan Analysis.

# ■ Drivers of Chinese Medical Device Global Expansion – Internal Factors

National policies continue to support the global expansion of innovative medical devices. Leading companies, by drawing on hands-on experience from early internationalization efforts, have developed replicable models for global expansion, effectively lowering market entry barriers and compliance risks.

## Chinese Policies Support Global Expansion of Innovative Devices

**Financial Support:** In the first three quarters of 2024, China supported the global expansion of export-oriented enterprises through measures such as expanding export credit insurance, strengthening credit support, and improving cross-border settlement. Data shows that the foreign exchange hedging ratio reached 27%, with over 32,000 new "first-time account" clients. Cross-border RMB settlement totaled 8.9 trillion RMB, up 15%, helping mitigate the impact of exchange rate fluctuations on export costs. On the industrial side, at the end of 2023, the State Council launched regulatory reforms for drugs and medical devices, supporting faster review and clinical translation of high-end medical devices. The Beijing Robotics Innovation Center's high-end medical device CDMO project has also been launched in the Economic Development Zone. The synergy between financial and industrial policies is becoming a key driver for the high-quality global expansion of China's medical device industry.

**Exhibition Support:** China continues to strengthen support for medical device exhibitions and matchmaking platforms at both national and local levels to promote global expansion. The Shenzhen Development and Reform Commission has launched the "Expand International Markets" service brand, bringing together resources from state enterprises, business associations, and Hong Kong and Macau to support the globalization of local medical companies. United Imaging Healthcare showcased China's technological capabilities with high-end imaging equipment at the Arab Health Exhibition. The China International Medical Equipment Fair and the North Hongqiao International Medical Industry Conference focus on digital transformation and global procurement channels, helping companies commercialize their products abroad. A systematic exhibition policy and coordinated resource mechanism provide ongoing and effective support for the global expansion of Chinese medical device companies.

Innovation Vouchers are a form of "technology innovation currency" issued by the government to address the lack of innovation resources for small and medium-sized enterprises and the limited service incentives of universities. By purchasing services from universities and research institutions, the government supports innovation in micro, small, and medium enterprises, making the vouchers an inclusive policy tool that helps optimize science and technology resource allocation and promote collaboration between industry, academia, and research. In Shanghai, for example, over 60 million RMB worth of vouchers were issued in four rounds throughout 2024. This has effectively boosted innovation in the medical device sector, accelerated technological upgrades, and significantly improved the technological competitiveness and brand influence of domestically produced medical devices in China.

## Leading Chinese Medical Device Companies Started Globalization Early with Rich Experience

mindray

From 2000 to 2005, Mindray focused on global expansion through distribution. Between 2006 and 2012, they set up overseas offices and entered the U.S. market through acquisitions. From 2013 to 2016, they shifted to localized operations, expanded their international marketing networks, reached high-end customer segments, and strengthened their capabilities in core raw materials.

andon九安

In 2006, Andon Health introduced a voice-operated blood pressure monitor to the German market. By 2009, its products had been exported to more than 50 countries. In 2011, the company established a subsidiary in Silicon Valley, steadily building its distribution network. By 2022, supported by this network, the sales of its COVID-19 test kits saw a sharp increase in the U.S. market.

UNITED 联影 IMAGING

In 2018, United Imaging entered the U.S. market and established its North American regional headquarters. By 2023, five years later, its full range of imaging equipment had been deployed in over half of all U.S. states. The company's business has expanded to more than 65 countries and regions worldwide.

Source: Public Information, Frost & Sullivan Analysis.

# Drivers of Chinese Medical Device Global Expansion – External Factors

The overseas medical device market is large and continues to grow, covering core regions including North America, Europe, and Asia-Pacific. These regions vary significantly in technological maturity and growth potential. Meanwhile, product categories are expanding, forming a layered and diversified growth structure.

## Vast Global Medical Device Market

At present, the global medical device market is growing steadily, with a continuously expanding market size, wide application scope, and increasingly diverse regional distribution. In terms of market structure, the global medical device market has formed three core regional centers: North America, Europe, and Asia-Pacific, each with its own characteristics and advantages.

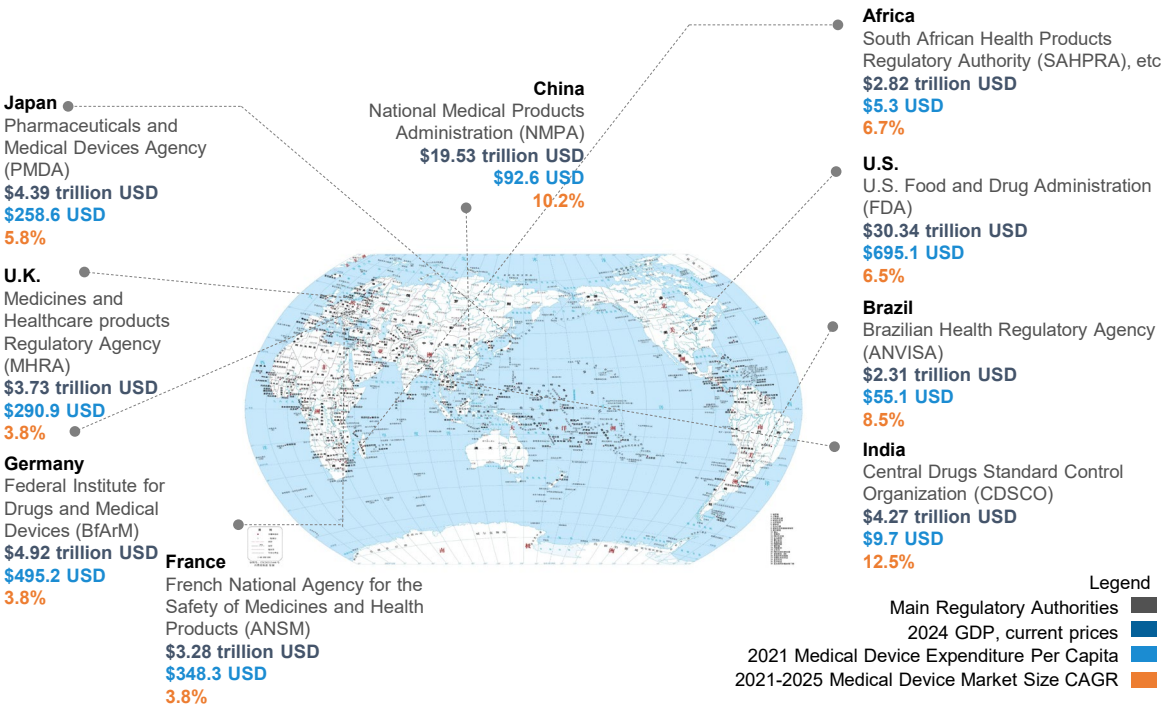
North America is the technological leader in the global medical device industry, with a mature healthcare system and high standards for market entry. The region is a global frontrunner in R&D, manufacturing, and application of medical devices, especially in high-end segments such as large-scale imaging equipment and implantable devices, where it holds clear technological and market advantages.

Europe is known for its high-standard healthcare system and strict quality regulations. It is also a major part of global medical device trade, attracting many international companies to set up branches or R&D centers in the region.

The Asia-Pacific region, supported by rapid economic growth and a large population base, has become one of the most promising areas in the global medical device market. With rising healthcare demand and improving healthcare infrastructure, its market is growing much faster than the global average. Countries like China and India are showing strong momentum in both demand and production of medical devices.

In terms of products, the global medical device market includes a wide range of categories, such as diagnostic equipment, therapeutic devices, rehabilitation devices, and monitoring systems, covering the entire process from diagnosis to treatment and recovery. At the same time, as medical technology advances and healthcare needs diversify, the medical device market continues to segment. Emerging areas such as telemedicine devices and wearable medical technologies are growing rapidly, further expanding market boundaries.

**Fig. Global Medical Device Market Analysis**




Source: Public Information, Frost & Sullivan Analysis.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# Drivers of Chinese Medical Device Global Expansion – External Factors

**Chinese medical device industry holds a core competitive advantage in cost-effectiveness. Along with China's growing global influence and the increasing recognition of Chinese brands in international markets, this serves as an external driving force for the industry's global expansion.**

## Price Competitiveness of Chinese Medical Devices

Chinese medical device companies have built strong price competitiveness in overseas markets by leveraging their significant cost structure advantages. Thanks to lower labor and raw material costs, they are able to maintain product performance while offering competitive pricing strategies.

For example, in the ultrasound equipment segment, comparable Chinese products are priced 10%–20% lower than U.S. domestic brands. As the technical complexity increases, the price gap is expected to widen. Under the same budget constraints, Chinese equipment can offer better configurations and service packages at the same price point.

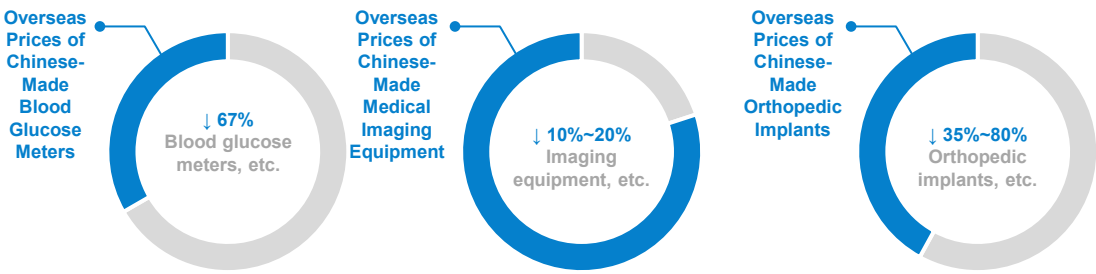
In more mature categories such as blood glucose meters, the average unit price of Chinese products is nearly 50% lower than that of international brands. Even when achieving 80%–90% of the performance of overseas products, they are priced at only about one-third, showing a clear price advantage.

In the high-value medical consumables segment, Chinese produced alternatives also show strong price competitiveness. For example, vascular interventional consumables are priced 20%–60% lower than similar products, and orthopedic implants are priced 35%–80% lower.

This "performance-to-cost" differentiated competition strategy allows Chinese companies to maintain reasonable profit margins while creating a substitution effect in international markets, especially in price-sensitive regions. It has become a key strategic support for Chinese medical equipment to break through technological barriers and reshape the global industry landscape.

In addition, affected by regulations, medical device prices in China tend to fluctuate significantly, with some categories experiencing sharp and inconsistent price reductions. In contrast, pricing systems in overseas markets are relatively stable.

**Fig. Price Differences Between Some Chinese Medical Devices and Similar Products in Developed Countries**




## Rising Global Influence of China

China has become the world's second-largest economy and continues to grow its global influence through international initiatives such as the Belt and Road Initiative. These efforts have strengthened China's presence in the global economy. China is also actively involved in global governance, playing an important role in international organizations like the United Nations and the World Trade Organization, where it promotes multilateralism and international cooperation.

In addition, China has made significant progress in technological innovation, boosting its global competitiveness in science and technology. It has also promoted Chinese culture abroad by establishing Confucius Institutes, distributing film and television content, and using social media platforms, all of which have helped increase cultural recognition and enhance China's soft power.

As China's international influence and global standing continue to rise, recognition of Chinese manufacturing is growing among overseas users. In the medical device sector, high-quality equipment and technical solutions from China are steadily entering global markets. This trend is not only advancing the global expansion of Chinese manufacturing but also contributing to global public health, further strengthening China's role in the global economy and technology landscape.

Source: Public Information, Frost & Sullivan Analysis.

# Drivers of Chinese Medical Device Global Expansion – Strategic Intentions

The strategic goal of Chinese medical device companies in their global expansion is to overcome domestic growth bottlenecks and achieve sustained development through technological innovation and global brand building.

**Revenue Growth** — **Expanding into international markets to discover new growth curves**

As competition in the domestic market intensifies and growth slows, Chinese medical device companies are urgently seeking new growth drivers. Policy changes, price wars, and cost-control pressures have made it necessary for companies to look for external revenue sources. Developed and emerging markets show strong demand for high-quality medical devices, and compared with the low profit margins caused by price cuts in China, overseas markets often offer higher unit prices and profitability. Gaining recognition in international markets also helps companies build a global brand image, laying a foundation for long-term growth.

**Industry Exchange** — **Creating opportunities for global collaboration and promoting partnerships with overseas research institutions**

Medical device technologies advance quickly, and global innovation networks play a key role in product upgrades and breakthrough developments. By working with international peers and leading research institutions, companies can access the latest scientific progress and improve their R&D capabilities. Taking part in international academic exchanges and joint projects enhances a company's technical image and strengthens its role in global standard-setting. These partnerships also help bring new technologies to market faster, increasing overall competitiveness.

**Talent Acquistion** — **Recruiting Overseas Talent to Enhance R&D and Manufacturing Capabilities**

In a globalized environment, top talent and an international perspective are key drivers of continuous innovation. By bringing in global talent, companies can overcome domestic talent constraints and gain access to advanced technologies and management practices. These professionals often have strong international experience and resources, helping companies better understand global market needs, improve product quality, and boost competitiveness. Their involvement supports technological innovation and alignment with international standards. A diverse global team also helps companies build a broader perspective and become more adaptable and creative when facing cultural and market challenges.

**Overseas Financing** — **Attracting Overseas Financing**

Overseas financing not only provides sufficient capital but also signals a company's strength and credibility to the outside world. While relying on domestic capital markets, accessing overseas funding helps diversify sources and reduce financing risks. Securing international investment raises global visibility and builds market trust, offering both capital and strategic resources for future global expansion. With stronger financial support, companies can invest more in R&D, speed up product innovation, and expand their market reach, supporting large-scale and sustainable international growth.

**Brand Upgrading** — **Enhancing Brand Influence to Boost Both Overseas Revenue and Domestic Sales**

By expanding into international markets, Chinese medical device companies can build strong overseas channels and increase brand recognition, helping shape a trusted image for "Made in China." This growing brand influence not only drives more international orders but also strengthens domestic consumer confidence. In addition, diverse global market demands push companies to improve their technologies and product quality. This promotes internal innovation and industrial upgrading, further supporting sales growth in the domestic market alongside global expansion.

Source: Public Information, Frost & Sullivan Analysis.

# History of Chinese Medical Device Global Expansion

**Chinese medical device industry has followed an international growth path of "resource accumulation – technology buildup – demand-driven development – compliance improvement." It has progressed from early low-cost global expansion, to technology-driven growth, to emergency-driven breakthroughs during the pandemic, and finally, to mid- to high-end transformation through process upgrades in the post-pandemic era.**

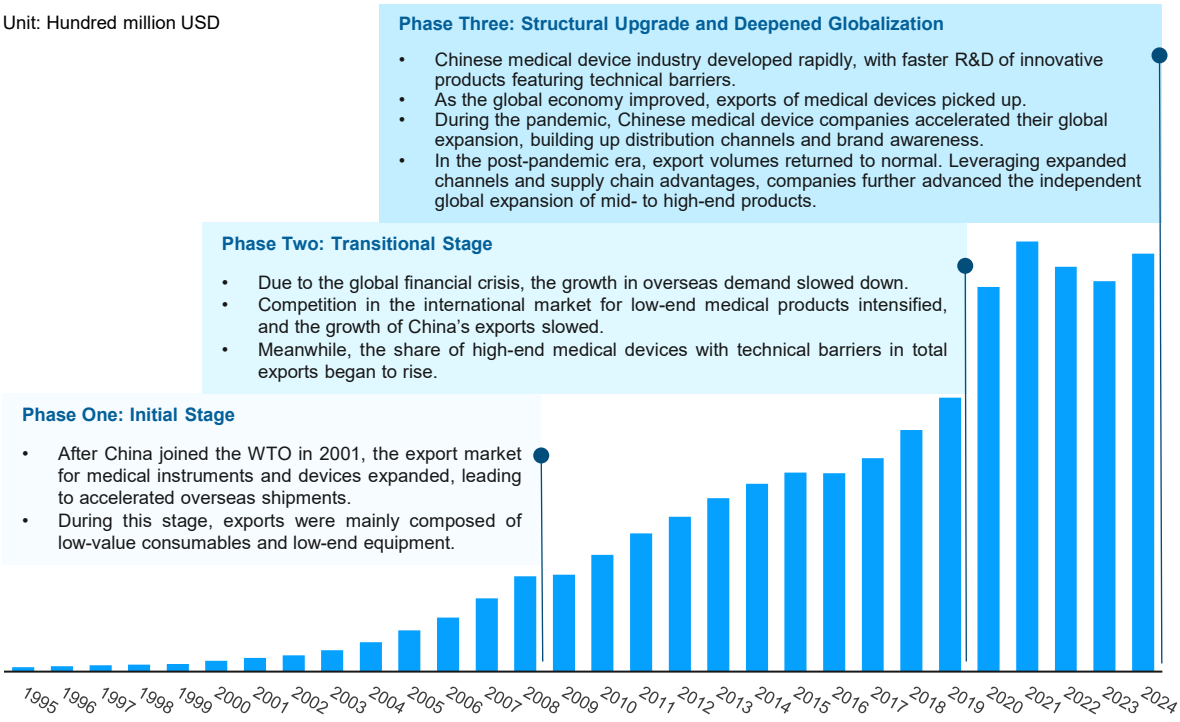
## Analysis of the Global Expansion Journey of Chinese Medical Device Companies

The medical device industry is highly R&D- and capital-intensive, requiring significant research investment and resource allocation. In the early stages, Chinese medical device companies mainly entered the basic healthcare segment, which was insufficient for long-term development. After China joined the WTO in 2001 and global trade barriers eased, companies such as Mindray, Andon Health, Shenzhen Anke, Shinva, Lepu Medical, and SonoScape began expanding into overseas markets. This helped them accumulate resources for R&D and gradually build competitive advantages. However, during this period, Chinese firms relied on cost advantages, mainly exporting low-value medical consumables to markets in Europe and the U.S.

Since 2010, more companies have joined the global expansion process. These companies had already built strong technical and R&D capabilities in China, and their overseas distribution networks were becoming more mature. In this context, firms such as Edan Instruments, Biolight, United Imaging, and Snibe Diagnostic accelerated their overseas market strategies and entered a fast track of international growth.

After 2020, due to the global spread of COVID-19, many molecular diagnostics companies accelerated their global expansion. This was mainly driven by urgent market demand for specific medical products, such as ventilators, COVID-19 detection-related items including antigen test kits, antibody test kits, PCR test reagents, and PCR instruments. Companies like Orient Gene, Hotgen Biotech, and All Test expanded overseas businesses and shifted focus from domestic market to international markets. This shift was not only the result of corporate planning but also a direct response to market needs. By 2023, the world had entered the post-pandemic era. With a general economic slowdown worldwide, business performance in the China region faced increasing pressure. As a result, companies were driven to improve their R&D and production processes, enhance product compliance and competitiveness in global markets, and upgrade from low- to mid- and high-end products.

**Fig. Chinese Medical Instruments and Devices Export Value from 1995 to 2024**




Source: Public Information, Frost & Sullivan Analysis.

Data Source: General Administration of Customs of the People's Republic of China





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# General Overview of Chinese Medical Device Global Expansion

China's global expansion in medical devices is marked by both higher volumes and improved quality. Export values keep rising, product mix is upgrading, and market coverage is becoming more diverse. This reflects strong global competitiveness and momentum in supply chain upgrading.

## Major Export Product Categories

Chinese medical device exports continue to grow strongly, with rising export values, more refined product structures, and increasingly diverse market presence.

In recent years, while maintaining an edge in medical consumables, Chinese companies have made rapid gains in high-tech fields such as medical equipment and in vitro diagnostics (IVD), highlighting strong innovation and independent R&D capabilities.

According to export data in 2024, medical equipment accounted for the largest share at 43.6%, followed by medical consumables at 38.0%. IVD reagents and instruments made up 10.5% and 3.3%, respectively. Although rehabilitation products and dental devices had smaller shares, they also show China's broad competitiveness in the global market. This structure reflects both the industry's technological progress and its success in expanding markets.

**Fig. Chinese Medical Device Export Overview (2020–2024) — Breakdown by Product Type**

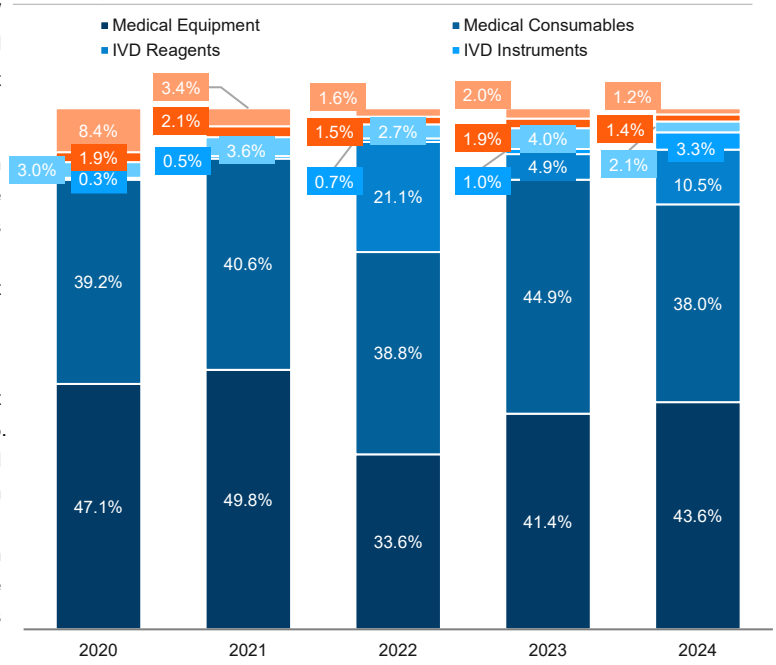
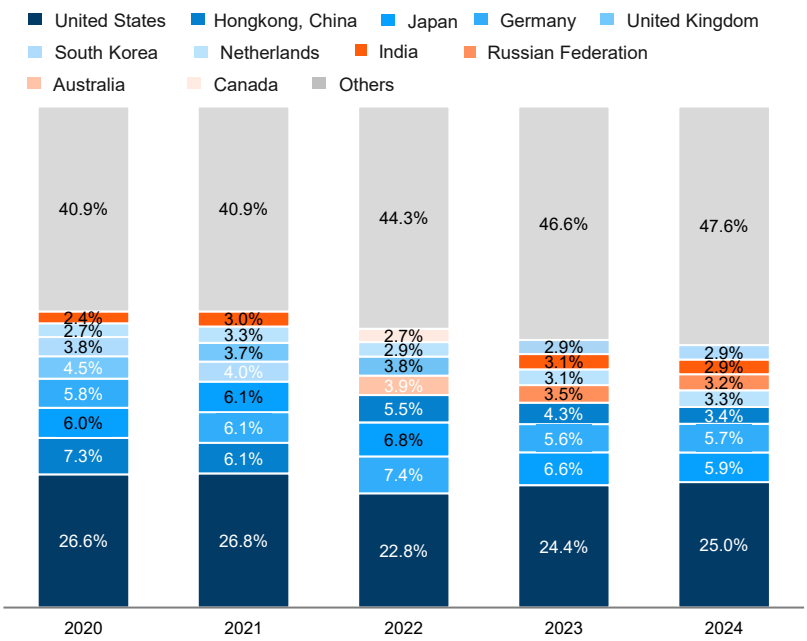



**Fig. Chinese Medical Device Export Overview (2020–2024) — Breakdown by Country and Region**




Source: Public Information, Frost & Sullivan Analysis.

## Key Destination Countries/Region

With growing global demand and strong policy support in China and abroad, Chinese medical device companies are expanding their global presence. They continue to focus on Europe and North America while actively entering emerging markets such as Southeast Asia, Africa, and the Middle East to manage risks and seize new growth opportunities.

In 2024, the United States remained the largest single export market, accounting for 25.0%. Japan, South Korea, Germany, and the United Kingdom were also key destinations. At the same time, Russia's large population and rising healthcare needs created new growth opportunities, also with the retreat of Western companies. Since 2023, exports to Russia have increased significantly.





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# General Overview of Chinese Medical Device Global Expansion

**Chinese medical device companies show a diversified competitive landscape in their global expansion, adopting differentiated strategies to explore international markets. They shift between high-end technological breakthroughs and cost-effectiveness advantages flexibly, driving exports toward higher added value. Over time, they are building a multi-level international product portfolio.**

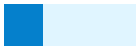
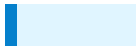
## Overview of Export Sub-sectors

Chinese medical device companies have gradually developed distinct niche segments during global expansion, with noticeably different international strategies across various fields. In certain areas, such as IVD and low-value consumables, companies have gained market recognition quickly by leveraging cost-effectiveness, mature manufacturing processes, and cost advantages, leading to rapid expansion across many emerging global markets. In imaging diagnostics and high-end medical devices, companies have increased R&D investment and enhanced international certifications to gradually overcome technical barriers. With premium products, they are entering mature markets in Europe and North America, further strengthening brand influence and market share.

At the same time, trends across different niche segments reflect companies' accurate understanding of global market needs. In some markets, product innovation and clinical validation are key to gaining market share, while in others, success depends more on channel development and localized service capabilities. Chinese companies continue to adjust their product mix and market strategies, pursuing large-scale expansion in lower-end markets while adopting more refined operations in mid-to-high-end segments. This diversified strategy is gradually shifting the overall export structure toward higher technological content and greater added value.

Overall, as global demand for medical devices continues to rise, the competitive dynamics across different segments are also evolving. By continuously improving product development, integrating supply chains, and building global sales networks, companies are gradually forming a product portfolio that covers various technology levels and application scenarios. This lays a solid foundation for Chinese medical devices to gain greater influence in the global market.

**Fig. Globalization Ratio of Various Categories of Chinese Medical Devices**

| | Globalization Ratio | Logic of Globalization | Trend Analysis | Company Examples |
|---|---|---|---|---|
| Low-Value Consumables |  | • Low-value consumables are a clinical necessity, with strong demand in overseas markets.<br>• Chinese manufacturers benefit from cost advantages.<br>• Overseas sales channels are monopolized by leading players, establishing stable ODM/OEM contract manufacturing partnerships. | • Continuous innovation in technology.<br>• Stable, large-volume orders from highly loyal clients.<br>• Independent control of the supply chain to better manage costs.<br>• Expansion of high-margin proprietary brands in target markets. | bluesail+ 蓝帆医疗 · 中红医疗 · 振德医疗 ZHENDE · KDL 康德莱 |
| IVD |  | • COVID-19 testing and POCT have reached significant scale in overseas markets, with sales channels already established.<br>• Molecular diagnostics and chemiluminescence testing are seeing rapid overseas growth, though there is still room for further improvement.<br>• Companies have built up brand awareness, capital strength, and sales channels. | • Leveraging channel advantages, more categories of IVD products are entering global markets.<br>• With advancements in technology and a more complete supply chain, mid- and low-end products continue expanding in developing countries, while high-end instruments and full-range reagents compete in developed markets. | 东方生物 688298 · 圣湘生物 Sansure Biotech Inc. · 华大基因 BGI · Assure Tech 安旭生物 688075 |
| Medical Devices |  | • The international presence of Chinese ultrasound, monitoring, respiratory, and oxygen-generation home-use devices is already relatively high.<br>• High-end imaging equipment, surgical robots, and endoscopes are undergoing rapid global expansion. | • Localization of key components to replace imports.<br>• Accelerated global expansion of mid- and high-end products.<br>• Ongoing breakthroughs with major overseas clients. | mindray 迈瑞 · UNITED 联影 IMAGING · CHISON 祥生 · BMC |
| High-Value Consumables |  | • High-value consumables focus on clinical value, with strong user retention and high barriers to market entry.<br>• Innovative products are priced higher overseas, and Chinese companies can compete globally by leveraging new technologies and clinical resources. | • Clinical and technical advantages of products are at the core of global expansion.<br>• Strategic planning for overseas certifications and market entry.<br>• Building up channels and developing localized teams in key regions. | BRIOHEALTH · 南微医学 · 乐普医疗 LEPU MEDICAL · TOUCHSTONE · MEDPRIN 迈普医学 |

Source: Public Information, Frost & Sullivan Analysis.

# Chapter 2
# Strategies and Case Studies of Chinese Medical Device Companies Going Global

02

# Basic Strategies for Global Expansion for Chinese Medical Device Companies

The medical device industry spans the entire value chain, including R&D, manufacturing, distribution, promotion, and large-scale procurement. Through technological innovation, large-scale production, academic services, and coordinated demand integration, it operates in a collaborative manner. Under global expansion, a cross-border industrial ecosystem has been established, driving the industry's upgrade toward integrated health solutions.

## Medical Device Value Chain and Expansion Strategies

From production to sales, the medical device value chain includes multiple stages and participants, forming a complex ecosystem.

Medical device companies are responsible for R&D, manufacturing, and quality control. They invest heavily in technological innovation to meet clinical needs and bring products to market through distributors or direct sales.

Distributors serve as the link between manufacturers and healthcare providers. They handle regional sales, inventory, and end-user development. In addition to sales, they provide academic promotion and related services to help hospitals understand the products and complete the "last mile" of market access.

Organizations such as GPOs (Group Purchasing Organizations) consolidate the needs of healthcare institutions and use scale advantages to negotiate with manufacturers, aiming to reduce procurement costs.

At each stage, medical device companies can leverage strengths to pursue global expansion and build a cross-border industry ecosystem covering R&D, distribution, and application.

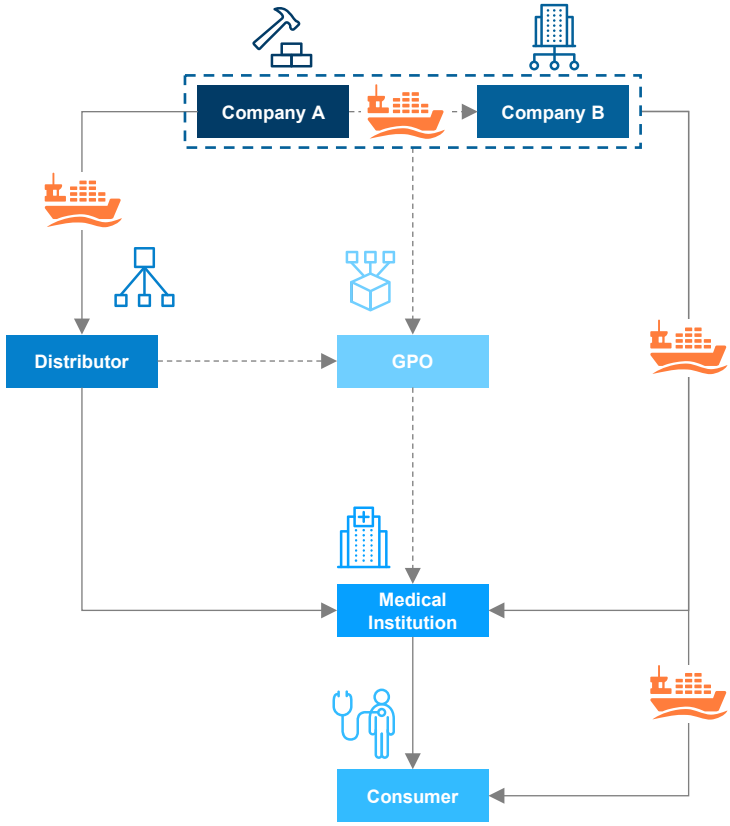



**Fig. Basic Strategies for Global Expansion for Chinese Medical Device Companies**

| | |
|---|---|
| **Distribution Model** | Enterprises expand into international markets by working with local distributors or agents, supplying products in bulk and settling through commissions. This enables low-cost market penetration. |
| **Direct Sales Model** | Enterprises bypass intermediaries and sell directly to end users such as hospitals through localized operations and sales teams. By working with GPOs/IDNs and using digital marketing, they build independent brands and strengthen market control. |
| **Building Overseas Capacity** | Enterprises invest directly in target markets by setting up factories, R&D centers, or joint ventures. This supports localized production and supply chain deployment, helps avoid trade barriers, and enables quick market response. It is suitable for companies with strong capital and technical capabilities. |
| **OEM/ODM** | Enterprises supply standardized or customized products to overseas brands, quickly entering the global market by leveraging cost advantages from scaled production. |
| **Overseas M&A** | Enterprises expand globally by acquiring or merging with overseas companies, gaining access to their technology, channels, or market share. This approach suits companies with strong financial and integration capabilities. |
| **Cross-border E-commerce** | Enterprises connect directly with overseas consumers or buyers through online platforms, bypassing traditional intermediaries to enable global sales. Digital marketing and efficient logistics help reduce costs and improve transaction efficiency. This model is suitable for low-value consumables and home-use devices with low technical barriers and scattered demand. |

Source: Public Information, Frost & Sullivan Analysis.

# Basic Strategies for Global Expansion for Chinese Medical Device Companies

A mature distribution model offers full-chain service capabilities, effectively reducing entry barriers. It is particularly suitable for small and medium-sized enterprises. With controllable costs and diversified risks as its core strengths, this model helps companies quickly distribute products and gain market feedback.

## Basic Strategies for Global Expansion for Chinese Medical Device Companies --- Distribution Model

The distribution model is a commonly used and relatively mature strategy for global expansion of Chinese medical device companies. Distributors, with years of experience in integrating local market resources, maintaining customer relationships, and interpreting regulatory policies, can offer full-chain services including inventory stocking, channel development, marketing, logistics, and after-sales support. By leveraging the distributor's network, market knowledge, and customer base, companies can reduce initial entry barriers. This model is particularly suitable for small and medium-sized enterprises that are unfamiliar with local regulations and cultural norms.

**Fig. Main Service Scope of Distributors**

| Stocking | Terminal Development | Sales | Delivery | After-Sales Service |
|---|---|---|---|---|
| Medical device products come in large varieties and complex models. For high-value consumables with significant unit prices, the stocking function is usually handled by distributors. | Distributors serve as a link between manufacturers and medical institutions at all levels, matching resources to hospitals and specialists and are responsible for channel development and customer maintenance. | Distributors are in charge of equipment sales in designated regions. Based on hospital needs, they conduct bundled sales of multiple related products. | The delivery and installation process of large medical devices is complex, and high-value consumables involve two-way logistics. Distributors can use their own channels to support companies in completing product delivery. | Overseas distributors, based on their experience, provide high-quality after-sales support and work with companies to discuss solutions, meeting users' personalized after-sales needs. |

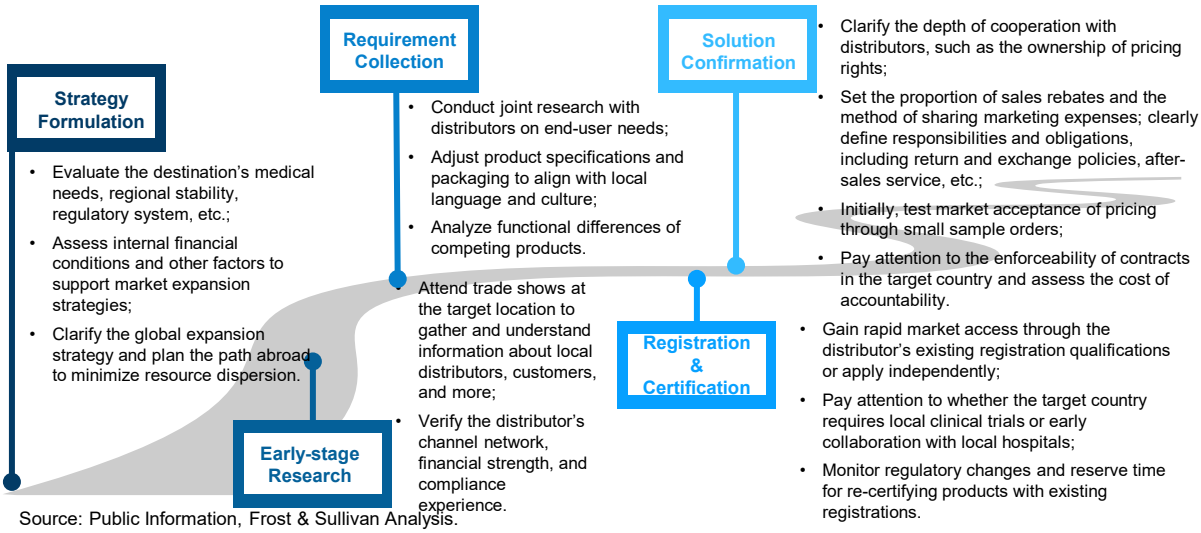
**Advantages**

- **Lowering Entry Barriers:** Distributors are familiar with local regulations, healthcare systems, and distribution networks, enabling quick market entry.
- **Resource Optimization:** Companies do not need to build their own logistics, warehousing, or distribution systems. This keeps initial investment low and supports rapid expansion for small and medium-sized enterprises.
- **Market Fluctuation Buffer:** Distributors take on risks related to inventory, exchange rates, and policies, allowing companies to focus on R&D and manufacturing.
- **Compliance Support:** Some distributors assist with local registration and certification, helping reduce compliance costs for companies.

**Challenges**

- **Lack of End-User Management:** Companies have limited control over end-user sales and services. Relying on distributors may lead to lower customer satisfaction.
- **Risks of Long-Term Dependence:** Heavy reliance on distributors may weaken a company's ability to build its own channels, creating challenges when shifting to direct sales or engaging with end customers.
- **Profit Margin Pressure from Revenue Sharing:** Distributors typically take a portion of the gross margin, further squeezing already thin profit margins.
- **Risk of Cross-Regional Parallel Trading:** Distributors in different regions may engage in unauthorized cross-region sales due to profit conflicts, disrupting the pricing system.

**Fig. Key Steps in the Distributor Model**




Source: Public Information, Frost & Sullivan Analysis.





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# Basic Strategies for Global Expansion for Chinese Medical Device Companies

Overseas factory construction is a capital-intensive and long-term global expansion strategy, where companies localize their supply chains through direct investment. Its main benefits include stronger supply chain resilience and better global resource allocation, but companies must also face high investment costs, cross-cultural management issues, and geopolitical risks.

## Basic Strategies for Global Expansion for Chinese Medical Device Companies --- Overseas Manufacturing Capacity Building

Overseas factory construction is a capital-intensive and long-term global strategy. By directly investing in production facilities in target markets, companies can localize their supply chains, stay close to end-user demand, and avoid trade restrictions. This approach is suitable for leading companies with strong financial capacity, mature technology, and long-term goals for market leadership. Its main advantages include stronger supply chain resilience and improved brand value, but it also involves high initial investment, challenges in cross-cultural management, and geopolitical risks.

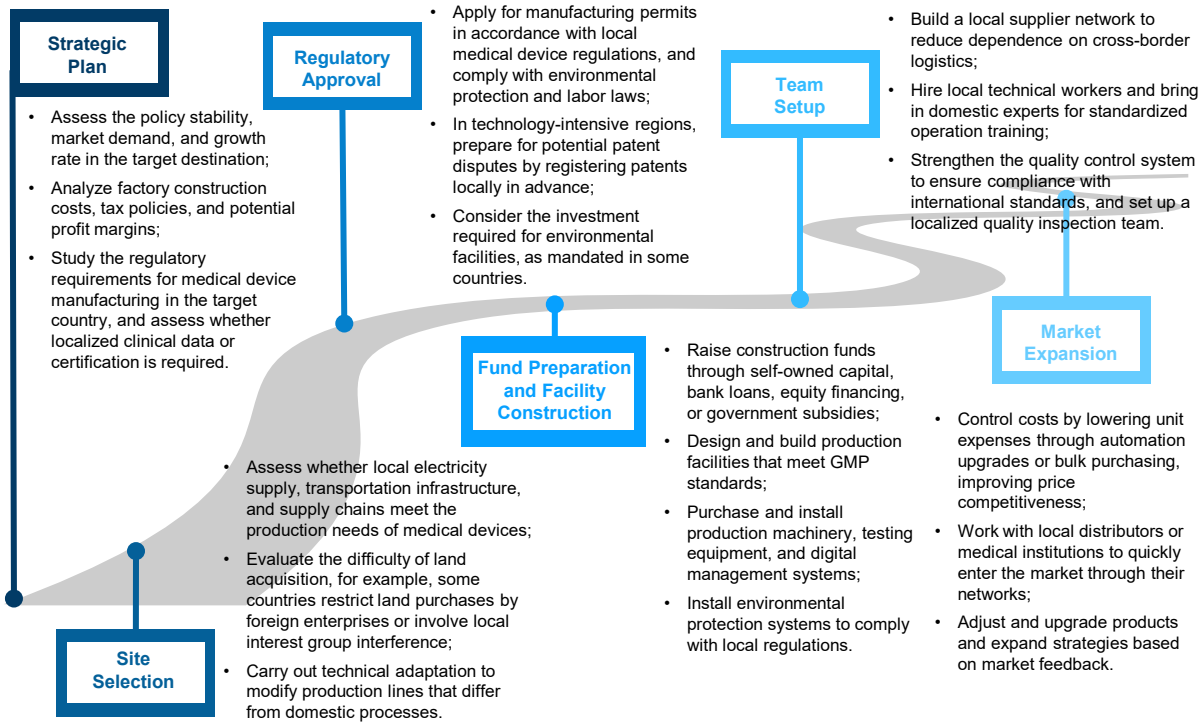
**Advantages**

- **Enhancing overall strength:** Building production bases and sales networks overseas helps companies expand into international markets more quickly, strengthen brand image, and offer better products and services.
- **Integrating global resources:** Overseas factory construction allows companies to take advantage of local resources, reduce costs for raw materials, labor, and logistics, and improve overall efficiency.
- **Avoiding trade barriers:** Setting up factories in export markets enables direct market access, helping companies avoid high tariffs, trade quotas, and geopolitical uncertainties.
- **Diversifying risks:** It improves supply chain security and reduces reliance on a single market during global instability.

**Challenges**

- High investment costs: Overseas factory construction involves large capital and management expenses, and companies must also deal with risks related to local regulations, policy changes, and cultural differences.
- Compliance challenges: Companies may face strict compliance requirements in target countries, including land acquisition, medical device production standards, patent registration, and environmental regulations.
- Localized supply chain: Companies need to quickly understand local market, build supplier networks, secure raw material supply and product distribution, form localized teams to provide end-to-end services and gain customer trust.

**Fig. Key Steps of Overseas Manufacturing Capacity Setup**




Source: Public Information, Frost & Sullivan Analysis.





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# Basic Strategies for Global Expansion for Chinese Medical Device Companies

The ODM/OEM model in the medical device industry helps optimize production capacity and resource allocation through large-scale customized manufacturing, enabling quick monetization of capacity.

## Basic Strategies for Global Expansion for Chinese Medical Device Companies --- OEM/ODM

The contract manufacturing model focuses on "manufacturing for export," where companies enter global markets by providing OEM services to overseas brand owners. Its advantages include low initial investment and quick capacity utilization, especially effective for bypassing trade barriers. However, OEM manufacturers often face long-term challenges such as low profit margins, weak bargaining power in the value chain, and sensitivity to order fluctuations.

**Fig. Comparison Between OEM and ODM Models in Medical Device Field**

| | OEM (Original Equipment Manufacturer) | ODM (Original Design Manufacturer) |
|---|---|---|
| **Definition** | Produces according to the brand owner's design, specifications, and technical requirements. Products are sold under the brand's name. | Designs and manufactures independently. The brand owner may select existing designs for private labeling or request customization. |
| **Core Characteristics** | The brand owner controls design and technology. The OEM is responsible for manufacturing only. | The manufacturer handles both design and production. The brand owner focuses on marketing and sales. |
| **Cooperation Model** | "Built to specification" — driven by the brand owner. | "Turnkey solution" — one-stop design and manufacturing by ODM. |

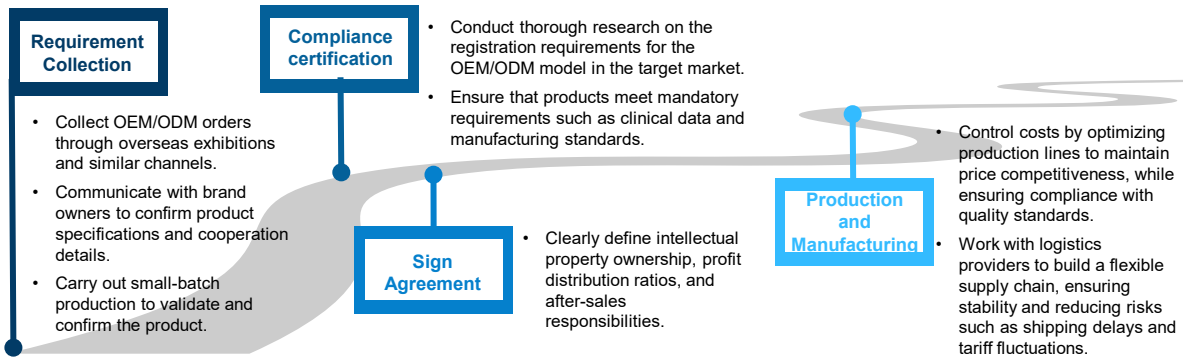
### Advantages

- **Low Technical Barrier:** Follows the brand owner's design and technical specs. Requires minimal R&D and IP management.
- **Capacity Optimization:** By taking on overseas orders, companies can maximize the use of idle capacity, smooth out seasonal production fluctuations, and spread fixed asset depreciation more efficiently.
- **Resource Optimization:** In global supply chains, OEMs focus on manufacturing and shed non-core assets like marketing networks for more efficient allocation of resources.
- **Niche Upgrading Opportunity:** Requires low initial investment and helps absorb capacity quickly. Often used as a transitional model in early global expansion, building scale and experience for future overseas facilities.

### Challenges

- **Lack of Autonomy:** In the OEM/ODM model, Brand owners hold pricing and profit power due to stronger R&D and brand value.
- **Compliance Requirements:** OEM regulations vary by country. Companies must review and follow local laws to avoid legal or operational issues.
- **Low Profit Margins:** Since OEMs do not benefit from brand premiums, they must control costs while ensuring efficiency, quality, and price competitiveness.
- **Weak to Brand Development:** OEM/ODM models hinder proprietary brand growth. Risks include product homogenization and tech dependence, which hurt long-term competitiveness.

**Fig. Key Steps of the OEM/ODM Model**




The transition of medical device companies from OEM/ODM production to global expansion under their own brands is a strategic step to move up the global value chain and regain industry influence. This transformation is based on technological R&D, with continued investment in core areas such as precision manufacturing, biomaterials, and artificial intelligence to build differentiated competitive advantages. For example, Yuwell started as an OEM manufacturer and gradually established a global production and sales network for products such as blood pressure monitors and oxygen concentrators through acquisitions, innovation-driven R&D, and brand development.

Source: Public Information, Frost & Sullivan Analysis.



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# Basic Strategies for Global Expansion for Chinese Medical Device Companies

Medical device companies achieve rapid integration of technologies, markets, or distribution channels through mergers and acquisitions, generating synergies and accelerating global expansion. For home-use devices and certain low-value consumables, cross-border e-commerce breaks geographical barriers by reaching end customers directly via online platforms.

## Basic Strategies for Global Expansion for Chinese Medical Device Companies --- Mergers and Acquisitions

The core of the M&A strategy is to leverage capital to quickly acquire scarce resources, aiming to overcome technological barriers and enter high-end markets. By acquiring overseas targets with core technologies or mature distribution channels, companies can bypass regulatory restrictions and brand recognition barriers, thus gaining presence in high-barrier markets like Europe and the United States.

This approach helps shorten R&D cycles and strengthen coordination across the industry chain, especially in fields with large technology gaps or high policy sensitivity. Acquiring internationally recognized brands also enables companies to inherit existing market trust and enhance brand premium.

However, hidden liabilities such as patent disputes or environmental penalties in the acquired assets may weaken expected synergies. Additionally, foreign investments in sensitive technologies face increasing scrutiny in developed countries. This requires companies to have strong target screening capabilities and resilience in international operations.

### Tianyi Medical Acquires Nikkiso's CRRT

On February 14, 2025, Tianyi Medical announced the completion of the full acquisition of the CRRT (Continuous Renal Replacement Therapy) business from Japan's Nikkiso Co., Ltd.

- **Acquired Business Overview:** Nikkiso operates in four key industries, including medical devices, aerospace, industrial equipment, and deep ultraviolet LED technology. It is a leading manufacturer of dialysis machines in Japan and ranks third globally in installed CRRT devices.
- **Post-Acquisition Strategic Plan:** This acquisition will enable Tianyi Medical to rapidly enter the global CRRT market and create a synergistic "device + consumables" business model alongside its existing blood purification consumables. Tianyi Medical will become the first Chinese company capable of providing comprehensive CRRT solutions worldwide.

### Mindray Acquires HyTest

On September 22, 2021, Mindray completed the acquisition of 100% equity in Finland's HyTest Invest Oy (hereinafter referred to as "HyTest Bio") and its subsidiaries, with a transaction price of €532 million Euros.

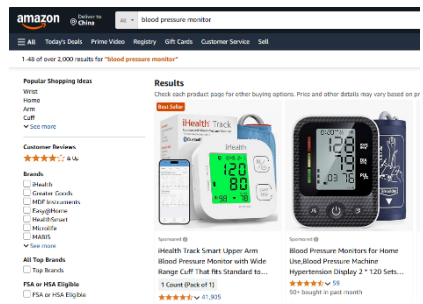
- **Acquired Company's Main Products:** Founded in 1994, HyTest Bio is a world-leading supplier of upstream raw materials for in vitro diagnostics (IVD). Its main products include monoclonal antibodies, antigens, and polyclonal antibodies, serving many major global IVD companies.
- **Post-Acquisition Strategic Plan:** The acquisition fills many gaps in China's upstream IVD raw materials sector. Mindray Medical will strengthen its core raw material research and production capabilities, increase the proportion of self-manufactured core raw materials, and help resolve the "bottleneck" issue in upstream raw material supply for in vitro diagnostics.

## Basic Strategies for Global Expansion for Chinese Medical Device Companies --- Cross-border E-commerce

The cross-border e-commerce model relies on digital capabilities to build an asset-light and highly agile system for market penetration. By directly reaching end users through online platforms, companies can bypass intermediary margins and improve gross profits. Data-driven decisions based on user behavior analysis enable precise demand targeting and flexible product design adjustments. Combined with Chinese domestic manufacturing strengths, this supports small-batch, multi-run production to meet the fragmented demand in emerging markets.

This model depends heavily on the development of end-to-end digital capabilities and the setup of localized service networks. Different countries have varying restrictions on online medical device sales, resulting in high compliance complexity. Additionally, remote technical support may not fully cover after-sales services, posing risks to brand reputation.

Fig. Home Blood Pressure Monitors on the Amazon Platform




Therefore, companies need to enhance data integration across the entire process, from production to logistics, to shorten delivery cycles. They should also spread risk by operating across multiple platforms, avoiding overreliance on a single e-commerce channel, and combining self-operated websites with regional vertical platforms.

Source: Public Information, Frost & Sullivan Analysis.

# Global Expansion Paths and Case Studies for Chinese Medical Device Companies

Companies of different sizes need to leverage their own strengths to navigate the challenges of global expansion. Mature companies can rely on their resources, brand strength, and market penetration to expand internationally, while emerging companies should use their flexibility and innovation to overcome limitations through partnerships and market adaptability.

## By Company Size

### Mature Medical Device Enterprise

- These companies have strong financial strength, mature product lines and operational models, and solid brand power.
- Due to their size and influence, they are often closely watched in global trade and geopolitical interactions.
- They adopt direct sales or distributor models under their own brands, establish overseas factories to reduce geopolitical risks, and expand their business lines through mergers and acquisitions.

### Rising Medical Device Enterprise

- These companies focus on specific niche areas and have unique technological or product advantages.
- They still face challenges in resources, brand recognition, and market penetration.
- In the early stages, they prioritize overseas registration and visibility. They build brand awareness and connect with local distributors and target customers through international marketing and participation in exhibitions.
- They establish sales networks in target markets quickly through distributors and business partnerships.

mindray

**Financial and Product Strength**

As of the first half of 2024, the company held 20.599 billion RMB in cash, demonstrating strong financial strength.

The company's product lines span life information and support, in vitro diagnostics, and medical imaging, offering "one-stop" products and intelligent digital solutions.

**Logic Behind Going Global**

Expand globally rather early, achieving deep market presence through multiple strategies. Initially entered international markets rapidly via a distribution model, and continuously expanded operations through acquisitions and the establishment of overseas offices. This helped grow the marketing network and gain access to high-end customer segments. In 2022, the company began constructing the Longhua base as its global supply chain headquarters, further reinforcing its independently controlled supply chain capabilities.

**Global Brand Status**

According to the 2024 first-half annual report, Mindray Medical consistently ranked among the top three globally in core product segments such as patient monitors, anesthesia machines, ventilators, defibrillators, hematology analyzers, and ultrasound systems, demonstrating its strong product competitiveness and brand influence.

- **Direct Sales & Distribution:** Mindray adopts different sales strategies based on regional characteristics, combining direct sales and distribution to penetrate local markets. The company has built a global marketing network covering more than 190 countries and regions and developed a relatively mature organizational structure. In the North American market, for example, Mindray focuses on large, high-end clients such as IDNs. By the first half of 2024, it had covered over 80% of U.S. IDNs and signed exclusive supply agreements with the top 10 IDN healthcare institutions and the largest surgical center operator in the U.S.
- **Globalized Manufacturing:** Mindray continues to enhance overseas localized production capabilities, expanding both global localized network and warehouse layout. By the end of 2024, more than 10 overseas localized production bases, including one in Mexico, are expected to be operational.
- **Mergers & Acquisitions:** Mindray actively implements a global acquisition strategy and has acquired nearly 10 international companies. In 2008, it acquired the patient monitoring business of U.S.-based Datascope; in 2013, it acquired U.S.-based ZONARE to obtain high-end ultrasound imaging technology; and in 2023, it acquired Germany-based DiaSys, a company specializing in in vitro diagnostics.

BRIOHEALTH

Founded in 2008, BrioHealth designed the innovative fully magnetically levitated (Mag-Lev) implantable left ventricular assist device (LVAD), engineered to treat patients suffering from advanced heart failure by offering mechanical circulatory support solutions. The BrioHealth group, comprising BrioHealth Technologies (Suzhou, China), BrioHealth Solutions (Burlington, US), and BrioHealth BV (Amsterdam, Netherland), integrates specialized engineering, clinical research capabilities, and regulatory expertise to globally advance next-generation ventricular assist technology, with the strategic aim of becoming a leading global medtech company transforming cardiac care.

The CH-VAD, developed by BrioHealth Technologies (Suzhou, China) as China's inaugural next-generation fully Mag-Lev LVAD, obtained market release approval from the National Medical Products Administration (NMPA) in November 2021. The BrioVAD System utilizes upgraded peripheral components while sharing an identical pump and percutaneous lead with the CH-VAD. Both systems, positioned as fully Mag-Lev LVAD platforms, incorporate unique design features, including a magnetic suspension mechanism, optimized blood flow path, minimized pump size, advanced percutaneous lead architecture, and specialized peripheral components, which are anticipated to yield significant clinical improvements in patient outcomes.

In 2024, the BrioVAD System became one of a limited number of active implantable medical devices (AIMDD) to receive conditional FDA Investigational Device Exemption (IDE) approval, thereby permitting the commencement of enrollment in the INNOVATE Trial. This study is precisely designed to rigorously assess the effectiveness and safety of the BrioVAD System. Following successful completion of the Safety Phase, BrioHealth Solutions was granted authorization from the FDA in August 2025 to proceed with the Pivotal Phase. The BrioVAD platform has undergone extensive preclinical research, evaluating critical parameters such as hemodynamics, hemocompatibility, and device durability. Encouraging clinical results demonstrated to date with the CH-VAD regarding survival and rates of adverse events provide strong support for the INNOVATE Trial.

All patient enrollment within the INNOVATE Trial has secured insurance coverage approval from U.S. Medicare and other applicable insurance plans, guaranteeing reimbursement for associated device costs, clinical examinations, and services. This critical milestone provides clear evidence for the product's future commercial rollout in the US market.

Source: Public Information, Frost & Sullivan Analysis.

# Global Expansion Paths and Case Studies for Chinese Medical Device Companies

Different types of medical devices have distinct characteristics. Large equipment companies must overcome high thresholds in technology, transportation, and after-sales services. High-value consumables companies depend on clinical collaborations and strong distributor networks. Home-use device companies rely on cost advantages to explore markets through distributors and cross-border e-commerce.

## By Product Type

### Large Medical Equipment

- The equipment is large, with complicated production processes and high technical requirements. Installation and after-sales services are demanding. Cross-border transportation of complete machines is costly. Data security and compliance requirements are strict.
- Setting up production facilities overseas helps reduce tax burdens. Building localized teams allows for better after-sales support. A dual-track sales model combining direct sales and distributors is adopted.

### High-Value Consumables

- The technology is complex and involves significant technical barriers. Clinical application is highly dependent on physicians, with decision-making power concentrated in their hands.
- Overseas training is conducted, and collaborations are formed with leading hospital experts to strengthen technological advantages. High-quality distributors are selected, with capabilities in technical support, clinical guidance, and after-sales service. Strategic mergers and acquisitions are pursued to quickly gain access to local resources.

### Household Medical Devices

- Manufactured at scale domestically, these products offer cost advantages and have relatively low reliance on installation and after-sales service.
- Sales and after-sales services are mostly handled by distributors. With cost advantages, OEM services are provided for overseas home-use medical device brands. Some home-use medical devices are sold directly to consumers through cross-border e-commerce.

UNITED 联影 IMAGING

**Core Business Products**

Focusing on core technologies in large-scale medical equipment such as medical imaging devices and radiation therapy products, United Imaging has launched over 120 products to the market, including MR, CT, and PET/CT systems; In addition, the company offers United Imaging Cloud Services to enable cloud-based coordination between equipment and applications, as well as the sharing of medical resources.

**Overseas Revenue Share**

The company has achieved sales in regions including the United States, Japan, Europe, Africa, and Southeast Asia. In 2023, the company generated 1.659 billion RMB in overseas business revenue, representing a year-on-year increase of 53.97% and accounting for 14.85% of total main business revenue, maintaining a steady upward trend overall.

- **Overseas Production Bases:** The company plans to build new production facilities in regions such as Southeast Asia and Latin America, while simultaneously developing an overseas supplier system. It aims to gradually increase the proportion of the local supply chain and establish integrated manufacturing centers that encompass planning, procurement, production, and logistics.
- **Global Spare Parts Inventory:** Spare parts warehouses have already been established in the United States, Mexico, Argentina, and South Africa. Additional warehouses are planned in the United Kingdom, the Netherlands, Saudi Arabia, Vietnam, Ethiopia, and Brazil.
- **Sales and Operations Team Development:** The company engages in deep collaboration with high-quality local distributors, while also establishing subsidiaries and dedicated teams in target regions.

Source: Public Information, Frost & Sullivan Analysis.

# Global Expansion Paths and Case Studies for Chinese Medical Device Companies

Different types of medical devices have distinct characteristics. Large equipment companies must overcome high thresholds in technology, transportation, and after-sales services. High-value consumables companies depend on clinical collaborations and strong distributor networks. Home-use device companies rely on cost advantages to explore markets through distributors and cross-border e-commerce.

## By Product Type

yuwell 鱼跃

**Core Business Products**

Yuwell's products are primarily focused on respiratory oxygen therapy, diabetes care, infection control solutions, home-use electronic diagnostics, in vitro diagnostics, emergency and clinical equipment, and rehabilitation devices.

**Cost Advantage**

The company has overcome overseas patent barriers, optimized its supply chain system, and leveraged economies of scale to achieve year-on-year improvement in gross profit margin.

- **Overseas Team Development:** The company continues to build a professional marketing system by improving team development, end-user sales promotion, institutional design, and user management. Through strengthening the localization of overseas teams, export channels have been continuously expanded. The overseas team has proven its marketing capabilities through major international public health events, with performance steadily improving.
- **E-commerce Model:** The company has established flagship stores on all major e-commerce platforms, with steadily growing direct-to-consumer capabilities. Its marketing promotion and online sales performance across platforms for key products remain at the forefront of the industry.

PEIJIA

**Core Business Products**

Focusing on high-end medical devices in the fields of structural heart disease and neurovascular intervention, the company has developed a relatively comprehensive product portfolio and solutions in both areas.

**Global Innovation Platform**

The company has established global innovation and R&D centers in countries such as the United States, Canada, and France to conduct cutting-edge technology research and product development. This enhances its international innovation capabilities and global brand recognition, laying a solid foundation for the global expansion of future technologies and products.

- **Overseas Training:** Actively engaged in international training and education, the company integrates global innovative medical programs and builds diverse platforms through its international medical advisory team. In 2023, early clinical data on its innovative devices were presented at the TCT conference and received international recognition, marking a significant milestone in its global business development. The company provides surgical training, product feature education, and intraoperative support services for physicians and surgical teams.
- **Distributor Management:** Training is provided to new distributors on storage, logistics, and transportation of membrane products to ensure temperature-controlled cold chain delivery. Additional training is conducted on product features and surgical procedures to enable distributors to provide basic service support.

Source: Public Information, Frost & Sullivan Analysis.

# Global Expansion Paths and Case Studies for Chinese Medical Device Companies

For different target markets, companies need to develop targeted global expansion strategies to address the high purchasing power and strict compliance standards in developed countries, as well as the weak infrastructure and fast market growth in emerging markets.

## By Target Market

### Developed Country Markets

- High purchasing power; mature market and procurement systems; strict regulatory approval requirements; high labor costs.
- Participate in local sales models by joining GPOs, IDNs, and similar organizations.
- Use both direct sales and distributor models, and adjust the focus based on specific market conditions.
- Focus on technological innovation, obtain regulatory certifications in developed markets, gradually build brand recognition, and strengthen overall capabilities.

### Emerging Country Markets

- Limited purchasing power; low labor costs; strong relationship-based business culture; uneven distribution of medical resources and low penetration in primary healthcare markets.
- The distributor model supports deep localization, leveraging knowledge of local policies, tender processes, and customer relationships to reduce entry barriers.
- Leverage policy advantages to promote cooperation with government projects and enter local markets.

WEGO 威高

**Globalization Achievements**

Wego's main business covers clinical medical devices, pharmaceutical packaging, orthopedic implants, interventional products, and blood management.

In 2023, overseas revenue accounted for more than one-quarter of total revenue, marking an increase of approximately 7.3% year-on-year. Within overseas revenue, the United States contributed nearly 40%, followed by Asia, and then Europe, the Middle East, and North Africa.

- **Combination of Direct Sales and Distribution:** According to the 2023 annual report, Wego had a total of 7,530 overseas customers, including 3,265 hospitals, 2,022 other medical institutions, and 2,243 distributors.
- **M&A Integration to Expand in Europe and the U.S.:** Mergers and acquisitions are a key strategy for Wego Medical to enter global markets quickly. For example, in 2018, Wego acquired U.S.-based Argon Medical Devices. By leveraging Argon's strong sales network and technological advantages in the U.S. and Europe, the acquisition helped promote Wego's products overseas and accelerate global expansion.
- **Expansion into Southeast Asia:** By the end of 2024, Wego received a $250 million USD loan from the International Finance Corporation (IFC). According to the board, the loan will support the company's business expansion in Southeast Asia, as well as capital expenditure and R&D investment in China.

Eyedeal

**Global Achievements**

The company focuses on ophthalmic medical devices and the global supply of medical grade polymer materials. Its products include intraocular lenses (IOLs) for cataract treatment, glaucoma drainage tubes, refractive correction IOLs, and orthokeratology lenses.

In collaboration with Dr.Leonard Pinchuk, a member of the American National Academy of Engineering, the company has obtained a global patent for cross-linked polyisobutylene (xPIB) materials.

Fully master the synthesis and production of polyisobutylene (PIB) materials and supplies medical-grade polymer materials worldwide.

- **Enhancing visibility through international conferences:** The company participates in global academic events such as the Joint Meeting of Japan-Korea-China Ophthalmologists and the American Society of Cataract and Refractive Surgery (ASCRS) Annual Meeting to showcase its technological achievements and gradually strengthen its academic influence in the global ophthalmology community.
- **Supporting the "Healthy Silk Road" initiative:** The company donated 5,000 intraocular lenses free of charge to the Lifeline Express China. These lenses are used in the Chinese "Lifeline Express" projects and charitable programs with partner countries in the "Belt and Road Initiative", helping cataract patients regain their sight. These efforts enhance the company's brand image and create favorable conditions for its global business expansion.
- **Bringing in global talent to strengthen team development:** In collaboration with Dr.Leonard Pinchuk, member of the American National Academy of Engineering, the company established grade provincial-level academician workstation focusing on the R&D of high-polymer medical raw materials and ophthalmic products. It built the Eyedeal raw materials mass production platform and successfully commercialized several innovative medical devices, including intraocular lenses and ophthalmic implant systems.
- **Global collaboration:** The company is expanding the application of PIB in various medical device fields, promoting new material applications and collaborations across various medical areas, and addressing unmet medical needs that were previously constrained by material performance.

Source: Public Information, Frost & Sullivan Analysis.

# Chapter 3
# Sub-sector Analysis of Chinese Medical Device Global Expansion

03

# Analysis of Chinese Medical Equipment Global Expansion

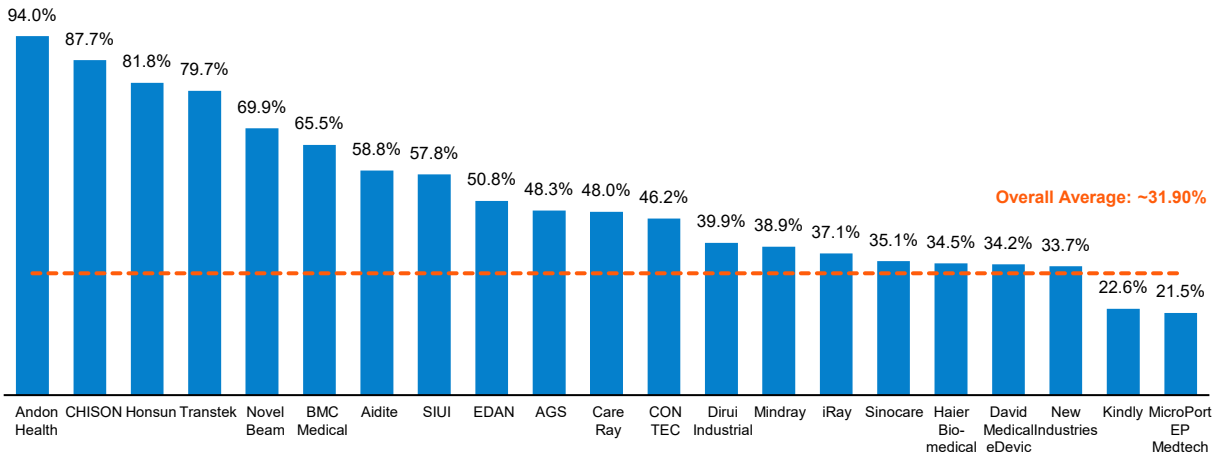
**Chinese medical equipment companies have accelerated their global expansion in recent years. Basic equipment has entered the global market by leveraging cost advantages and large-scale manufacturing, while high-end products are gradually gaining international recognition with their cost-effectiveness and improving quality.**

## Current Status of Chinese Medical Equipment Global Expansion

In recent years, Chinese medical equipment companies have made notable progress in global expansion, with their international presence growing rapidly. According to data from the General Administration of Customs of China, medical equipment exports reached an export value of 17.69 billion USD in 2020. In 2021, due to the COVID-19 pandemic, the total import and export volume peaked at 36.56 billion USD. Although exports declined in 2023, they remained above pre-pandemic levels.

In the basic equipment sector, Chinese companies have entered the global market by leveraging large-scale production and cost advantages, holding strong price competitiveness in categories such as patient monitors, blood pressure monitors, and blood glucose meters. At the same time, in the high-end equipment segment, Chinese companies are gradually gaining visibility. Chinese MRI machines, ultrasound systems, endoscopes, anesthesia machines, and other mid-to-high-end equipment are increasingly recognized by overseas medical institutions for their cost-effectiveness and improving quality.

**Fig. Selected Chinese Medical Equipment Companies Overseas Revenue Share, 2023**




## Prospects of Chinese Medical Equipment Global Expansion

Chinese medical equipment companies are facing several practical challenges in their global expansion:

- In the trade environment, exports of complete equipment often face anti-dumping and countervailing investigations. Some countries impose high tariffs on Chinese medical equipment, which significantly reduce their cost advantage. In addition, regulatory standards for medical equipment vary across countries, and the certification processes are often complicated, making it hard for Chinese equipment to quickly access overseas markets.
- Furthermore, key components such as high-voltage generators, X-ray tubes, and detectors still depend on imports, which limits the competitiveness of Chinese medical equipment companies to some extent.
- Moreover, entering public hospitals in other countries is difficult. Cultural differences and local business practices create barriers for Chinese companies in overseas market promotion.
- After-sales service is another major challenge. Incomplete service networks and slow response times affect user experience and limit customer satisfaction.

However, a path to overcoming these challenges is gradually emerging. As global attention to health continues to grow, the global medical equipment market is expected to keep expanding. The development of primary healthcare systems in developing countries is creating demand for mid-range equipment, which aligns well with the strengths of Chinese companies. In terms of technological advancement, Chinese companies are continuing to innovate. Looking ahead, with continued improvements in technology R&D, quality management, and international operations, alongside national policy support and the Belt and Road Initiative, Chinese medical equipment companies are expected to gain a larger share of the global market. This will further promote industry internationalization and support the transition from “Made in China” to “Chinese Brand.”

Source: Public Information, Frost & Sullivan Analysis.

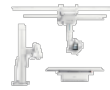
# Analysis of Chinese Medical Equipment Global Expansion – Imaging Equipment

Imaging equipment including CT, MRI, X-ray, and ultrasound systems belongs to the category of high-end diagnostic equipment. In terms of global expansion, Chinese companies have made technological breakthroughs and are gaining market share. However, they still face challenges such as patent barriers, supply chain risks, and limited brand premium.

## Overview of Medical Imaging Equipment

Medical imaging refers to the non-invasive technology and process used to capture images of internal body parts. It uses equipment such as X-ray imaging systems, MRI systems, ultrasound diagnostic equipment, and nuclear medicine systems to display the structure or density of internal organs and tissues. These images help doctors make diagnostic decisions and assess a patient's overall health.

**Fig. Common Types of Medical Imaging Equipment**

| Equipment Type | Description | Example Products |
|---|---|---|
| **X-ray Imaging Equipment** | X-rays are emitted from the X-ray tube, pass through human tissues, and are received by a detector to generate images of the body. Depending on clinical application needs, the imaging modes include 2D static imaging, 2D dynamic imaging, and 3D tomographic imaging. |  |
| **X-ray Computed Tomography (CT)** | CT is a type of X-ray imaging. When X-rays pass through human tissues, they are detected and converted into digital signals. These signals are processed by a computer to generate cross-sectional or 3D images of the examined area. |  |
| **Magnetic Resonance Imaging (MRI)** | MRI uses the nuclear magnetic resonance effect of certain atomic nuclei in human tissues to capture radiofrequency signals. These signals are processed by a computer to reconstruct images of specific layers of the body. |  |
| **Ultrasound Diagnostic Equipment** | Based on ultrasound imaging principles, ultrasound waves travel differently through various human tissues. These differences are used to generate images. The image features are analyzed to assess physiological conditions and pathological changes. |  |
| **Nuclear Medicine Diagnostic Equipment** | This category mainly includes positron emission and single-photon radionuclide labeling technologies. Appropriate radioactive isotopes are used as tracers and injected into the human body. Their distribution and changes in intensity within specific organs are tracked using external radiation detectors to obtain images or information about radionuclide distribution. |  |
| **Ophthalmic Imaging Equipment** | Uses technologies such as Optical Coherence Tomography (OCT), Fluorescein Fundus Angiography (FFA), high-frequency ultrasound, and confocal microscopy to provide full coverage of the eye, from the retinal panorama to the corneal endothelium, including both static morphology and dynamic function. |  |

## Challenges of Chinese Medical Imaging Equipment Global Expansion

### 1 *Weak R&D Capabilities in Core Components*

In CT equipment, core components like high-voltage generators, X-ray tubes, and detectors make up 60% to 70% of the total cost. For high-end models, key parts such as CT tubes, high-voltage generators, and detectors still rely heavily on imports. This supply chain setup poses a serious "suppress and block" risk.

### 2 *High Tariffs on Finished Products*

High-end medical equipment, such as imaging equipment, often face high tariff barriers in export markets. The U.S., for example, has imposed a 25% import tax on MRI equipment from China. These tariffs sharply raise import costs, which are passed along the supply chain and significantly reduce the price competitiveness of Chinese products in global markets.

### 3 *Intense Market Competition*

In high-end medical equipment, global leaders build strong technology barriers through core patents, which often lead to intellectual property disputes. Since multinational companies have long dominated global markets, Chinese brands hold less than 10% of the high-end market share. To break into the market, many Chinese companies use low-pricing strategies to gain share, but this greatly squeezes their profit margins.

### 4 *Data Compliance and Cybersecurity*

Smart medical equipment face cross-border data restrictions. Regions like the EU (under GDPR) and the Middle East require medical data to be stored and transmitted locally. AI-based medical software must pass extra compliance checks. Connected equipment may face cybersecurity reviews in export markets and need pre-installed data encryption and compliance frameworks.

Source: Public Information, Frost & Sullivan Analysis.

# Analysis of Chinese Medical Equipment Global Expansion – Imaging Equipment

**The global high-end medical imaging equipment market remains dominated by multinational giants. Chinese companies are accelerating their penetration into the mid- to high-end market and deepening local partnerships, pushing Chinese equipment from technology export toward a new stage of joint academic standard development.**

## Current Global Expansion Status and Challenges of Chinese Imaging Equipment

At present, the global high-end medical imaging equipment market is still dominated by the three multinational giants—GE Healthcare, Philips Healthcare, and Siemens Healthineers, which together accounted for over 65% of the market share in 2022, forming a technological monopoly in core areas such as CT, MRI, and PET-CT. In recent years, as Chinese equipment manufacturers have continuously overcome key technical bottlenecks in components such as detectors, X-ray tubes, and magnets, the quality of their equipment and clinical recognition have significantly improved. Supported by government procurement policies, domestic equipment is rapidly expanding into the mid- to high-end market.

***Chinese medical imaging equipment has made significant progress in technological breakthroughs and global expansion***

In recent years, driven by independent innovation and coordinated development across the industrial chain, Chinese imaging equipment industry has achieved huge progress in both core technology breakthroughs and global expansion. The industry has established a strategic upgrade path from gaining a stronghold in the domestic market to achieving success in global competition.

Novel Medical is rooted in independent innovation and has established the “Tsinghua-Novel Medical Nuclear Medicine Imaging Joint Research Center” in cooperation with Tsinghua University. Leveraging Tsinghua University’s world-class scientific research in medical physics, the company has mastered several core technologies, including γ detectors, multi-pinhole collimators, and dual-layer crystal DOI-PET detectors, forming a complete technological ecosystem from radionuclide development to imaging output.

Novel Medical’s product lines cover clinical SPECT and SPECT/CT, preclinical animal PET/SPECT/CT, and intelligent nuclear radiation monitoring systems. Overall performance indicators have reached international advanced levels, addressing gaps in relevant technical fields in China. The company’s independently developed Insight four-dimensional quantitative SPECT/CT system, equipped with high-throughput SPECT detectors and high-performance CT, meets the diverse imaging needs of nuclear medicine departments and provides strong support for precise clinical diagnosis.

***High-end ophthalmic equipment companies build global competitiveness***

High-end ophthalmic equipment companies are expanding across product categories to meet clinical needs and capture cutting-edge market segments, leveraging technological barriers to establish differentiated advantages. At the same time, they are implementing long-term branding strategies to enhance international influence, narrow gap with overseas industry leaders, and accelerate global expansion with high-value-added innovative products, breaking into developed markets in Europe and the United States. Companies such as Intalight and TowardPi Medical have adopted the latest swept-source technology, achieving global

Intalight, founded in Silicon Valley by a team of overseas returnees, focuses on innovation and iteration in ophthalmic diagnosis and treatment technologies. The company has independently developed and launched the Dream OCT™, Dream Full-Eye Biometer, and Dream Ultra-Widefield True Color Fundus Camera, which perform excellently in product specifications, algorithms, and function integration. These products continue to improve technical indicators for high-end ophthalmic equipment. As of now, over 550 units of the Dream OCT™ have been installed in China, consistently ranking among the top in OCT installation volume, and are expected to hit new sales records in 2025, further expanding market share. With CE certification in the EU and ongoing global expansion, the Dream OCT™ is gaining international traction and has been installed in more than 30 leading hospitals across the U.S., Europe, South America, and the Asia-Pacific region. These include Bascom Palmer Eye Institute at the University of Miami, Harvard Medical School, Stanford University, Doheny Eye Institute at UCLA, Moorfields Eye Hospital in the UK, Vienna General Hospital of the Medical University of Vienna, and Tokyo Medical and Dental University in Japan. The product has been widely adopted by globally renowned ophthalmology experts such as Professor Philip Rosenfeld, Professor Ricky Wang, Professor David Huang, and Professor SriniVas Sadda.

TowardPi Medical, leveraging the scientific research of Professor Li Huo’s team at Tsinghua University, has developed the ophthalmic OCT products “BMizar” and “Yalkaid”. These have achieved over 500 domestic installations in China, maintaining a leading market share, with their average selling price significantly exceeding that of imported products. In July 2024, after receiving the first CE-MDR certification in China for an OCT product, TowardPi rapidly entered the European market, selling over 60 units within six months. It has quickly climbed into the top five in EU market share and achieved sales in the UK, France, Germany, Switzerland, and Italy. In September 2024, TowardPi launched the “Boyun” and “Fuxue” ophthalmic surgical microscopes, breaking the monopoly of foreign optical giants in the high-end surgical microscope market.

***China’s ultrasound medicine industry builds a global collaboration network, achieving dual breakthroughs in technology export and academic standard-setting***

Taking Mindray as an example, as a leading Chinese company in the ultrasound field, Mindray has not only focused on standardized physician training within China but also expanded its international cooperation: On one hand, under the Belt and Road Initiative, the company has signed memorandum of medical cooperation with six participating countries. On the other hand, it has continued to deepen the China–Africa Health Silk Road, following the 2021 ultrasound medicine cooperation agreement signed between the Chinese Medical Doctor Association and multiple African countries. This has formed a comprehensive global expansion model integrating technical training, equipment export, and academic collaboration

Source: Public Information, Frost & Sullivan Analysis.

# Analysis of Chinese Medical Equipment Global Expansion --- Life Support Equipment

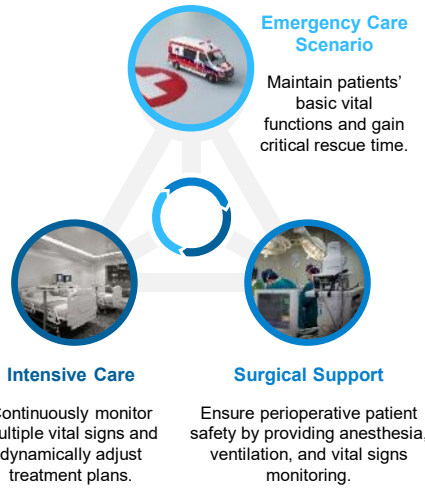
Life support systems provide emergency resuscitation, intensive care, and surgical anesthesia for critically ill patients. In core equipment categories such as ventilators and anesthesia machines, Chinese companies have achieved high global market shares through technological advancements.

## Overview of Chinese Life Support Equipment

Life support systems are integrated medical solutions built from high-performance medical equipment . They are mainly used to provide multi-organ function support and maintain physiological balance for critically ill patients. In emergency situations, they offer artificial life support, such as cardiopulmonary resuscitation equipment and ventilators, to quickly stabilize vital signs. In intensive care units, multi-parameter monitoring systems, including dynamic blood pressure and oxygen saturation tracking, are used to optimize treatment through real-time data. During surgery, these systems support anesthesia management and respiratory and circulatory functions using anesthesia machines and intelligent infusion systems, ensuring patient safety during the perioperative period.

Ventilators and anesthesia machines are key equipment in life support systems. Both contain essential components such as gas sources, flow meters, and breathing circuits. For example, an anesthesia machine delivers anesthetic agents to a patient's lungs through a mechanical breathing circuit. The anesthetic is vaporized in the vaporizer and mixed with oxygen or air to form a specific concentration of anesthetic gas. This gas is then delivered to the lungs, where it creates a partial pressure in the alveoli, diffuses into the bloodstream, and suppresses the central nervous system, achieving general anesthesia.

**Fig. Main Application Scenarios of Life Support Systems**




## Current Global Expansion Status of Chinese Anesthesia Machines

According to data from the General Administration of Customs of China, the total export volume of anesthesia machines in 2024 reached approximately 21.34 million units of machines, with a total export value of about 1.88 billion RMB. Major export destinations include the United States, Russia, Germany, the United Arab Emirates, Australia, and Brazil. In Africa, the export value of anesthesia machines has increased each year since 2020, reaching RMB 158 million in 2024, with a CAGR of 39.39%. Another fast-growing market is the Eurasian Economic Union (EAEU), whose member states include Russia, Kazakhstan, Belarus, Kyrgyzstan, and Armenia.

According to a 2021 report by WISMAR on China's anesthesia equipment import and export market, the top three continents for anesthesia machine exports were Europe, Asia, and North America. The top three purchasing countries by export value were the United States ($25.87 million USD, 15.49%), Germany ($23.10 million USD, 13.84%), and India ($16.97 million USD, 10.16%).

**Fig. Chinese Anesthesia Machine Export Value and Volume, 2019–2024**

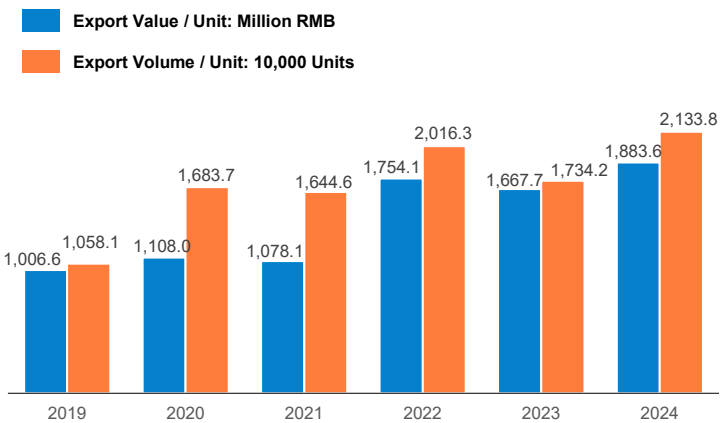
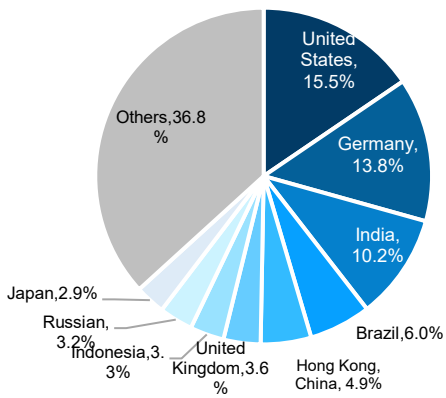



**Fig. Major Export Destinations of Chinese Anesthesia Machines by Export Value, 2021**




Source: Public Information, Frost & Sullivan Analysis.





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# Analysis of Chinese Medical Equipment Global Expansion --- Life Support Equipment

Chinese anesthesia machines and supporting equipment face strict certification barriers in global expansion. Countries are raising biosafety standards, while additional compliance requirements have significantly raised the threshold for market access, such as clinical data localization and traceable after-sales supervision.

## Global Expansion Prospects of Chinese Anesthesia Machines


- **Core Components:**
  Key components such as flow sensors, pressure sensors, and precision control solenoid valves are priced at several thousand yuan each. The cost of critical components accounts for 15% to 20% of the total, with domestic Chinese manufacturers primarily relying on imported products.
- **Competitive Landscape:**
  According to QYResearch, the global anesthesia machine market is highly concentrated. The top three manufacturers: GE Healthcare, Dräger, and Mindray, account for over 70% of global market share. Regionally, North America leads with 37% of global consumption, followed by Asia-Pacific at 36% and Europe at 22%.
- **Regulatory Environment:**
  In recent years, biosafety standards for respiratory and anesthesia medical equipment have been continuously tightened worldwide. The FDA strongly requires anesthesia and respiratory equipment to undergo biological safety evaluation in accordance with ISO 18562 and relevant ISO 10993 series standards (including ISO 10993-5, ISO 10993-10, ISO 10993-18, and ISO 10993-17) to identify potential biological risks. The NMPA has also enhanced regulatory oversight and is accelerating alignment with international safety evaluation systems.

## Analysis of Pain Points in the Global Expansion of Chinese Medical Device Companies

**Diverse and Complex International Regulatory and Certification Barriers:**
Regulatory requirements for medical device market access vary significantly across regions. For example, the U.S. FDA's 510(k), the EU CE-MDR, and Japan's PMDA all involve complex procedures, long approval timelines, and high costs. Companies must invest substantial resources to manage these processes.

**Technology and Intellectual Property Risks:**
**Patent Barriers and Infringement Risks:** In mature categories such as staplers and stents, Western companies have established strong patent portfolios to form technological barriers. Chinese manufacturers may face infringement lawsuits when entering these markets.
**Weaknesses in R&D and Clinical Validation:** High-end products for global markets must meet international standards for clinical evidence. However, clinical trial data generated in China may not be recognized overseas, requiring new studies abroad which will significantly increase osts.

**Evolving Regulatory Environments:**
Countries and regions, such as the EU, have tightened requirements for clinical data, Quality Management Systems (QMS), and traceability. Companies must continuously monitor regulatory updates and adjust their strategies accordingly.
Developing countries like India and Brazil may impose local manufacturing requirements or policies of import substitution, and may protect their domestic industries through tariffs and non-tariff barriers.

**Data Compliance and Cybersecurity:**
**Cross-border Restrictions on Data Transmission:** Markets such as the U.S., EU, and the Middle East impose strict regulations on the localization and transmission of medical data. AI-driven medical software is subject to additional compliance reviews.
**Cybersecurity Reviews:** Internet connected devices (e.g., remote monitoring equipment) may raise security concerns in destination countries. Companies must proactively implement data encryption and compliance frameworks in advance.

EMERGO by UL

- ***Usability Localization and Clinical Collaboration***

For respiratory anesthesia devices and patient monitoring equipment that must adapt to diverse clinical settings, Emergo by UL can support collaboration with local medical institutions to optimize product features, such as language interfaces and power supply compatibility, and conduct usability studies based on human factors engineering.

- ***Global Supply Chain Optimization***

Emergo by UL helps companies establish subsidiaries or manufacturing sites overseas by offering regulatory consulting and quality management system support to meet local production requirements.

- ***Patent Strategy and Infringement Avoidance***

For innovative technologies such as surgical robots, Emergo by UL can assist in analyzing international patent landscapes to help avoid intellectual property infringement risks.

- ***Integration of AI and Remote Technologies***

For intelligent applications in surgical robots and imaging equipment, such as AI algorithms and 5G remote control, Emergo by UL can provide consulting on updates to relevant technical standards.

Source: Public Information, Frost & Sullivan Analysis.

# Analysis of Chinese High-value Consumables Global Expansion

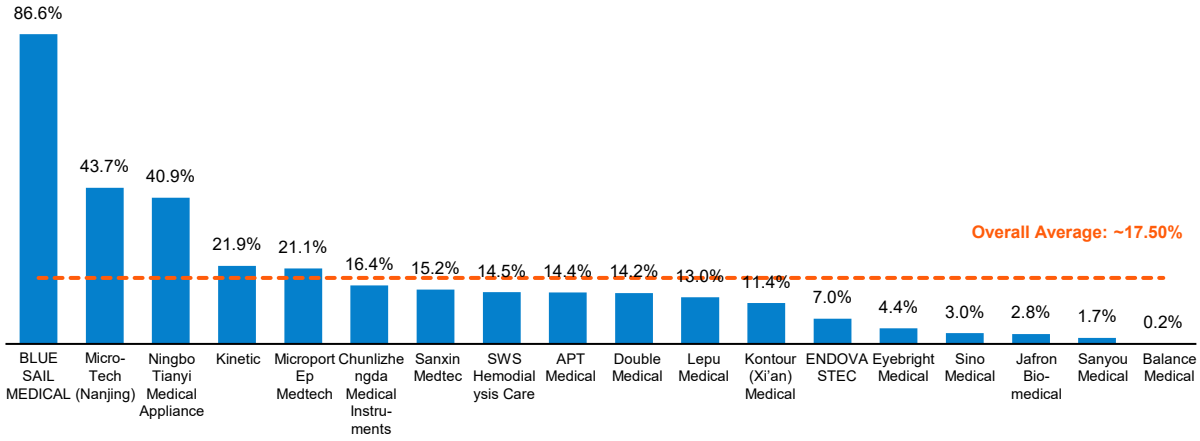
**The Chinese high-value medical consumables industry is accelerating its technological upgrades and increasing the localization rate. Companies are overcoming technical and market barriers to advance their global expansion. Some leading enterprises have obtained multiple overseas approvals, achieving breakthroughs in both developed markets, such as Europe and the United States, as well as in emerging markets.**

## Current Global Expansion Status of Chinese High-value Consumables

In recent years, Chinese high-value medical consumables industry has grown rapidly, with notable improvements in technology, a broader product portfolio, and steadily increasing localization rates. Some segments have reached internationally advanced standards. High-value medical consumables mainly include vascular intervention devices, orthopedic implants, blood purification products, dental, surgical, ophthalmic, non-vascular intervention, and neurosurgical products. These products act directly on the human body, require very high safety standards, and are relatively expensive, making them a critical part of the medical field.

According to publicly available annual reports, in 2023, the average proportion of overseas revenue for Chinese high-value medical consumables companies was 17.50%, indicating a certain level of engagement in global markets. However, due to the high barriers to global expansion, international established players still dominate the market. With growing R&D capabilities and improved manufacturing standards, Chinese companies are gradually overcoming technical and market obstacles in their efforts to gain a foothold internationally. For example, companies such as Mindray and Wego have made initial progress in overseas market development. Some of their products have received CE certification in the EU and FDA approval in the US, successfully entering high-end markets in Europe and the United States, while also gaining a certain market share in emerging regions such as Southeast Asia and Latin America.

**Fig. Selected Chinese High-Value Consumables Companies Overseas Revenue Share, 2023**




## Global Expansion Prospects of Chinese High-value Consumables

Currently, Chinese high-value medical consumables companies face multiple challenges in global expansion: fierce international competition with established multinationals holding advantages in brand, channels, and clinical data; insufficient academic and clinical support overseas; high product performance thresholds and stringent, varied regulatory requirements across markets; as well as cultural barriers and the need for localized services and post-sales support. For active implantable products among high-value consumables, Chinese products still face many challenges in going global, such as technological innovation, product quality, and international clinical recognition. The overall number of such products is relatively small, and their global expansion remains in the early stages. Despite challenges, China's high-value consumables show strong global potential, with domestic firms making notable strides in technology, quality, and branding.

Eyedeal Leveraging cross-linked polyisobutylene (xPIB) materials, the xPIB intraocular lens (IOL) developed and manufactured using this material has achieved technological leadership. It has completed clinical trials in China and taining registration certificates in China, initiated clinical trials in Europe, and is preparing for clinical trials in the United States. Supportive national policies from China and the advancement of the “Belt and Road Initiative” have created favorable conditions for Chinese high-value medical consumables companies to expand globally. Actively responding to these opportunities, Eyedeal has partnered with the Lifeline Express China to support ongoing cataract treatment charity programs in Belt and Road partner countries, fulfilling its public welfare mission while steadily expanding its global footprint. Eyedeal’s certified hydrophobic acrylic IOL is also steadily gaining market exposure and shares both in China and around the globe. Looking ahead, as Chinese companies further enhance technological innovation, international operations, and clinical data capabilities, high-value medical consumables are expected to achieve even greater breakthroughs in global expansion.

Source: Public Information, Frost & Sullivan Analysis.

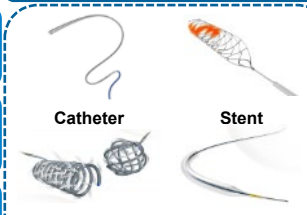
# Analysis of Chinese High-value Consumables Global Expansion --- Vascular Intervention Products

As core devices for minimally invasive vascular treatments, vascular interventional high-value consumables have long faced challenges in global expansion due to their technical complexity and market promotion difficulties. In recent years, with technological advancements and innovative expansion models, Chinese produced consumables have gradually overcome barriers in overseas markets.

## Overview of Chinese Vascular Intervention Products

Vascular interventional therapy refers to minimally invasive procedures under medical imaging guidance, using devices like puncture needles, guidewires, and catheters to deliver consumables to lesion sites through the vascular system. Common procedures include arterial embolization, angioplasty, and cerebral angiography. Related high-value consumables mainly include coronary balloons, electrophysiology catheters, and aortic covered stents. Based on anatomical application, they can be broadly categorized into electrophysiology, coronary intervention, structural heart disease, pacemaker-related, neurointerventional, peripheral vascular intervention, and general interventional materials.

**Fig. Vascular Interventional Consumables Category**

| Category | Example Products | Technical Challenges | Represent Companies |
|---|---|---|---|
| Cardiovascular Intervention<br>Neurovascular Intervention<br>Peripheral Vascular Intervention |  | • Small-Diameter Artificial Blood Vessel<br>• Precision of Drug-Coated Controlled Release<br>• Controllable Material Degradation<br>• Precision Manufacturing Technology<br>• Cleanliness and Particulate Control<br>• … | 归创通桥 ZYLOX-TONBRIDGE<br>PEIJIA 沛嘉医疗<br>MicroPort 微创<br>鼎科医疗 DK MEDTECH<br>Lifetech SCIENTIFIC<br>乐普医疗 LEPU MEDICAL |

## Current Global Expansion Status and Challenges of Chinese Vascular Intervention Products

- **Lack of competitiveness from technical perspective:** Take balloons as an example. While most Chinese balloons perform similarly to imports for common lesions, there remains a notable gap in treating complex cases, product diversity, and production scale. During product registration, Chinese companies often choose simpler clinical cases, but actual clinical use demands capabilities for many complex conditions. Technically, global giants maintain significant advantages in patents, advanced materials, and core algorithms. Chinese firms need to enhance R&D collaboration and prioritize innovation to close the gap. Vascular interventional consumables covered by medical insurance are still dominated by imported products in China. In 2022 and 2023, imports (including those from Hong Kong, Macau, and Taiwan) accounted for 53% and 49% respectively, despite the growing share of chinese products.
- **High market entry barriers:** Vascular interventional high-value consumables must be operated by physicians, and physician preferences significantly influence product adoption, which raises the entry barrier. With established international brands already present, Chinese brands often struggle to gain quick market access. Some firms have pursued overseas expansion through acquisitions, which offer faster access but come with high costs. Furthermore, differences in regulations and clinical practices across countries increase the risk of non-compliance.

## Chinese vascular interventional consumables are rapidly expanding and securing a place in the global market

DK MEDTECH
DEVELOP UNIKUE

**Refined domestic market strategy and dual-track layout:** In the coronary segment, DK Medtech has formed early strategic partnerships with Medtronic and Asahi INTECC. Leveraging the mature marketing systems of these global giants, the company jointly promoted domestically developed innovative products during the initial brand-building phase.

At the same time, the company has built its own sales team to establish a leading reputation in the hemodialysis vertical, creating a treatment ecosystem with a multi-lifecycle product portfolio.

**Global strategic layout and expansion:** Using its Singapore subsidiary as an overseas base, the company showcased DKutting LL, its lower-limb scoring balloon, at the Leipzig Interventional Course (LINC) in Germany as part of the world's largest RCT study on specialty balloons, enhancing international recognition. Globally, DK Meditech has expanded into Europe, the U.S., the Asia-Pacific region, Japan, and South Korea through both its own channels and partnerships with major industry players.

At the same time, DK Medtech has reached a strategic partnership with the American company Mozarc to promote the DK Medtech own branding in the U.S. market by leveraging Mozarc's commercial channels, jointly addressing the clinical challenges faced by kidney patients during dialysis.

Source: Public Information, Frost & Sullivan Analysis.

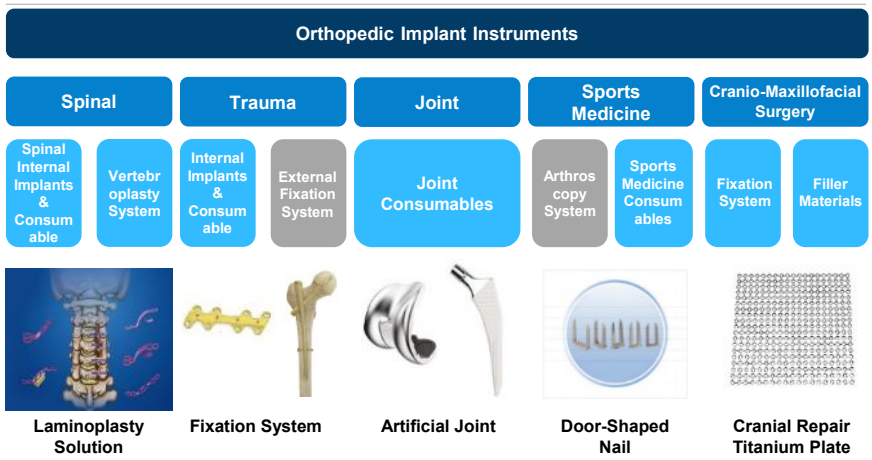
# Analysis of Chinese High-value Consumables Global Expansion --- Orthopedic Material

Orthopedic materials, as core devices for skeletal repair, are benefiting from accelerating global aging and technological advancement. Their penetration rate continues to rise, and the market size keeps expanding.

## Overview of Chinese Orthopedic Material

Orthopedic materials are medical devices specifically designed for the repair, replacement, or enhancement of the skeletal system, and their performance directly affects treatment outcomes. In orthopedic procedures, material selection must balance biocompatibility, mechanical stability, and long-term durability. These factors are essential for surgical success and patient recovery. Based on anatomical application, orthopedic materials are categorized into five main types: spinal, trauma, joint, sports medicine, and cranio-maxillofacial.

**Fig. Types of Orthopedic Materials**




## Current Global Expansion Status and Challenges of Chinese Orthopedic Material

There is a significant supply-demand imbalance in Chinese orthopedic device market, with the penetration rate of joint replacement much lower than that of developed countries. For example, knee replacement surgeries are far more common in the United States than in China. A similar pattern is seen in the field of hip replacements. Clinical research suggests that this difference is closely related to the variation in joint load distribution caused by differing obesity rates in the two countries. In developed countries, mature healthcare reimbursement systems and large population bases have driven the orthopedic materials market into a steadily growing blue ocean.

**Fig. Comparison of Joint Replacement Implant Penetration Rate in China and the U.S., 2020**

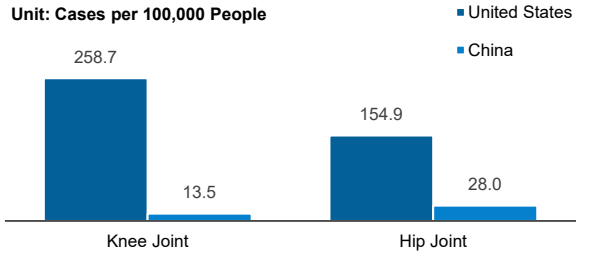
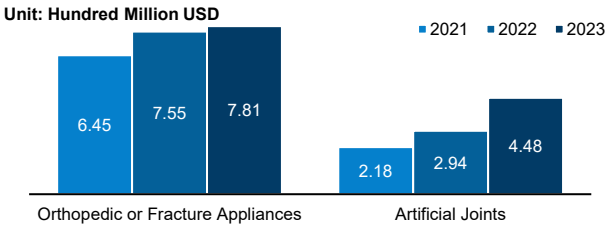


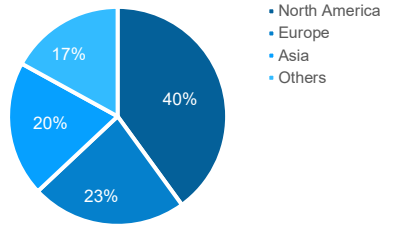

**Fig. Export Value of Orthopedic Implants from China, 2021–2023**




Note: Data sourced from the Online Statistics Query Platform of the General Administration of Customs of the People's Republic of China.
Orthopedic or fracture-related instruments include trauma, spine, and sports medicine.
Due to changes in statistical criteria starting in 2022, there may be slight discrepancies in the data.

Source: Public Information, Frost & Sullivan Analysis.

**Fig. Global Orthopedic Market Composition by Region, 2021:**




According to data from the China Customs Statistics Online Query Platform, China's total exports of orthopedic implants reached approximately USD 1.229 billion in 2023, representing an 18% year-on-year increase. Among them, exports of orthopedic or fracture-related instruments totaled around USD 781 million, up 4% year-on-year. Exports of artificial joints increased by 52% from the previous year, reaching USD 448 million.

In terms of export destinations, the United States, Hong Kong (China), Belgium, Russia, and Singapore were the main markets for Chinese orthopedic implants in 2023, together accounting for 56% of total export value. With the accelerating trend of global aging and ongoing technological improvements in China, the country's orthopedic device exports are expected to continue growing steadily, offering high-quality medical solutions to patients around the world.



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# Regulatory Overview of Chinese High-value Consumables Global Expansion

**Due to the high-risk nature of vascular interventional and orthopedic consumables, regulatory authorities require long-term follow-up of clinical data and have set strict standards for material biocompatibility testing. Full-process supervision raises the qualification threshold for companies entering this field.**

## Regulatory Requirements for Global Expansion of High-Value Consumables

Cardiovascular interventional devices and orthopedic implants, classified as Class III high-risk medical devices, are subject to strict regulatory requirements. The U.S. FDA requires high-risk devices to undergo Pre-Market Approval (PMA), with complete preclinical and clinical trial data to demonstrate their safety and effectiveness. Similarly, under the EU Medical Device Regulation (MDR), clinical evaluation is mandatory, and clinical trials may be required. Detailed technical documentation must be submitted, covering material selection, manufacturing processes, and quality control.

Post-market, these devices are subject to strict production quality management and traceability/recall systems. In the U.S., post-market surveillance is conducted via the MAUDE (Manufacturer and User Facility Device Experience) adverse event reporting system. Additionally, the Unique Device Identification (UDI) system requires each device to carry a unique code, enabling full traceability from manufacturing to use. Under EU MDR, manufacturers and authorized representatives must take immediate recall action if they discover or are informed of any issues that may pose a risk to public health or safety.

To meet the demands of globalization, the FDA participates in the Medical Device Single Audit Program (MDSAP), allowing mutual recognition of audits among regulatory agencies in the U.S., EU, Canada, and two other countries. A single audit enables market access in multiple countries. Currently, U.S. medical device regulation is shifting toward precision medicine, with Real-World Evidence (RWE) being included in regulatory evaluations.

EMERGO by UL

### *Globally Aligned Regulatory Access Services Tailored to Specific Consumable Characteristics*

Regulatory Breakthroughs for High-Risk Consumables: Provide targeted regulatory review support based on the type of high-value medical consumables to address complex compliance challenges.

Technical Documentation and Biocompatibility Solutions: Assist in drafting test reports in compliance with ISO 10993 and ISO 11135 standards, offering targeted solutions for issues related to chemical characterization and toxicological risk assessment of consumables.

### *Clinical Evidence and Multi-national Mutual Recognition Strategies*

Efficient Clinical Data Conversion: Convert clinical trial data under China NMPA standards into evidence chains compliant with FDA and EU requirements; design international multicenter trial protocols to enable simultaneous approvals in the U.S. and Europe.

Real-World Data Application: Assist in establishing EU post-market clinical follow-up plans, leveraging real-world evidence to demonstrate the long-term safety of high-risk medical consumables.

### *Customized Compliance Services for Supply Chain and Manufacturing*

Sterilization and Cleanroom Manufacturing Control: Provide standardized quality system development for critical sterilization processes to mitigate overseas recall risks.

Localized Global Supply Chain Layout: Support enterprises in establishing local warehouses or contract manufacturing in target markets to meet real-time supply demands.

### *Intellectual Property and Market Risk Barriers*

Patent Strategy and Infringement Risk Management: Analyze international patent barriers for high-value medical consumables and plan design-around or cross-licensing strategies.

Post-Market Surveillance and Emergency Response: Establish EU-compliant vigilance systems to swiftly manage and report adverse events in overseas markets.

### *Precision Expansion into Emerging Markets and Brand Empowerment*

Rapid Market Access in Belt and Road Regions: After obtaining CE certification, medical dressings can leverage the ASEAN AMDD mutual recognition mechanism to complete registration in Singapore, Malaysia, and Thailand within 48 weeks. For Saudi Arabia, Arabic labeling and expedited registration support are provided.

Source: Public Information, Frost & Sullivan Analysis.

# Analysis of Chinese In Vitro Diagnostics (IVD) Global Expansion

**Chinese IVD industry is accelerating its global expansion by leveraging technological upgrades and cost advantages. Exports of IVD reagents and instruments have continued to grow in the U.S., Europe, and emerging markets, gradually increasing China's presence in the global IVD market.**

## Current Status of In Vitro Diagnostics (IVD) Global Expansion

In vitro diagnostics (IVD) refers to the testing of human samples, such as blood, bodily fluids, and tissues, using consumables and equipment outside the human body to obtain clinical diagnostic information. The IVD market is segmented into clinical laboratory testing, biochemical diagnostics, immunodiagnostics, molecular diagnostics, microbiological diagnostics, and point-of-care testing (POCT). A typical IVD process requires the coordinated use of diagnostic instruments and corresponding consumables, with consumables offering companies a stable and recurring revenue stream.

In recent years, driven by factors such as an aging population, increased per capita healthcare spending, cost-control policies in medical insurance, and technological progress, China's IVD industry has shown significant market potential. However, the global IVD market developed early, features rapid technological advancements, and is highly competitive. Since 2000, with the implementation of cost-control policies by healthcare systems worldwide, smaller companies have gradually been acquired due to cost disadvantages, leading to industry consolidation. During this process, Chinese IVD companies have accelerated their global expansion by leveraging technological advances and cost advantages.

According to data from the General Administration of Customs of China, China's IVD exports in 2023 showed structural differences. Exports of IVD reagents reached $2.11 billion USD, reflecting a slight decline from 2022; exports of IVD instruments remained stable, totaling $2.92 billion USD for the year, demonstrating strong competitiveness in global markets. By region, the United States remained the largest export market for China's IVD instruments, with exports totaling $350 million USD in 2023. Russia and Indonesia ranked second and third, respectively, as key export destinations for Chinese IVD instruments.

**Fig. Export Value of IVD Reagents from China, 2022–2023**

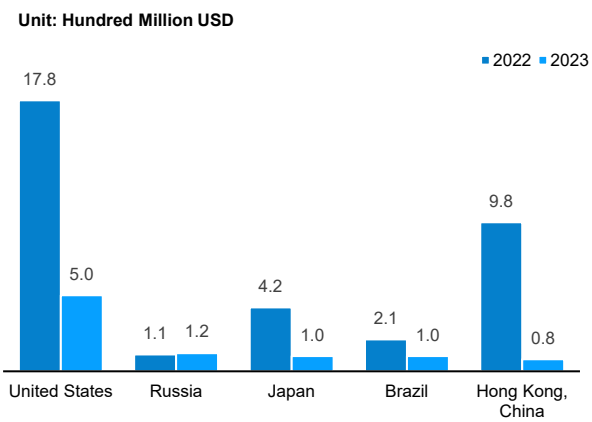
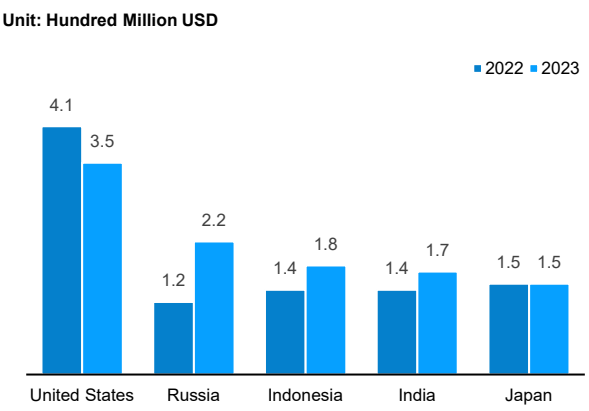



**Fig. Export Value of IVD Instruments from China, 2022–2023**




## In Vitro Diagnostics (IVD) Global Expansion Challenges

The Chinese IVD market is highly competitive and fragmented, with many manufacturers and no clearly leading company.

In comparison, the overseas IVD market is dominated by international giants like Roche and Johnson & Johnson, which have strong brands and advanced technologies but offer relatively expensive products.

Under the influence of the centralized procurement policy, Chinese IVD industry is facing fiercer internal competition. As a result, many companies are looking to overseas markets, aiming to use their cost advantages to gain international market share and drive business growth.

However, Chinese IVD companies still face several challenges in global expansion, including competition from international brands, strict overseas regulatory requirements, and limited local service capabilities. In the future, as Chinese IVD companies improve their R&D capabilities and gain more experience in market expansion, they are expected to capture a larger share of the global market and further drive the industry's global expansion.

Source: Public Information, Frost & Sullivan Analysis.

# Analysis of Chinese In Vitro Diagnostics (IVD) Global Expansion

IVD equipment, consumables, and service companies are adopting differentiated strategies to effectively address challenges such as overseas regulatory compliance, data security, market access, and post-market management, steadily advancing their global expansion.

## In Vitro Diagnostics (IVD) Global Expansion Strategies

### IVD Equipment Going Global

- IVD equipment includes clinical biochemical analyzers, immunoassay analyzers, hematology analyzers, urine analyzers, microbiology testing systems, and molecular diagnostic devices.
- Generally adopt direct sales or distribution models.

**Overseas Destinations**

India, Egypt, Brazil, Russia

**Representative Companies**

mindray, Snibe 新产业生物, Autobio 安图生物

### IVD Consumables Going Global

- IVD consumables include sample collection and processing consumables, test reagent consumables, reaction carriers and auxiliary consumables, and supporting consumables for diagnostic equipment.
- Collaborate with research institutions and multinational manufacturers; or adopt distribution models.

**Overseas Destinations**

United States, United Kingdom, Germany, France

**Representative Companies**

菲鹏生物 FAPON BIOTECH, Vazyme

### IVD Services Going Global

- IVD services mainly offer support and assurance for in vitro diagnostics, including technical R&D services, manufacturing services, and quality control and testing services.
- Participate in local LDT models through mergers and acquisitions; or establish own LDT facilities.

**Overseas Destinations**

Europe, Middle East, North Africa, Asia-Pacific

**Representative Companies**

华大基因 BGI, 金城医药 JINCHENG PHARMA, Novogene 诺禾致源

EMERGO by UL

✓ ***Addressing Core IVD Challenges — Complex Regulation and Performance Verification***

Emergo by UL provides targeted global market entry pathways based on IVD classifications and addresses specific requirements of the target markets.

Emergo by UL coordinates global laboratory resources to complete testing in compliance with ISO 20916 (clinical performance studies) and CLSI EP series (precision/sensitivity), thereby avoiding redundant investments.

✓ ***Breaking IVD Data Barriers — Multi-Country Mutual Recognition of Clinical Evidence***

Translate clinical data from NMPA to evidence chains that meet FDA and CE requirements, reducing redundant testing; design customized, stratified clinical trials to provide a "one source, multiple uses" trial plan.

✓ ***Post-Market Surveillance and Risk Management***

Global vigilance system setup: Emergo by UL facilitates real-time adverse event reporting through the European Eudamed system in compliance with EU IVDR Article 82 (Post-Market Performance Follow-up). For the FDA's MDR (Medical Device Reporting) and CAPA (Corrective and Preventive Actions), Emergo by UL ensures rapid response capabilities.

For AI-driven imaging analysis software, Emergo by UL provides tailored service solutions to meet the regulatory requirements of different regions.

Technology upgrade compliance support: Emergo by UL assists companies in rapidly completing changes such as reagent formulation modifications through the FDA SUP mechanism; instrument software upgrades can be submitted simultaneously to multiple countries with one click via Emergo's "Global Change Management Platform."

✓ ***Rapid Market Access in Emerging Markets — Policy Benefits and Localization Adaptation***

Some emerging markets recognize FDA/CE certifications, and Emergo by UL can assist in converting these approvals for those markets; Emergo by UL also brings together global experts to handle language localization of labeling and other submission materials.

**Precise Matching of Global Access Pathways to IVD Classifications**

| | | | |
|---|---|---|---|
| High Risk | Companion diagnostics, tumor genetic testing, etc. | EU IVDR Class C/D | Develop Performance Evaluation Plan (PEP) and clinical evidence |
| | | US FDA PMA/De Novo | Assist in conducting clinical multicenter studies |
| Medium to Low Risk | Blood glucose meters, routine biochemical reagents, etc. | EU IVDR Class B | Use equivalent device strategy to shorten CE certification cycle |
| | | US FDA 510(k) | Provide pre-submission consultation to resolve "predicate device" selection disputes |

**Coordinating Global Resources to Achieve Cost Reduction**

A COVID-19 antigen test reagent completed simultaneous CE and WHO EUL validations through cooperation with an EMA-recognized laboratory partnered by Emergo by UL, reducing costs by 35%.

Cost Reduced: 35%

**China Data, Global Translation**

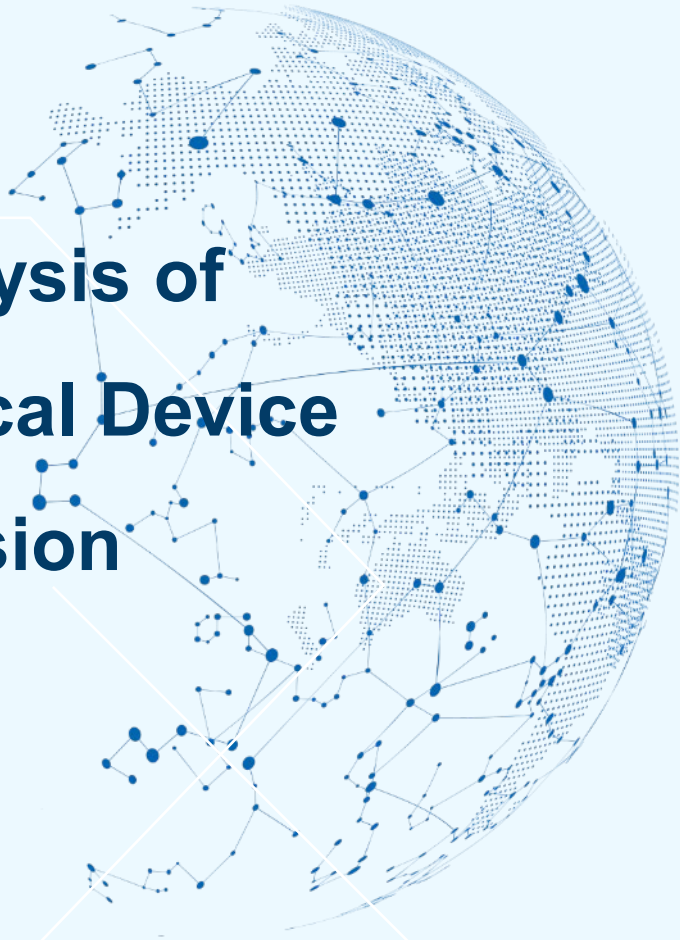
A lung cancer of a country ctDNA detection reagent utilized data from 300 Chinese patients and, through review by an EU notified body, shortened the CER preparation time by 50%.

Cost Reduced: 35%

Source: Public Information, Frost & Sullivan Analysis.

# Chapter 4

# Regional Analysis of Chinese Medical Device Global Expansion



04

# Developed Regions and Countries Market Analysis – United States

The United States has a developed economy, a large population, and strong medical demand, creating huge market potential. However, Chinese medical device companies seeking global expansion face multiple challenges, including geopolitical barriers, supply chain localization, tightening insurance reimbursements, and medical litigation risks.

## Developed Economy, Large Population, High Medical Demand

**Economy[1]**

- **27.7 trillion USD** GDP
- **↑2.9%** Year-over-year growth
- **83,000 USD** GDP per capital

**Population[1]**

- **330 million** Total population
- **↑0.5%** Year-over-year growth
- **17.4%** Aging population ratio (65 years and older)

**Healthcare Expenditure[2]**

- **4.5 trillion USD** Healthcare expenditure
- **17.3%** Percentage of GDP
- **14,000 USD** Per capita healthcare expenditure

**Patients[3]**

- **Top 5 causes of death:** cardiovascular diseases, cancer, unintentional injuries, stroke, chronic lower respiratory diseases
- **78.4** Average life expectancy

Note 1: Based on World Bank data, 2023; Note 2: Based on CMS (Centers for Medicare & Medicaid Services), 2022; Note 3: Based on literature, 2023

## Private Insurance Dominance, DRG Payment System, Healthcare Cost Optimization, CMS to Encourage Innovation

In the United States, the health insurance system mainly consists of public and private insurance. Public insurance includes Medicare and Medicaid, while private insurance, offered by health insurance companies, covers most of the working-age population.

In terms of payment models, the U.S. adopts the Diagnosis-Related Groups (DRG) prepayment system. The DRG model sets a fixed fee for each disease group, encouraging medical institutions to optimize resource allocation and reduce unnecessary spending.

There are mechanisms to apply directly to the U.S. Centers for Medicare & Medicaid Services (CMS) for special reimbursement of innovative medical devices. These are crucial for supporting clinical use and research of novel devices. For example, the New Technology Add-on Payment (NTAP) allows manufacturers, after review, to receive reimbursement for device-related research and service costs, accelerating clinical research.

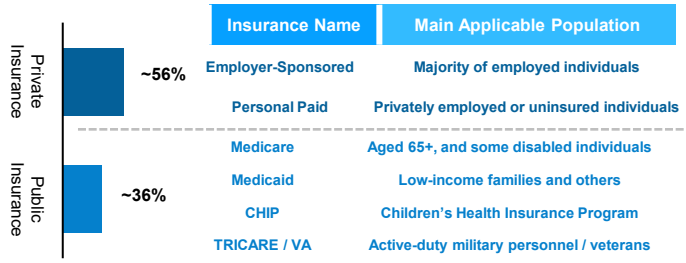



**Figure: Class B China medical device approved for CMS (Sept. 2025)**

| Company | | Product | CMS Approval Date |
|---|---|---|---|
| 同心医疗 BRIOHEALTH | BRIOHEALTH | BrioVAD | 2024.06.21 |
| 启明医疗 VENUS MEDTECH | VENUS MEDTECH | VenusP-Valve | 2023.12.14 |
| MicroPort | MircoPort | Firehawk | 2021.01.28 |

## Chinese Medical Device Global Expansion Key Challenges in the U.S. Market


Source: Public Information, Frost & Sullivan Analysis.

Amid escalating trade tensions, the U.S. has released several tariff lists since 2018. In July 2018, a 25% import tariff was imposed on $34 billion USD worth of Chinese goods, including medical devices and their components. This led to reduced market competitiveness, higher export costs, and risks of decreased net profits for exporters. In addition, the U.S. tightened visa policies for Chinese tech professionals and companies, which has to some extent limited the ability of Chinese firms to build overseas teams.

When entering the U.S. market, Chinese medical device companies need not only to sell products locally but may also need to localize production. This requires building a full operational chain, including pre-sales technical support, logistics and compliance during sales, and an after-sales service system. However, in an unfamiliar market environment, Chinese firms often lack in-depth knowledge of U.S. healthcare regulations, market culture, and consumer needs. At the same time, they face major challenges in building localized teams, supply chains, and service networks.

As the population ages and medical innovations grow, payers face rising healthcare costs. The U.S. is advancing DRG-based payment reforms, which push hospitals to cut equipment procurement budgets. Most hospitals have joined Group Purchasing Organizations (GPOs) to consolidate demand and lower device prices. Data shows that GPOs help hospitals save an average of 10% to 18% on medical devices compared to direct purchases. Therefore, Chinese companies need a clear understanding of reimbursement and procurement processes across different product types to improve product accessibility.

Some Chinese companies lack core technology patents in high-end medical devices and rely on imitation-based innovation, which increases the risk of lawsuits. The U.S. enforces a strict product liability system. If a device causes a medical incident due to design flaws or quality issues, companies may face substantial compensation claims. In addition, the U.S. has strict laws on medical data security and patient privacy, and individual states have separate data privacy regulations, which further complicate compliance efforts.

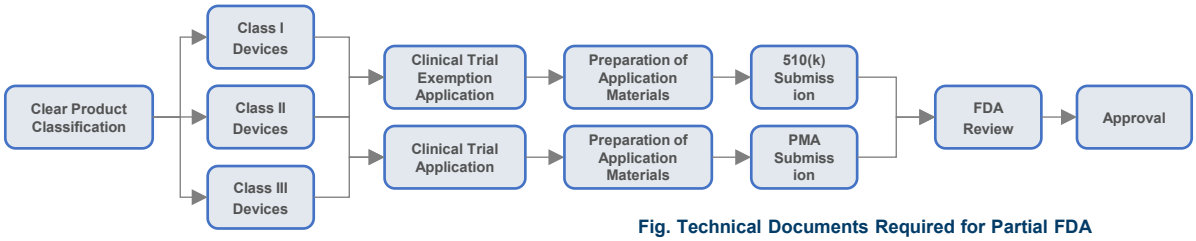
# Developed Regions and Countries Market Analysis – United States

**The FDA launched the ASCA Program to offer standardized solutions for the industry. By using FDA-recognized laboratories for testing, companies can improve the compliance and reliability of test results, while also streamlining the registration process and reducing compliance costs.**

## Strict Lifecycle Regulation of Medical Devices

The U.S. medical device regulatory system is led by the Food and Drug Administration (FDA), which has established a strict oversight network covering the full lifecycle from R&D to manufacturing and distribution. Its core approach is to ensure product safety and effectiveness through scientific review and ongoing oversight. The FDA classifies medical devices into Class I, II, and III. The U.S. submission process typically involves determining the product classification, preparing application documents, and submitting either a 510(k) notification or a Premarket Approval (PMA) application. The PMA process is globally recognized as one of the most stringent regulatory routes for medical device market authorization, characterized by high costs and lengthy timelines. It represents the highest approval standard for high-risk medical devices, applicable to life-sustaining or life-supporting products with potentially significant risks. Very few Chinese products have obtained this approval, with industry experts estimating that only a single-digit number of medical devices from China secure PMA clearance annually.

**Fig. Medical Device Registration Process in the United States**




The FDA continues to strengthen regulation across the entire lifecycle of medical devices, with stricter requirements for testing data from third-party laboratories. The FDA specifically reminds manufacturers to carefully assess third-party labs conducting performance testing, and requires that all test results be independently verified before submission. It also stresses that manufacturers are responsible for the qualification of third-party data sources and must ensure that all submitted data is truthful and accurate.

**Fig. Technical Documents Required for Partial FDA Submission of Medical Devices**

| | |
|---|---|
| Product Description | Functions, design, materials, technical specifications, etc. |
| Performance Test Reports | Functional, mechanical, electrical, biocompatibility tests, etc. |
| Risk Management Documents | ISO 14971 standard, identifying and controlling potential risks. |

## FDA ASCA

To ensure the safe and effective supply of medical devices and regulated laboratory equipment, and to improve regulatory efficiency, the U.S. FDA launched the Accreditation Scheme for Conformity Assessment (ASCA). Laboratories accredited under the ASCA program must meet several requirements, including appropriate equipment and facilities, qualified personnel, and an effective quality management system. The FDA encourages medical device manufacturers to work with ASCA-accredited laboratories and emphasizes the need for independent evaluation of all third-party data.

By choosing FDA ASCA-accredited laboratories, medical device manufacturers can improve the accuracy, reliability, and impartiality of test results, increasing confidence in the data. Manufacturers can submit data in preferred formats, which helps reduce additional requests that may delay the review process and lowers the need for extra information to meet standards. This also improves predictability of compliance, simplifies the process, and increases efficiency, helping save both time and costs.

UL Solutions

As a global leader in safety science, UL Solutions operates ASCA-accredited laboratories in multiple locations worldwide. These laboratories provide product testing to support companies in demonstrating compliance with U.S. Food and Drug Administration (FDA) compliance requirements for medical devices.

UL Solutions' FDA ASCA accreditation covers many medical device standards involved in projects, helping to reduce the likelihood of redundant or revised testing and minimizing FDA reviewers' requests for additional information.

- ✓ Save time and costs through streamlined documentation requirements.
- ✓ Provide flexibility and consistency from single tests to premarket certification reviews according to manufacturers' needs.
- ✓ Conduct medical device testing in accredited laboratories to help build confidence in product safety and performance

Source: Public Information, Frost & Sullivan Analysis.

Note*: As of April 21, 2025

# Developed Regions and Countries Market Analysis – European Union

The EU has a developed economy, diverse healthcare needs, and a range of reimbursement models. Market access for medical devices depends on CE certification and compliance with individual member state regulations. In addition, government-led centralized procurement and pricing negotiations place higher requirements on Chinese companies for compliance and operations.

## Prosperous Economy, Diverse Medical Needs, High Life Expectancy

**Economy[1]**

- **18.59 trillion USD** GDP
- **↑0.4%** Year-over-year Growth
- **410,000 USD** GDP per Capita

**Population[1]**

- **450 million** Total Population
- **↑0.2%** Year-over-year Growth
- **22%** Aging Population Proportion (65 years and older)

**Healthcare Expenditure[2]**

- **1.65 trillion Euros** Healthcare Expenditure
- **10.4%** of GDP
- **3,685 Euros** Healthcare Expenditure per Capita

**Patients[3]**

- **Top 5 Causes of Death:**
  Cardiovascular Diseases, Cancer, COVID-19, Respiratory Diseases, Accidents
- **81.5** Average Lifetime

Note 1: Based on World Bank, 2023 data; Note 2: Based on official EU sources, 2022 data; Note 3: Based on official EU sources, 2023 data

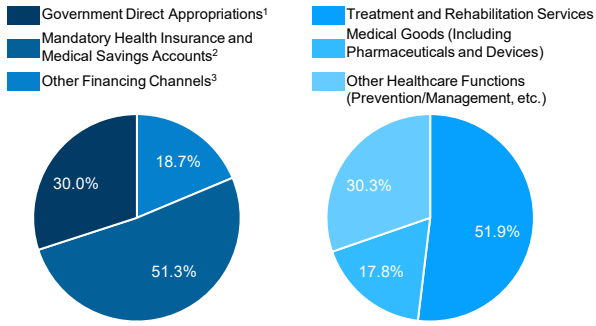
## Comprehensive Welfare System, Diverse Insurance Models

With many member states and frequent population mobility, the EU bases social security and healthcare coverage on individuals' economic conditions and place of residence, rather than nationality. The European healthcare system combines different models, such as publicly funded health insurance, social health insurance, and hybrid systems, offering a wide range of services to both citizens and foreign residents.

**Fig. Major Froms of Health Insurance in the EU**

| | Description | Representative Countries |
|---|---|---|
| National Welfare System | Government-controlled, emphasizes accessibility and equity of services. Funding mainly relies on taxation. | (United Kingdom), Sweden, etc. |
| Social Insurance System | Mandatory health insurance contributions from employers and employees, with government subsidies to cover shortfalls. | France, Germany, Belgium, etc. |
| Hybrid Insurance Model | Combination of public funding and private insurance. | Greece, Hungary, etc. |

**Fig. Major Forms of Healthcare Expenditure and Their Proportions in the EU, 2022**




Note 1: Mainly refers to the National Health Service model; Note 2: Mainly refers to the Social Insurance model; Note 3: Includes private insurance and others

## Leading Global Standards, CE Mark Widely Accepted

The EU enforces a unified and strict regulatory system for medical devices, centered on the Medical Device Regulation (MDR EU 2017/745) and the In Vitro Diagnostic Medical Device Regulation (IVDR EU 2017/746). These replace the previous medical device directives and significantly increase regulatory requirements. Devices are classified by risk: Class I (low risk), Class IIa (low to medium risk), Class IIb (medium to high risk), and Class III (high risk). In vitro diagnostic devices follow a separate classification under the IVDR. High-risk products require certification by Notified Bodies, while low-risk products may be self-declared by the manufacturer. Key regulatory focuses include stricter clinical data requirements, a more traceable EU medical device database (EUDAMED), and stronger post-market surveillance.

The CE mark is accepted not only across the European Economic Area (Iceland, Norway, Liechtenstein) but also in Turkey, Switzerland, and certain Middle Eastern and Southeast Asian markets (such as the UAE, Saudi Arabia, and Singapore). Acceptance levels vary: Switzerland requires CE marking for only some products, while Turkey fully adopts EU standards. Before export, companies must check the regulations of target countries and meet any additional local certification requirements to ensure compliance.

## Pricing Negotiation to Balance Reimbursement, Affordability, and Profitability

EU member states commonly adopt a pricing system driven by public health insurance. National or regional agencies engage in strategic negotiations with medical device manufacturers to balance three key goals within the healthcare budget: patient affordability, reasonable company profits, and regulatory compliance. This is supported by a tiered reimbursement structure, by using a DRG-based prospective payment system at the base level, and additional reimbursement mechanisms for expensive and innovative technologies at the supplementary level. This combined model of negotiated pricing and tiered payment avoids the risks of fully market-based pricing and promotes efficient allocation of healthcare resources through policy innovation.

Source: Public Information, Frost & Sullivan Analysis.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# Developed Regions and Countries Market Analysis – European Union

Chinese medical device companies face challenges when expanding into the EU market, such as differences in market environment, regulatory certification barriers, and high costs of local operations. By improving regulatory understanding and providing full-process support like certification guidance, companies can greatly enhance market access efficiency and long-term operation quality.

## Chinese Medical Device Global Expansion Key Challenges in the EU Market

**Complex Market Environment**

Healthcare systems in EU countries are fragmented, with large differences in healthcare structures and payment models. Recently, the EU has strengthened supply chain localization policies, such as the European Chips Act, which indirectly affects the stability of the medical device supply chain and increases uncertainty for Chinese exporters.

**Regulatory Compliance Challenges**

EU regulations are strict, and certification procedures are complex. In 2024, the Medical Device Regulation (MDR) will be further tightened, especially with stricter clinical evidence and risk management requirements for high-risk products. The MDR and IVDR transition periods have been extended to 2027–2028, requiring companies to maintain strict compliance throughout the product lifecycle. The EU leads globally in environmental standards, which continue to evolve, so companies must constantly monitor and adjust their production and compliance strategies.

**Local Operational Costs**

The EU has strict environmental requirements for raw materials and components, such as the REACH regulation, forcing companies to adjust their R&D and design approaches to fit green supply chain management. International logistics also face tariff fluctuations and customs delays (e.g., after Brexit), which increase operating costs.

**Market Entry Sequence by Country**

Market access systems differ across EU countries. Some Eastern European countries like Hungary and Greece have strategic locations in Europe, skilled and well-educated labor forces, and good infrastructure. They are often used by companies as gateways into the EU market. For some Class III medical devices, companies prefer certification in countries like Germany and the Netherlands, where regulations are stricter but the markets are larger, to enhance brand credibility.



Source: Public Information, Frost & Sullivan Analysis.

# Developed Regions and Countries Market Analysis – FDA & CE Certification

**Emergo by UL Insight: Certification is not just a "threshold," but a test of a company's global capabilities — requiring systematic improvements from R&D compliance to supply chain resilience.**

## FDA&CE Certification Challenges

FDA registration (for the U.S. market) and CE-MDR/IVDR certification (for the EU and most global regions) are legally required for market access. Without these certifications, products cannot be legally sold. Certification marks act as global "trust endorsements" of a company's technical strength and quality commitment. They directly affect hospital purchasing, insurance coverage, and patient choice. Leading companies build product barriers through certification, and Chinese manufacturers must overcome these barriers to compete internationally. For companies, FDA registration and CE-MDR/IVDR certification are a "passport" and a "foundation of trust" in the global market.

In recent years, medical device market access requirements in the EU and U.S. have become stricter. The EU's new Medical Device Regulation (MDR) is now in effect, along with several MDCG guidance documents, increasing manufacturers' workload to meet MDR requirements. Recently, the European Commission approved a proposal to extend the MDR transition period, which benefits some eligible legacy devices. It is important for companies to fully understand this proposal. Meanwhile, the U.S. FDA continues to update its regulations. For example, new EMC guidelines are in force. Cybersecurity, both before and after product launch, has become a key focus for the FDA. The FDA requires manufacturers to include cybersecurity in their quality management systems and to continuously monitor threats and apply appropriate measures after product release. These regulatory changes pose challenges for manufacturers.

In 2022, only 12% of Chinese companies exporting medical devices to the U.S. held FDA certification. Since the EU MDR took effect, the average CE certification process has lengthened by 6 to 12 months, and more than 30% of small and medium-sized enterprises have been forced out of the market..

***Emergo by UL Insight: Certification is not just a "threshold," but a test of a company's global capabilities — requiring systematic improvements from R&D compliance to supply chain resilience.***

**Fig. Key Differences and Challenges Between FDA and CE Certification**

| Dimension | FDA Certification | CE Certification | EMERGO by UL |
|---|---|---|---|
| Classification Logic | Risk-based: Class I / II / III | Rule-based: MDR/IVDR classification system. | Provides classification prediction tools to avoid misjudgment (e.g., orthopedic implants upgraded from MDD Class II to MDR Class III). |
| Clinical Evidence | Emphasizes "substantial equivalence" (510(k)) or rigorous PMA data | Requires "clinical evaluation + post-market follow-up" throughout the lifecycle. | Designs data-bridging strategies across China, US, and EU to reduce redundant trials (e.g., cardiovascular stent data conversion from China). |
| Quality System | FDA 21 CFR Part 820 (QSR), subject to unannounced inspections | Based on ISO 13485, with MDR reinforcing technical documentation review. | Provides integrated GMP/QSR system setup and mock audits to reduce inspection risks. |
| Technical Focus | Emphasis on performance safety and real-world effectiveness | Focus on risk management (EN ISO 14971) and clinical utility. | Customized documentation frameworks (e.g., AI algorithm validation aligned with FDA AI/ML guidance and MDR Annex I). |
| Approval Timeline | 510(k): 10–12 months average; PMA: 18–24 months | MDR certification extended to 10–18 months. | Shortens review time by 30% through pre-submission consultation and documentation screening (e.g., CE certification for endoscope completed in just 9 months). |

**Source: Public Information, Frost & Sullivan Analysis.**

# Cybersecurity in Medical Devices and Solutions

**The integration of advanced information technologies into medical devices has greatly improved the efficiency of the healthcare industry. However, it has also raised cybersecurity concerns, leading regulators in many countries to introduce new rules. These regulations place additional compliance requirements on medical device companies.**

## Challenges of Cybersecurity in Medical Devices

The integration of advanced information technologies into medical devices has greatly improved the healthcare industry, enhancing both efficiency and effectiveness in medical services. However, it has also brought new challenges for patients, healthcare providers, and medical device developers and manufacturers. The healthcare industry has become a main target for hackers and cybercriminals. This puts private and confidential medical data at risk and threatens patient safety and health. According to Verizon's 2025 Data Breach Investigations Report, there were 1,710 security incidents in the healthcare sector over the year, with 1,542 involving confirmed data breaches. The leading cause was system intrusion, including ransomware attacks. In February 2024, Change Healthcare, a subsidiary of UnitedHealth Group, suffered a cyberattack that caused 872 million USD in financial losses and exposed sensitive medical data of around 190 million Americans. This became the largest healthcare data breach in U.S. history.

In response, regulatory authorities have issued cybersecurity-related requirements, including guidance from the U.S. Food and Drug Administration (FDA), Health Canada's cybersecurity guidelines, the European Union Medical Device Regulation (MDR), and the Health Insurance Portability and Accountability Act (HIPAA).

**Fig. Cybersecurity Regulations and Requirements for Medical Devices in the United States, Canada, and the European Union**

| Country | Core Regulations | Regulatory Requirements |
|---|---|---|
| USA | • FDA "Cybersecurity in Medical Devices" Guidance: Emphasizes that cybersecurity is part of device safety and the quality system regulation. Manufacturers must implement security throughout the product lifecycle and update SBOMs.<br>• HIPAA Updates: Require healthcare providers to encryptprotected health information (PHI). | • Market Access Control: The FDA ensures compliance through market entry controls (if application denial or recalls). Non-compliance may lead to financial losses and reputational damage.<br>• SBOM Mandatory Requirement: Device premarket submissions must include a Software Bill of Materials (SBOM). |
| Canada | Guidance on Machine Learning-enabled Medical Devices (MLMDs): Incorporates transparency principles across the entire product lifecycle to support safe and effective MLMD use. | Premarket Review: MDL applicants must submit cybersecurity-related information to Health Canada, demonstrating the safety of software-based or software-containing devices. |
| EU | MDR: Requires that medical devices meet General Safety and Performance Requirements (GSPR) related to cybersecurity, including threat analysis during design, data encryption, access control, and post-market surveillance. | Technical Documentation Requirements: Must include 12 types of documents such as security risk management plans, verification reports, and post-market surveillance plans, ensuring traceability throughout the lifecycle. |

**UL Solutions** **Committed to supporting companies to resolve risks related to cybersecurity, data privacy, and interoperability**

UL Solutions provides a comprehensive range of services across the entire development life cycle. These include gap analysis to identify non-conformities and errors during the early design phase, customized testing and evaluation services throughout the development process and complete UL 2900 assessment and certification services. Among these, the UL 2900-2-1 certification, recognized by the FDA, applies to the cybersecurity of medical devices and software. It certifies products, components, devices or systems based on standardized and testable criteria, assessing and benchmarking software vulnerabilities and weaknesses that may affect the cybersecurity environment.

### Core Value of UL 2900-2-1

- **Enhancing full life cycle security of medical devices**

The standard focuses not only on cybersecurity design during product development, but also on continuous risk management after the product is launched, supporting device safety over its entire life cycle. This aligns closely with the FDA's guidelines on life cycle security management for medical devices.

- **Accelerating FDA clearance and approval processes**

By following UL 2900-2-1, manufacturers can cite the standard as **evidence of compliance** when submitting premarket applications such as FDA 510(k) and Premarket Approval (PMA) routes, helping reduce review delays caused by cybersecurity issues and shorten the time to market.

- **Responding to global regulatory convergence trends**

Beyond the U.S., regulators in countries such as Canada and South Korea are gradually adopting the UL 2900 series as the basis for cybersecurity assessment. This supports the goal of **"certify once, apply in multiple markets."**

- **Establishing a unified cybersecurity assessment framework**

UL 2900-2-1 provides measurable testing criteria for connected medical devices and establishes a standardized testing protocol, helping manufacturers and **regulators assess risks using a consistent approach.**

### Types of Testing and Certification Services Provided by UL Solutions

- Medical Devices and Accessories
- In Vitro Diagnostic (IVD) Medical Devices and Accessories
- Software as a Medical Device (SaMD), such as mobile applications, web applications, and cloud solutions.

### How UL Solutions Supports Medical Device Manufacturers

**Reduce compliance costs**

UL 2900-2-1 provides clear testing pathways and tools to systematically address FDA cybersecurity requirements, avoiding redundant resource investments. For example, UL Solutions' Cybersecurity Assurance Program (CAP) helps manufacturers streamline testing processes and reduce trial-and-error costs during development.

**Enhance market competitiveness and trust**

Devices certified by UL Solutions can be labeled as "Compliant with FDA Consensus Standards," serving as an important reference for healthcare institutions during procurement. For example, a certain patient monitor became the first China-made medical device to receive this certification, significantly boosting its brand reputation.

**Technical support for full life cycle management**

UL 2900-2-1 requires manufacturers to establish a comprehensive risk management system covering the entire product life cycle from design to retirement. This includes secure design, vulnerability response plans, coordinated application with the National Institute of Standards and Technology (NIST) Cybersecurity Framework, helping manufacturers address evolving cyber threats and reduce the risk of recalls caused by security incidents.

**Promoting technological innovation and collaboration**

The testing methods of UL 2900-2-1 (such as fuzz testing and dynamic analysis) encourage manufacturers to adopt advanced technologies to optimize software architecture, while also fostering collaboration with third-party security organizations to enhance technical transparency.

Source: Public Information, Frost & Sullivan Analysis.

# Developed Regions and Countries Market Analysis – Japan

As a super-aged society, Japan imposes strict regulations on medical device market access. Combined with the high coverage of universal health insurance and a hospital-driven procurement system, this has created a market environment dominated by local companies, marked by high price sensitivity and significant technical barriers.

## Aging Population, Heavy Elderly Care Burden

**Economy[1]**

- **4.2 trillion USD** GDP
- **↑1.7%** Year-over-year Growth
- **34,000 USD** GDP per Capita

**Population[1]**

- **120 million** Total Population
- **↓0.5%** Year-over-year Decline
- **30%** Aging Population Proportion (65 years old and above)

**Healthcare Expenditure[2]**

- **46.7 trillion JPY** Healthcare Expenditure
- **11.5%** of GDP
- **5,251 USD** Healthcare Expenditure Per Capita

**Patients[3]**

- **Top 5 Causes of Death:** Ischemic Heart Disease, Stroke, Lower Respiratory Infections, Respiratory Cancers, Digestive Cancers
- **84.5** Average Lifetime

Note 1: Based on World Bank, 2023 data; Note 2: Based on OECD, 2022 data; Note 3: Based on WHO, 2021 data

## Universal Health Coverage through Evolving Demand and Policy

Japan's healthcare system is based on universal health insurance. Its core idea is to build a mutual support network by having all citizens share the cost of insurance, with dependents automatically covered. With just an insurance card, patients can visit any medical institution and receive necessary medical services, such as treatment and medications, by paying a fixed portion at the point of care. This ensures equal access to basic healthcare for all.

This system design ensures fairness in healthcare and supports its sustainability through a risk-sharing mechanism. It builds a full-life-cycle medical safety network, helping Japan reach an average life expectancy of over 84 years, which is one of the highest in the world. By adjusting insurance payment standards and enforcing strict medical cost accounting, Japan has effectively curbed the rise in healthcare spending in a super-aged society. This ensures universal, high-quality services and enables the sustainable use of medical resources, forming a key foundation for the stable functioning of Japan's super-longevity society.

**Fig. Types of Public Health Insurance in Japan and Their Coverage**

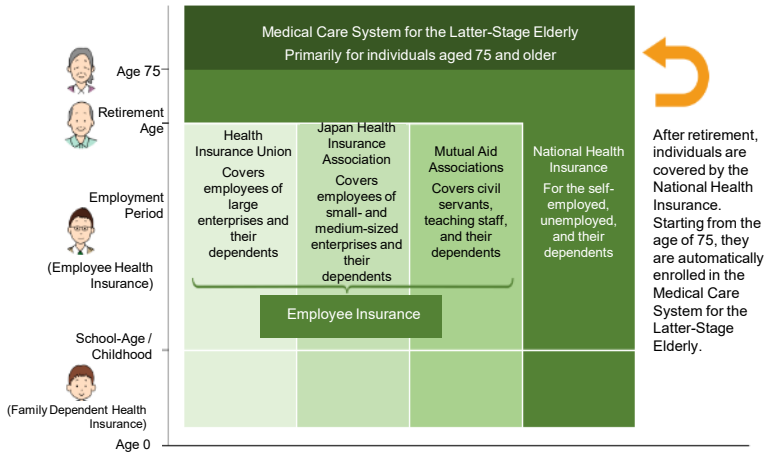
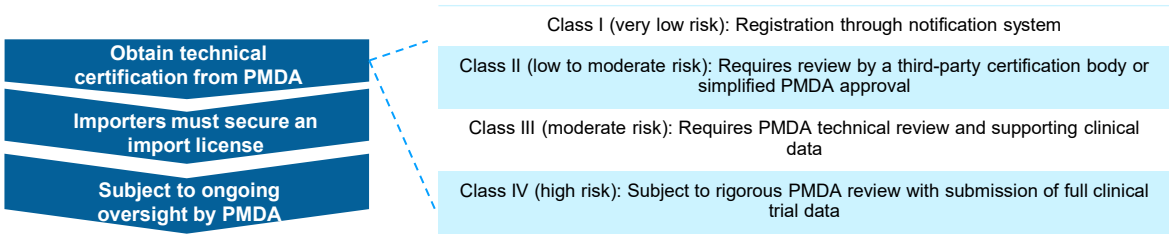



Image Source: Japan Medical Association

## PMDA Oversees Entire Lifecycle

Japan's medical device regulatory system is based on the Pharmaceuticals and Medical Devices Act (PMD Act), with duties shared between the Ministry of Health, Labour and Welfare (MHLW) and the Pharmaceuticals and Medical Devices Agency (PMDA). To enter the market, medical devices must receive technical certification from PMDA, with different registration procedures depending on the product's risk class. Importers must obtain import licenses and ensure full compliance with Japanese regulations. After registration, PMDA continues to oversee the device's safety and effectiveness. Importers are also responsible for product tracking and recall, maintaining compliance throughout the entire product lifecycle.

**Fig. Medical Device Regulatory Process in Japan**




Source: Public Information, Frost & Sullivan Analysis.





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# Developed Regions and Countries Market Analysis – Japan

**Japan's medical device market access and pricing are closely tied to the national health insurance system, creating a positive cycle of cost control and industry development. Chinese companies are accelerating their expansion into Japan by improving product performance and continuously innovating to meet local market needs.**

### Strict Tendering and Procurement, Centralized Management over Medical Device Price

Japan manages medical device procurement and pricing mainly through the national health insurance system. All devices must first qualify for reimbursement before entering the market. Medical institutions then negotiate or conduct tenders based on the set insurance payment prices, allowing centralized price control. For pricing, Japan introduced a functional group reimbursement system in 1993, grouping similar devices together. It uses a combination of comparative and cost-based pricing methods, while also referencing the Foreign Average Price (FAP) to adjust pricing. Reimbursement prices are revised every two years to help control total medical spending. To encourage innovation, Japan provides incentives such as technical add-ons or creating new categories, balancing cost control with ongoing medical device innovation.

### Chinese Medcial Device Global Expansion Key Challenges in Japan

**Slow certification process**

Japan classifies medical devices into four risk levels: Class I, II, III, and IV. Devices at different risk levels follow different approval pathways. For example, low-regulation Class II and Class III devices can be reviewed by third-party certification bodies. However, high-risk devices (high-regulation Class III and Class IV) must be approved directly by the Pharmaceuticals and Medical Devices Agency (PMDA), under strict standards and with long review timelines. In addition, Japan requires re-examination within a set period after initial approval, which extends regulatory oversight across the entire product lifecycle and increases uncertainty for companies.

**High performance requirements**

Japanese domestic companies in Japan are highly competitive in high-end products, with precise manufacturing and product stability becoming the market mainstream. As a result, imported products must not only lead in functionality but also meet the highest standards in craftsmanship, materials, and overall system safety. Even minor flaws may lead to rejection during approval.

**Slowing market growth**

According to the "Medical Device Industry Vision 2024" released by Japan's Ministry of Economy, Trade and Industry, Japan's global market share in medical devices fell from 22.1% in 1990 to 7.3% in 2018, with slow overall growth. As a result, Japanese domestic companies are also actively pursuing global expansion to increase their overseas market share, which has intensified competition for imported products to some extent. Japan's aging population and declining birthrate have long-term effects on market demand. While this has driven growth in areas such as telemedicine and home health monitoring, overall investment is no longer growing at a rapid pace.

**Aging population and declining birth rate**

As population aging accelerates, Japan's demand for chronic disease management, rehabilitation care, telemedicine, and home medical devices has increased significantly. At the same time, the declining birthrate has reduced market demand for pediatric and maternal care products. As a result, product development should shift toward elderly care and treatment of adult chronic diseases. Chinese companies need to fully understand the specific needs of the Japanese market and meet consumer expectations for ease of use, product safety, durability, and data connectivity through localized innovation.

**Source: Public Information, Frost & Sullivan Analysis.**

# Developed Regions and Countries Market Analysis – Canada

As a high social welfare economy, Canada's medical device market is shaped by its universal healthcare coverage and long medical wait times. Its decentralized hospital procurement system leads to intense price competition, creating dual challenges for Chinese companies in both product differentiation and cost control.

## Macroeconomy and Demographics of Canada

**Economy[1]**

- **2.14 trillion USD** GDP
- **↑1.2%** Year-over-year Growth
- **53,000 USD** GDP per capita

**Population[1]**

- **40 million** Total population
- **↑2.9%** Year-over-year Growth
- **19%** Aging population proportion (65 years and older)

**Healthcare Expenditure[2]**

- **235.9 billion USD** Healthcare expenditure
- **11.2%** of GDP
- **6,319 USD** Per capita healthcare expenditure

**Patients[3]**

- **Top 5 causes of death:** Cancer, heart disease, accidental injuries, cerebrovascular disease, chronic lower respiratory diseases
- **81.7** Average Lifetime

Note 1: Based on World Bank data, 2023; Note 2: Based on OECD and Statistics Canada data, 2022; Note 3: Based on Statistics Canada data, 2023

## Healthcare System of Canada

Canada's universal healthcare system, known as Medicare, is based on the principles set by the federal Canada Health Act and managed by each province and territory. It is funded through taxation and covers all citizens and permanent residents, allowing them to receive essential medical services, such as doctor visits, hospital stays, and surgeries, free of charge with a health card.

As each of Canada's 13 provinces and territories operates its own healthcare plan, the definition of "medically necessary services" varies. This leads to differences in coverage for services such as dental care, vision care, and prescription drugs across regions. Non-urgent treatments may involve long wait times, and services like physical therapy often require out-of-pocket payment or private insurance. Although public healthcare is the system's core, rules for interprovincial care and the use of supplementary insurance remain key concerns for residents.

## Medical Device Regulation of Canada

Health Canada uses a risk-based classification system for regulating medical devices, dividing them into four classes. For Class I devices (e.g., non-invasive equipment), manufacturers or distributors must obtain a Medical Device Establishment License (MDEL). For Class II to IV devices (e.g., blood glucose meters, implantable devices), manufacturers must apply for a Medical Device License (MDL) and submit technical documents and clinical data, depending on the risk class. Distributors or importers of Class II to IV devices must also hold an MDEL. Manufacturers of Class II to IV devices must comply with the CAN/CSA-ISO 13485 standard, implement full lifecycle quality management, and undergo ongoing compliance inspections by Health Canada.

## Chinese Medcial Device Global Expansion Key Challenges in Canada

**Complex market access process**

Canada's medical device market has high entry barriers, with a strict approval process. Companies are required to submit detailed clinical data, safety validation results, and quality management system documents. The entire process is lengthy and must fully comply with the Canadian Medical Devices Regulations (CMDR). In addition, healthcare providers expect not only clinical evidence of product quality but also long-term strategic partnerships to build trust, further raising the difficulty of market entry.

**Strict reimbursement policies**

Canada's medical device market is strictly regulated by the healthcare reimbursement system. On one hand, companies must meet complex reimbursement standards, and products need to pass clinical value assessments and cost-effectiveness evaluations. On the other hand, they must follow pricing mechanisms and find a balance between cost control and technological innovation.

**Intense market competition**

Canada's medical device market faces dual competitive pressures. On one hand, Canadian domestic and Western brands have built strong brand recognition through long-term market presence. U.S. manufacturers, in particular, benefit from geographic proximity and similar regulatory standards, giving them a market advantage and over half of the market share. On the other hand, in the post-pandemic era, the Canadian government is strengthening the security of the medical supply chain and accelerating efforts to enhance the resilience of its domestic medical device industry.

**Source: Public Information, Frost & Sullivan Analysis.**

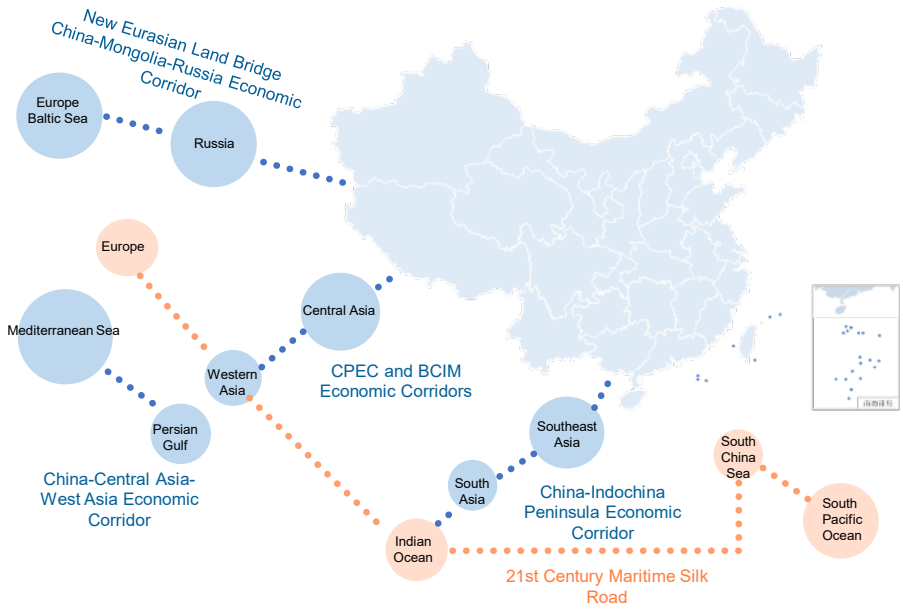
# Countries and Regions of the "Belt and Road Initiative" Market Analysis

**Under the Belt and Road Initiative's push for deeper international cooperation, policy support and infrastructure connectivity work together to help medical device companies overcome export barriers and, through localized efforts, advance medical collaboration in participating countries.**

## Background of "Belt and Road Initiative"

In September and October 2013, China proposed the "Silk Road Economic Belt" and the "21st Century Maritime Silk Road." Together, they form the Belt and Road Initiative (BRI), which has attracted global attention and gained active participation from many countries. Upholding the principle of openness, the BRI aims to enhance connectivity in transportation, energy, and digital infrastructure to promote the free flow of economic factors, efficient allocation of resources, and deep market integration. It seeks to broaden the scope of regional cooperation, raise its quality, and deepen partnerships, building a regional economic system that is open, inclusive, balanced, and shared. By April 2019, the "six corridors, six connectivity routes and multiple countries and ports" connectivity framework had taken shape. Today, the BRI serves as an effective platform for promoting shared prosperity and development across multiple sectors.

**Fig. "Six Corridors and Six Routes"**




## "Belt and Road Initiative" Policy Support for Medical Device Industry Development

Through the "14th Five-Year Plan for the Development of the Medical Equipment Industry," the Chinese government clearly supports medical device companies in using the Belt and Road Initiative to explore international markets, offering policy support and favorable conditions that open up broad opportunities overseas. The BRI's infrastructure connectivity has greatly improved logistics and trade efficiency. It has created more economical, efficient, and stable export channels for medical devices and promoted the cross-border flow of labor, capital, technology, and other production factors, building bridges for cooperation between companies and institutions in BRI countries. For example, Mindray Medical has established branches in BRI countries and carried out a special "Women's Health" program in cooperation with local governments and healthcare institutions. In Egypt, it has set up four training centers and thirteen training schools, training a total of 1,500 obstetrics and gynecology professionals, with over 80,000 annual users of Mindray ultrasound devices.

At present, countries along the BRI have become key markets for China's medical device exports. From 2019 to 2023, China's medical device exports to these countries grew from 33.496 billion RMB to 65.885 billion RMB, with a CAGR of 18.43%. These markets now play an important role in China's medical device trade. As the BRI continues to advance, these countries will further strengthen their strategic position in China's medical device trade and play an increasingly vital role in the future.

Source: Public Information, Frost & Sullivan Analysis.

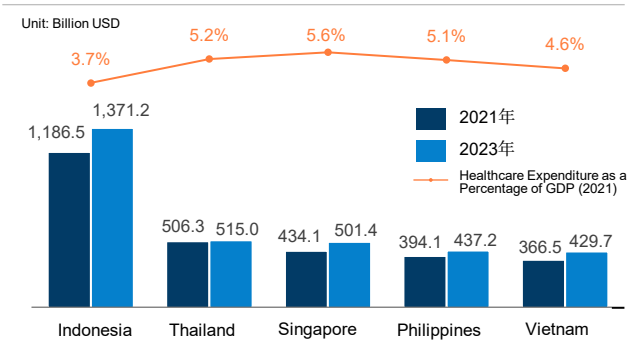
# Countries and Regions of the "Belt and Road Initiative" Market Analysis --- Southeast Asia

**Southeast Asia's large and youthful population continues to drive steady growth in healthcare demand. However, the region's medical infrastructure remains underdeveloped, leading to a high reliance on imported medical devices to bridge supply gaps. At the same time, the adoption of advanced technologies is gradually improving the regional healthcare environment.**

## Rapid Growth in Healthcare Spending

Southeast Asia, located at the intersection of Asia and Oceania and spanning both the Pacific and Indian Oceans, is an important global hub and one of the world's most densely populated regions. It includes 11 countries: Vietnam, Laos, Cambodia, Thailand, Myanmar, Malaysia, Singapore, Indonesia, Brunei, the Philippines, and Timor-Leste. In recent years, healthcare spending across Southeast Asian countries has outpaced their economic growth, showing strong market potential. This growth is mainly driven by population aging and the increasing prevalence of chronic non-communicable diseases such as obesity and diabetes, which are steadily pushing up healthcare demand in the region.

**Figure: GDP and Healthcare Expenditure in Southeast Asian Countries**

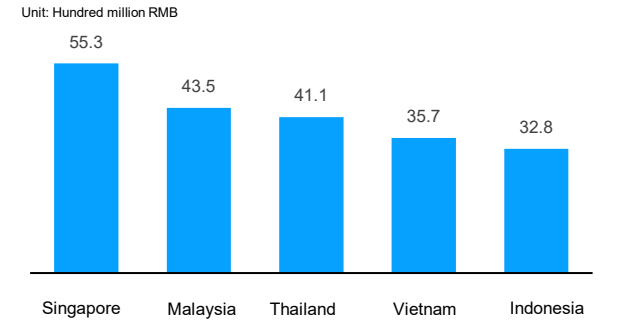



## Many Countries Have Heavy Dependence on Imports

Southeast Asia's medical device manufacturing industry remains relatively weak, with production capacity concentrated in low-value products. As a result, most countries in the region rely heavily on imported medical devices. According to the 2024 White Paper on China's Medical Device Global Expansion to Southeast Asia, imports account for over 80% of medical devices in Singapore, Malaysia, Vietnam, and the Philippines.

Compared to the more mature and large-scale markets of China, Europe, and the United States, Southeast Asia, as an emerging economy, faces more structural challenges in healthcare, including underdeveloped infrastructure, limited purchasing power among residents, and insufficient diagnostic technologies and innovation systems.

**Figure: China's Exports of Medical Devices to Selected Southeast Asian Countries in 2023**




## Deepening International Cooperation, Enhancing Medical Device Global Expansion to Southeast Asia to Improve Healthcare Infrastructure

While developing their domestic healthcare systems, Southeast Asian countries are also strengthening regional cooperation through the "ASEAN+" health cooperation framework, which is centered around the ASEAN Socio-Cultural Community. This framework focuses on promoting universal health coverage with East Asian partners including China, Japan, and South Korea. Through joint declarations and action plans, it has effectively advanced the regional progress toward universal health coverage. As cooperation with China deepens, a series of favorable policies, such as the Belt and Road Initiative, China-ASEAN Economic and Trade Cooperation, and the Regional Comprehensive Economic Partnership (RCEP), have been implemented, advancing economic and trade ties and creating a supportive policy environment for the global expansion of Chinese medical devices into Southeast Asia.

In 2023, China's exports of medical devices to core Belt and Road countries grew by 9.87% year-on-year, continuing a stable growth trend. The accelerated development of healthcare infrastructure, demographic shifts increasing demand, and improvements in local medical technology are bringing three structural opportunities to the region: rising demand for equipment upgrades driven by the expansion of primary healthcare, growing application of high-end devices supported by the development of specialty hospitals, and greater potential for technological collaboration enabled by digital healthcare transformation. This demand-driven growth is expected to interact positively with China's technology exports. By deepening cooperation across the industrial chain and improving localized service networks, Chinese medical devices will continue to enhance their competitiveness in the regional market.

Southeast Asian countries also play a key role in cross-border trade. In response to high tariffs imposed by some countries on Chinese goods, re-export trade through third countries has become an effective way to restructure export routes. Chinese products are first shipped to a transit country, then re-exported to the final destination. This approach helps bypass direct export tariffs and restores price competitiveness. For instance, Vietnam applies zero quota management and maintains relatively low tariff rates on medical device imports, making it an ideal hub for re-export trade.

Source: Public Information, Frost & Sullivan Analysis.

# Countries and Regions of the "Belt and Road Initiative" Market Analysis --- Southeast Asia

**Medical device regulations and policies in Southeast Asia are fragmented. Chinese companies expanding into the region must tackle multiple market entry challenges at the same time, including regulatory registration, localizing clinical data, and adapting their supply chains.**

## AMDD Promotes Information Sharing of Medical Device

The ASEAN Medical Device Directive (AMDD) promotes collaboration and information sharing on medical devices in Southeast Asia. It covers ten ASEAN countries, excluding Timor-Leste. As of 2023, nine countries have accepted or ratified the AMDD. The directive sets out detailed rules for the placement, registration, and regulation of medical devices in the region.

**Fig. Medical Device Regulation in Selected Southeast Asian Countries**

| | Singapore | Malaysia | Thailand | Indonesia | Vietnam |
|---|---|---|---|---|---|
| Regulatory Authority | Health Sciences Authority (HSA) | Medical Device Authority (MDA), under the Ministry of Health | Medical Device Control Division (MDCD), under the Thai FDA | National Agency of Drug and Food Control (NADFC), under the Ministry of Health | Department of Medical Equipment and Construction (DMEC), under the Ministry of Health |
| Registration Pathway | Class A devices are exempt from registration. Class B, C, and D devices follow multiple possible pathways. | Class A devices apply directly to MDA. Class B, C, and D must first undergo assessment at local Conformity Assessment Bodies (CABs). | Class 1: Listing system; Class 2 & 3: Notification procedure; Class 4: Licensing procedure. | All Classes (A–D): Must register via the online medical device registration platform. | Class A/B: Register online with provincial health departments; Class C/D: Register online with DMEC. |

Due to differences in economic development levels and regulatory systems among ASEAN member states, the implementation of the ASEAN Medical Device Directive (AMDD) varies significantly across countries. These discrepancies have hindered the progress of regional integration for medical device market access. Companies must develop tailored entry strategies based on the specific regulations of each target country, with particular attention to localization and compliance requirements in countries like Laos and Vietnam, where AMDD adoption has been slower.

For key markets under the Belt and Road Initiative, Emergo by UL provides local registration and customs clearance support based on the AMDD mutual recognition framework. In addition, Emergo by UL has developed an innovative fast-track channel for CE-certified products. For example, after obtaining EU certification for medical dressing products, companies can leverage this mechanism to expedite the registration process in Singapore, Malaysia, and Thailand.

## Chinese Medical Device Global Expansion Key Challenges in Southeast Asia


Southeast Asian countries differ widely in economic foundation, healthcare development, demographics, and cultural background. For example, in terms of aging population, only Singapore and Thailand have relatively high aging rates—13% and 15% respectively—exceeding the global average, while other countries in the region have younger populations with aging rates below 10%. Although the AMDD provides unified guidelines for areas such as market access, classification, registration, and clinical trials of medical devices, notable regulatory differences still exist among member states in practice.

Development levels vary across Southeast Asia. Countries like Singapore and Malaysia have higher education standards and better public awareness of healthcare, while in some other countries, the skills of primary healthcare workers and their experience in equipment maintenance are still limited, requiring companies to strengthen after-sales support. In addition, religious and cultural customs, as well as the influence of traditional medicine, call for greater localization in product design and marketing. On the infrastructure side, issues such as unstable electricity supply also demand higher durability standards for medical devices.

Some countries in Southeast Asia have high standards for medical devices, and Chinese companies expanding globally must compete with established players from developed countries like the U.S., Japan, and Germany. For instance, Singapore, with its mature medical market and globally advanced adoption of new technologies, offers a level playing field for medical device companies. Chinese firms need to compete with top international companies in both technology and management, while highlighting their strengths in cost and quality to gain greater market share.

Southeast Asia experiences year-round high temperatures and heavy rainfall. These hot and humid conditions can accelerate the degradation of medical devices containing sensitive components and materials, reducing their operational lifespan. Companies must design products that are resistant to heat and humidity, in line with the climatic conditions of the target markets, to ensure reliable device performance.

Source: Public Information, Frost & Sullivan Analysis.

# Countries and Regions of the "Belt and Road Initiative" Market Analysis --- Middle East

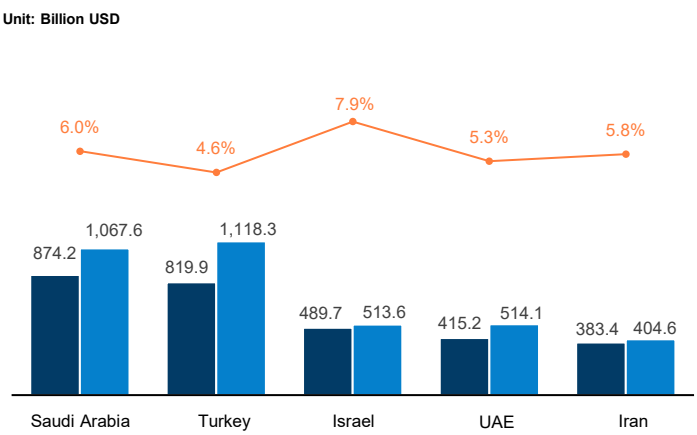
Medical device regulations and policies in Southeast Asia are fragmented. Chinese companies expanding into the region must tackle multiple market entry challenges at the same time, including regulatory registration, localizing clinical data, and adapting their supply chains.

## Highly Dependent on Energy, with a Single-Sector Economic Structure

The Middle East generally refers to a broad geographic region that includes 17 countries such as the United Arab Emirates, Saudi Arabia, Qatar, and Turkey, with a total population of around 434 million.

In recent years, the Middle Eastern economy has shown dual characteristics—stability driven by energy and transformation driven by reform. Gulf countries have maintained economic stability through oil resources while advancing diversification strategies. Emerging economies like Turkey and Israel are opening up new growth paths through technological innovation and the expansion of service industries.However, the region still faces frequent geopolitical conflicts, rising youth unemployment, and a single-sector economic structure.

**Fig. GDP and Healthcare Expenditure in Middle Eastern Countries**




## High Purchasing Power and Strong Medical Demand, Policy Support on Medical Infrastructure

### Market preference for digital and high-end products

Saudi Arabia, Turkey, and the United Arab Emirates are the three largest medical device markets in the Middle East and are actively promoting the development of digital healthcare and telemedicine. For example, Mindray's "UltraSync" platform integrates artificial intelligence and other advanced technologies to meet the demand for medical imaging connectivity and has been well received by many high-end hospitals in the region. In addition, developed countries such as Saudi Arabia and the UAE have strong consumer purchasing power and a well-developed medical tourism industry, which leads to high expectations for medical technologies and services, and a growing demand for premium medical products.

### Economic strength and payment capacity

Except for war-affected countries such as Syria and Iraq, most nations in the Middle East have strong economic strength, ranking among the world's leading economies. These countries also have high-quality and well-established healthcare systems and medical insurance schemes, providing a solid economic foundation for the growth of the medical device market.

### Burden of chronic diseases

Due to local dietary and lifestyle habits, many Arab countries in the Middle East have traditional diets that are high in meat, oil, and sugar, leading to a high prevalence of diseases such as diabetes and obesity. According to the International Diabetes Federation, the prevalence of diabetes in the Middle East has reached 16.2%, with the number of cases expected to grow at the second-highest rate globally. As the burden of chronic diseases continues to increase, countries in the region are expected to see rising demand for chronic disease management devices and diagnostic imaging equipment.

### Policy-driven development of healthcare services

Saudi Arabia's "Vision 2030" includes a planned investment of $65 billion USD to upgrade its healthcare infrastructure by building 290 new hospitals and 2,300 primary healthcare centers, aiming to improve the quality and accessibility of medical services. The implementation of this plan offers major opportunities for Chinese enterprises in areas such as equipment supply, technology cooperation, and localized manufacturing. In addition, Middle Eastern countries, especially Saudi Arabia, have clearly introduced a "trade for capacity" policy, encouraging Chinese companies to establish joint ventures, carry out technology transfers, and set up local production.

Source: Public Information, Frost & Sullivan Analysis.

# Countries and Regions of the "Belt and Road Initiative" Market Analysis --- Middle East

**Medical device regulations and policies in Southeast Asia are fragmented. Chinese companies expanding into the region must tackle multiple market entry challenges at the same time, including regulatory registration, localizing clinical data, and adapting their supply chains.**

## Chinese Medical Device Fast Global Expansion in the Middle East

The Middle East market is relatively mature, maintains friendly ties with China, and has relatively low tariffs, creating a favorable export environment for Chinese medical device companies. Chinese medical devices are experiencing positive growth in their global expansion into the Middle Eastern market. As an emerging market along the Belt and Road Initiative, the Middle East, especially Saudi Arabia, the UAE, and Turkey, has become a key destination for Chinese medical device exports. Additionally, the UAE, as a major economic hub in the Middle East, offers considerable potential and opportunities. Many Chinese companies have set up operations in Dubai, using it as a transit hub to export to the UAE and other Middle Eastern countries, further strengthening and expanding their market share in the region.

According to estimates from JOINCHAIN, China's total medical device exports to Middle Eastern countries reached 24.361 billion RMB in 2024, marking a year-on-year increase of 26.24% and showing strong growth momentum. Among them, exports to Saudi Arabia, the UAE, and Turkey accounted for 60.53% of the total, with all three markets also showing significant growth.

## Regulatory Analysis of Medical Device in the Middle East

Medical device regulation in the Middle East is fragmented. While Gulf Cooperation Council (GCC) countries, including Saudi Arabia, Kuwait, the UAE, Qatar, Oman, Bahrain, and Yemen, have implemented partial mutual recognition mechanisms, and international certifications such as CE and FDA can serve as technical support to simplify reviews, companies are still required to complete local registration.

**Fig. Medical Device Regulation in Some Middle Eastern Countries**

| Country | Main Regulatory Authority | Regulatory Overview |
|---|---|---|
| **Saudi Arabia** | Saudi Food and Drug Authority (SFDA) | • SFDA classifies medical devices and in vitro diagnostic reagents into classes A, B, C, and D.<br>• Medical devices must be registered with SFDA via the "Medical Device List" or obtain Medical Device Marketing Authorization (MDMA) based on risk classification.<br>• FDA/CE certifications may be used to waive certain redundant testing requirements. |
| **UAE** | Ministry of Health and Prevention (MoHAP) | • UAE classifies medical devices into four classes: I, II, III, and IV.<br>• The registration process includes classification confirmation, preparation of technical documentation (product description, performance, safety, effectiveness data, etc.), and application submission via the MoHAP website.<br>• Devices approved in the EU, US, Australia, Canada, or Japan can benefit from simplified registration. |
| **Turkey** | Ministry of Health | • Turkey classifies medical devices into 4 categories: Class I, IIa, IIb, and III.<br>• Imported medical devices must have CE certification. Products with CE certification from the EU can enter the market directly, but those from other countries require additional testing. |

Source: Public Information, Frost & Sullivan Analysis.

# Countries and Regions of the "Belt and Road Initiative" Market Analysis - Middle East

The medical device regulatory environment in the Middle East combines international certification requirements with localized registration processes. Chinese companies entering the market must meet equivalent standards such as the EU CE mark and U.S. FDA approval, and also pass regional compliance reviews like those set by the Gulf Cooperation Council (GCC). This creates dual challenges in adapting technologies and ensuring supply chain resilience.

## Chinese Medical Device Global Expansion Key Challenges in the Middle East

**Significant market differences**

The 17 countries and regions in the Middle East differ in economic development, population size, business environment, market access, and policy frameworks, resulting in varied healthcare markets. For example, the United Arab Emirates has strong healthcare infrastructure and delivers high-end medical services, while Saudi Arabia is in a phase of rapid development but still has underdeveloped healthcare infrastructure. Companies pursuing global expansion into the region should develop country-specific strategies to integrate into local markets more effectively.

**influence of religious and cultural factors**

Religious and cultural traditions in the Middle East directly shape consumer behavior, social values, and interpersonal relationships. When pursuing global expansion into the region, Chinese medical device companies must comply with local language regulations and avoid culturally sensitive symbols. Before establishing business relationships, companies should gain a basic understanding of the region's religious and cultural context to build trust and facilitate cooperation.

**Complex and volatile political situation**

The Middle East's complex and changing situation, marked by political unrest, religious tensions, and major power rivalries, has slowed the development of healthcare infrastructure. In some countries, procurement plans have been delayed due to fiscal pressures or international sanctions.

**Challenges of localization targets**

The Middle Eastern market places high importance on localized services. In December 2023, Saudi Arabia set clear localization targets: 60% for medical and healthcare professionals, 30% for medical device engineering and technical roles, and 40% for medical device sales and import-related positions. In addition, countries such as the United Arab Emirates, Qatar, Kuwait, and Oman have also introduced policies to promote local manufacturing.

**Insufficient brand awareness**

The Middle Eastern market has long been dominated by strong competitors from Europe and the United States, which have built strong brand recognition and efficient product supply chains in the region. With high logistics costs and complex distribution networks, Chinese products entering the Middle East must be competitive enough to go head-to-head with those from Europe and the U.S.

Source: Public Information, Frost & Sullivan Analysis.

# Countries and Regions of the "Belt and Road Initiative" Market Analysis - Latin America

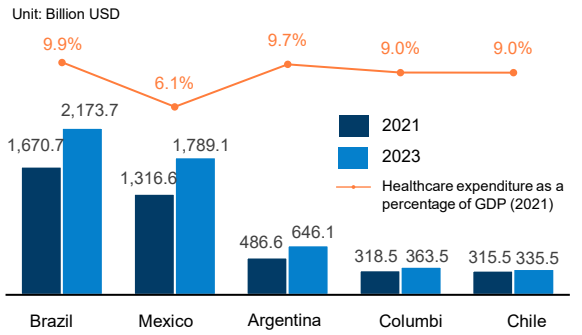
**Driven by demographic dividends and economic growth, healthcare demand in Latin America continues to rise. As the dual centers of the regional medical market, Brazil and Mexico serve as key strategic hubs for Chinese companies to strengthen their presence in Latin America and act as bridges to navigate geopolitical challenges.**

### Large but Uneven Economy, Population Potentials and Dividend Co-existed

Latin America consists of 33 Spanish- and Portuguese-speaking countries, including Mexico, Central America, South America, and the Caribbean. Major economies in the region include Brazil, Mexico, Argentina, and Colombia. With a total population of around 650 million and a combined GDP exceeding $6 trillion USD, the region is experiencing medium to high economic growth, though development levels vary widely between countries.

Brazil, which contributes about 30% of the region's GDP, stands as the core of the region due to its large economy and industrial base. Mexico, benefiting from its position in the North American Free Trade Agreement (NAFTA) region, has developed into a trade hub connecting North and South America. Both countries play critical roles in regional economic integration, resource development, and international cooperation.

**Fig. GDP and Healthcare Expenditure in Latin American Countries**




### Brazil has the Broad Medical Device Market and Mexico as Key Market in the Trade Chain

In the first half of 2024, exports of medical devices to Latin America increased by 18.04%, with a year-on-year growth of 9.3%. The region shows significant economic disparities. Countries with lower development levels rely entirely on imported medical devices, while more advanced economies both export and import, especially high-end medical devices. Taking Brazil as an example, Chinese medical device exports have performed strongly. According to data from Pure Global, the number of newly registered Chinese medical devices in Brazil has increased significantly. In Brazil's new medical device registrations in 2024, Chinese products accounted for nearly 30%.

Brazil has a relatively complete medical device industry and is capable of producing most medical equipment locally. However, certain high-end electronic imaging diagnostic devices, such as CT scanners, MRI machines, and PET scanners, still rely on imports from Europe and the United States. Cosmetic appearance is highly valued in Brazil, and some plastic surgeries are even covered by public health insurance. In addition, as the population ages, the burden of chronic disease treatment is increasing, creating significant market demand for devices and consumables related to diabetes and cardiovascular diseases. Due to ongoing challenges in controlling infectious diseases such as dengue fever and Oropouche fever, there is also considerable market potential in the in vitro diagnostics (IVD) sector.

Brazil's medical device market access system is based on a risk classification framework, with different regulatory pathways depending on the product risk level. The Brazilian Health Regulatory Agency (ANVISA) divides the registration process into a simplified registration (Cadastro) for low-risk products and a full registration (Registro) for medium- and high-risk products. To support innovation in medical technology, Brazil has been continuously improving its regulatory system, for example, issuing special regulations for custom-made medical devices in 2019 and revising its overall medical device regulations in 2022 to accommodate new materials and technologies. In addition, for Class I medical devices and in vitro diagnostic (IVD) products, Brazil established a special notification-based approval pathway in 2019, which simplified the entry process for low-risk products.

Public hospitals and clinics in Brazil are funded by the government, and the public healthcare system covers all medical expenses. When purchasing high-value medical devices, public hospitals must initiate a tender process by publishing bidding requirements on official government websites. Only companies with valid business licenses can participate in the bidding. Chinese companies can leverage their cost-effectiveness to enhance their competitiveness in these procurement processes.

Mexico is the second-largest medical device market in Latin America. With a population of over 130 million and a GDP exceeding $4 trillion USD, the country continues to show strong demand for healthcare. In 2023, the Mexican government allocated 5.7% of its GDP to the healthcare sector, accelerating infrastructure development.

Mexico enforces strict regulation of medical devices through the Federal Commission for the Protection Against Sanitary Risks (COFEPRIS). Devices are classified into low-risk and Class I to Class III categories. To complete the registration process, companies must submit technical documents, clinical trial data, and other required materials.

Mexico holds a geographic advantage as the largest importer of U.S. medical devices. Its proximity helps reduce transportation costs and delivery times. Trade agreements such as the North American Free Trade Agreement (NAFTA) and its successor, the United States-Mexico-Canada Agreement (USMCA), have lowered tariffs and trade barriers for Mexican medical devices entering the U.S. market, making them more price competitive. Mexico also serves as a transit hub, facilitating the entry of products from other countries into the U.S. market.

Source: Public Information, Frost & Sullivan Analysis.

# Countries and Regions of the "Belt and Road Initiative" Market Analysis - Latin America

The Latin American market has unique language and cultural requirements, which increase the difficulty of regulatory compliance. Some Chinese medical devices entering Brazil are required to obtain INMETRO certification, which involves the review of technical documentation, factory audits, and localized testing.

## Chinese Medical Device Global Expansion Key Challenges in Latin America

**Economic volatility**

The Latin American region faces significant economic volatility. Inflation, sharp exchange rate fluctuations, and periodic economic crises directly impact consumer purchasing power and the investment capacity of medical institutions, leading to unstable demand in the medical device market. In addition, global economic uncertainty raises financing and operating costs, making it more difficult for companies to develop long-term strategies.

**Lack of transparency**

The lack of transparency is mainly reflected in market regulation, policy changes, and the competitive landscape. Countries in Latin America differ significantly in regulations, certification standards, and medical procurement policies. Meanwhile, data is often released neither promptly nor in sufficient detail, making it difficult for companies to access accurate information for market entry, risk assessment, and product positioning. In addition, language and cultural differences create communication barriers that make it harder for businesses to quickly understand market trends and competitor activities.

**Localization challenges**

The Latin American market is geographically distant from China, and the inadequate infrastructure in some countries increases the difficulty and cost of building logistics, warehousing, and after-sales service networks. The long distance results in longer shipping times and higher risks. At the same time, local markets often have fragmented sales channels, limited talent availability, and underdeveloped service systems, further complicating localization efforts for companies.

**Intense competition**

European and American brands have long-standing advantages in technology, brand trust, and after-sales service systems, and they have already built mature networks in the Latin American market. With the support of local marketing and service teams, they are able to better meet local consumer needs, forming strong market barriers and creating significant competitive pressure for Chinese companies.

### Brazil Medical Devices: INMETRO Certification

Brazil's medical device registration system is overseen by the Brazilian Health Regulatory Agency (ANVISA) and follows a risk-based classification. Class I and II devices go through a simplified Cadastro process, while Class III and IV devices require full Registro registration and must comply with ANVISA's GMP. Companies should prepare technical documents, compliance materials, and market plans in advance to ensure successful entry into the Brazilian market.

Medical devices marketed or sold in Brazil face complex and constantly evolving compliance procedures, including product testing, INMETRO certification for specific types of devices, BGMP inspections, and ANVISA registration.

Most active medical electrical equipment and certain non-active medical devices must be certified by a certification body accredited by INMETRO before they can obtain ANVISA registration.

INMETRO only accepts test reports issued by its recognized organizations or by members of international accreditation bodies such as IAAC, EA, or ILAC. Approved devices will receive a certification from INMETRO and be authorized to display the INMETRO certification mark.

UL Solutions

**Brazilian subsidiary, recognized as a certification body by INMETRO (National Institute of Metrology, Standardization and Industrial Quality), is authorized to provide audit and certification services for medical device manufacturers in Brazil.**

The INMETRO certification primarily involves the review of the product's technical documentation.

This review consists of two main components:

The UL Solutions Brazil team conducts an on-site QMS audit of the Brazilian Representative in Brazil. — *Brazil*

In China, the UL Solutions China team carries out a QMS audit of the local medical device manufacturer. — *China*

Source: Public Information, Frost & Sullivan Analysis.

# ■ ISO 13485 / MDSAP / INMETRO

**ISO 13485, MDSAP, and INMETRO are important quality management system (QMS) certifications in the medical device industry. These certifications help manufacturers ensure product quality and meet the requirements of global markets.**

## ■ ISO 13485 Quality Management System Certification: about Medical Device Manufacturer

ISO 13485 is an independent standard specifically developed for the medical device industry. With this standard, companies can respond flexibly to market changes and global competition. Certification is granted only after passing an on-site audit conducted by a qualified auditor, followed by annual surveillance audits.

The ISO 13485 certification follows a three-year audit cycle and includes the following audit activities:

### Certification Audit

A full audit of the manufacturer's Quality Management System (QMS) in accordance with requirements consists of two stages:

**Stage 1**

Through an on-site audit or evaluation of essential company information, the company's eligibility for certification is determined. This process includes a review of sample quality management documentation.

The company will receive a corresponding audit report, which includes a list of any identified nonconformities.

**Stage 2**

The actual implementation of the quality management system will be audited, and its effectiveness will be evaluated.

Once full compliance with all requirements is confirmed, the organization will be issued a certificate, demonstrating the completeness of its quality management system and its conformity to the standard.

### Surveillance Audit

In the two years following initial certification, annual surveillance audits are conducted to measure ongoing compliance with ISO 13485 and any applicable regulatory programs.

### Recertification Audit

A recertification audit is performed in the final year of the three-year certification cycle. This evaluates the progress and ongoing performance of the registered QMS and initiates a new three-year certification cycle.

## ■ Medical Device Single Audit Program (MDSAP)

**Concept and Purpose**

The Medical Device Single Audit Program (MDSAP) is an international cooperation framework initiated by the International Medical Device Regulators Forum (IMDRF). It aims to establish a unified audit standard and process by authorizing third-party auditing organizations recognized by the IMDRF to conduct a comprehensive compliance audit of medical device manufacturers. A single audit report can simultaneously fulfill the regulatory requirements of multiple participating countries.

**Audit Cycle**

The MDSAP audit cycle takes every three years and includes an initial audit, surveillance audits in the first and second years following certification, and a recertification audit in the third year. The initial audit comprises two stages, with the second stage involving a full assessment of the manufacturer's QMS.

**Advantages and Role**

MDSAP not only reduces the resource burden of multiple audits for manufacturers but also enhances transparency and consistency in global medical device regulatory oversight through international regulatory collaboration. This contributes to a more efficient and secure global distribution system for medical devices

**Participating Organizations**

Currently, the regulatory authorities participating in the MDSAP program include the U.S. FDA, Health Canada, the Australian Therapeutic Goods Administration (TGA), Japan's Pharmaceuticals and Medical Devices Agency (PMDA), and Brazil's Brazilian Health Regulatory Agency (ANVISA).

**About ISO 13485 / MDSAP / INMETRO certification audit services**

***One application, two Audits, three certificates***

Medical device companies can apply for ISO 13485: Medical devices – Quality management systems, the Medical Device Single Audit Program (MDSAP) and INMETRO certifications at the same time through UL Solutions. Both ISO 13485 and MDSAP certifications involve two-stage audits, and the audit services for both certifications can be scheduled to take place simultaneously. Upon successful completion, eligible companies will receive two separate certificates. For the INMETRO certification, one of the audits must take place at the manufacturer's factory in China. This audit can be arranged to coincide with either stage of the ISO 13485 or MDSAP audit. If all certification requirements are met, the corresponding certificate will be issued.
This audit approach offered by UL Solutions helps reduce the overall audit time and lower compliance costs for companies.
By simplifying a key step in the medical device approval process, UL Solutions supports Chinese medical device manufacturers in bringing their products to global target markets more quickly and efficiently.

**Source: Public Information, Frost & Sullivan Analysis.**

# Countries and Regions of the "Belt and Road Initiative" Market Analysis - Africa

Africa has a large population and growing medical needs. China's exports of medical devices to Africa have been steadily rising. However, Chinese companies face multiple challenges, such as weak payment capacity, the need for localized operations, supply chain alignment, and differences in healthcare systems.

## Diverse Economies among Different Countries, Significant Healthcare Gaps

Africa is commonly divided into North Africa, Sub-Saharan Africa (further split into West, Central, East, and Southern Africa), and special regions such as the Sahel and the Horn of Africa, each with distinct characteristics. In terms of total GDP, the continent's "big three" economies are Egypt in the north, Nigeria in the center, and South Africa in the south. Overall, Africa's economic development remains behind, facing systemic issues such as insufficient medical resources, poor healthcare infrastructure, widespread infectious diseases, and high mortality rates.

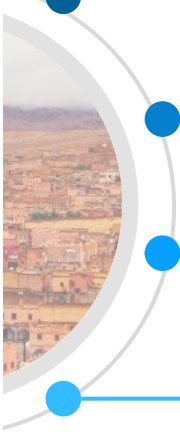
**Figure: GDP and Healthcare Expenditure in Afrian Countries**

| Region | | Representative Country | 2023 GDP per Capita (USD) | 2021 Health Expenditure per Capita (USD) | Major Diseases |
|---|---|---|---|---|---|
| North Africa | Primarily Arab culture and Islamic religion; economy relies on oil, natural gas, and tourism | Egypt | 3,728 | 615.5 | Ischemic heart disease, chronic non-communicable diseases |
| | | Morocco | 3,889 | 515.8 | Ischemic heart disease, chronic non-communicable diseases, tuberculosis |
| West Africa | Centered around Nigeria; economy depends on oil and agriculture | Nigeria | 1,688 | 220.4 | Lower respiratory infections, malaria, cholera, Lassa fever |
| | | Ghana | 2,318 | 247.9 | Stroke, tuberculosis, malaria, pneumonia |
| Central Africa | Rich in mineral resources but plagued by frequent conflict | DR Congo | 673 | 45.6 | HIV/AIDS, tuberculosis, malaria, monkeypox |
| East Africa | Rapid economic growth and strategic geographic position, but affected by drought and regional conflicts | Kenya | 2,113 | 237.0 | Tuberculosis, HIV/AIDS, cholera, malaria |
| | | Ethiopia | 1,511 | 81.7 | Malaria, lower respiratory infections, diarrheal diseases, HIV/AIDS |
| Southern Africa | Led by South Africa; relatively high level of industrialization | South Africa | 6,138 | 1209.9 | Acute upper respiratory infections, tuberculosis, HIV/AIDS, malaria |
| | | Angola | 2,566 | 198.6 | Lower respiratory infections, tuberculosis, malaria, cholera, cancer |

## Low Purchasing Power, Focus on Low-value Consumables

According to data from the General Administration of Customs of China, in 2021, Chinese medical device exports to South Africa totaled $353 million USD, with medical consumables making up nearly 80%. South Africa was the largest destination for such exports, with a trade surplus of $344 million USD. Besides South Africa, other major destination countries included Egypt, Nigeria, Morocco, and Algeria, which together accounted for over 50% of exports in the first three quarters of 2022. In 2023, China's total medical device exports to Africa reached $1.966 billion USD, a year-on-year increase of 3.03%. Overall, China's exports to Africa are centered on medical consumables, showing regional concentration, stable country distribution, and steady market growth.

## Chinese Medical Device Global Expansion Key Challenges in Africa



**Immature Market System**

Africa's medical market lacks a comprehensive regulatory system. Some countries rely on international certifications such as the FDA and CE. At the same time, weak local distribution networks and asymmetric market information lead to high costs for both market entry and product maintenance.

**Limited Payment Capacity**

Medical demand in Africa continues to grow, but health insurance coverage is generally below 30%, and most patients pay out of pocket. With daily income often under 3 USD, the market is highly sensitive to price. This creates a dilemma for Chinese medical device companies, they must compete with international products while keeping costs low to maintain affordable pricing, putting pressure on profit margins.

**Insufficient Localization and Service Networks**

The African market relies heavily on distributor-based models. Companies often outsource after-sales and maintenance services to local agents, which helps expand distribution quickly but results in disconnected service chains and a lack of customized solutions for different regions. Meanwhile, the shortage of skilled technical personnel and poor infrastructure further limit operations, leading to high training costs and difficulties in building a reliable logistics network.

**Volatile External Environment**

According to the Country Guide, some African countries face serious exchange rate fluctuations, debt risks, and political unrest. For example, the Ethiopian birr has depreciated more than threefold over the past ten years, and strict foreign exchange controls make it hard for businesses to receive payments. In some areas, project delays and payment issues are common due to clients' weak financial capacity, leading to cash flow risks. In addition, unstable security conditions affect companies' ability to establish and operate locally.

**Source: Public Information, Frost & Sullivan Analysis.**

# Countries and Regions of the "Belt and Road Initiative" Market Analysis - Russia

Russia's medical device sector has faced supply chain disruptions due to international geopolitical tensions. This has created a strategic window of opportunity for Chinese companies to expand into the high-end medical equipment market by leveraging their cost-effectiveness and localized service advantages.

## Macroeconomy and Demographics of Russia

**Economy[1]**

- **2.02 trillion USD** GDP
- **↑3.6%** Year-on-Year Growth
- **13,800 USD** GDP per Capita

**Population[1]**

- **144 Million** Total Population
- **↓0.3%** Year-on-Year Decline
- **17%** Aging population proportion (65 years and older)

**Healthcare Expenditure[2]**

- **138 Billion USD** Healthcare Expenditure
- **7.39%** of GDP
- **919 USD** Healthcare Spending per Capita

**Patients[3]**

- **Leading Causes of Death:** Acute upper respiratory infections, ischemic heart disease, stroke, tracheal/bronchial/lung cancer
- **73** Average Lifetime[4]

Note 1: Based on World Bank, 2023 data; Note 2: 2023 data; Note 3: Based on WHO, 2021 data; Note 4: Based on World Bank, 2022 data

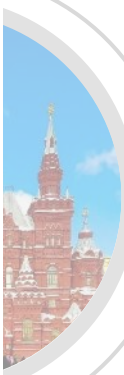
## Strategic Opportunity for Export to Russia

Chinese medical device exports to Russia are entering a strategic window of opportunity. Due to the ongoing geopolitical situation, Russia's medical device market, traditionally dominated by Europe and the United States, has seen supply chain disruptions, opening a path for Chinese companies. The growth of Russia's medical device market is driven by three key factors: continued increases in government investment in healthcare; a rapidly aging population, which is driving demand for chronic disease management and rehabilitation services; and the deepening of China-Russia strategic cooperation, which creates a favorable environment for medical technology partnerships. Chinese companies are currently expanding into the Russian market, especially in high-end segments such as diagnostic imaging and infectious disease prevention, by leveraging their cost-performance advantage and localized service capabilities.

In recent years, the Russian government has intensified its efforts to reform the healthcare system. By 2022, the Russian medical device market had reached a size of approximately *$12 billion USD*. Although domestic manufacturers in Russia have achieved a certain scale, they mainly focus on basic equipment and supplies. High-end medical devices are still largely dependent on imports, such as interventional devices and intensive care equipment. Multinational medical device companies hold a significant share of the Russian market, typically by establishing subsidiaries within the country. The market is now showing clear demand trends: high-end, multifunctional, and smart devices are becoming increasingly preferred. With a growing focus on disease prevention and rising demand for home-use medical equipment, the Russian medical device market is projected to reach around *$14 billion USD* by 2025.

Among the Belt and Road countries, Russia ranks first in terms of Chinese medical device export volume. In 2024, Chinese medical device exports to Russia reached *$1.418 billion USD*. Although this represents a year-on-year decline, Russia has been the fastest-growing export destination for Chinese medical devices in recent years, and its market potential remains highly promising.

## Chinese Medical Device Global Expansion Key Challenges in Russia



**Complex market access procedures**

Chinese companies must submit a large amount of documentation to meet Russian regulatory requirements, including technical documents, clinical evaluation reports, and manufacturer details. For companies unfamiliar with local laws, this process is very challenging. The complexity of registration lies not only in the documents themselves, but also in the long approval period. Even with all documents prepared, approval can take more than a year, often delaying companies' market entry plans.

**Lack of multi-disciplinary talent**

Russia requires all registration documents to be officially translated into Russian. However, professional Russian medical translation resources are limited in China. Communication between Chinese and Russian parties often relies on English, which is not the native language for either side. Staff language abilities vary, increasing the risk of translation mistakes that may affect approval results. In addition, cultural differences and business habits can also lower the success rate of commercial negotiations.

**Intensified market competition**

Russia is promoting import substitution in the medical device sector through tax reductions, financial subsidies, and R&D support for local manufacturers. The government also gives priority to purchasing locally made products, making imported medical devices less competitive in both price and market share. For some key product categories, Russia has imposed import bans, directly blocking foreign companies from entering those markets. These policies have reduced the competitiveness of Chinese products, forcing companies to adjust their product portfolios or even exit certain niche segments, which further narrows their profit margins.

**Uncertainty in political and economic environment**

Regulatory updates to Russia's medical device registration system often lack transparency and advance notice, requiring companies to invest significant resources to track ongoing changes. In addition, global political tensions have increased risks, such as the possibility of stricter import controls caused by sanctions or diplomatic issues. This uncertainty makes it hard for companies to plan long-term strategies and raises the hidden costs of market entry. Under these conditions, companies in the medical device industry must also consider risks such as local currency depreciation, payment difficulties, and expectations of economic slowdown when doing business with Russia.

**Source: Public Information, Frost & Sullivan Analysis.**

# Countries and Regions of the "Belt and Road Initiative" Market Analysis - India

As an emerging economy, India is seeing growing demand for healthcare, bringing Chinese medical device companies two key opportunities: improving cost-performance and expanding market presence.

## Fast-growing Economy, Large Population, Increasing Medical Spending in India

**Economy[1]**

- **3.57 trillion USD** GDP
- **↑8.2%** Year-over-year growth
- **2490.79 USD** GDP per capita

**Population[1]**

- **1.438 billion** Total population
- **0.9↑%** Year-over-year growth
- **7%** Aging population proportion (65 years and older)

**Healthcare Expenditure[2]**

- **103.98 billion USD** Healthcare expenditure
- **3.28%** of GDP
- **74 USD** Healthcare expenditure per capita

**Patients[3]**

- **Top 5 causes of death:** COVID-19, Ischemic heart disease, Chronic obstructive pulmonary disease, Stroke, Diarrheal diseases
- **67.3** years Life expectancy

Note 1: Based on World Bank, 2023 data; Note 2: Based on World Bank, 2021 data; Note 3: Based on WHO, 2021 data

## Diverse Market in India, High-end Equipment Relies on Imports

India is actively exploring ways to build an inclusive healthcare network. Through the PM-JAY National Health Assurance Scheme, the government provides hospitalization coverage for 40% of the poor population, showing its strategic commitment to universal healthcare. The Indian medical market is developing in diverse directions. Private healthcare institutions account for 75% of the market and play a key role in service delivery. Their strong capacity in high-end diagnostic equipment (CT, MRI, PET) has helped raise overall medical standards, but it also concentrates resources among patients with stronger payment ability. In total healthcare spending, 75% comes from private out-of-pocket payments, while only 25% comes from public funding. Government investment in healthcare is far below global average levels.

Since the implementation of the Medical Device Rules (MDR) in 2017 and the upgrade to a classification-based management system in 2020, India's regulatory framework has gone through three stages of evolution. However, while compliance procedures have become more detailed, Indian domestic industry development has not kept up. These regulatory improvements mainly focus on the qualification of imported products rather than strengthening local innovation capabilities. Reports show that around 75%–80% of medical devices in India rely on imports, and the import value is expected to exceed $10 billion USD by 2025.

## Rapid Growth of Chinese Medical Device in Exports to India

In 2023, Chinese medical device exports to India reached 7.601 billion RMB, increasing to 8.362 billion RMB in 2024, a year-on-year growth of over 10%, remaining at a high level. Mindray Medical supplies monitors and anesthesia machines to major private hospitals, and handheld ultrasound systems from Angell Technology have also entered the Apollo hospitals network. Indian leading companies like Transasia and Trivitron purchase Chinese equipment or components for local assembly and distribution.

## Chinese Medical Device Global Expansion Key Challenges in India

**Complex regulations / High entry barriers**

India's medical device regulatory system is jointly managed by the Central Drugs Standard Control Organization (CDSCO) and various state-level authorities, resulting in inconsistencies in regulatory interpretation and enforcement. The registration process is complicated. Since 2020, all medical devices have been subject to mandatory registration and licensing based on classification from Class A to D. Compliance requirements also apply to product labeling, user manuals, and advertising. High-risk devices must submit more detailed clinical data and quality management certifications. Companies are required to establish local manufacturing or contract manufacturing in India to meet registration standards, which significantly increases entry barriers and operating costs.

**Price sensitivity**

In India's healthcare system, most of the population has limited purchasing power and is highly sensitive to product prices, especially in small and mid-sized hospitals and primary-level markets. Local companies offer more competitive pricing, forcing Chinese firms to keep narrowing their profit margins. Yuwell Medical reported that Indian distributors often reject entire containers due to issues with a single product and push hard for lower procurement prices, leaving very little room for profit and increasing the difficulty of cooperation.

**Geopolitical and trade risks**

Since the China-India border conflict, India has gradually imposed import restrictions on certain Chinese products and may implement higher tariffs or quota controls in the future for trade protection purposes. Although Chinese medical devices have advantages in both technology and pricing, and market demand remains strong, the export environment faces policy-related uncertainties. To reduce risk, some companies have started considering re-export trade through Southeast Asia.

**Heavy reliance on distribution channels**

Most Chinese companies do not have local subsidiaries in India and mainly rely on partnerships with local distributors. However, the overall business environment in India is challenging, and control over distribution channels is weak. Distributors are highly sensitive to pricing and after-sales services, leading to high communication and management costs. Key risks are concentrated in payment, returns, and after-sales processes. Experts note that a conservative "cash on delivery" model is widely used, which limits deeper market expansion and brand development efforts.

Source: Public Information, Frost & Sullivan Analysis.

# Chapter 5

# Key Difficulties and Trends of Chinese Medical Device Global Expansion

05

# Key Difficulties Analysis of Chinese Medical Device Global Expansion

**For Chinese medical device companies, going global without a clear globalization strategy and a full-process solution covering market access, distribution channels, and regulatory compliance will significantly increase the cost of trial and error.**


### Strategic Positioning Unclear: Lack of alignment between self-assessment of capabilities and strategic path selection

***If companies fail to systematically assess their technological capabilities and resource endowments, it can lead to mismatches in strategic path selection and result in fragmented strategic objectives.***

Some medical device companies suffer from unclear strategic positioning, which disrupts balanced decision-making processes. For example, some companies equate a single technological breakthrough with market competitiveness but lack a comprehensive system to evaluate their core capabilities. This cognitive bias results in arbitrary and ungrounded strategic decisions. Without firm strategic focus, management frequently shifts development directions, causing scattered resource allocation. More importantly, vague strategic positioning also leads to misjudgment in resource planning, resulting in imbalanced distribution.

To address this issue, companies need to establish a systematic strategic framework. This includes defining technological boundaries through measurable indicators and using strategic alignment tools to coordinate both financial and non-financial goals, ensuring stability and flexibility in strategic direction throughout the globalization process.

### Global Expansion Hindered: Absence of a systematic master plan and essential capabilities

***In global expansion, the absence of a structured plan, complete process framework, and detailed execution measures leads to challenges in market selection, regulatory strategy, and channel development.***

Some companies lack a phased and structured approach in their global expansion, which hinders international market development. They have not built a complete framework from market research to compliance execution, and lack a deep understanding of key implementation details. For instance, market entry decisions are often made solely based on local demand, without considering the compatibility of local healthcare infrastructure, differences in payment capacity, and the complexity of the competitive landscape. In the certification stage, the focus is often limited to obtaining regulatory approval, with little attention to clinical data localization strategies. In terms of channel development, there is excessive reliance on distributors, while neglecting market-specific procurement decision chains.

These issues are because of the lack of a professional international regulatory team, a shortage of cross-functional talent with cross-cultural management experience, and the absence of a flexible decision-making model for global expansion. As a result, there is a gap between strategic planning and execution, early-stage market research does not align with mid-stage implementation, and technological strengths fail to convert into commercial success.

EMERGO by UL

***Support Chinese companies in overcoming global expansion bottlenecks through end-to-end services (regulatory, clinical, manufacturing, and market access)***

**Regulatory Consultation & Market Access Support**

**Target Market Regulatory Adaptation: Provide tailored registration and customs clearance support for European, American, and emerging markets.**
**Technical Documentation and Quality Management Systems: Assist companies in preparing technical documents that comply with international standards, ensuring product design validation, risk analysis, and clinical data compliance.**

**Clinical Trials & Localization Strategies**

**Multicenter Clinical Trial Design: Develop clinical trial protocols for complex products that meet the regulatory requirements of target countries.**
**Localization of Usability Adaptation and Clinical Collaboration: Assist in partnering with local medical institutions to optimize product functionality and conduct human factors usability studies tailored to different healthcare settings.**

**Supply Chain & Manufacturing Compliance**

**Global Supply Chain Optimization: Assist companies in establishing subsidiaries or production bases overseas to meet manufacturing requirements;**
**Production Compliance and Audits: Provide GMP audits, factory inspections, and supplier management services to ensure products comply with the manufacturing standards of target markets.**

**Intellectual Property & Risk Management**

**Patent Strategy and Infringement Avoidance: For innovative technologies such as surgical robots, offer support in analyzing international patent landscapes to mitigate risks of intellectual property infringement.**
**Risk Management and Recall Response: Establish global post-market surveillance systems and develop emergency plans for product recalls to reduce operational risks in overseas markets.**

**Market Expansion & Brand Building**

**Market Analysis and Competitive Strategy: Provide analysis of the competitive landscape in target markets to help companies develop differentiated strategies.**

**Technology Upgrades & Standards Evolution**

**Integration of AI and Remote Technologies: Provide consulting on updates to technical standards in response to the growing demand for smart medical devices.**
**Real-Time Monitoring of International Standards: Track regulatory changes such as the EU MDR and FDA digital health guidelines to ensure that enterprise technology upgrades align with the latest requirements.**

Source: Public Information, Frost & Sullivan Analysis.

# Key Difficulties Analysis of Chinese Medical Device Global Expansion

**Chinese medical device companies often face difficulties in accurately selecting target markets during global expansion due to a lack of precise assessment of overseas healthcare system complexities and regional characteristics, limited understanding of local competitive dynamics, and overreliance on a single market by some companies**

## Inaccurate Expansion Destination Assessment

### Enterprises lack accurate assessment of the healthcare system and reimbursement mechanisms in target markets.

***Insufficient attention to the differences in healthcare reimbursement systems across target markets makes it difficult for companies to accurately adjust product positioning and develop differentiated market entry strategies.***

These differences have a significant impact on how medical device companies position their products. Many companies lack accurate judgment when facing various insurance models and procurement decision chains. For example, in the U.S., the commercial insurance, driven system and the key role of Group Purchasing Organizations (GPOs) require companies to focus on cost-effectiveness and large-scale supply. In Europe, where healthcare payments are mainly government-funded, companies need to prioritize public tender rules and long-term cost control. In developing markets such as India and Brazil, policies may favor local production or import substitution, and may include tariff and non-tariff barriers to protect domestic industries.

### Over-reliance on a single market weakens adaptability to market fluctuations

***Overconcentration on a single market can lead to one-way dependency between resources and market outcomes, reducing a company's resilience to external fluctuations.***

When a company focuses too much on one market, it can easily fall into a cycle where investment and feedback are locked into a single path. This kind of path dependency weakens its ability to respond to unexpected changes. If the target market experiences sudden policy changes, economic shifts, or demand fluctuations, companies without diversified market presence may see their revenue structure disrupted due to a lack of alternative markets. In the context of globalization, companies that fail to evaluate policy stability and economic links across markets, and instead rely too much on one market, will lack the risk-mitigation capacity that diversified layouts offer.

### Insufficient awareness of compliance risks in destination markets leads to resource inefficiencies

***Companies face increasing difficulty in sustaining the high costs required to manage complex compliance processes, due to significant differences in certification regulations across markets and a trend toward stricter oversight.***

Market access rules vary widely. For example, the U.S. FDA offers the 510(k) fast-track pathway; the EU has implemented the comprehensive CE-MDR regulatory framework; and Japan's PMDA enforces strict technical standards. Companies must cope with high costs, long approval timelines, and the need to build complex compliance management systems.

Both the U.S. and the EU are tightening their regulatory regimes. The EU not only enforces the new MDR rules but also issues detailed technical guidance through MDCG documents. Although transition deadlines for certain legacy devices have been extended, many manufacturers still lack the ability to fully interpret regulatory clauses and manage compliance risks. Meanwhile, the U.S. FDA is proactively incorporating cybersecurity into lifecycle regulation and has issued updated EMC (electromagnetic compatibility) guidelines. These regulatory upgrades significantly increase the difficulty of technical adaptation for companies.

### Lack of foresight into overseas competitive landscapes hinders strategic planning

***Many companies face strategic blind spots in global expansion due to a lack of systematic research into overseas competitive landscapes, including technical barriers set by foreign companies and channel monopolies built by local brands.***

There is a disconnect between companies' understanding of international rules and the actual competitive environment. The relatively relaxed domestic patent system has led to inertia in R&D planning. As a result, companies often find themselves unprepared when facing stricter global intellectual property regulations. This lack of forward-looking planning results in frequent overseas patent disputes, rising rates of litigation losses, and damage to brand reputation, which severely limits their global expansion.

Many companies also lack in-depth assessment of competitive dynamics in target markets. They underestimate the channel advantages and brand equity of local players and overlook the technical barriers established by well-established multinational firms. This leads to an overestimation of their own product strengths, making it difficult to compete in highly competitive environments.

Source: Public Information, Frost & Sullivan Analysis.

# Key Difficulties Analysis of Chinese Medical Device Global Expansion

**A deficient understanding of foreign registration protocols and quality standards results in an inability to maintain compliance, triggering regulatory or quality incidents**

## Lack of Understanding of Market Access Procedures

### Divergent and evolving global standards demand more robust quality and operational systems

***Regulatory standards for emerging product categories are often unclear, and key regulations are frequently updated. This leads companies into repeated communication due to classification disputes and makes it difficult to adjust compliance strategies over time.***

Registration and regulatory frameworks vary globally based on local realities and market factors; achieving a precise, in-depth, and professional understanding of these diverse policies is a significant challenge for corporate operations and product control. Ambiguity comes from different markets lacking clear definitions for new product categories, while dynamism is reflected in frequent updates to major regulations such as the EU MDR and the FDA's digital health guidelines. Requirements for clinical data, quality management systems (QMS), and traceability continue to increase, making real-time strategy adjustments challenging. This uncertainty significantly raises compliance costs. Many companies choose to work with professional service providers and adopt real-time regulatory monitoring systems to better align technology upgrades and reduce risk during global expansion. In some countries, such as the EU, which recently updated MDR, regulatory requirements for clinical data, QMS, and traceability are becoming stricter, yet many companies still lack the ability to keep up and adapt their strategies accordingly.

### As medical device technology advances, testing standards become more demanding

***Regulatory standards for emerging product categories are often unclear, and key regulations are frequently updated. This leads companies into repeated communication due to classification disputes and makes it difficult to adjust compliance strategies over time.***

Medical devices are becoming more complex and require advanced testing and certification to assess safety, performance, and compliance with regulations. Active medical devices, due to their nature, may pose risks during use, such as electric shock, fire, or mechanical injury, potentially harming users or patients. The most direct way to assess their safety from design to use is to conduct tests based on electrical safety standards. By developing a complete testing strategy, manufacturers can streamline testing and certification, save time, and simplify compliance. As modern medical devices often operate in complex electromagnetic environments, regulations in many countries require them to function properly without causing harmful electromagnetic interference to other equipment. This is known as EMC (Electromagnetic Compatibility) requirements. EMC testing helps evaluate potential interference between nearby devices and the risk of harm to people or the environment. It also verifies whether a device can perform as expected in its intended electromagnetic environment.

UL Solutions provides testing and certification services, including electrical safety, EMC, and cybersecurity, for active medical devices, helping companies meet complex regulatory requirements.

UL Solutions

As a safety science expert, UL Solutions is dedicated to driving innovation in the healthcare industry. With decades of technical, regulatory, and clinical expertise, it helps companies address regulatory challenges and bring products to market faster.

UL Solutions' testing and compliance engineers work closely with standards committees to stay informed of the latest updates and upcoming changes to standards. These committees include the American National Standards Institute (ANSI) and the International Electrotechnical Commission (IEC).

UL Solutions offers one-stop services to support companies to save time and reduce costs. Its full range of services includes final product testing, certification, and verification, covering electromagnetic compatibility (EMC), wireless, safety, interoperability, cybersecurity, and biocompatibility testing, as well as global market access.

Source: Public Information, Frost & Sullivan Analysis.

# Key Difficulties Analysis of Chinese Medical Device Global Expansion

In the global expansion of Chinese medical device companies, challenges may arise due to the lack of teams with local decision-making capabilities on the operational side, and the continued reliance on traditional export models on the supply chain side, leading to limited real-time responsiveness. At the same time, companies must seek a balance between building technological trust and breaking through market competition.


### Weak local team building and supply chain

***Many companies face limited international operational capabilities and difficulties in building overseas teams. Some lack real-time supply capacity and overlook localized market needs, further increasing the difficulty of aligning their supply chains.***

Although some companies have established overseas branches, their operations are often limited to sales functions and lack teams with real authority, management capability, and local decision-making power. International teams need to understand local healthcare systems and cultural contexts, but many companies lack cross-border management experience and face challenges in managing cross-cultural conflicts.

On the supply chain side, many companies still follow a traditional export model for product delivery, lacking local warehousing and real-time supply mechanisms. Their ability to provide fast delivery and localized after-sales support is weak, which affects customer decision-making. Moreover, without local warehousing, companies cannot adjust their product offerings in time, leading to mismatches between supply and demand and increasing the difficulty of supply chain alignment.

### Complex execution mechanisms: weakened organizational collaboration leads to difficulties in strategy implementation

***Ambiguous responsibilities between headquarters and overseas branches, limited decision-making authority at local offices, and a disconnect between strategic planning and execution have led to low strategic implementation efficiency for some companies.***

In the process of global expansion, some companies continue to use a vertically centralized management model from their domestic operations, exposing deep-rooted issues in organizational structure and control. Overseas branches often lack decision-making power and are reduced to mere execution units, making it difficult to respond to complex and fast-changing market competition. While initial market entry may be achieved, rigid structures and inflexible processes make it hard to establish a deeper, long-term presence.

Weak organizational coordination and outdated execution mechanisms have become major obstacles to improving localization capabilities. In some cases, strategic goals are not aligned with resource allocation, and there is a gap between strategic planning and execution. As a result, companies struggle to turn strategic visions into actionable operational systems, leading to low efficiency in strategy implementation.

### Low brand trust and pressure from international competition

***The "Made in China" stereotype and geopolitical risks, along with intense global market competition, make it difficult for companies to balance technological security with market trust.***

Chinese medical devices face low brand recognition in overseas markets. In developed countries such as those in Europe and North America, there is price sensitivity toward low- to mid-end devices, but a lack of brand trust in high-end products from Chinese manufacturers. In addition, U.S.-China trade tensions and technological decoupling have raised concerns in some markets about the technological security of Chinese firms, especially in areas like AI medical devices involving data privacy. As a result, companies face difficulties in gaining market access without solid clinical data, promotions from KOLs, or by acquiring local brands.

At the same time, global competition remains fierce. Western companies have long dominated the high-end market, while local players in emerging markets compete through low-price strategies. Chinese manufacturers face dual pressures from both ends of the market.

Source: Public Information, Frost & Sullivan Analysis.

# Trends Analysis of Chinese Medical Device Global Expansion

## Trend 1 *Increased R&D Investment and Product Innovation*

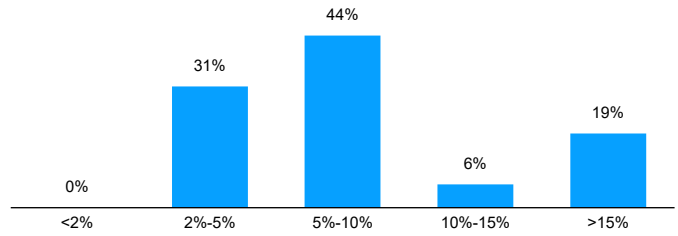
**Chinese medical device companies need to strengthen their global competitiveness through technological innovation and R&D, and accelerate overseas certifications to overcome market barriers.**

As the global medical device market moves toward high-end, smart, and specialized development, Chinese companies are accelerating the development of a competitiveness system centered on independent R&D. By increasing R&D investment and focusing on core technologies, they are making real progress in innovation.

According to Roland Berger's Global Medical Device Report 2024, which surveyed 600 executives from medical device companies, most companies see R&D as a key area for improving profitability.

In 2023, leading companies such as Mindray, SonoScape, and Lepu Medical each allocated over 10% of their revenue to R&D, covering areas including ultrasound, medical imaging, in vitro diagnostics, and interventional devices.

**Figure: R&D Capability and Potential for Profitability Improvement**




Data Source: Roland Berger, Global Medical Devices Report 2024; X-axis: Expected Profitability Improvement Potential

Chinese medical device companies are accelerating their global expansion through strategic upgrades, using technological innovation to enhance global competitiveness. They are continuously increasing R&D investment in advanced areas such as AI-assisted diagnostics, minimally invasive interventional devices, 3D-printed customized implants, and biodegradable biomaterials, while also deepening market insights along the Belt and Road countries, focusing on the needs of primary healthcare access and the prevalence of local diseases, and speeding up localized clinical trials and product registration. This trend is driving a shift in Chinese medical devices from cost-based advantages to value-driven innovation, while also reshaping the global medical technology landscape by building a global ecosystem.

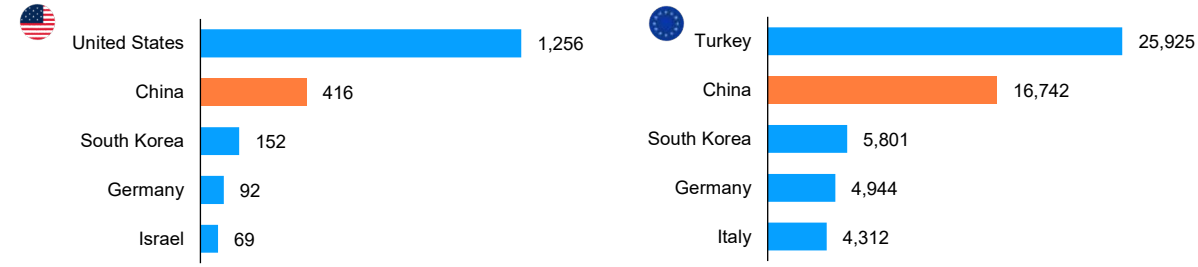
## Trend 2 *Alignment with International Standards, Pursuit Global Certification*

**International certification is not only a compliance requirement but also a foundation for building brand trust. Companies need to achieve breakthroughs through standardized systems and localized adaptation.**

In recent years, Chinese medical device companies have accelerated their alignment with international standards by actively pursuing FDA and CE certifications. These certifications have significantly improved the international competitiveness of their products. By leveraging the global recognition of these certifications, companies have created fast-track registration pathways in overseas markets. Data shows that Chinese companies are now among the global leaders in the number of FDA and CE certifications obtained. This not only shows that their product technologies meet international standards, but more importantly, creates an amplifying effect that facilitates market access.

As FDA and CE certifications set global benchmarks with strict requirements for product development, quality management systems, and clinical trials, companies can use the same compliance system to quickly convert certification results, significantly reducing registration timelines in emerging markets such as Southeast Asia, the Middle East, and Latin America. For example, once a device receives CE certification and enters the EU, its technical documents and test reports can be directly recognized by countries that follow EU standards. Similarly, FDA approval experience offers valuable reference for medical device license applications in countries such as Canada and Australia.

**Figure: Status of Chinese Medical Device Overseas Registrations, January–October 2024**




Source: Public Information, Frost & Sullivan Analysis.





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# Trends Analysis of Chinese Medical Device Global Expansion

**Trend 3** *Improved Cross-cultural Communication and Regulatory Awareness*

**Localization capability is the key to managing risks and improving efficiency. It requires a full-scale layout across teams, compliance, and supply chains.**

Chinese medical device companies are improving cross-cultural communication through multiple strategies, laying the foundation for global expansion in areas such as regulatory adaptation, cultural integration, and business environment understanding.

On the regulatory side, companies conduct in-depth studies of international standards such as FDA and CE, set up dedicated compliance teams, and ensure full regulatory compliance throughout the process from R&D to registration. Some companies have built registration networks covering Europe, North America, and Southeast Asia to speed up the application of certification results.

In terms of cultural integration, companies recruit talent with diverse cultural backgrounds to form international teams and enhance employees' cross-cultural awareness through language training and cultural programs.

To adapt to different business environments, companies have built global market monitoring systems to track healthcare policies, market access barriers, and supply-demand changes in various countries.

With these integrated cross-cultural strategies, Chinese medical device companies have not only achieved steady growth in exports but are also playing an increasingly important role in the global healthcare ecosystem.

**Trend 4** *Diversified Strategies for Global Branding*

**In response to growing international competition, Chinese medical device companies are adopting diversified strategies to increase their global brand influence and shift from a price-driven to a value-driven approach.**

First, accurately targeting key markets is essential. Companies are no longer focused on a single market but instead conduct in-depth research on medical needs, regulations, and market conditions in different countries, tailoring their global expansion strategies and product portfolios accordingly. Second, building a localized operational system is key to improving brand recognition. By forming partnerships, setting up local branches, and building local teams, companies can better understand local needs, deliver culturally relevant services, and respond quickly to market changes. Additionally, active participation in international academic exchanges and industry exhibitions, along with digital marketing tools such as multilingual websites, social media campaigns, and online streaming, helps enhance the brand's professional image, international reputation, visibility, and public perception. Through these strategies, Chinese medical device companies are establishing a presence in the global healthcare market with an image of innovation, professionalism, and reliability.

**Frost & Sullivan, leveraging its global reach, advances corporate globalization projects in four orderly stages**

| | Stage 1: Strategy Formulation | Stage 2: Industry Evaluation | Stage 3: Global Promotion | Stage 4: Value Assessment |
|---|---|---|---|---|
| | 1 Strategic Consulting Services | 2 Global Industry Evaluation Services | 3 Global Brand Promotion Services | 4 Product Value Assessment Services |
| Sub-modules | a) Corporate due diligence and product research<br>b) Analysis and summary of overseas expansion cases and experiences<br>c) Based on the company's own globalization capabilities and strategy, draw lessons from overseas expansion cases to develop an international expansion strategy | a) Assessment of potential licensing regions<br>b) Analysis of regulatory policies in the licensing regions<br>c) Evaluation of indications, including analysis of disease burden and current treatment status in potential regions<br>d) Assessment of the global competitive landscape and market development potential | a) In-depth overseas articles<br>b) Global release of the Blue Book<br>c) Entrepreneur interviews<br>d) Frost & Sullivan Growth Innovation Leadership (GIL) Award<br>e) Compilation of information on relevant overseas industry conferences | a) Product value assessment<br>b) International analysis and promotion book for product globalization |
| Research Methods | • Due diligence of company management<br>• Interviews with clinical Principal Investigators (PIs) of external products<br>• Interviews with experts experienced in international expansion<br>• FSI database<br>• Internal analysis by Frost & Sullivan | • Interviews with epidemiologists and clinical experts in the authorized regions of external products<br>• Interviews with market experts in the authorized regions of external products<br>• FSI database<br>• Internal analysis by Frost & Sullivan | • Due diligence of company management<br>• FSI database<br>• Interviews with clinical Principal Investigators (PIs) of external products<br>• Internal analysis by Frost & Sullivan | • Due diligence of company management<br>• Interviews with external market experts in the authorized regions for the product<br>• Interviews with clinical Principal Investigators (PIs) of external products<br>• FSI database<br>• Internal analysis by Frost & Sullivan |

Source: Public Information, Frost & Sullivan Analysis.

# Chapter 6

# Profiles of Selected Globalized Medical Device Companies and Service Providers

06

Safety. Science. Transformation.™

# UL Solutions provides comprehensive life cycle support for the medical device industry

Navigating regulatory compliance can be challenging, particularly in the healthcare and life sciences industries. As technologies and devices evolve, global standards will change. As regulations around the world evolve, manufacturers must stay in tune with current requirements to get medical devices to your target markets. As a global safety science leader, UL Solutions helps medical device manufacturers by evaluating their products for compliance to applicable standards and regulatory requirements necessary to access their target markets.

## Our Services

### Regulatory services – medical device compliance support:

- Quality management system (QMS) certification for medical device manufacturers: ISO 13485
- Medical Device Single Audit Program (MDSAP) certification
- EU Medical Devices Regulation (MDR 2017/745) conformity assessment
- EU In Vitro Diagnostic Medical Devices Regulation (IVDR 2017/746) conformity assessment
- UKCA certification

### Medical device testing and certification services:

- Electrical safety and usability testing for active medical devices
- Electromagnetic compatibility (EMC) and wireless radio frequency (RF) testing and certification
- Non-clinical testing (biocompatibility, chemical characterization)
- Cybersecurity testing and certification
  - Cybersecurity certification for medical devices
  - UL 2900 Cybersecurity Assurance Program (CAP)
  - Healthcare technology cybersecurity
  - Medical device penetration testing
- Packaging and transportation testing
- Optical testing and certification
- INMETRO certification for Brazil

UL Solutions.com.cn

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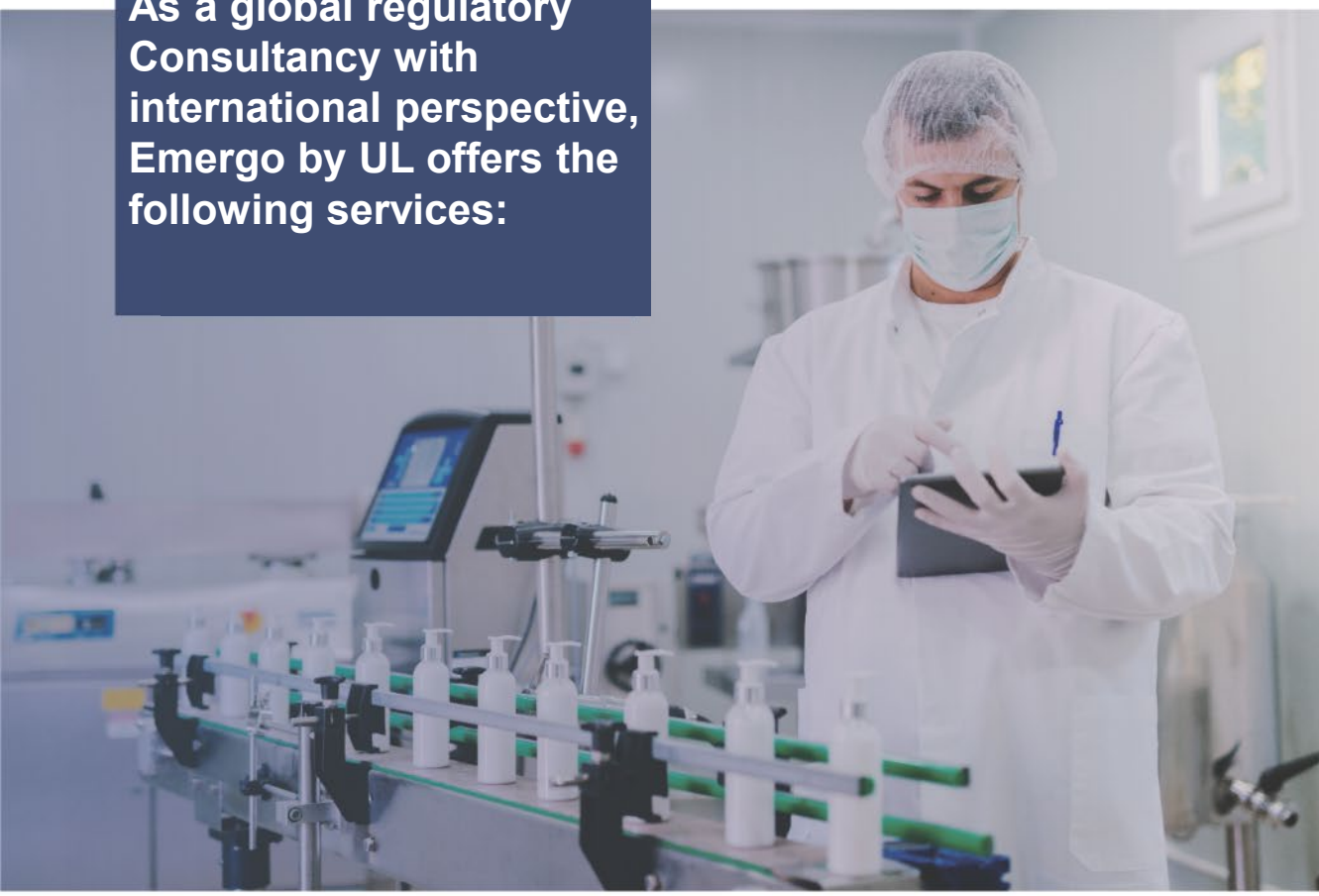
# As a global regulatory Consultancy with international perspective, Emergo by UL offers the following services:



## Medical device registration services

- Registration of medical devices and IVDs in 24 markets
- Local Authorized Representative services in 19 markets
- Quality management system (QMS) compliance support
- Post-market regulatory consulting services
- RAMS® (Regulatory Affairs Management Suite) platform for regulatory operations

## Human factors engineering and usability services

- User research and market analysis
- Use-related risk analysis
- User interface design and prototyping
- Usability testing and evaluation
- Global regulatory compliance and guidance analysis
- Training workshops and forums

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If you have relevant business inquiries, please email:
Kiki.Chou@ul.com or
lst.aus.salesleadsasia@ul.com



EMERGO by UL

# AllBright Law Offices

## Law Firm Introduction

Shanghai AllBright (Suzhou) Law Firm ("AllBright Suzhou") was officially established in 2010 with the approval of the Department of Justice of Jiangsu Province. It is the fourth branch office of AllBright Law Offices established nationwide and is now firmly among the top law firms in Suzhou. AllBright has been recognized many times by the Ministry of Justice of China, its subordinate judicial authorities, legal industry associations, internationally renowned legal media, and leading rating agencies as one of China's top legal service providers.

As a branch of a nationally distinguished and internationally recognized law firm, AllBright Suzhou will continue to deepen its presence in Suzhou. With a spirit of craftsmanship, it is committed to handling each matter and case with care, advancing professional precision and service excellence, and promoting high-quality development in legal services.

## Providing Comprehensive, Efficient, and High-Quality Legal Services

Since its establishment, AllBright Suzhou has provided clients with comprehensive, efficient, and high-quality legal services across various fields, including mergers and acquisitions, litigation and arbitration, corporate governance and compliance, corporate restructuring, banking, insurance, securities listing, private equity and venture capital, corporate reorganization, foreign investment, overseas investment, real estate, international trade, intellectual property, labor relations, tax law, antitrust, and unfair competition law.

1. Clients Served Include **Central Enterprises**, **State-Owned Enterprises**, **Listed Companies**, and **Private Enterprises**.
2. The industries covered by our clients span **healthcare and pharmaceuticals**, **digital technology** and **artificial intelligence**, **automotive equipment and manufacturing**, **consumer goods and retail**, **energy**, **natural resources and environmental protection**, **state-owned assets and enterprises**, **aerospace**, and more.
3. Numerous Fortune **Global 500 companies**, **multinational corporations**, **foreign-invested enterprises**, **international and domestic financial institutions**, and **investment funds** have become long-term clients and trusted partners of AllBright Suzhou.

## One of China's Top Legal Service Providers

AllBright has been recognized multiple times as one of China's top legal service providers by the Ministry of Justice of China, its affiliated judicial authorities, legal industry associations, leading international legal media, and authoritative rating agencies.

**Awards and Honors Received by AllBright Suzhou Over the Years**

- 2023 and 2024 China Business Law Awards 2024 (Jiangsu Region)
- 2023 Excellent Economic Contribution Award of Suzhou Industrial Park
- 2022 Excellent Law Firm Award of Suzhou Industrial Park
- Recognized as an Advanced Unit for Charity Service in Suzhou for Seven Consecutive Years (2018–2024)
- 2019 Leading Award for High-Quality Development in the Legal Industry
- Outstanding Law Firm of Suzhou (2010–2014)

Source: Public Information, Frost & Sullivan Analysis.

# AllBright Law Offices

## The AllBright Pharmaceutical and Healthcare Committee

The AllBright Pharmaceutical and Healthcare Committee is one of the key industry committees established to support the firm's ongoing upgrade and refinement of its legal services and practice areas.

AllBright has extensive experience serving the medical health and pharmaceutical industries. Its legal team has long been rooted in the field, with deep understanding of industry practices and operations. The team closely follows sector developments and trends, and consistently delivers professional, one-stop legal services within this industry context. These services include, but are not limited to, chinese and international capital markets, mergers and acquisitions, private equity and venture capital, intellectual property protection, corporate operations and compliance, and dispute resolution.

## Clients and Business Scope Covering the Entire Value Chain of the Healthcare and Pharmaceutical Industry

**Client Types and Business Areas**

- Drug research and development
- Clinical trial research
- Pharmaceutical manufacturing
- Elderly care and wellness services
- Medical device R&D and manufacturing
- Licensing and distribution
- Life Sciences
- Veterinary pharmaceuticals
- Biopharmaceuticals
- Various private equity/venture capital investments
- Hospitals and other healthcare providers
- Biopharmaceutical funds and incubation platforms

**Provision of Tailored Services**

Based on client needs, AllBright works closely with leading third-party institutions in the medical health and pharmaceutical industries, including top securities and investment banks, accounting firms, financial advisors, medical consultants, pharmaceutical economics experts, and research institutions. **Through a customized approach, AllBright provides clients with multi-dimensional and comprehensive services.**

Thanks to the dedication and continued efforts of the entire firm, AllBright and several of its partners have been featured in multiple rankings, including ALB, LEGALBAND, The Legal 500, IFLR1000, and Chambers & Partners, for their expertise, experience, and achievements in the medical health and pharmaceutical industries. The firm was also nominated for the "ALB Medical and Healthcare Firm of the Year" in both 2022 and 2023.

IFLR1000 LEGALBAND ASIAN LEGAL BUSINESS ALB The LEGAL 500

Source: Public Information, Frost & Sullivan Analysis.

# Company Specializing in Tumor Early Detection----- KANTE Biotechnology

## Company Introduction

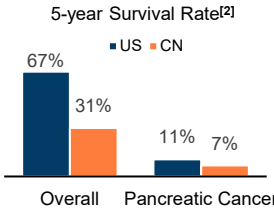
Kante Biotechnology is a leading company focusing on precise tumor prevention, and it is also among the early enterprises to deploy the miRNA technology. Based on its miRNA and AI technology platforms, the company achieves highly accurate early detection and early management of tumors. By virtue of original and cutting-edge technologies, it has built a number of cancer pipelines. The diagnostic products cover gastrointestinal tumors such as pancreatic and liver cancers, as well as gynecologic and hormone-related tumors including ovarian and prostate cancers. These products are applicable to various scenarios, including early screening and diagnosis, companion diagnosis, and prognosis monitoring for both specific cancers and pan-cancers.

## Product Introduction

- Kante Biotechnology is one of the few ***Chinese enterprises that have cracked global challenging problems.***
- Its products are highly scarce regarding cancer categories and technology paths, and are recognized as ***First-in-Class products.*** It has the ability to ***gain initial access to top Grade A tertiary hospitals in China, create global cash flow***, and capture a significant market share in the early phase.

### 1. Meet the unmet global needs and seize the first-mover position across the globe

**Global Problem**




- Early diagnostic tools for pancreatic cancer have been scarce for a long time. As a result, ***80%*** of patients[1] receive a pancreatic cancer diagnosis at the advanced tumor stage
- PANCGUARDIAN® bridges the gap in the diagnosis and treatment of the "king of cancers". It allows the early identification of cancerous changes, ***with a 90%–100% surgical resection rate***[3], and thus improves patients' survival outcomes.

**Solution from KANTE**

***Pancreatic Cancer*** **Early diagnosis Kit**
**(Original Tumor Markers + qPCR Technology Method)**


**PancGuardian®**

### 2. Break Through Detection Bottlenecks and Adapt to Risk Population Management

It overcomes the limitations of existing blood tumor marker detection revealed in the Guidelines for the Diagnosis and Treatment of Pancreatic Cancer (2022 Edition)

### 3. Clear Precursor Diseases Enable Precise Identification with Rigid Demand

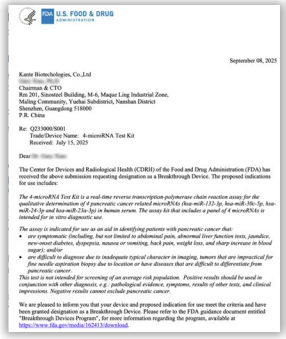
Based on ***"diabetes—inflammation—carcinogenesis,"*** the product precisely identifies the manageable population that has a definite need for screening and real demand. Yet, the pancreas is concealed in location.

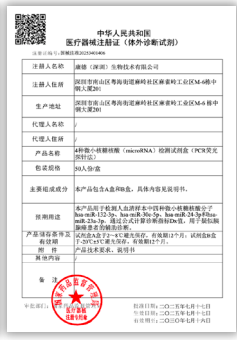
## Product Advantages of PancGuardian®

### Authoritative Accreditations

- **Class III Medical Device Registration Certificate Issued by China's National Medical Products Administration**

  (Registration No.: CN20253401406)
- **Breakthrough Device Designation from the U.S. Food and Drug Administration (FDA)**
- **Medical Device Division, Department of Health, Government of the Hong Kong Special Administrative Region**





### Technology Upgrade

- ***The Spanish Cancer Center states that delayed diagnosis leads to the high mortality rate of pancreatic cancer***[4]
- Suitable for people with Lewis antigen-negative blood type who cannot express CA19-9, making up ***nearly 10% of the Chinese population***[6]


The technology is endorsed by the Expert Consensus on Molecular Diagnosis of Early Pancreatic Cancer (2023 Edition)

**95%** Sensitivity

**97%** Specificity

Validated Multiple In Situ Cases

- ✓ Non-invasive
- ✓ User-friendly Operation

Source: Company Website, Frost & Sullivan Analysis





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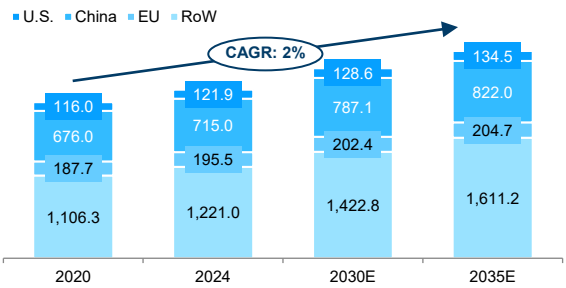
# Company Specializing in Tumor Early Detection ----- KANTE Biotechnology

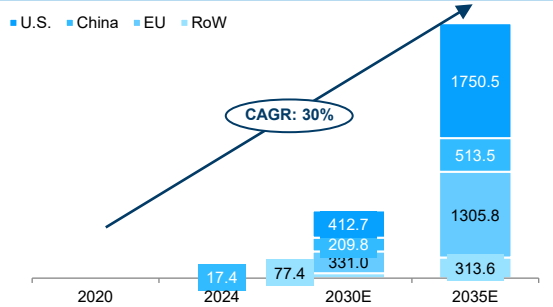
## Customer Analysis of PancGuardian®

1. ***Strong Stickiness of Screening Needs:*** *Diabetes is a key precursor of pancreatic cancer. Around 1% of newly diagnosed diabetics over 50 will develop pancreatic cancer within three years*[8]
2. ***apid Expansion of Market Scale:*** High-sugar diets have led to a rapid expansion of the diabetic and especially the younger population. *The prevalence among males aged 20–24 has jumped from 1.99% to 7.42%, while the incidence among those under 40 has tripled roughly*[7]

**Global Pancreatic Cancer Eligible Population (Million) for Early Detection**




**Massive High-Risk Groups (e.g. T2DM) Fuel Market Expansion (Million USD)**




| Applicable Departments | Related Indications | | |
|---|---|---|---|
| **Endocrinology** | • New diabetic cases | | • Long-term diabetics with poorly controlled blood sugar |
| **Gastroenterology** | • Chronic pancreatitis, pancreatitis with diabetes, pancreatic masses (suspected pancreatic cancer)<br>• Persistent symptoms including abdominal distension, abdominal pain, fever, weight loss (recurrent indigestion)<br>• Unexplained weight loss, jaundice, skin itching, etc. | | |
| **Surgery** | • Pancreatic space-occupying lesions | • Recurrent chronic pancreatitis | • Symptoms like abdominal pain, painless jaundice, back pain, etc. |
| **Physical Examination Center Health Management Center** | • Individuals with familial pancreatic cancer history<br>• Those on long-term high-sugar, high-fat diets | | • Obesity, diabetes<br>• People with long-term smoking, heavy drinking or irregular lifestyles |

## Corporate Competitive Strengths

Leveraging the founder's original technologies and clinical resources, ***the company focuses on the global gaps in cancer management where no effective solutions are available***. It has built a diversified product matrix, accumulated more than ***50 core*** intellectual property rights, and established clear and solid technical barriers.

**Original Technology for Global Untapped Markets**

**Lead National Major Research Projects**

The company has been selected as ***the leading unit for the liquid biopsy project of pancreatic cancer early screening***, which is a major special project for the prevention and treatment of four major chronic diseases under the ***Healthy China 2030*** initiative, and takes the lead in the systematic research of national-level major research projects

The company has established in-depth strategic cooperation with global diagnostic giants Quest Diagnostics and LabCorp. Its core products and technologies have successfully entered over ***100 medical institutions*** including Peking Union Medical College Hospital and Changhai Hospital of Shanghai.

**Possess Global Revenue Realization Capability**

**Rigorous Quality Control and Full-process Compliance**

A full-process quality management system has been established, strictly complying with domestic and international standards such as ***ISO13485.*** Multi-dimensional quality control ensures stable product performance and reliable results, supporting global market access and clinical application. projects

*Reference: ; [1]Nan S, Shi Q, Chen C, et al. The relationship between pancreatic cancer and diabetes mellitus[J]. Journal of Clinical Hepatology,2022,38(12):2882-2886; [2] Frost & Sullivan: 2024 Blue Book on the Development of the Tumor Molecular Diagnosis Industry; [3] https://www.pumch.cn/detail/10644.html [4]https://www.cnio.es/en/news/publications/diabetes-type-3c-early-manifestation-pancreatic-cancer/; [5]NMPA Approval Report for PanGuardian; [6]https://pubmed.ncbi.nlm.nih.gov/29123975/ (Guo M, Luo G, Lu R, Shi W, Cheng H, Lu Y, Jin K, Yang C, Wang Z, Long J, Xu J, Ni Q, Liu C, Yu X. Distribution of Lewis and Secretor polymorphisms and corresponding CA19-9 antigen expression in a Chinese population. FEBS Open Bio. 2017 Oct 4;7(11):1660-1671. doi: 10.1002/2211-5463.12278. PMID: 29123975; PMCID: PMC5666394.); [7] Zhou, YC., Liu, JM., Zhao, ZP. et al. The national and provincial prevalence and non-fatal burdens of diabetes in China from 2005 to 2023 with projections of prevalence to 2050. Military Med Res 12, 28 (2025).https://doi.org/10.1186/s40779-025-00615-1; [8] Consensus Opinions on Early Screening and Monitoring of High-Risk Populations for Pancreatic Cancer in China (2021, Nanjing) Citation: Chari ST, Leibson CL, Rabe KG, et al. Probability of pancreatic cancer following diabetes: a population-based study[J]. Gastroenterology, 2005,129(2):504-511. DOI: 10.1016/j.gastro.2005.05.007.*

Source: Company Website, Frost & Sullivan Analysis

# Company in the Early Cancer Screening Industry – Ammunition Life-Tech

## Company Introduction

艾米森 Life technology

Wuhan Ammunition Life-tech Co., Ltd., founded in January 2015, is a high-tech enterprise focused on the R&D, registration, manufacturing, and commercialization of non-invasive early screening products for major malignant tumors worldwide. The company has been recognized as a National "Little Giant" Enterprise for Specialized and Innovative Businesses and a "Gold Seed" Enterprise for IPO preparation. Its headquarters, R&D center, manufacturing facilities, and medical testing laboratories are located in Wuhan Optical Valley Biolake, with branch offices in Beijing, Shenzhen, and Suzhou.

## Product Advantages

### Extensive Production Line

Ammunition Life-tech has developed 21 products covering high-incidence cancers of the gastrointestinal system, female reproductive system, respiratory system, urinary system, as well as pan-cancer detection.

### Authoritative Clinical Guidelines Included

IColocomf has been included in the "Chinese national clinical practice guidelines on prevention, diagnosis and treatment of early colorectal cancer", jointly issued by multiple academic societies. Both IColocomf and IColohunter are cited in the "Expert consensus on technical specifications for colorectal cancer screening in physical examination", released by the National Cancer Center of China.

### Comprehensive Intellectual Property Portfolio

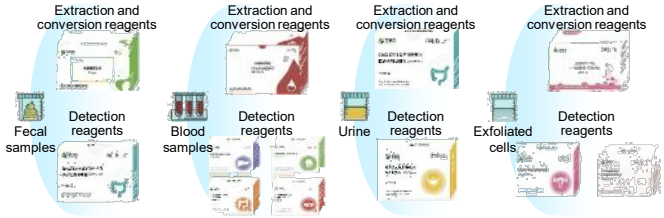
As one of the leading enterprises in early cancer screening and diagnosis, the company has built a globally advanced technology platform with fully independent intellectual property rights. It has filed 185 patent applications and obtained more than 80 granted patents, ranking among the top domestic enterprises in this field by patent volume.

### Strong Regulatory Approval Capabilities

The company has secured four NMPA approvals and licensed one additional NMPA approval to an external partner. It has also obtained 12 CE certifications, six UK MHRA approvals, and multiple registrations in other countries, along with 18 Class I medical device filings in China.

## Product Testing System

### *1* Develop dedicated reagents for different sample types to maximize product performance




### *2* Automate and standardize the testing process to reduce operational errors and improve detection efficiency

Testing process: based on Ammunition's proprietary methylation detection platform.

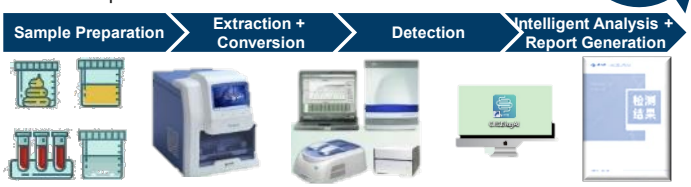
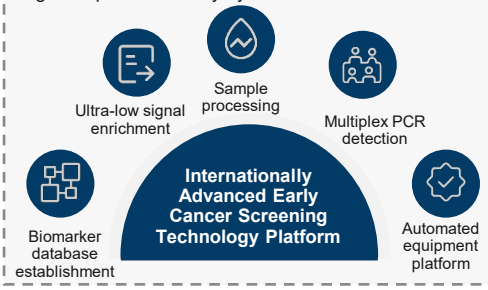



**Figure: Ammunition Life-Tech Products**


**Tumor Methylation Detection Technology Platform**

Ammunition Life-tech has built a diversified testing system centered on its proprietary Methylation Navigation Technology. The platform incorporates exclusive ultra-low signal enrichment technology and methylation PCR sensitivity enhancement, increasing signal capture efficiency by more than tenfold.




Source: Company Website, Frost & Sullivan Analysis





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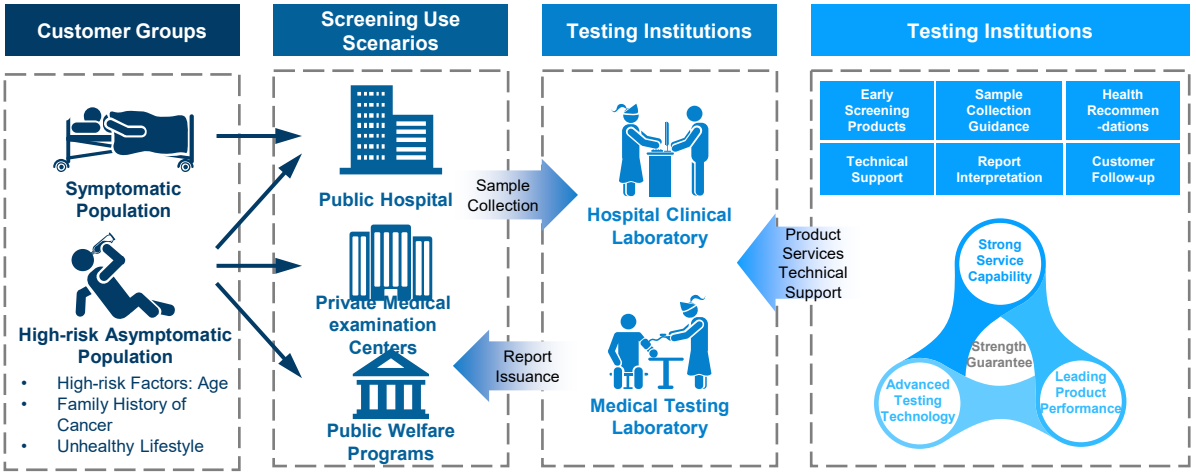
# Company in the Early Cancer Screening Industry – Ammunition Life-Tech

## Business Model




## Supporting Early Cancer Screening

### Corporate Partnerships

Ammunition Life-tech has established strategic partnerships with leading companies including Roche Diagnostics, Kindstar Global, Sinopharm, Jointown Pharmaceutical Group, Wuhan EasyDiagnosis Biomedicine Co., Ltd., and Guangzhou KingMed Diagnostics Group Co., Ltd., ***establishing a cancer early screening ecosystem that integrates technology, services, and distribution channels.***

### Collaborations with Medical Institutions

- ***Over 200*** collaborations with top-tier (Three-A) hospitals
- ***More than 1,000*** cooperative health check-up centers
- ***Over 100*** partnered medical testing laboratories

### Public Welfare Early Screening

The IColocomf ® colorectal cancer public welfare screening project has been implemented in regions including Hubei and Xinjiang, receiving unanimous positive feedback for its excellent performance.

- Approximately ***10,000*** colorectal cancer (IColocomf®) public screening tests conducted
- Sample qualification rate ***over 95%***
- Positive detection rate in healthy populations approximately ***5.4%***
- Colonoscopy compliance rate significantly higher than industry average, with ***87.8%*** of cases showing precancerous lesions

### Public Health Screening Programs

- A fully automated molecular testing medical laboratory with a daily testing capacity of ***3,000*** samples.
- An ***intelligent***, integrated ***information*** system that supports ***the entire cancer screening workflow***.
- Covered healthy communities, enterprises, schools, customs departments, and government officials.
- Primary healthcare at the grassroots level, serving ***over 100,000*** individuals across ***county-level hospitals***.

## Competitive Advantages

**Industry-leading Patent Portfolio and Robust Intellectual Property**

Ammunition Life-Tech ranks at the forefront of the Chinese early cancer screening and diagnosis industry in terms of patent volume, with ***185*** patent applications, over ***80*** granted patents, and ***more than 10*** PCT patents. The company has also published scientific papers with a cumulative SCI impact index ***exceeding 100***.

**Comprehensive Tumor Methylation Detection Technology Platform**

The company has built a diversified testing system centered on its proprietary Methylation Navigation Technology. This platform features exclusive ultra-low signal enrichment and methylation PCR sensitivity enhancement technologies, improving signal capture efficiency by ***more than 10 times.***

**Strategic Resources and Top-tier Expert Collaboration to Lead the Industry**

With strategic collaborations from global IVD leaders such as Roche Diagnostics and Eurofins, Ammunition Life-tech has secured a strong position in cancer early screening. The company partners with ***more than 200*** top-tier hospitals, including Peking Union Medical College Hospital and West China Hospital, and works closely with ***academicians and leading clinical experts.***

艾米森 Life technology

**Strong Regulatory Credentials and Diversified Product Lines**

Ammunition Life-Tech has obtained ***4 NMPA approvals*** and licensed out ***1 NMPA certificate to external partner***. The company holds ***12 CE certificates***, ***6 UK MHRA certifications***, and several approvals from other countries. A total of ***21 products*** have been fully developed and are available as LDT services.

**Rapid Commercial Expansion Domestically and Globally, with Strong Growth Potential**

The company's products are widely adopted across China and have reached international markets, with clients in nearly ***30*** countries and regions, including the UK, Singapore, Thailand, Saudi Arabia, Iran, and Israel.

Source: Company Website, Frost & Sullivan Analysis





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# Optical Molecular Imaging Surgical Navigation Device Company — DPM

## Company Introduction

DPM (including Beijing Digital Precision Medicine Technology Co., Ltd. and Zhuhai Dipu Medical Technology Co., Ltd.) was incubated by the Institute of Automation of China and established in 2016. It is the result of research accumulated through multiple major national projects. Its early research received support from the National 973 Program, the National Major Scientific Research Instrument Development Project of the National Natural Science Foundation of China, and the National Nanoscience and Technology Program of the Ministry of Science and Technology, among others. The company has been awarded the Second-Class State Scientific and Technological Progress Award, the Second-Class State Technological Invention Award, and the Gold Medal at the 43rd International Exhibition of Inventions Geneva.

DPM focuses on high-end medical technology and has been recognized as a national-level "Specialized, Refined, Unique, and Innovative ('Little Giant') Enterprise." Its business currently encompasses a range of high-end intraoperative optical molecular imaging surgical navigation devices and imaging agents, all independently developed and manufactured, forming a closed-loop model of "equipment + consumables." Looking ahead, leveraging novel magnetic nanoparticle imaging technology for disease screening, DPM aims to expand from precision surgery into the broader field of precision health.

## Development History

**1996** — Theoretical Research with Chinese Academy of Sciences

**2003** — Molecular Imaging – Theoretical Algorithm Research in Medical Imaging
- Published a Series of SCI Papers on Theoretical Methods;
- State Scientific and Technological Progress Award
- Best Invention Award Granted by the World Intellectual Property Organization (Top 1/3000);
- Gold Medal at the International Exhibition of Inventions (IEI) China

**2014** — The China National Basic Research Program (973 Program)
- The State Technological Invention Award;
- Prototype, Test Model;
- National Science and Technology Infrastructure Program;
- Gold Medal at the 8th International Exhibition of Inventions

**2016** — DPM Founded
- Gold Medal at the International Exhibition of Inventions;
- Gold Medal at the Geneva International Exhibition of Inventions;
- National Innovative Medical Device Approval;
- Completed Angel Round Financing;
- Science and Technology Service Network Initiative (STS Program) of the Chinese Academy of Sciences;
- First Prize in the Finals of the China Medical Device Innovation and Entrepreneurship Competition;
- Subsidiary Recognized as a Seed Unicorn Enterprise

**2021** — 4K Fluorescence Product Approval
- Obtain the title of Beijing Innovative Medical Device;
- China Patent Excellence Award;
- National Postdoctoral Research Workstation;
- Two Group Standards Released for the First Time in the Industry

**2022** — Selected Company in the MIIT "AI Medical Device Innovation Task List"
- 3D 4K Fluorescence Endoscopic Imaging System Obtained Registration Certificate;
- Intelligent Eye H280, H380 and Wise Eye Z1000 Products All Obtained Registration Certificates;
- Second Prize at HICOOL 2022 Global Entrepreneurship Competition;
- Project Approved under the "14th Five-Year Plan" National Key R&D Program;
- Eighth Batch of Excellent Domestic Medical Devices

**2023** — DPM Signed a Strategic Cooperation Agreement with Johnson & Johnson
- First Prize of Huang Jiasi Science and Technology Progress Award by the Chinese Society of Biomedical Engineering;
- Biotechnology and Information Technology Integration Application Engineering Project by the National Development and Reform Commission (NDRC);
- 8K Fluorescence Endoscopic Imaging System Obtained Registration Certificate;
- Led the Formulation of Seven Group Standards;
- R&D under the "14th Five-Year Plan" National Key R&D Program of China

**2024**
- ✓ Recognized as a "Specialized, Refined, Unique and Innovative ('Little Giant') Enterprise" by MIIT
- ✓ X-nova Platform Endoscopic Imaging System Approved for Market Launch
- Optical 3D Fluorescence Endoscopic Device Received FDA Approval;
- Completed C2 Round Financing;
- Winner Unit of MIIT AI Medical Device Innovation Task Completion;
- Recognized as a Beijing Foreign-funded R&D Center

**2025** — Continuing to Deepen Efforts in the Field of Molecular Imaging, with Promising Prospects Ahead

## Company Advantages

### Proprietary Product Series
- DPM's optical molecular imaging surgical navigation products have obtained more than **30 NMPA registrations;**
- **2 CE-MDR certifications** in the EU;
- **2 FDA certifications** in the U.S.;
- DPM has led and participated in drafting **7 industry group standards**, including China's first group standard for fluorescence endoscopy, filling a key gap in the field.

### Established Clinical Applications and Global Recognition
- DPM continues to advance the clinical practice of fluorescence-guided surgery. **Clinical outcomes related to its products have been published multiple times in international journals;**
- DPM has also received high praise in dedicated articles **by renowned overseas medical experts.**

Jeffrey A. Norton, Chair of the Department of Surgical Oncology, Stanford University School of Medicine

Peter Licht, President of the European Association for Cardio-Thoracic Surgery

Hak So Choi, Professor, Harvard Medical School

### Grown Significant International Impact
- DPM has been deeply engaged in the field of fluorescence-guided precision medicine for years. Its core R&D team has been invited multiple times by global academic organizations to author technology development overviews;
- DPM has published cover articles in top journals such as **Nature Reviews Bioengineering and Nature Reviews Clinical Oncology,** demonstrating its leading global influence.

Source: Public Information, Frost & Sullivan Analysis

# Optical Molecular Imaging Surgical Navigation Device Company — DPM

## Key Products and Technology Advantage

**Globally Pioneering 8CMOS Technology**

Dual-channel 4K-resolution 3D imaging supports independent white-light and fluorescence imaging, and generates 60 fps 3D fluorescence fusion images with no visual delay or dizziness.

**AI-Powered Image Enhancement Algorithms**

Supports automatic exposure control, fluorescence fusion, and fluorescence enhancement, clearly highlighting lesions, tissues, and blood vessel structures, and precisely defining lesion margins.

**High-Efficiency 785 nm Excitation Light**

Delivers low thermal effect on tissue and high fluorescence sensitivity, enabling precise lesion localization while ensuring safety for both surgeons and patients.

**Designed to Meet Clinical Needs**

Provides practical functions such as image and video storage, easy switching between 2D/3D viewing, and clinical mode selection, offering surgeons an immersive experience.

**2022**

DPM launched China's first 3D 4K fluorescence endoscopic imaging device certified by the NMPA.

**2024**

It's also the first optical 3D fluorescence endoscopic imaging device approved by the U.S. FDA.
The system has since been innovatively upgraded into a multifunctional 3D 4K fluorescence endoscopic imaging platform.

**Adaptive Depth-of-Field Adjustment**

No need for manual focusing during surgery, allows smoother surgical operations.

**Open and Expandable Imaging Platform**

Compatible with different endoscopic cameras, supports open-surgery fluorescence imaging, and can be integrated with fluorescence molecular imaging systems and smart smoke evacuation systems to provide optimal fluorescence-guided surgery solutions.

Figure: Examples of Key Products

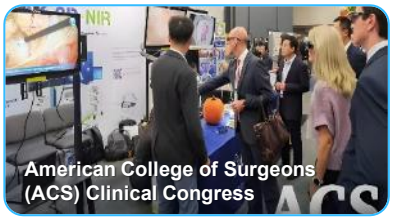
Platform 3D/4K/Fluorescence Full-Function Endoscopic Imaging System: X-nova

3D 4K Fluorescence Integrated Imaging Endoscopic System: D3800 Series

4K Fluorescence Imaging Analysis Open and Endoscopic System: H3800 Series + C2000 Series Dual-System

## Global Academic Influence

As a leading Chinese company in the field of molecular imaging, DPM has leveraged its innovative ultra-high-sensitivity fluorescence molecular imaging technology to appear consecutively at the 2024 and 2025 clinical meetings of the American College of Surgeons (ACS), the annual meeting of the American Association for Thoracic Surgery (AATS), and the annual meeting of the American Society of Clinical Oncology (ASCO). It became the first Chinese surgical device brand to participate in all three top international academic conferences simultaneously. Through systematic international academic activities, DPM has showcased its technological strength alongside leading global medical device companies. Its product performance and clinical application innovations have received widespread attention and positive feedback from global experts. This also reflects the growing international academic influence of Chinese high-end medical equipment companies and provides a successful example of leveraging technological innovation to drive global brand recognition for the international expansion of industry products.




American College of Surgeons (ACS) Clinical Congress


American Association for Thoracic Surgery (AATS) Annual Meeting


American Society of Clinical Oncology (ASCO) Annual Meeting

Source: Public Information, Frost & Sullivan Analysis

# High-end Ophthalmic Medical Device Company — Eyedeal

## Company Introduction

Eyedeal is a high-tech enterprise specializing in the R&D and manufacturing of high-end ophthalmic medical devices and offering a global supply of multiple medical grade polymer materials. Led by world-class academicians and experienced experts from China and overseas, the company is committed to the innovative development of ophthalmic implantable medical devices including intraocular lenses (IOLs). Eyedeal owns independent intellectual property rights for its cross-linked polyisobutylene (xPIB) material, achieving full-process autonomy from raw material synthesis to product manufacturing. In addition, the company's capabilities in high-purity synthesis and large-scale production of various polymer materials, including polyisobutylene (PIB), have reached international advanced levels, providing broader and better material options to meet previously unmet medical needs.

**Figure: Development History of Eyedeal**

**Establishment — 2014-2016**

Introduction of Proprietary Material and Launch of Domestic IOL R&D

- In 2014, founder Mr.Guo Guangxu partnered with Dr. Len Pinchuk, a member of the American National Academy of Engineering, **to introduce his patented cross-linked polyisobutylene (xPIB) polymer material**.
- In Jan. 2015,Xi'an Eyedeal Medical Technology Company Limited established , **focusing on applying xPIB materials to the development of ophthalmic intraocular lenses (IOLs).**
- In Sep. 2015, **Eyedeal® completed the facility that integrates R&D, manufacturing, and operations.**

**Development — 2017-2020**

Leading National Projects to Build an Independent Innovation System from Materials to Products

- In 2017, **Eyedeal led the "Next-Generation Intraocular Lens Materials and Products Development" project** under the National Key R&D Program's "High-Performance Biomaterials" initiative.
- In 2019, **the company established an academician expert workstation and a postdoctoral innovation base,** bringing together global research expertise.
- In May 2020, Eyedeal's new-generation intraocular lens project based on xPIB material was accepted **into the NMPA "Special Approval Procedure for Innovative Medical Devices."**
- in Dec 2020, eyedeal comleted a series A finding

**Breakthrough — 2021-2022**

Achieving Dual Breakthroughs in Clinical Trials and Material Mass Production, with International Recognition for Technical Achievements

- In Oct. 2021, **Eyedeal launched domestic clinical trials for its new-generation IOLs** developed using xPIB medical polymer material.
- In 2022, **the National Key R&D Program project passed its acceptance review.** The research findings were presented at the **ASCRS** Annual Meeting, where **they received the Excellent Academic Presentation Award.**
- In Oct. 2022, Eyedeal's independently developed **aspheric hydrophobic acrylate intraocular lens received market approval from NMPA.** The product had also obtained EU CE certification in 2021.

**Acceleration — 2023-2025**

Accelerating Commercialization and Advancing the Platform-Based Development of Chinese Ophthalmic Implant Materials

- In March. 2023, Eyedeal **completed a Series B financing round, raising hundreds of millions of RMB** to support commercialization and global expansion.
- In early 2024, the innovative xPIB IOLs completed clinical trials and data analysis in China, **and an application for a registration certificate was submitted to the NMPA.**
- In Mar. 2025, Eyedeal **signed a strategic cooperation agreement with Pantheon Vision in the U.S.** to jointly advance the R&D and global commercialization of bioengineered corneas, further expanding and consolidating its polymer material platform business.
- In Apr. 2025, **two clinical outcomes of Eyedeal's flagship product,** the Eyedeal xPIB IOL, were presented at the **ASCRS Annual Meeting. The results demonstrated superior visual stability and capsular bag positioning compared to mainstream imported IOLs, earning recognition from international experts.**
- As of Jul. 2025, three-year clinical follow-up data showed that the xPIB intraocular lens exhibited **no glistening lower PCO,** and **more precise postoperative refractive outcomes**, demonstrating advantages over existing technologies.

## Competitive Advantages

Eyedeal's proprietary synthesis and industrial-scale production of xPIB material, with its broad potential applications in medical devices, combined with technological exclusivity and leading comparative clinical results of its IOL products, give the company end-to-end control from material synthesis to regulatory approval. Supported by multinational partners and policy-driven capital, these advantages establish Eyedeal's long-term competitive protection in both "high-end product substitution domestically" and "differentiated competition globally."

**Figure: Eyedeal's Competitive Advantages**

**1 Global Patents and Synthesis Process for xPIB New Material**

Eyedeal holds global invention patents for cross-linked polyisobutylene (xPIB). With its excellent optical properties and biocompatibility, this material has enabled a new generation of IOLs that are glistening-free and feature high refractive index and Abbe value. Polyisobutylene also has significant application potential in various implantable medical devices, including orthopedics, neurosurgery, and thoracic surgery, achieving international leadership in both purity and production capacity of high-end medical polymers.

**2 Leading Clinical Evidence**

Dual randomized controlled trial (RCT) data presented at ASCRS 2025 showed that the xPIB IOL outperformed Alcon's AcrySof®, the company's longest-standing and most widely implanted intraocular lens, in key metrics such as refractive accuracy and capsular bag stability. Post-market clinical data further demonstrated superior outcomes compared with control products, including the absence of glistenings.

**3 End-to-End Independent Control**

Official disclosures show that Eyedeal has established R&D platforms including an academician workstation, an engineering research center, and a post-doctoral base, and has commissioned a smart factory in Xi'an with an annual capacity of 1 million IOLs. The Eyenable® IOL has obtained both NMPA and CE certifications, validating a fully independent pathway covering material development, production, and regulatory approval. The Eyedeal (xPIB) IOL is positioned for the high-end global market, with the entire production process under in-house control.

**4 Boosted by Policies and Capital**

The National Key R&D Program, the NMPA Green Channel, and a Provincial Engineering Center provide triple policy support. Combined with Series B financing of hundreds of millions of RMB and collaboration with global partners such as Heidelberg University and Pantheon Vision, these factors are transforming R&D and material strengths into faster registration and market entry.

Source: Company Website, Frost & Sullivan Analysis.

# High-end Ophthalmic Medical Device Company — Eyedeal

## Technological Advantages

Eyedeal has taken cross-linked polyisobutylene (xPIB) medical polymer material as its core innovation platform, breaking nearly 30 years of stagnation in global IOLs material development. xPIB offers a high refractive index, high Abbe number, and excellent elongation, enabling larger optics 10L to be implanted through micro-incisions. In both in vitro and clinical comparisons, it shows virtually "zero glistening", significantly improving postoperative visual quality. In Apr. 2025, two clinical studies on Eyedeal's flagship product - Eyedeal xPIB IOL were presented at the ASCRS annual meeting. Results demonstrated superior visual stability and capsular bag positioning compared with mainstream imported IOLs, earning recognition from global experts. Eyedeal's Scientific Advisory Board is chaired by Dr. Len Pinchuk, the inventor of xPIB and a member of the American National Academy of Engineering, and includes two additional academy members as well as Prof. Gerd Auffarth, Chairman of the Department of Ophthalmology at Heidelberg University, Germany.


**2025.04.28**

**ASCRS 2025 | Eyedeal Presents Dual Clinical Results for xPIB Intraocular Lens**

## Material Advantages

Eyedeal has developed technical expertise in the synthesis and industrial-scale production of multiple materials, including xPIB and SIBS. The company has successfully applied xPIB beyond IOLs, supplying PIB materials for artificial corneas, orthopedic implants, heart valves, and vascular grafts, demonstrating significant commercial potential.

**Figure: Eyedeal Polyisobutylene Application Prospects**


## Product Advantages

In recent years, Eyedeal has accelerated the development of its product portfolio based on its proprietary cross-linked polyisobutylene (xPIB) material. This has resulted in a product lineup centered on IOLs and supported by a range of complementary ophthalmic devices.

**Intraocular Lenses (IOLs):**

The Eyedeal™ xPIB Intraocular Lens leverages the material's inherent hydrophobicity (contact angle of 97.2°) and excellent biocompatibility to reduce bacterial adhesion, significantly lowering the risk of postoperative endophthalmitis.

The Eyenable™ Hydrophobic Acrylic IOL is made from a self-synthesized Acylic material. Its aspheric design effectively meets routine clinical needs, while its accessible pricing makes it well suited for high-volume surgeries in public hospitals under strict medical insurance cost controls.

**Orthokeratology Lenses (OK Lenses):**

Eyedeal's Orthokeratology Lenses (OK Lenses) are manufactured using a self-synthesized biocompatible material featuring high oxygen permeability and a low wetting angle. Its unique segmented optical design is more in line with the characteristics of the Asian eye and is more comfortable. The new precision machining process produces higher quality products.

**Phakic Intraocular Lenses (ICL):**

Eyedeal is developing a new generation of phakic intraocular lenses (ICLs) based on its globally patented cross-linked polyisobutylene material. This material offers superior biocompatibility, reducing adverse reactions, and is primarily intended to help patients with high myopia restore their vision.

**Glaucoma Drainage Tubes:**

Eyedeal is developing proprietary glaucoma drainage tubes that utilize the material's anti-fibrotic properties to reduce capsular overgrowth and extend tube patency. Their unique pore design enables controlled, stepwise aqueous humor drainage, helping prevent postoperative hypotony. Designed for minimally invasive glaucoma surgery (MIGS), these tubes are suitable for elderly patients and those with coagulation disorders.

Source: Public Information, Frost & Sullivan Analysis.

# Advanced Cardiovascular Medical Device Company - MitrAssist

以心医疗 MitrAssist

## Company Introduction

MitrAssist is a globally leading comprehensive cardiovascular platform company focused on the innovation, industrialization, and global commercialization of premium cardiovascular medical devices. It is the only company worldwide that spans all three major cardiovascular areas, which includes coronary intervention, structural heart, and heart failure. MitrAssist is also among the few top-tier companies with globally independent intellectual property and multi-technology track achievements.

MitrAssist operates four R&D centers in China, Israel, and Germany. Its direct sales network covers both China and the U.S., and large-scale commercialization began in the second half of 2023. The company employs about 250 people worldwide and has established a distributor network in nearly 30 countries and regions. MitrAssist aims to be a leading global comprehensive cardiovascular platform company. Its portfolio includes Class III cardiac valve therapy products , Class II heart failure monitoring products, and Class III interventional coronary drug coated balloons. The company holds 132 granted global patents and is among the world's first cardiovascular innovators to develop transcatheter mitral valve replacement (TMVR) systems. To date, it has raised over 300 million USD from investors including Fosun Pharma, Centurium Capital, 6 Dimensions Capital, Shanghai Jiading State-owned Assets, China International Capital Corporation, Hefei State-owned Assets, Ping An, and CITIC Capital.

## Development History

**2017**
- Established Shanghai Headquarters and Global Operations Center.
- **Series A 25 million**

FOSUN PHARMA 复星医药
中国平安 PING AN

**2020**
- Completed 1-year postoperative follow-up for the first patient treated with the TMVR.
- The ReDS lung fluid measurement device **has collected clinical data from 6,000 cases in the U.S.**
- **Series B 70 million USD**

CENTURIUM CAPITAL 大钲资本 | 6 Dimensions Capital 通和承 | 元禾控股 YUANHE HOLDINGS
中信证券 CITIC SECURITIES | CICC 中金公司

**2021**
- Successfully **initiated multi-center regulatory clinical implantations** for the TMVR device.
- Completed R&D and animal testing for the new-material valve series.

**2022**
- Achieved the world's first clinical implantation of a **new-material Transcatheter Aortic Valve Replacement (TAVR) device.**
- ReDS was **the first to enter commercialization** in the US.
- **Series C1 18 million USD**

6 Dimensions Capital 通和承

**2023**
- ReDS has entered **commercialization** in China.
- Paclitaxel Drug Coated Balloon (DCB) has received NMPA approval in China and is **in commercial use**.
- Completed first-in-man (FIM) implantation of 10 cases of **new material TAVR**, with promising clinical follow-up results.
- **New material surgical valve** has entered the type-testing phase.
- **Series C2 520 million RMB**

CENTURIUM CAPITAL 大钲资本 | 嘉定国资 | 合肥产投集团 | 混改集团 | 安元基金 ANYUAN FUND | 滨湖集团

## Technical Advantages

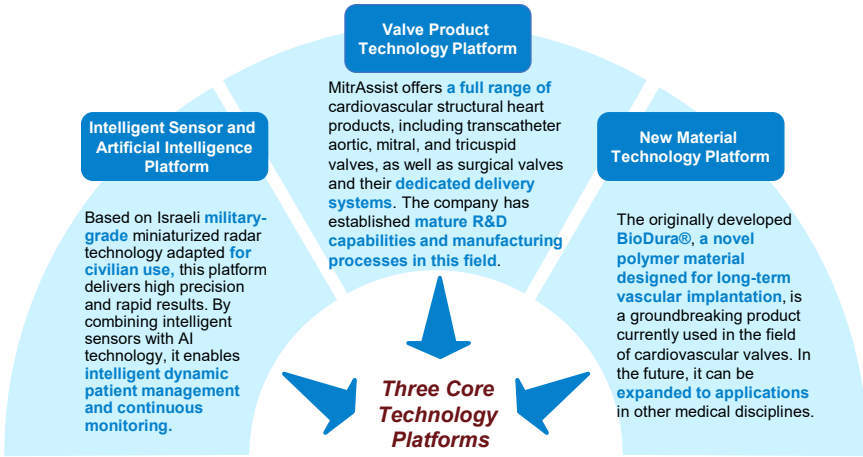
MitrAssist has built a differentiated framework that reflects the key characteristics of a top-tier cardiovascular enterprise:

As a multi-product platform company, MitrAssist has an extensive presence in the three most critical cardiovascular device segments: coronary intervention, structural heart, and heart failure.

With a strong portfolio of independent intellectual property, the company holds 132 granted global invention patents.

With advanced innovation capabilities, MitrAssist has established robust competitive barriers. Its product lead the industry in clinical progress, and its heart failure monitoring devices and paclitaxel DCB have already been commercialized, laying the groundwork for global sales channels ahead of future product approvals.

**Figure: The Three Core Technology Platforms of MitrAssist**




Source: Public Information, Frost & Sullivan Analysis.



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# Advanced Cardiovascular Medical Device Company - MitrAssist

## Product Pipeline

**Product Introduction**

**Heart Failure Products**

**ReDS® Lung Fluid Measurement Series**

Heart failure is an irreversible disease, with pulmonary edema being the direct cause of hospitalization for 90% of heart failure patients. Currently, ReDS® is the only non-invasive, accurate, and non-implantable lung fluid measurement device available. It uses Israeli military radar technology and provides convenient, easy operation (a detection time of only 45 seconds). ReDS® holds over 70 international patents (42 granted and 28 pending) and has been used in more than 6,000 clinical cases. Extensive clinical data show that ReDS® can reduce heart failure rehospitalization and mortality rates by 91%, extend patient survival, and maintain quality of life.

**Structural Heart Products**

**MitraFix® Mitral Valve Interventional Replacement Series (for Patients with Mitral Regurgitation)**

MitraFix® is the only product worldwide that enables mitral valve implantation via 3 access routes: transapical, transatrial, and transfemoral, with the shortest left ventricular component height. The procedure is fully guided by ultrasound, eliminating the need for scarce hybrid operating rooms. Surgeons can complete the skin-to-skin procedure in just 10 to 15 minutes. The transapical approach has conducted 63 regulatory clinical trial implantations, demonstrating high patient survival rates and stable long-term results.

**Polymer New Material Valve Series**

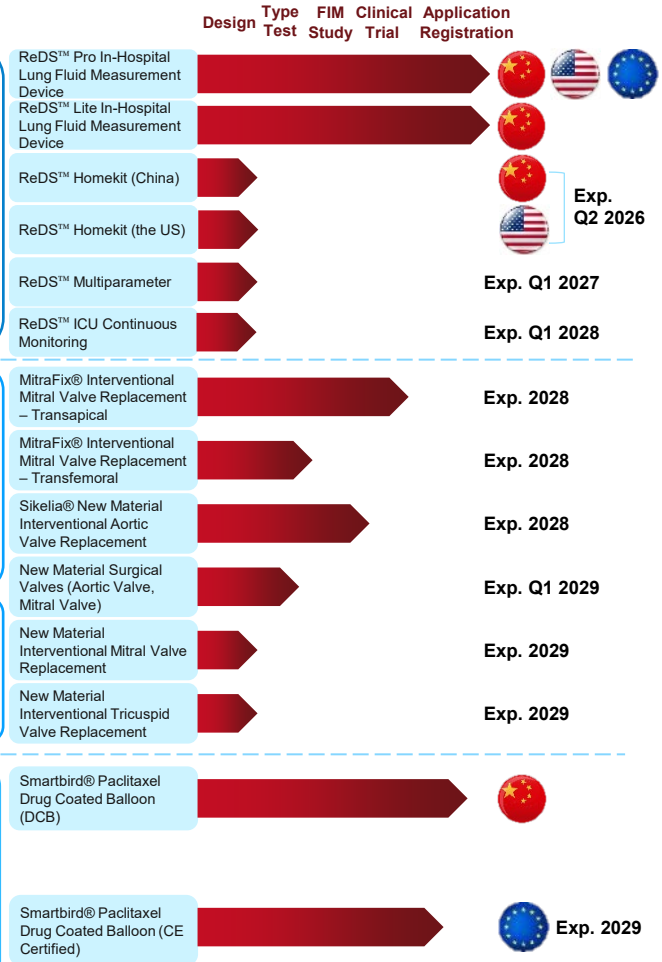
Featuring revolutionary materials and manufacturing technology, these valves offer an implant lifespan of up to 25 years, compared to 8–15 years for conventional bioprosthetic valves. Delivered as pre-mounted dry valves with no need for preoperative assembly, they are fully retrievable and cost only 20% to 10% of the price of bioprosthetic valves.

**Coronary Products**

**Smartbird® Fourth-Generation Paclitaxel Drug Coated Balloon (DCB)**

In vascular interventional therapy, Smartbird® employs an innovative dispersant, Propylene Glycol Laurate, which serves both adhesive and dispersing functions. As a commonly used cardiovascular drug, it also provides antioxidant and antithrombotic effects and may have synergistic action with paclitaxel. This achieves superior drug transfer efficiency and higher tissue drug concentration. In vitro simulations demonstrate that after passing through stent struts three times, 93.95% ± 1.9% of the drug remains, making it especially suitable for treating in-stent restenosis and bifurcation lesions.

**Approval Status**




## Honors and Awards


MitrAssist's global first-in-class new material interventional valve product won the National Finals Merit Award (the highest honor) at the 2022 National Disruptive Technology Contest by Ministry of Science & Technology of China.


Selected by the Transcatheter Cardiovascular Therapeutics (TCT) Conference, the most authoritative interventional cardiology conference in the U.S., as one of the Top 11 Global Innovative Cardiovascular Technologies in 2024, MitrAssist is the only Chinese company on the list.


In January 2024, MitrAssist was awarded by the Shanghai Municipal Government as the sole representative enterprise of "Future Materials" among Shanghai's Top Five Future Industries.

Source: Public Information, Frost & Sullivan Analysis.

# Partner Acknowledgement

During the compilation of the 2025 Blue Book on the Current Status and Trends of Global Expansion of Chinese Medical Devices, UL Solutions provided valuable support through its global experience in technical compliance and professional insights. As a leading global expert in safety science and compliance services, UL Solutions has cultivated deep expertise in the medical device industry. Its global certification network, in-depth understanding of international regulatory requirements, and risk management solutions across the entire product lifecycle offer key pathways for Chinese companies to overcome technical barriers and achieve localized compliance. Especially under the current context of tightening international regulations and significant regional standard differences, UL Solutions helps Chinese medical device companies align precisely with target market access requirements by bridging technical and regulatory gaps, thereby significantly shortening the product global expansion cycle. We sincerely thank UL Solutions for its industry trend analysis, compliance strategy recommendations, and case study support, all of which have added practical value and a global perspective to the Blue Book and contributed to the steady and sustainable global development of chinese medical device industry.

During the compilation of the 2025 Blue Book on the Current Status and Trends of Global Expansion of Chinese Medical Devices, we sincerely thank AllBright Law Offices for its professional support and industry insights. As one of China's leading full-service law firms, AllBright brought critical legal perspectives and practical experience to the core chapters of the Blue Book through its strong foundation in international trade, cross-border investment, compliance risk management, and dispute resolution. The AllBright team provided detailed legal analysis and case interpretations on key topics related to the global expansion of medical devices, including compliance challenges, overseas market access policies, intellectual property protection, and risks in cross-border mergers and acquisitions. In particular, its research on global regulatory developments, differences in national legal systems, and recommendations for building corporate compliance frameworks helped lay a solid legal foundation for the Blue Book, enabling companies to systematically avoid legal and policy risks in global expansion. Furthermore, its in-depth interpretation of international regulations such as the EU MDR and U.S. FDA provided valuable guidance for the industry. AllBright's contributions not only enriched the content of the Blue Book but also strengthened its value as a practical tool for companies formulating global expansion strategies. We express our sincere gratitude to AllBright Law Offices and look forward to continued collaboration in advancing the global development of chinese medical device industry.

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