Deloitte.

德勤

Insights into Chinese Medical Device Companies Going Global
-- Popular Target Markets Overview and Key Success Factors

MAKING AN IMPACT THAT MATTERS since 1845

Feb 2024

Introduction

Chinese medical device companies are facing many challenges in the domestic market, such as severe homogeneous competition in low-value consumables and weak R&D capabilities in imaging diagnostic instruments. Meanwhile, the growth potential of overseas medical device markets remains promising resulted by factors such as large incremental segmented markets, and price-advantage of Chinese medical devices products in comparison to the oversea products due to higher overall pricing environment in the global markets. Therefore, the globalization of Chinese medical device companies is imperative.

To enable Chinese medical device companies to select the appropriate target market, grow steadily in the target market, and showcase the competitiveness of made-in-China products, Deloitte China Life Sciences team selected seven popular target markets in the global medical device industry, including the United States, Germany, France, the United Kingdom, Brazil, Malaysia, and Singapore. Deloitte China has collaborated with Deloitte's Life Sciences teams from the regional offices for several months to complete the report "*Insight into Chinese Medical Device Companies Going Global – Popular Target Markets Overview and Key Success Factors*".

The report presents in-depth research on the macroeconomy, healthcare system, market overview, regulatory system and other elements of the suggested target markets, demonstrates the characteristics of each market, analyzes the main models of Chinese medical device companies' entry into various markets, highlights the main challenges faced by Chinese medical device companies in the market, and outlined the key success factors and implementation suggestions for Chinese medical device companies to expand their oversea business.

Deloitte is committed to escorting Chinese enterprises going global and providing services and support for the globalization of Chinese medical device enterprises through enriched overseas experience, in-depth industry insights and strong professional capabilities.

Stanley Dai, Deloitte China deputy CEO, Deloitte China Chief Strategy Officer, and Deloitte China Consulting CEO, notes that Chinese players are increasingly proceeding towards globalization, with the vigorous development of the domestic medical device market. “The core of ‘Made in China’ is changing along with the trend of Chinese enterprises going global,” he says. “It now holds a different meaning of high-tech represented by Chinese medical technology, in contrast with the traditional manufacturing products of the past. This evolution is continuously bringing new strength to the broad group of Chinese companies that aspire to expand their businesses in overseas markets.”

Jens Ewert, Deloitte China Life Sciences & Health Care Industry leader, says, "The goal in globalization of Chinese medical device companies is not only to expand market share and enhance brand impact, but also an important approach for enterprises to enhance their global competitiveness and achieve long-term sustainable development.“

Carrie Xiao, Deloitte China Life Sciences Sector leader and Consulting leader, adds, “In the process of going overseas, Chinese enterprises need to formulate a far-sighted strategic plan, build a stable operating system, and establish strong support functions to achieve sustainable globalization development goals.”

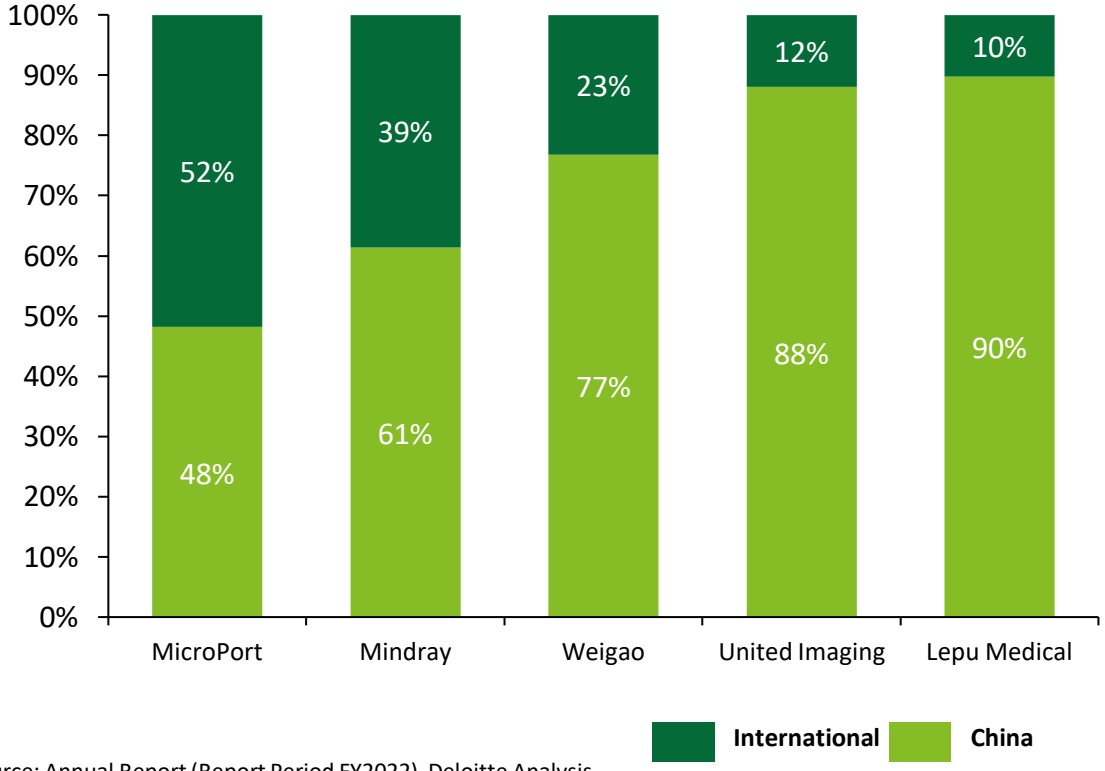
“Deloitte China will continue to collaborate with life sciences teams in other member firms, incorporate project experience and local research results to provide strong and localized support for Chinese medical device companies going global.”

Contents

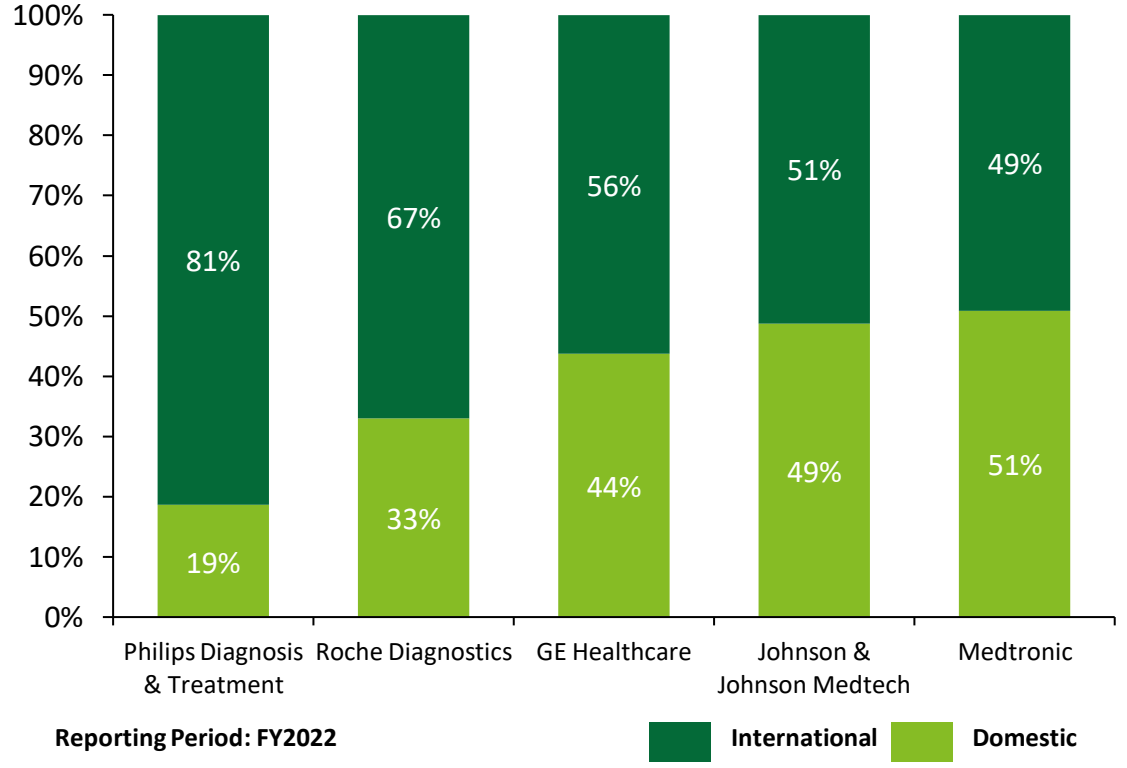
Globalization of China Medical Device Companies

The average percentage of international revenue of China's leading medical device companies is between 20-30%, while the average proportion of international revenue of Global leading medical devices companies is between 50-60%. There is a **large gap in the share of international revenue** of leading enterprises in China's medical device field in comparison with leading international medical device enterprises, and the **globalization potential for China's medical device companies is significant**.

Leading Chinese Medical Device Companies - Share of Global Revenue



Leading Global Medical Device Companies – Share of Global Revenue



Source: Annual Report (Report Period FY2022), Deloitte Analysis

The Need for Chinese Medical Device Companies to Go Global

Multiple Challenges in the Chinese Medical Device Market

Import-reliant diagnostic imaging
Weak R&D innovation capability

Small and scattered low-value-consumable companies
Severe homogenization competition

Low import substitution rate in the patient aid sector
Focus on middle- and low-end products

Orthopedic device price plummets after centralized procurement
Struggling non-top firms

Domestic challenges

Overseas opportunities

Massive Potential in the Overseas Medical Device Market

Vast overseas market expansion potential

Higher margins and stability in product prices

Significant growth potential for Chinese companies on oversea market penetration

Chinese devices' cost-performance advantage

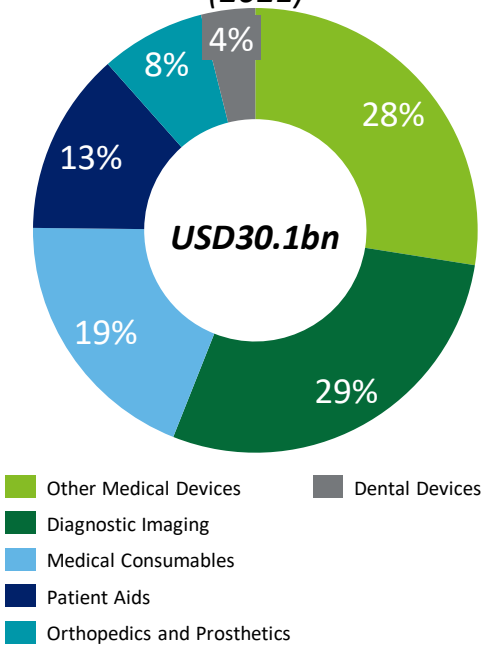
Enhanced overseas recognition of Chinese brands during the COVID-19 pandemic

Source: Deloitte Analysis

Multiple Challenges in Chinese Medical Device Market

Chinese Medical Device Segment Market Share

(2021)



Import reliance due to weak R&D capability

- *Although the diagnostic imaging sector has a significant market share, middle- and high-end imaging devices remain reliant on imports due to their high R&D innovation requirements and account for the largest proportion (31%) of imported medical devices*

Chinese market monopolized by foreign brands

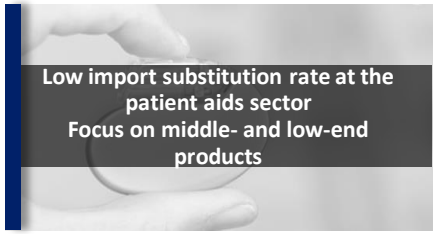
- *In 2021, China's middle- and high-end medical imaging market was monopolized by GE, Philips and Siemens (for example, in the CT sector, CR3 was ~70%)*

Small and medium sized Chinese players

- *Although numerous Chinese market players specialize in low-value consumables, over 90% of them are small and medium sized, with annual revenues between RMB30 million and RMB40 million*

Fierce homogenization competition

- *With updated technology, increased healthcare demand and tightened regulation in the future, scale manufacturing capacity and cost control ability become companies' critical success factors amid fierce product homogeneity competition*



Focus on middle- and low-end products

- *In the patient aids sector, Chinese companies mainly produce middle- and low-end products and their capability to develop products with higher technical barriers, such as pacemakers and ventilators, still needs enhancing. The domestic substitution is progressing slowly*

Low import substitution rate

- *Take pacemakers as an example. Their localization rate is only 5%. Medtronic, Abbott, and Boston Scientific account for over 80% of the market share, while only three Chinese companies have approved products, including Lepu Medical, LifeTech Scientific and Chuangling Heart Rhythm Management Medical Devices*

Centralized procurement focuses on orthopedic devices

- *Orthopedics is a key sector for volume-based purchasing, such as joint prostheses, spinal devices and sports medicine devices.*

Price plummets

- *Volume-based purchasing slashes prices. In 2022, the joint prosthesis price slumped by 82% YoY on average. As top companies gained market share, other companies must make their cost control and technology R&D more competitive*

Source: Open data, Deloitte Analysis

Potential in Overseas Medical Device Market

Promising and Attractive Overseas Medical Device Market

Broad Overseas Market

- *The global medical device market totaled over USD480 billion in 2021, with the U.S. as the largest market (>40%) and Western Europe as the second largest (~25%)*

Large segment expansion potential

- *In segment terms, domestic and overseas markets differ in segment expansion potential. For instance, the orthopedic device segment can expand by eight times*

High product prices

- *Medical device prices overseas are higher than those in the domestic market. For example, the coronary stent price in the United States is about 6-10 times that in China*

Stable prices

- *Medical device prices overseas are stable. For example, Edwards SAPIEN 3 valve (for Aortic Stenosis) has maintained its unit price at USD32,500 since its introduction in 2011*

Chinese companies' room for overseas expansion

- *Products offered by Chinese medical device companies have price advantage in comparison to products with similar quality standard and functionalities provided by leading Global medical device companies. China's medical device enterprises have great potential in globalization, the average international revenue of the leading enterprises only account for 20-30%*

Chinese devices' great cost-performance advantage

- *Chinese medical devices have improved performance and competitive price. Chinese ventilators, for example, achieved favorable balance of trade, with BMC Medical (marketing with self-brand) and Mehow (as ResMed' component supplier) as typical companies*

Enhanced overseas recognition of Chinese medical devices during the COVID-19 pandemic

- *Overseas markets widely recognized Chinese medical devices during the COVID-19 pandemic, especially low-value consumables with low technical barriers and middle- and low-end medical equipment, laying a solid foundation for Chinese medical device companies to go global*

Key Insights

Under the price control through centralized procurement, Chinese medical device companies may **actively expand overseas:**

- Through objectively analyzing **product superiority** and developing targeted global strategy scheme
- The companies already recognized by the market may further enhance their competitiveness by quickly improving their **R&D, manufacturing, and supply chain** capabilities

Source: Open data, Deloitte Analysis

Openness of Overseas Medical Device Market

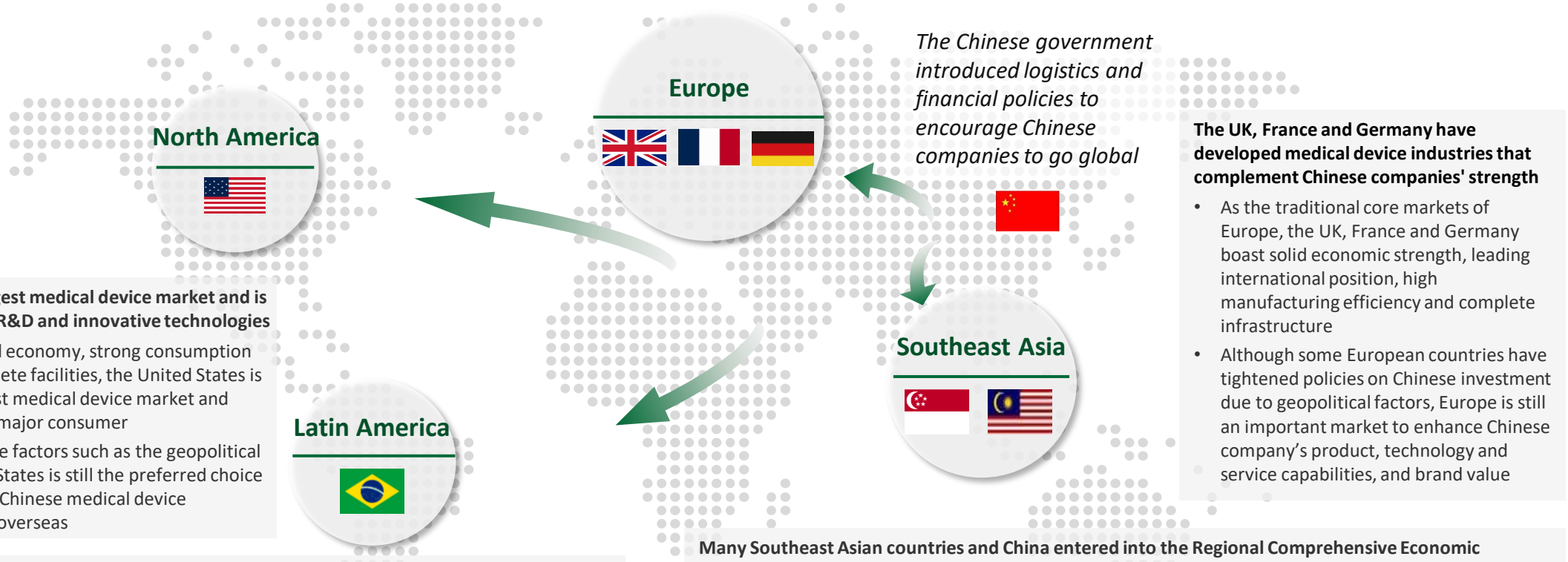
Market Access Overview

The global MedTech industry is a relatively open market. Most countries adopt similar regulatory requirement procedures despite the difficulty (time & efforts needed) of product registration varies. The difficulty for product registration highly depends on the classification of the specific medical devices (e.g., Class I, II, III).

Source: Open data, Deloitte Analysis

Contents

Southeast Asia, Europe and North America are top destinations, while emerging markets, such as South America, Africa and the Middle East, are showing potential



The U.S. has the largest medical device market and is the global leader in R&D and innovative technologies

- With a developed economy, strong consumption power and complete facilities, the United States is the world's largest medical device market and Chinese devices' major consumer
- Therefore, despite factors such as the geopolitical risks, the United States is still the preferred choice for many leading Chinese medical device companies to go overseas

Brazil, Latin America's largest economy, urgently needs to develop its medical device market

- Brazil is highly urbanized, and more than half of Brazil's population is considered middle class
- Brazil is the world's eighth-largest healthcare market and Latin America's largest medical device market
- Chinese companies expanding in Brazil account for only 1%, far lower than those from the U.S., Japan and other regions, with room for expansion
- China-Brazil agreements and policies, such as local currency settlement and taxation agreements, facilitate Chinese companies

The UK, France and Germany have developed medical device industries that complement Chinese companies' strength

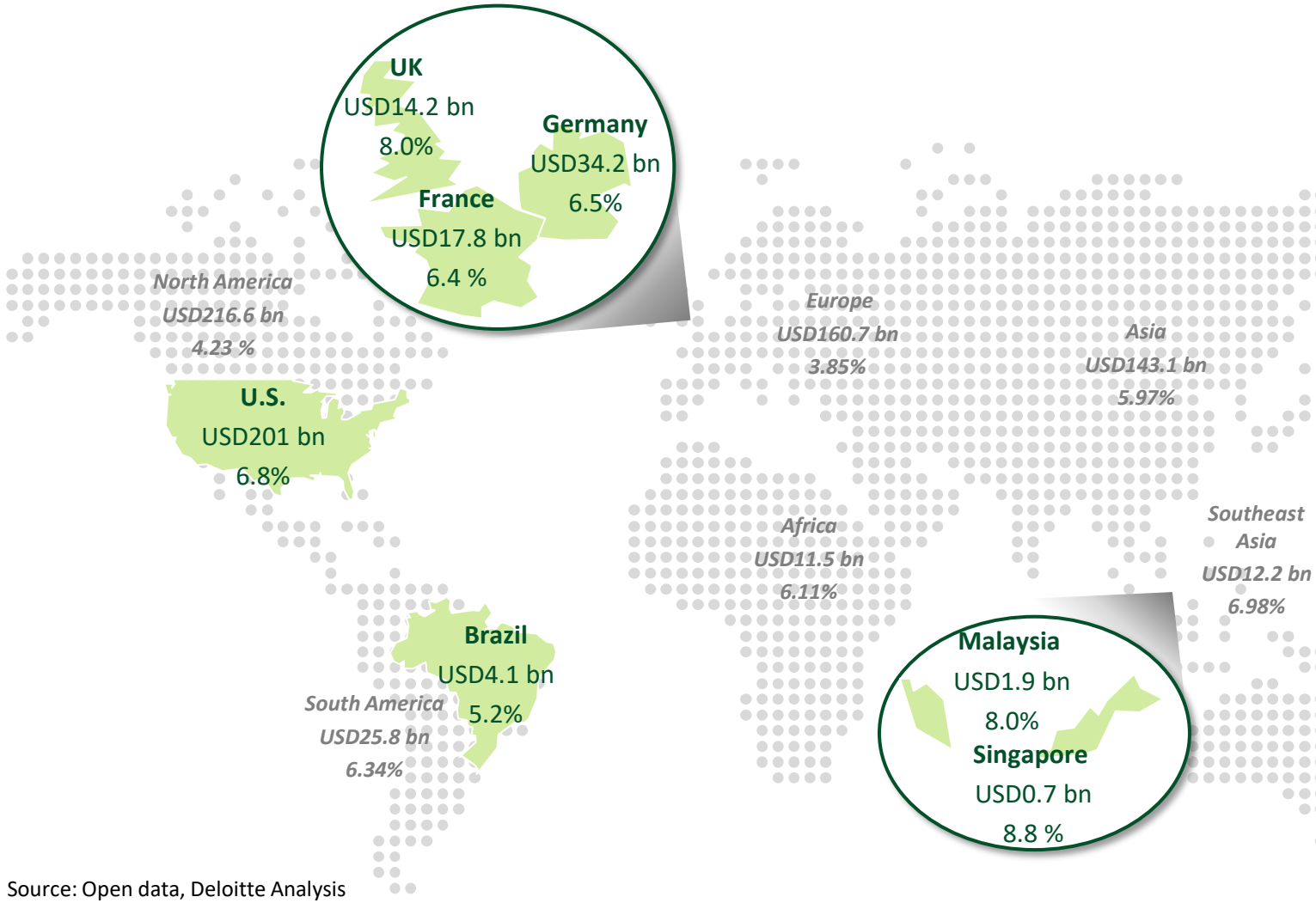
- As the traditional core markets of Europe, the UK, France and Germany boast solid economic strength, leading international position, high manufacturing efficiency and complete infrastructure
- Although some European countries have tightened policies on Chinese investment due to geopolitical factors, Europe is still an important market to enhance Chinese company's product, technology and service capabilities, and brand value

Many Southeast Asian countries and China entered into the Regional Comprehensive Economic Partnership (RCEP) for close cooperation; Singapore and Malaysia are the top destinations for device companies to extend their business presence into Southeast Asia

- With many ethnic Chinese, mature markets and high consumption power, Singapore and Malaysia are more receptive to Chinese products
- In Singapore, resources and facilities are complete, trade is free and taxes are low
- Policies and related institutions (Investment Development Authority, Chinese Chamber of Commerce, etc.) facilitate Chinese companies
- As the business center of Southeast Asia, Singapore can be the gateway to the Southeast Asian market

来源：公开数据，德勤分析

In terms of market size, the European and American medical device markets are large and mature, and emerging markets, such as South America and Southeast Asia, show a high growth rate and development potential



Country	Market Size 2021 (USD bn)	2021-2026 CAGR	Health Spending Per Capita 2022 (USD)
U.S.	201.0	6.8%	13,341
Germany	34.2	6.5%	6,135
France	17.8	6.4%	4,926
UK	14.2	8.0%	4,827
Brazil	4.1	5.2%	963
Malaysia	1.9	8.0%	520
Singapore	0.7	8.8%	3,506

Source: Open data, Deloitte Analysis

Popular Target Market – U.S. (1/4)

Macroeconomy[1]

GDP

USD25.46 trillion
GDP (Gross Domestic Product)

2.2%↑
YoY Growth

USD76,500
GDP per capita

Demographics

Total population: 340 million

0.4%↑
YoY Growth

17%
Percentage of seniors[2]

Health Spending

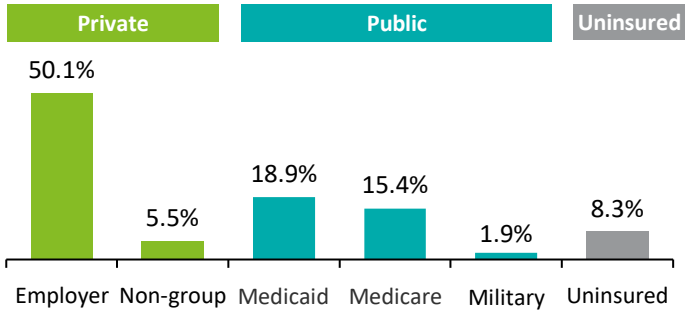
USD13,341
Health spending per capita

16.9%
Health spending as a share of the GDP

Healthcare System

Payer Overview

Health Insurance Status Distribution of the Total U.S. Population In 2021



The U.S. does not have universal health insurance:

- Health care costs are covered through different private and public insurance programs. The insured population of the U.S. is covered under **employer-sponsored, non-group, and publicly funded health insurance.**

Private payers are dominating:

- **Private (nearly 70%) is the main form of health insurance coverage** among the U.S. population. The health insurance **market is highly concentrated**, where the top five insurers have a combined market share of nearly 50%

Public insurance only covers some groups:

- **Medicaid:** Mainly provides health coverage to eligible low-income individuals or families, and the benefits provided include outpatient/inpatient hospital services, physician services or emergency hospital services, prescription drugs, etc.
- **Medicare:** The largest health insurance payer in the United States, initially covering people aged 65 or older, regardless of income or medical history, but now expanding to citizens under 65 with permanent disabilities and end-stage renal disease

Patient Overview

Cardiovascular diseases, cancers, and COVID-19 become leading causes of death	In 2022, cardiovascular diseases, cancers, accidents and COVID-19 are the leading causes of death in the United States; the remaining leading causes were stroke, chronic lower respiratory diseases, Alzheimer's disease, diabetes, chronic liver disease, etc.
Non-communicable diseases (NCDs) rise	The morbidity of NCDs, such as dementia, diabetes and some cancers, has been rising in recent years.
Life expectancy falls	Life expectancy for the U.S. population in 2021 was 76.4 years, a decrease of 0.6 year from 2020.

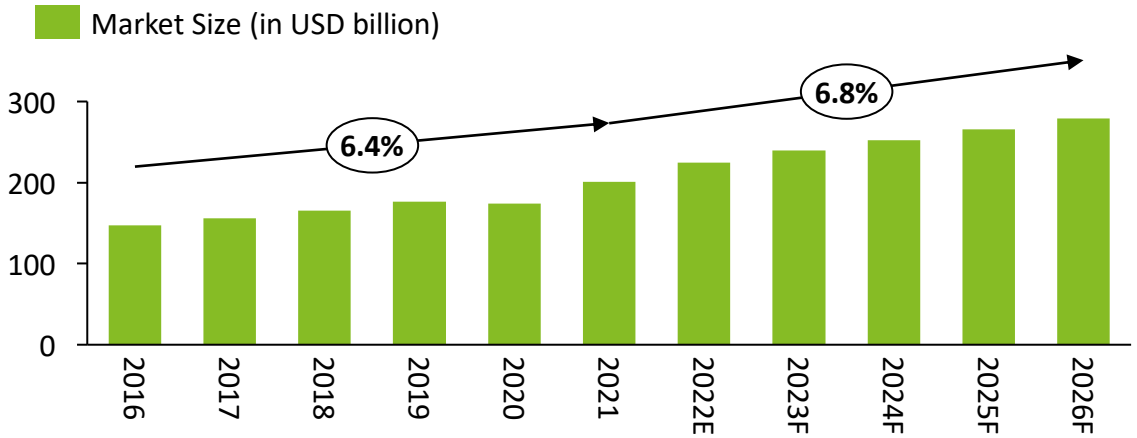
Notes: 1. Macroeconomic data source from statistics for 2022; 2. Percentage of seniors refers to the percentage of the population aged 65 and older

Source: Open data, Deloitte Analysis

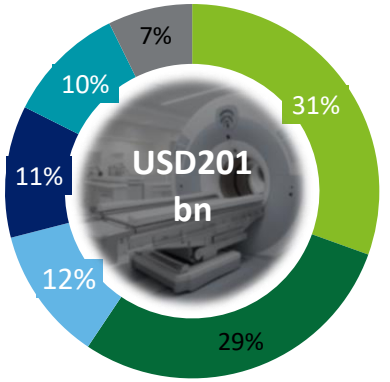
Popular Target Market – U.S. (2/4)

Medical Device Market Overview

U.S. Medical Device Market Size Forecast



Market Segment Size in 2021



2021-2026 CAGR

Other Medical Devices	7.7%
Diagnostic Imaging	7.3%
Medical Consumables	6.6%
Patient Aids	6.4%
Orthopedics and Prostheses	6.3%
Dental Devices	6.1%
Total	**6.8%**

Key Growth Drivers

- ***Economy:*** The world's largest economy/consumer market, high R&D investment, and vital innovation driving force
- ***Healthcare Market:*** Continuous growth and aging of population, and increasingly common chronic diseases, boost demand for health care; high health spending per capita and as a share of GDP reflect American people's strong health consciousness; the healthcare system actively uses new technologies and novel devices to improve health care level
- ***Policy:*** The *21st Century Cures Act* helps promote basic research, therapy development, and achievement transformation, and accelerates the approval of novel devices; new Medicare rules expand the novel device coverage; policy support promotes the formation of regional innovation centers (e.g., California, Minnesota)

Key Growing Segments

- ***Segments:*** The U.S. medical device segments' growth rate varies slightly, with a CAGR of 6.8% from 2021 to 2026; the sectors of **other medical devices** and **diagnostic imaging** are growing rapidly
- ***Medical Device Imports:*** **Imports accounted for approximately 30% of the U.S. medical device market**, reaching a record high of USD63 billion in 2021; **Mexico** was the largest supplier (representing 18.1% of total imports), and imports from the **EU** accounted for one third, Ireland being the leading supplier in the EU (11.8%)
- ***China Exports:*** China was **the second largest medical device supplier** to the U.S. (12.5%). Chinese suppliers featured prominently in the **patient aids** sector (over a quarter of the import total), as well as the sectors of other medical devices, medical consumables, and dental devices

Source: Open data, Deloitte Analysis

Popular Target Market – U.S. (3/4)

Medical Device Regulatory System

Medical Device Regulator

U.S. Food and Drug Administration (FDA)

As a comprehensive consumer protection agency of the U.S. federal government, the FDA has the Center for Devices and Radiological Health (CDRH) to regulate firms that manufacture, package, or sell medical devices in the United States.

Regulator

FDA

- Center for Drug Evaluation and Research
- Center for Biologics Evaluation and Research
- Center for Food Safety and Applied Nutrition
- ...
- **Center for Devices and Radiological Health**

Office of Policy, Office of Strategic Partnerships & Technology Innovation, Office of Product Evaluation & Quality, Office of Communication & Education, Office of Science & Engineering Laboratories, Office of Management

Registration Policy

- FDA classifies medical devices into Class I, II, and III, depending on the intended use of the device and the risk the device poses to the patient and/or the user. **Regulatory control increases from Class I to Class III.** The device classification regulation defines the regulatory requirements for a general device type. FDA has established classifications for approximately 1,700 different generic types of devices.

Class I —— General Controls	Class II —— Special Controls	Class III —— Strict Controls
Assuring effectiveness and safety (approximately 47%)	*Subject to FDA requirements or industrial standards (approximately 46%)*	*GMP and PMA are required (approximately 7%)*

- **U.S. Agents:** Any foreign medical device or drug facility must register with FDA and identify a U.S. agent before entry into the U.S. The responsibilities of the U.S. agent include assisting the FDA in communications with the foreign facility; the agent has a legal role, but is not included in the product labeling
- **Registration Accelerating Pathway:**
  - ***Substantial Equivalence:*** For Class II and Class III devices, if the information submitted to the FDA demonstrates that the new device is **as safe and effective as the legally marketed device**, the PMA and clinical trials are not required, but a **510(k)** must be submitted to FDA with a performance test conducted. The approval lasts 90 days
  - ***Breakthrough Devices Program:*** For novel medical devices that have the potential to provide more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions, when complying with PMA, 510(k) and De Novo statutory standards, manufacturers can expect a prioritized review of their submission and be offered an opportunity to interact with FDA experts to efficiently address topics as they arise.

Marketing Policy

- FDA's current **Good Manufacturing Practices** (GMP) require any domestic or foreign manufacturer to establish a complete **quality system** for the design, manufacturing, packaging, labeling, storage, installation, and servicing of medical devices marketed in the United States. The regulations make sure that a medical device is **safe** for use **and effective**

Source: Open data, Deloitte Analysis

Popular Target Market – U.S. (4/4)

Major Market Entry Models of Chinese Companies

Local subsidiaries

- **Mindray** Medical established subsidiaries and offices in the United States and R&D centers in Silicon Valley, Seattle, and New Jersey. Mindray is building a leading cross-system medical product innovation system (OBM model) covering planning, R&D, and registration. Mindray Medical's professional direct marketing team partnered with the four major Group Purchasing Organizations (GPOs) in the U.S. to make its products cover nearly 10,000 terminal medical institutions in the U.S.

Distributors

- **Zhonghong Medical**, which specializes in disposable protective gloves for medical and industrial use, partners with large American medical device distributors (ODM model), such as Cardinal Health and McKesson, to develop, design, and produce customized products distributors sell and deliver to end customers

OEM

- **OSSIFER** equipped with workshops and equipment that comply with GMP standards, provides Class II and III sterile medical consumables OEM services for medical device manufacturers in the U.S.

Major Challenges in U.S. Market

Local operation

- For Chinese medical device companies interested in tapping into the U.S. market, there is a need to build local operations (**especially R&D, clinical, commercialization and other functions**, in addition to sales and marketing) as early as possible and gradually enhance brand awareness and influence

Supply chain localization

- The impact of the COVID-19 on the supply chain resulted in medical device supply shortage and surging material costs. As the U.S. government **directed manufacturing to return to the U.S.** through administrative measures and subsidies, Chinese medical device companies will face increasing competition from U.S. local firms in the future, and cross-border biological information and product transmission will be increasingly regulated

Tightened reimbursement

- With population aging and healthcare technology innovation, payers incur increasing health care costs and must exclude some medical devices (such as optional medical devices and rehabilitation devices) from coverage. Chinese medical device companies must have a deep understanding of American insurers' specific medical device **reimbursement policies** to improve product accessibility

Information security

- The U.S. has strict **patient privacy protection law, HIPAA** (Health Insurance Portability and Accountability Act). For Chinese medical device companies, any product that stores patient data must strictly comply with HIPAA information security requirements

Complaints and legal risks

- American consumers have a **high awareness of rights protection** and numerous medical dispute lawyer teams are available. If any product violates regulations and harms consumer rights, the manufacturer will face huge legal costs and damages

Source: Open data, Deloitte Analysis

Popular Target Market – Germany (1/4)

Macroeconomy[1]

GDP

USD4.06 trillion
GDP (Gross Domestic Product)

1.9%↑ YoY Growth

USD49,000 GDP per capita

Demographics

Total population: 84.40 million

1.3%↑ YoY Growth

22% Percentage of seniors[2]

Health Spending

USD6,135
Health spending per capita

11.4%
Health spending as a share of the GDP

Healthcare System

Payer Overview

Statutory Health Insurance
- Covering over 90% of the population, compulsory for low-income people
- Covering outpatient, medicine, surgery and hospitalization costs, and part of the rehabilitation treatment costs
- Provided by 145 competing, not-for-profit, self-governing sickness funds

Private Insurance
- Providing more benefits than the statutory health insurance
- Provided by 24 for-profit insurers and 19 not-for-profit insurers

Long-term Care Insurance
- Covering over 80% of the population
- Covering care costs, and the amount of benefits provided depends on the care grade assessed
- Covering part of the care costs, and the out-of-pocket payments the insured make are generally between 30% and 40%, which are mostly for the professional nursing services received in nursing homes; to be eligible for long-term care benefits, one must have been covered by health insurance

Patient Overview

High mortality rate

The German population's state of health is not as good as that in many other developed countries, and Germany is one of the countries with the highest mortality rate among developed countries (with a mortality rate of approximately 12.3‰ in 2022, while 8.2‰ in Switzerland, and 9.7‰ in the UK)

High incidence of cardiovascular diseases and cancers

In Germany, non-communicable diseases are the leading cause of death and morbidity, and changes in lifestyle and population structure determine their incidence rate. Cardiovascular diseases and cancers remain dominating, while the incidence rate of dementia, diabetes, mental health problems and musculoskeletal diseases is also rising

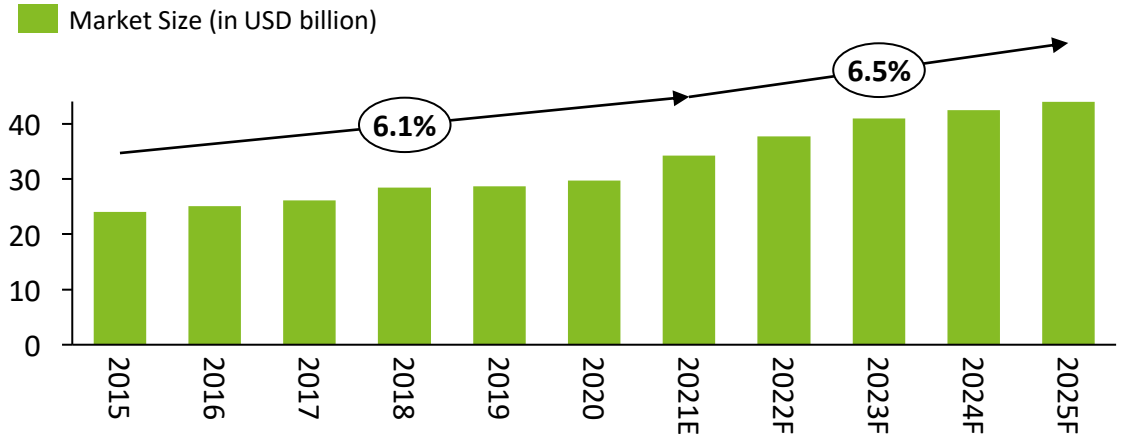
Notes: 1. Macroeconomic data source from statistics for 2022; 2. Percentage of seniors refers to the percentage of the population aged 65 and older

Source: Open data, Deloitte Analysis

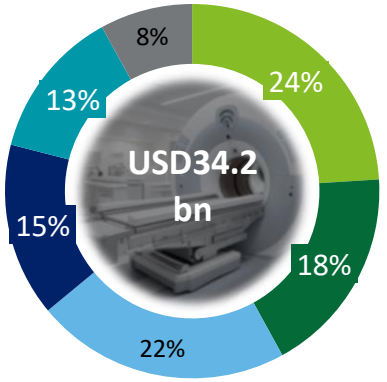
Popular Target Market – Germany (2/4)

Medical Device Market Overview

Germany Medical Device Market Size Forecast



Market Segment Size in 2021



	2021-2025 CAGR
Other Medical Devices	6.8%
Diagnostic Imaging	4.6%
Medical Consumables	5.4%
Patient Aids	5.8%
Orthopedics and Prostheses	9.4%
Dental Devices	7.8%
Total	**6.5%**

Key Growth Drivers

- ***Economy:*** As a leading economy in Europe with a high per capita GDP, Germany enjoys a free economic environment and globally leading manufacturing
- ***Healthcare Market:*** Germany has a larger population base among European countries, and its severely aging population and high incidence of chronic diseases boost healthcare demand; Germany enjoys high-level clinical research and advanced healthcare technology, especially the technology in the imaging sector
- ***Policy:*** Germany's *High-Tech Strategy 2025* promotes the integration of medical devices and artificial intelligence to further enhance medical device innovation and facilitate the development and expansion of the medical device market

Key Growing Segments

- ***Segments:*** The German medical device market segments' shares are relatively fixed. **Consumables** (~20%) and **imaging** (~17%) account for a larger proportion, while the **orthopedics and prostheses** sector has a higher growth rate
- ***Medical Device Imports:*** Germany is the world's major medical device exporter, while its import volume is low, **mainly importing consumables and other medical devices**; in supplier terms, the EU is the leading medical device supplier to Germany (57%), followed by the United States (24%) and China (13%)
- ***China Exports:*** China (13%) was Germany's second largest medical device supplier, without considering EU countries. In 2020, **diagnostic imaging** devices accounted for approximately 30% of China's exports (mainly electrodiagnostic apparatus), and **patient aid** devices nearly 25% (mainly therapeutic equipment)

Source: Open data, Deloitte Analysis

Popular Target Market – Germany (3/4)

Medical Device Regulatory System

Medical Device Regulator

Federal Institute for Drugs and Medical Devices (BfArM)

BfArM is responsible for administering medical device marketing, collecting, analyzing, and evaluating risks in the application of medical devices, and coordinating necessary measures based on reported adverse events

Regulator

Federal Ministry of Health

Federal **Institute for** Drugs and **Medical Devices (BfArM)**

Licensing 1	Licensing 2	Licensing 3	Licensing 4	**Medical Devices**	Information Technology, Clinical Trials	Federal Opium Agency	Research	...

Administering medical device marketing, collecting, analyzing, and evaluating risks in the application of medical devices, and coordinating necessary measures based on reported adverse events

Non-active Medical Devices	In-vitro Diagnostics	Active Medical Devices	Clinical Trials	Digital Health and Nursing Application

Classification and Registration

Class I (Low Risk)

- **Device Type:** Non-invasive and low-risk devices, such as thermometers and portable surgical instruments
- **Short approval timeline**

Class II (Medium Risk)

- **Device Type:** Class IIa includes some diagnostic facilities, dialyzers, syringes, etc.; Class IIb includes invasive devices, implantable devices, ventilators, etc.
- **Approval Process:** A device marketing authorization must be applied to the notified body, which will review the application and issue a CE certificate after review and approval
  - For Class IIa products, the manufacturer is responsible for product design, and the notified body mainly inspects the **quality system**
  - For Class IIb products, the notified body reviews the **quality system** and conducts **spot checks on samples**, while the manufacturer must submit **product design documentation**
- **Approval Timeline:** The registration is very complex, and **the approval will last 3 to 6 months**

Class III (High Risk)

- **Device Type:** Implantable devices, heart valve prostheses, cardiac pacemakers, etc., generally related to life support
- **Approval Process:** The notified body will conduct a review, inspect the quality system, conduct spot checks on samples, review the product design documentation, and specially examine the product risk analysis report.
- The registration is the most complex, **and the approval will last 3 to 9 months**

Source: Open data, Deloitte Analysis

Popular Target Market – Germany (4/4)

Major Market Entry Models of Chinese Companies

Local manufacturing facilities

- **Bluesail Medical** established manufacturing facilities and innovative R&D centers in Germany to enhance its capacity, expand product coverage (in the European region), and increase its local presence and influence

Local firm partnership

- **United Imaging Healthcare** strategically partnered with German company ITM Isotopen Technologien München AG in the fields of market, sales, imaging, and related products, focusing on innovation and optimization of precision health care imaging, and covering aspects of radiopharmaceuticals, image processing, imaging digitization, patient workflow, patient management and support

Local M&A

- **Wallaby Medical** quickly entered the German market by acquiring German company Phenox and leveraging its market channels
- **Mindray Medical** announced on Nov 30, 2023, on the acquisition cutover of 75% equity of German company DiaSys to improve its overseas supply chain platform and make it more competitive in the German market

Major Challenges in German Market

Data reliability

- Chinese medical device companies need to strengthen their own products' **clinical data collection and analysis**, and strictly comply with the German medical device registration regulations (such as managing health technology assessment and complying with the requirements regarding patient groups in clinical trials) to improve registration efficiency

Pricing and negotiation

- In Germany, the medical device **price is determined by the health insurance system.** Medical device companies expanding to Germany must be capable of negotiating favorable prices and reimbursement terms with health authorities/insurance institutions and offer innovative cooperation approaches to make their products more competitive in price

Local operation

- As Germany boasts the world's leading medical device brands, and German consumers and medical companies **prefer local, American, or other European companies**, Chinese companies must strengthen their local manufacturing and operation capabilities in Germany to enhance market awareness and acceptance

Supply chain compliance

- When ensuring a stable supply chain, Chinese medical device companies also need to know the requirements regarding human rights and environmental standards specified in **Germany's newly introduced *Act on Corporate Due Diligence in Supply Chains*** (effective as of January 1, 2023, for German companies and their suppliers)

Source: Open data, Deloitte Analysis

Popular Target Market – France (1/4)

Macroeconomy[1]

GDP

USD2.78 trillion
GDP (Gross Domestic Product)

2.6%↑ YoY Growth

USD40,900 GDP per capita

Demographics

Total population: 68 million

0.3%↑ YoY Growth

20% Percentage of seniors[2]

Health Spending

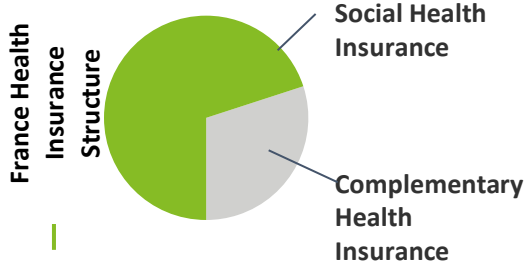
USD4,926
Health spending per capita

10.9%
Health spending as a share of the GDP

Healthcare System

Payer Overview

France runs a pluralistic health insurance system, mainly including social health insurance (Securite Sociale) and complementary health insurance (Mutuelle):



- Universal coverage (for all legal residents who have lived in France for at least three months)
- Administered by the French health insurance administration department
- Generally **reimbursing 70% of the health care cost**; funded by employee contributions and government taxes

- Including mutual insurance, commercial insurance, etc.
- Taken out by individuals or employers
- Complementary health insurance covers costs in addition to social health insurance, and the combination of the two can usually reimburse 100% of the health care cost

Patient Overview

High cancer incidence	Cancer is the top cause of death in France, with more than 3 million people living with or having had cancer and more than 450,000 new cases diagnosed each year
Rising neurodegenerative disease incidence	The number of people with neurodegenerative diseases, such as parkinsonism, multiple sclerosis, and Alzheimer's disease, is also on the rise
Rising life expectancy	In 2021, the life expectancy for the French population was 82.4 years, up 0.1 year from 2020; the life expectancy difference between men and women was 6.2 years, an increase of 0.1 year from 2020

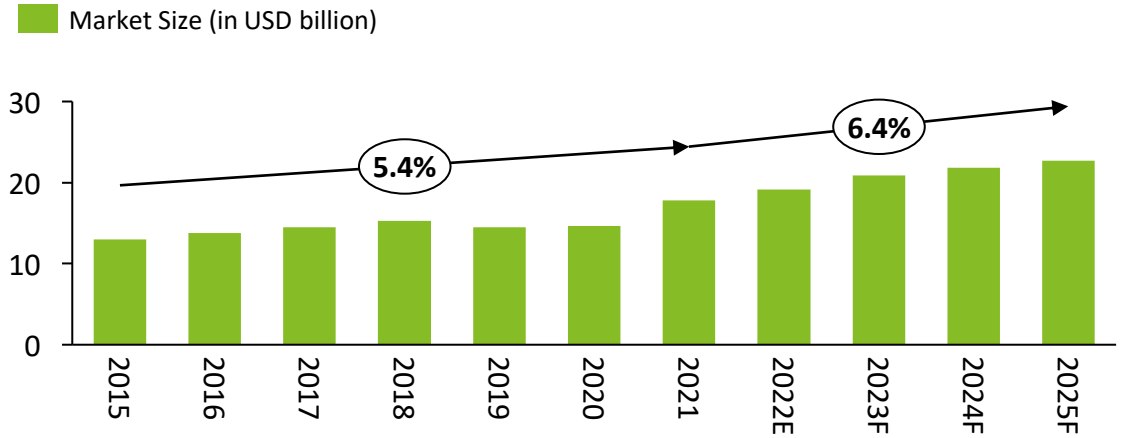
Notes: 1. Macroeconomic data source from statistics for 2022; 2. Percentage of seniors refers to the percentage of the population aged 65 and older

Source: Open data, Deloitte Analysis

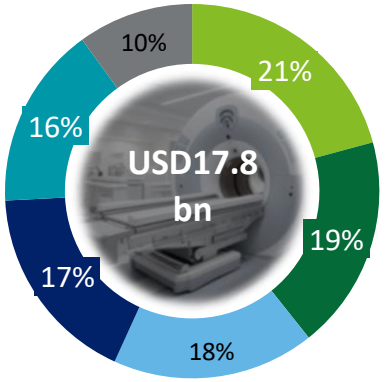
Popular Target Market – France (2/4)

Medical Device Market Overview

French Medical Device Market Size Forecast



Market Segment Size in 2021



2021-2026 CAGR	
Other Medical Devices	7.2%
Medical Consumables	5.8%
Orthopedics and Prostheses	7.2%
Diagnostic Imaging	5.4%
Patient Aids	4.6%
Dental Devices	8.9%
Total	**6.4%**

Key Growth Drivers

- ***Economy:*** As the third largest economy in Europe and the seventh largest globally, France enjoys a favorable economic environment and strong spending power
- ***Healthcare Market***: France has 20% of the EU population, which is noticeably aging, and increasingly common chronic diseases increase demand for health care; the universal health insurance and the government's healthcare institution investment and upgrade program are improving the healthcare environment and promote the iterative facility upgrading
- ***Policy:*** France's "Health Innovation Plan 2030" aims to make France the leading innovative European country in healthcare, promote the localization of medical device R&D and manufacturing, and facilitate access to innovative medical devices for healthcare institutions; the "100% Santé" decree intends to enable all those covered by French health insurance to access dental, optical and auditory care more efficiently, to further boost the demand for medical devices

Key Growing Segments

- ***Segments:*** The French medical device market is expected to expand at a CAGR of 6.4% from 2021 to 2026; the segments of dental devices, orthopedics and prostheses, and other medical devices are growing faster
- ***Medical Device Imports***: France relies on medical device imports, and its imports in 2020 accounted for nearly 80% of the market size; the **U.S.** is the first largest supplier, with U.S. imports accounting for nearly **20% of the market size**, followed by Germany and Switzerland, and EU countries totally supplied approximately 35%
- ***China Exports:*** China supplies **only 8%** of France's medical device imports, mainly including **low-value-added medical consumables, patient aids** and other medical devices, with great potential for market expansion, especially to high-value-added sectors

Source: Open data, Deloitte Analysis

Popular Target Market – France (3/4)

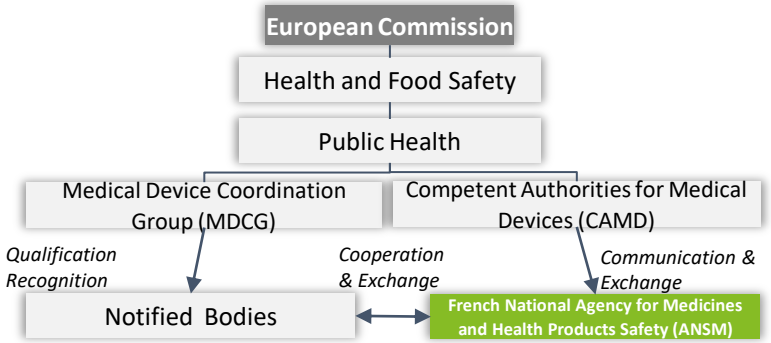
Medical Device Regulatory System

Medical Device Regulator

French National Agency for Medicines and Health Products Safety (ANSM)

ANSM regulates and continuously monitors all medicines and health products on behalf of the state to ensure their safety throughout their life cycle

Regulator



Under the EU Medical Devices Regulation (MDR) and In-Vitro Diagnostic Medical Devices Regulation (IVDR):

- The French National Agency for Medicines and Health Products Safety (ANSM), under the guidance of CAMD, regulates the medical device and in vitro diagnostic reagent market, authorizing clinical trials, inspecting the manufacturer site, and reviewing the conformity of devices that are being marketed, to **ensure safety and effectiveness**
- The EU MDCG-certified third-party notified body reviews the application information, **auditing the manufacturer's quality management system**, and issuing the **certificate of conformity**

Registration Policy

According to devices' intended use, term of use, the risk the device poses to the patient and/or the user, the EU classifies medical devices into:

Class I: *Most non-invasive devices*

Class II: *Surgical immersive devices and implantable devices for short- or long-term use*

Class III: *Products derived from human or animal tissues, etc., usually associated with life support*

Local representative: The EU MDR requires manufacturers outside the EU to designate a legally authorized representative within the EU to respond to competent authorities' requests, provide necessary information and documentation, cooperate in taking preventive or corrective actions, and make timely adjustments for compliance

Registration certification body: Class II and Class III medical devices are subject to the review of the third-party notified body certified by the EU MDCG, which will assess the application information, audit the manufacturer's quality management system, and issue a certificate of conformity; after obtaining this certificate, the manufacturer must make the declaration of conformity and the CE mark available before the product is marketed

Product Pricing Administration Policy

- In France, manufacturers price medical devices, but the devices reimbursed by the social health insurance are priced by manufacturers together with the Comité Economique des Produits de Santé (CEPS) by negotiation, and their three-year framework agreement specifies terms of price, payment arrangements, rebates and penalties; if any manufacturer and CEPS fail to reach an agreement within 180 days, CEPS has the right to unilaterally set the device's reimbursement price ceiling

Source: Open data, Deloitte Analysis

Popular Target Market – France (4/4)

Major Market Entry Models of Chinese Companies

Local subsidiaries

- **Mindray Medical** sets up branches and offices in France to market Mindray's products and provide after-sales service, implements the "direct marketing + distribution" sales model, and has established long-term partnership with local leading healthcare institutions

Local M&A

- In 2018, **MicroPort** acquired LivaNova's heart rhythm management business. This acquisition provided MicroPort with resources and manufacturing facilities in key European markets, expanding its European business, and providing European distribution channels for MicroPort's other products

Platform distribution

- **LyncMed** is a medical consumables export platform that sells to the Middle East and Europe through partnerships with CE and FDA certified suppliers. During the COVID-19 pandemic, LyncMed completed the 150-million-mask order from the French government within one month by allocating supplier resources across China

Major Challenges in French Market

Great price pressure under universal centralized procurement

- Both public and private hospitals in France **universally adopt the centralized procurement model**, and the three public central purchasing bodies and the two private ones have strong bargaining power. When the strict and random (random selection of doctors by the evaluation committee) evaluation mechanism ensures the quality, the low price wins the bid; the bid winner will be awarded a 100% share contract with a term of 2 to 4 years, so Chinese medical device companies must have competitive **scale supply capability, quality and price**

Hard partner selection

- Over 90% of the 1,300 plus medical device companies in France are **SMEs,** and the sub-sectors concentrate on **diagnosis, rehabilitation and surgery**, which poses challenges for Chinese companies expanding to the French market to select partners or M&A targets

Great cultural differences and high labor costs

- Chinese companies need to have a deep understanding of French business culture, gain the trust of the **French government, trade unions** and other business teams, and make local employees recognize Chinese companies, brands and corporate culture. At the same time, in France, the labor cost is high, the worker protection system is perfect, and companies must improve manufacturing environment and safety standards

Source: Open data, Deloitte Analysis

Popular Target Market – UK (1/4)

Macroeconomy[1]

GDP

USD3.07 trillion
GDP (Gross Domestic Product)

6.8%↑ YoY Growth

USD45,000 GDP per capita

Demographics

Total population: 68.60 million

0.5%↑ YoY Growth

19% Percentage of seniors[2]

Health Spending

USD4,827
Health spending per capita

10%
Health spending as a share of the GDP

Healthcare System

Payer Overview

- **National Health Service (NHS)**
  - **Primary care**
    - Primary health care, involving the policlinic and the community clinic, usually provided by professionals such as GPs, comprising 75% of the NHS budget
  - **Secondary care**
    - Hospital care, dealing with serious illness and surgical treatment, and coordinating and allocating medical resources; only the patients referred by GPs are accepted
- **Private Insurance**
  - Reimbursing health care costs generated in private hospitals (outside the NHS), also including critical illness and long-term care insurance
- **Social Medical Aid**
  - Mainly for the elderly, low-income people, pregnant women, children and people with certain diseases
  - Covering health care costs that are not covered by the NHS, including prescription fees, some eye and dental costs, etc.

Patient Overview

High cardiovascular disease incidence rate and obesity rate

- Due to behaviors such as smoking, drinking alcohol, and less exercise, the UK has registered high rates of obesity and the incidence of cardiovascular diseases, chronic respiratory diseases, and other diseases in recent years

High cancer incidence

According to IARC forecasts, new cancer cases in the UK will rise to 610,015 cases in 2040 from 457,960 in 2020, exhibiting a CAGR of 1.4%; in 2020, prostate cancer was the most common cancer in men in the UK, accounting for nearly 23.1% of male cancer cases, and breast cancer was the most common cancer in women, accounting for approximately 25.5%

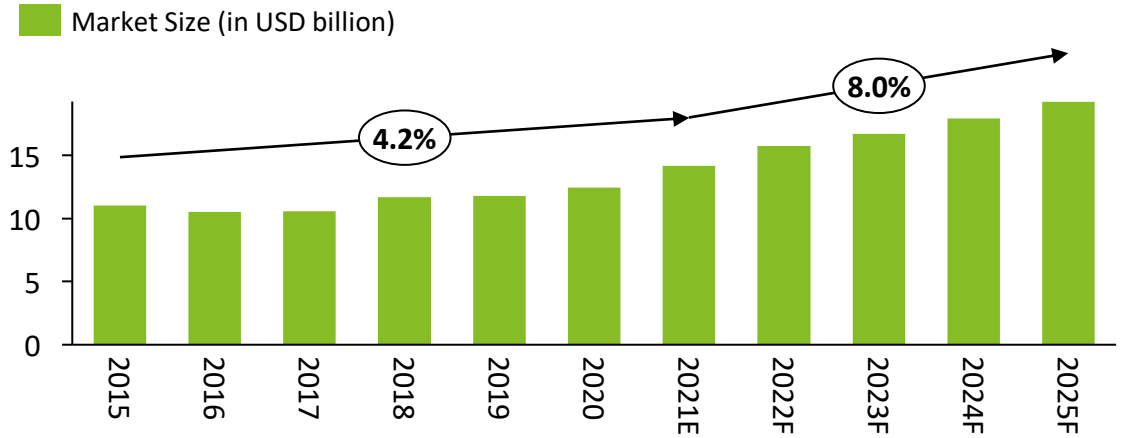
Notes: 1. Macroeconomic data source from statistics for 2022; 2. Percentage of seniors refers to the percentage of the population aged 65 and older

Source: Open data, Deloitte Analysis

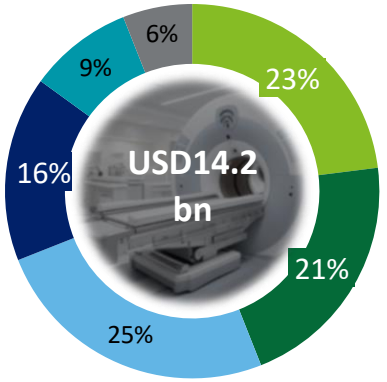
Popular Target Market – UK (2/4)

Medical Device Market Overview

UK Medical Device Market Size Forecast



Market Segment Size in 2021



2021-2025 CAGR	
Other Medical Devices	7.6%
Diagnostic Imaging	8.9%
Medical Consumables	7.3%
Patient Aids	8.1%
Orthopedics and Prostheses	8.2%
Dental Devices	7.9%
Total	**8.0%**

Key Growth Drivers

- ***Economy:*** As the world's fifth largest economy, the UK boasts advanced manufacturing, engineering machinery, chemical and related products, and healthcare
- ***Healthcare Market:*** The increasing aging population and high incidence of chronic diseases are driving demand for health care; healthcare companies boast high-level R&D, and the government heavily invests in R&D innovation in radiology and other fields to improve the overall level
- ***Policy:*** The UK government promotes medical device technology research and innovation through the Accelerated Access Review (AAR), financial support, tax cuts and other measures

Key Growing Segments

- ***Segments:*** **The consumables sector and the diagnostic imaging sector** dominated the UK medical device market, accounting for more than 20% of the market share. Thanks to the government's support to radiology R&D, the diagnostic imaging sector's CAGR will lead the other sectors over the next few years
- ***Medical Device Imports:*** The UK's imports totaled approximately USD1 billion in 2020; the EU was the leading supplier (58%), followed by the Netherlands (19%) and China (16%)
- ***China Exports:*** Although the diagnostic imaging sector has a larger share in the medical device market and is proliferating in the UK, imports from China only account for 8% and those from the EU dominate the market; China mainly exports consumables and patient aid devices to the UK

Source: Open data, Deloitte Analysis

Popular Target Market – UK (3/4)

Medical Device Regulatory System

Medical Device Regulator

Medicines and Healthcare products Regulatory Agency (MHRA)

The MHRA is the UK's competent government agency for medicines and medical devices. After Brexit, both pre-market and post-market regulation of medical devices are headed by the MHRA

Classification & Registration

Class I (Low Risk)

- Including non-active devices, such as surgical instruments, medical dressings, dental materials, etc.
- **Self-declaration** and compliance with applicable technical standards are generally required

Class II (Medium Risk)

- Class IIa, including diagnostic equipment, syringes, etc., with lower risk
- Class IIb, including joint prostheses, pacemakers, etc., with higher risk
- **Review and assessment** are required, generally involving **certification bodies**

Class III (High Risk)

- Including implantable heart valves, artificial hearts, etc.
- **Rigorous evaluation and verification**, including **technical documentation review, clinical evaluation and verification**, are required to demonstrate safety and effectiveness

- **UKCA:** The UK introduced a separate UKCA marking after Brexit. The previous EU CE marking is valid until June 30, 2024, and thereafter, the UKCA marking is required when the product is marketed in the UK market
- **UKRP:** The MRHA requires that if a manufacturer is located outside the UK, a UK Responsible Person (UKRP) must be designated to deal with all matters relating to the registration of the manufacturer's products in the UK
- **Regional particularity:** Northern Ireland remains subject to the EU medical device regulations and policies

Manufacturer Quality Management

- **Quality management system:** The UK medical device market has high quality management requirements for manufacturers, and manufacturers must establish and implement an effective quality management system to ensure stable and reliable product quality, and comply with relevant markings and requirements, such as ISO 13485 quality management system standards

Source: Open data, Deloitte Analysis

Popular Target Market – UK (4/4)

Major Market Entry Models of Chinese Companies

Local manufacturing facilities

- **Orient Gene** invested USD5 million in Scotland to establish a wholly-owned subsidiary, AccuBio Limited, and built manufacturing facilities to meet business expansion needs and nearby support in the European market.

Local subsidiaries

- **Kindly** invested GBP2 million to set up a wholly-owned subsidiary in the UK, aiming to compete in the UK local market with its brand, enhance its international influence and promote the sales volume in the European market

Local M&A

- **Zhende Medical** acquired the consumables business of Berendsen Healthcare in the UK to quickly expand to the UK market and enhance Zhende's presence and influence in the UK consumables sector.
- **AK Medical** acquired JRI Orthopaedics, a leading orthopedic brand in the UK, to increase its presence in the orthopedic upscale market.

Major Challenges in UK Market

Product differentiation

- The UK medical device companies **focus on product innovation**, and Chinese companies must make their products more competitive in the UK market through product innovation or differentiation

Channel building

- The UK has a **government-led** healthcare system, where procurement is organized by the government and implemented by regional hospitals, and British enterprises **prefer local brands,** which make it difficult for Chinese companies to establish partnership with local hospitals and get on the centralized procurement list

Talent recruitment

- In the UK, companies face **high labor costs** and sustained **labor shortage** after Brexit. When establishing subsidiaries, manufacturing facilities, and R&D centers in the UK, Chinese companies will face a short-term difficulty in talent recruitment, which may affect production and operation efficiency

Source: Open data, Deloitte Analysis

Popular Target Market – Brazil (1/4)

Macroeconomy[1]

GDP

USD1.92 trillion
GDP (Gross Domestic Product)

2.9%↑ YoY Growth

USD9,000 GDP per capita

Demographics

Total population: 203 million

0.2%↑ YoY Growth

9.9% Percentage of seniors[2]

Health Spending

USD963
Health spending per capita

10.2%
Health spending as a share of the GDP

Healthcare System

Payer Overview

Brazil has a fragmented health system divided in Public System and Supplementary System:

- The Brazilian public healthcare system is known as the "Unified Health System (Sistema Único de Saúde, or SUS)," is the world's largest public healthcare system with the broadest coverage. “SUS” covers 100% of Brazilians, free of any cost at the point of service and decentralized into national, state and municipal levels.
- Supplementary Health System (private) is voluntary, supplementary to Public System and regulated by ANS. In 2023, ~25% of Brazilians (50,6Mi*) had private health insurance plans mostly provided as an employment benefit. There are more than 650 health insurance companies, however 7 companies almost concentrate 40% of beneficiaries.

SUS Health Insurance Coverage: 100%

Private Insurance Coverage: **25%**

- In addition to effectiveness and safety, new devices must demonstrate cost-effectiveness before being covered by the SUS or supplementary health system. Overall, government procurement has strict standards and transparent evaluation processes

Patient Overview

High incidence of chronic diseases	The incidence of chronic diseases, especially cardiovascular diseases, cancer and central nervous system diseases, is increasing year by year. The top three deadly diseases are ischemic heart disease, stroke and lower respiratory infection
Rapid population aging	Currently, the number of the Brazilian population aged 60 and older exceeds that under 5. As life expectancy increases for those aged 30 to 50, Brazil will have more than 68 million older persons by 2050, making it the world's sixth largest country for aging population
Large difference in life expectancy between men and women	The Brazilian women's life expectancy is significantly higher than men's, mainly due to the high incidence of inter-male violence and traffic accidents. In 2020, the Brazilian men’s life expectancy was 72.5 years and women's, 79.7 years, a difference of 7.2 years, and this gap will persist in the future

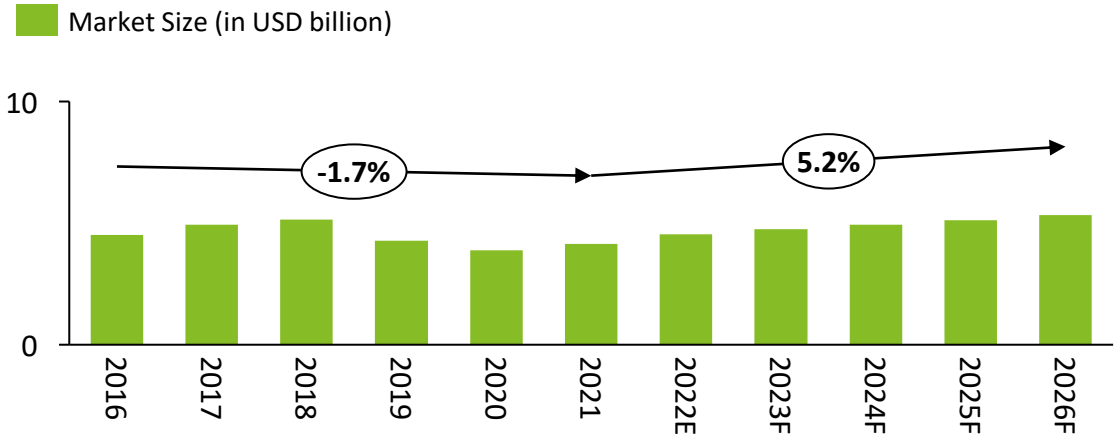
Notes: 1. Macroeconomic data source from statistics for 2022; 2. Percentage of seniors refers to the percentage of the population aged 65 and older

Source: Open data, Deloitte Analysis

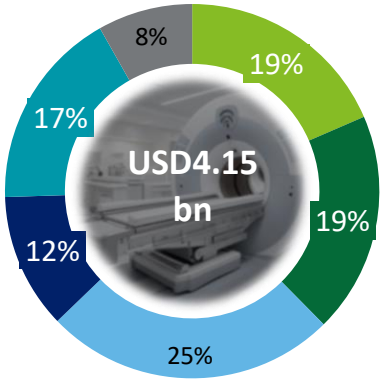
Popular Target Market – Brazil (2/4)

Medical Device Market Overview

Brazil Medical Device Market Size Forecast



Market Segment Size in 2021



	2021-2026 CAGR
Other Medical Devices	7.3%
Diagnostic Imaging	5.2%
Medical Consumables	5.1%
Patient Aids	2.5%
Orthopedics and Prostheses	5.2%
Dental Devices	3.0%
Total	**5.2%**

Key Growth Drivers

- ***Economy:*** The rising GDP, middle-class proportion, and residents' disposable income promote higher demand and stronger purchasing power for healthcare
- ***Healthcare Market:*** As the world's fifth largest country in terms of population, Brazil has an ever-expanding medical device market amidst intensifying aging, extended life expectancy, and high incidence of chronic diseases
- ***Policy:*** New regulations on patient-tailored devices help accelerate the market access of personalized medical devices. The regulator streamlined the Class I low-risk medical device reporting. Some medical devices are exempt from import taxes for the time being

Key Growing Segments

- ***Segments:*** Brazil's medical device market is expected to grow at a CAGR of 5.2% from 2021 to 2026. The segments of medical consumables and diagnostic imaging have a larger market share and a considerable growth rate
- ***Main Growing Segments:*** The rising incidence of chronic diseases, cardiovascular diseases, and cancer boosts the demand for medical imaging equipment, cardiovascular-related equipment, breast cancer screening and radiotherapy equipment, and other high-end equipment
- ***Medical Device Imports:*** Brazil's medical device market relies on imports. In 2021, imports accounted for **nearly 70%** of the market. The U.S. (23%) and China (20%) were the leading suppliers. Except for the orthopedics and prosthetics sector, China's exports were equal to those of the United States

Source: Open data, Deloitte Analysis

Popular Target Market – Brazil (3/4)

Medical Device Regulatory System

Medical Device Regulator

Brazilian Health Regulatory Agency (ANVISA)

The Brazilian Health Regulatory Agency (Agência Nacional de Vigilância Sanitária, ANVISA) is a self-governing agency linked to the Brazilian Ministry of Health, part of the SUS. ANVISA oversees all medical devices in Brazil

Registration Policy

- ANVISA requires that all devices must complete a device registration process. Under Brazilian regulations, non-Brazilian manufacturers that intend to import devices into or distribute devices in Brazil need a local **Brazilian Registration Holder (BRH)** based in Brazil to submit product registration applications, manage device registration and the **Brazilian Good Manufacturing Practice (BGMP)** certification, perform post-market supervision, and report recalls and incidents to ANVISA

Classification	Class I (Low Risk)	Class II	Class III	Class IV (High Risk)
Registration Timelines	30 days	<6 months	6-12 months (the timeline can be shortened with MDSAP or ISO certificate)	
Validity	No BGMP required and unlimited validity		BGMP required and 10-year validity	

Marketing Policy

- **Pricing:** The Brazilian government intervenes in medical device pricing. In March 2021, ANVISA approved a price regulation resolution to reduce medical device prices in Brazil. Medical device companies need to set prices according to the price supervision catalogue
- **Marketing channels:** Non-Brazilian medical device suppliers must have offices or appoint local agents or distributors in Brazil

Other Policies

- **High taxes:** Businesses in Brazil must pay over 90 types of taxes to the federal, state, and municipal administrations under complex taxation rules at the rate of 63.5%, 23.5%, and 13%, respectively. Taxes in Brazil are much higher than those in the United States and about twice as much as those in Mexico
- **High labor costs:** As each employee costs approximately 180% of their salary when benefits and taxes are considered, and the dismissal rules and regulations in Brazil are strict, foreign-owned enterprises cannot easily dismiss employees

Source: Open data, Deloitte Analysis

Popular Target Market – Brazil (4/4)

Major Market Entry Models of Chinese Companies

Local agents (partner holders)

- Manufacturers may appoint their partners that import their products into or distribute their products in Brazil to submit product registration applications and hold product registration certificates
- **Micro-Tech** holds certificates through its local distributor, Prometon

Local agents (third-party holders)

- The third-party local representative agency holds certificates and provides market access compliance services, while distributors sell products

Local subsidiary or marketing entity establishment/M&A

- **MicroPort Medical** established a subsidiary in 2017 to acquire its Brazilian agent's business, thus switching from distribution to direct marketing model
- **Mindray Medical** established a subsidiary, MRBR, in Brazil to market products

Local manufacturing entity establishment/M&A

- Entities must be qualified and licensed and have warehouses meeting the quality management requirements of BGMP.
- Entities must heavily invest when establishing or acquiring local manufacturing entities, but the Brazilian government will **give priority** and preferential policies **to local firms** at bidding

Major Challenges in Brazilian Market

Operating costs

- **High operating costs** due to strict labor regulations and high taxes in Brazil challenge Chinese companies' operating model and cost control after their entry into Brazil

Talent and partners

- Chinese companies that intend to enter the market through a light asset model will **heavily rely on BRH and agents/distributors** and thus need to **carefully select local partners** for registration and distribution, and evaluate the specific cooperation model

Revenue stability

- The Brazilian government will **intervene in medical device pricing** to lower prices. **Exchange rate fluctuations** will cause higher currency risks, and **low collection rates** and **long payment periods** may exist. Chinese device companies need to develop risk control and mitigation plans for uncertainties in advance

Political risks

- **Partisan bickering and civil unrest** could threaten the Brazilian overall economic development. Chinese device companies need to keep an eye on the local situation and policy changes to avoid civil unrest and other risks impacting their local operations

Source: Open data, Deloitte Analysis

Popular Target Market – Malaysia (1/4)

Macroeconomy[1]

GDP

USD496 billion
GDP (Gross Domestic Product)

8.9%↑ YoY Growth

USD12,000 GDP per capita

Demographics

Total population: 33.94 million

0.2%↑ YoY Growth

7.5% Percentage of seniors[2]

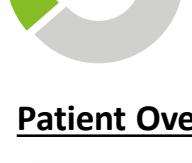
Health Spending

USD520
Health spending per capita

4.4%
Health spending as a share of the GDP

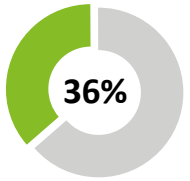
Healthcare System

Payer Overview



Malaysia has a universal healthcare system provided by the government

- The Malaysian government-funded **public healthcare system** with public hospitals as health service carriers is **not based on a national health insurance scheme.** Malaysian citizens who seek healthcare at government hospitals and clinics only pay a registration fee of RM1, without additional diagnosis/medication fees



Only 36% of Malaysian residents are covered by health insurance

- Nearly 14.3% of Malaysian residents purchase private health insurance, 14.6% are covered by health insurance through their employers, 7.3% covered by both, and the remaining 64% are uninsured

Patient Overview

High incidence of chronic diseases, such as obesity and diabetes

Half of Malaysians are obese and one-fifth have diabetes. The incidence rate of chronic diseases, such as cardiovascular diseases and respiratory diseases (including tuberculosis, and obstructive sleep apnea), is increasing

Surging cancer cases

In 2022, cancer cases in Malaysia more than tripled, compared to 2019. In addition to genetic factors, living habits are also a cause, especially less exercise and less healthy diet during the COVID-19 pandemic. Living habits may be a reason for the surging cancer cases during the past three years

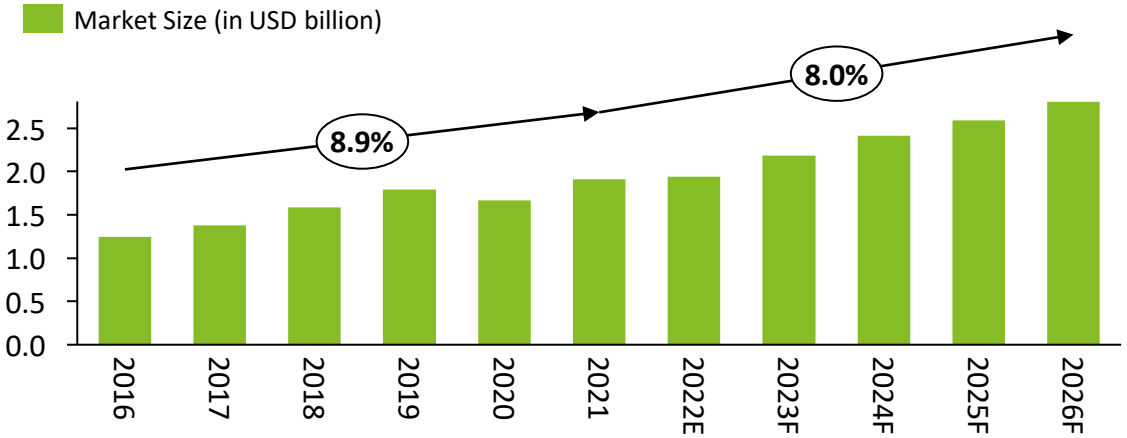
Notes: 1. Macroeconomic data source from statistics for 2022; 2. Percentage of seniors refers to the percentage of the population aged 65 and older

Source: Open data, Deloitte Analysis

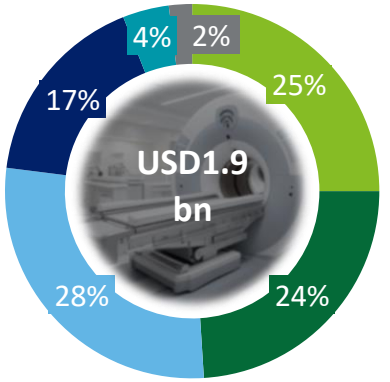
Popular Target Market – Malaysia (2/4)

Medical Device Market Overview

Malaysia Medical Device Market Size Forecast



Market Segment Size in 2021



	2021-2026 CAGR
Other Medical Devices	12.0%
Diagnostic Imaging	5.2%
Medical Consumables	6.3%
Patient Aids	8.8%
Orthopedics and Prostheses	8.2%
Dental Devices	4.1%
Total	**8.0%**

Key Growth Drivers

- ***Economy:*** Malaysia boasts a high per capita GDP and a relatively developed economy that is driven by foreign trade, focusing on petroleum, chemical, and electronic products
- ***Healthcare Market:*** Severe population aging, diabetes and obesity drive up the demand for healthcare, while the health tourism mainly for Asian medical travelers spur the market growth
- ***Policy:*** The Malaysian government is devoted to modernizing health care in Malaysia and encourages medical products diversification and high-end medical device manufacturing. At the same time, Malaysia has a foreign-investor-friendly business environment and new free trade agreements may lower market access barriers

Key Growing Segments

- ***Segments:*** High-end medical devices, especially **patient aids and diagnostic imaging** products, have a large market opportunity, and cardiovascular-related products best serve the local needs. In the Malaysian medical device market, **consumables and diagnostic imaging** sectors dominate with over 20% of the market share. For the government's efforts to modernize medical devices, the patient aids sector (especially portable devices) is proliferating
- ***Medical Device Imports:***

Largest Seller → *Malaysia mainly produces, and exports over 90% of, **low-value consumables and orthopedic/dental products**, and relies on **high-end device** imports* → Largest Buyer

Source: Open data, Deloitte Analysis

Popular Target Market – Malaysia (3/4)

Medical Device Regulatory System

Medical Device Regulator

Malaysia Medical Device Authority (MDA)

MDA is a statutory body under the Ministry of Health Malaysia to oversee and regulate the medical device industry

Conformity Assessment Body (CAB)

CAB reviews technical documentation and issues certificates

Registration Policy

- For all devices imported into or manufactured in Malaysia, non-Malaysian manufacturers need **a local authorized representative (AR)** to communicate with MDA for medical device registration and application filing. The AR must hold a business license and a Good Distribution Practice for Medical Device (GDPMD) certificate. CAB certificates and device registration certificates are required to be renewed every 5 years

Classification	Class A (Low Risk)	Class B	Class C	Class D (High Risk)
Registration Timeline	45 working days	100 working days	180 working days	220 working days
Registration Process	AR directly files registration application with MDA	AR submits technical documentation and CAB reviews the technical documentation		

Manufacturing Policy

- Medical device manufacturers must be ISO 13485 certified

Marketing Policy

- **Local company priority:** Under the Malaysian policy, overseas entities' direct marketing is allowed, but the Malaysian market, especially the public sector, gives priority to local renowned suppliers
- **Promotion content review:** Policies introduced in 2019 specified the content and conditions of medical device advertising and mandated the approval of registered medical devices' advertising

Procurement Policy

- Medical device procurement is mainly carried out by the Ministry of Health Malaysia and its subordinate departments. Local renowned suppliers generally win government tenders, and the government does not directly intervene in pricing or force price reductions

Source: Open data, Deloitte Analysis

Popular Target Market – Malaysia (4/4)

Major Market Entry Models of Chinese Companies

Local subsidiaries

- **Kindly** plans to invest RMB21.7 million to establish a subsidiary in Malaysia together with TP CONCEPT PRECISION SDN.BHD to develop disposable medical devices.
- **Lepu Medical** announced to establish a wholly-owned subsidiary in Malaysia to manufacture and market medical devices

Strategic partnerships

- **Shanghai Moge Biotechnology** strategically partners with ALPS Medical Centre Malaysia to work in healthcare and biology, and promote RCEP members' cooperation in healthcare

Clinical research cooperation

- **MicroPort Group** and the Ministry of Health Malaysia initiated clinical research cooperation on Firehawk® Rapamycin Target Eluting Coronary Stent System independently developed by MicroPort to further study the morbidity in patients with coronary heart disease in Malaysia and provide more relevant information for the cardiology department under the Ministry of Health

Major Challenges in Malaysian Market

Fierce competition

- Malaysian medical device products mainly include surgical and examination gloves, medical dressings, consumables catheters, blood glucose monitoring products, contact lenses and other consumables-related products. Due to the **fierce local competition**, Chinese companies need to carefully determine the segment to enter, to avoid homogenization competition with local products

Supply challenges

- Malaysia has 200 plus medical device manufacturers, of which more than 30 are multinationals **with offshore manufacturing facilities** in Malaysia (e.g., Abbott, Agilent and Braun), which challenges the supply chain capabilities of Chinese manufacturers entering Malaysia

Talent shortage

- All companies in the manufacturing sector are required to have an **80-20 ratio of workforce between local and foreign workers**, but Malaysia has been suffering labor shortage in recent years. Meanwhile, the local medical device manufacturing industry focuses on rubber products and other low-value consumables and has **limited high-end talent resources**. Therefore, Chinese companies may face a talent shortage after entry into Malaysia

Source: Open data, Deloitte Analysis

Popular Target Market – Singapore (1/4)

Macroeconomy[1]

GDP

USD0.47 trillion
GDP (Gross Domestic Product)

10.1%↑ YoY Growth

USD78,000 GDP per capita

Demographics

Total population: 5.64 million

1.8%↑ YoY Growth

25% Percentage of seniors[2]

Health Spending

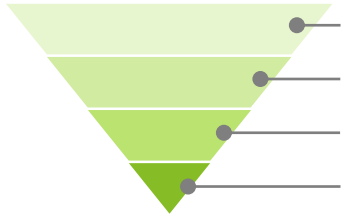
USD3,506
Health spending per capita

4.1%
Health spending as a share of the GDP

Healthcare System

Payer Overview

Singapore healthcare system is structured as **S+3M**:



S: Government subsidies, covering up to 80% of basic health insurance premiums

M: Personal healthcare savings account, mainly for small claims, and future health insurance premiums and security reserves

M: Basic health insurance and private health insurance, protecting Singapore citizens against large hospital bills

M: Government assistance, for needy Singaporean patients who are unable to afford their medical bills

In 2022, out-of-pocket expenditure as a share of health expenditure in Singapore was **28.5%**, showing a downward trend, while the government budget increased YoY

Patient Overview

Heavy chronic disease burden	Singapore's population is ageing rapidly, and the incidence rate of chronic diseases, such as diabetes, hyperlipidemia and hypertension, is rising. Specifically, the incidence rate of hyperlipidemia and hypertension is over 30%
Rising cancer cases	As a leading cause of death in Singapore, cancer happens to one in three Singaporeans. Stress levels and lifestyle changes significantly increased the cancer rate. Colorectal cancer and breast cancer are the common cancer
Emphasis on preventive care	The Singaporean government encourages citizens to take preventive measures, pay attention to preventive care, and effectively prevent chronic diseases through early screening, which increase the demand for medical devices

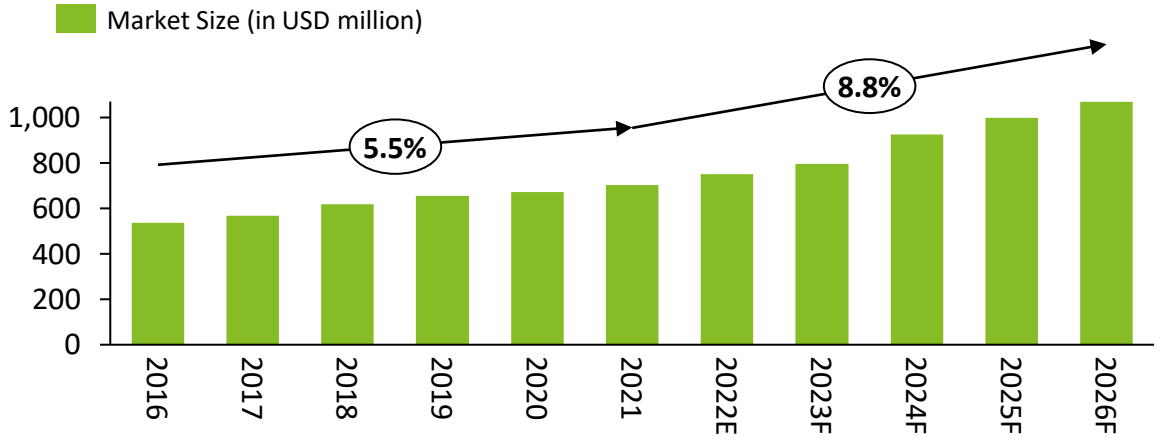
Notes: 1. Macroeconomic data source from statistics for 2022; 2. Percentage of seniors refers to the percentage of the population aged 65 and older

Source: Open data, Deloitte Analysis

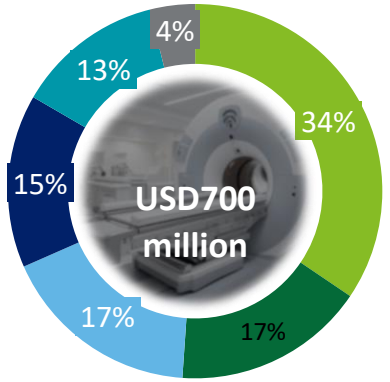
Popular Target Market – Singapore (2/4)

Medical Device Market Overview

Singapore Medical Device Market Size Forecast



Market Segment Size in 2021



	2021-2026 CAGR
Other Medical Devices	12.3%
Diagnostic Imaging	6.8%
Medical Consumables	8.8%
Patient Aids	3.7%
Orthopedics and Prostheses	7.9%
Dental Devices	4.5%
Total	**8.8%**

Key Growth Drivers

- ***Economy:*** As the only developed country with a high per capita GDP in Southeast Asia, Singapore highlights people's health, with a high health expenditure and a well-established healthcare system
- ***Trade:*** As a trade hub, Singapore **re-exports** most of the imported medical devices to other countries to satisfy their demand
- ***Demand:*** Singapore's serious aging and **rising chronic disease cases** raise the demand for health care and preventive care, thus driving the demand for diagnostic devices
- ***Policy:*** Singapore rolled out the Healthier SG, a long-term healthcare plan, increased health expenditure budgets, and provided **preferential policies** to foreign investors to promote the industry development

Key Growing Segments

- ***Segments:*** Singapore has a large medical device market. The large sectors of **diagnostic imaging and medical consumables** account for 17% of the market share, while the segments of **orthopedics and prostheses, as well as consumables**, grow faster
- ***Medical Device Imports:*** Singapore **highly relies on medical device imports (85%),** and mainly imports high-end equipment, such as **CT machines and MRI machines**. **The U.S.** is Singapore's largest medical device source, supplying nearly 40% of the imports
- ***China Exports:*** China supplies only **2%** of Singapore's medical device imports and mainly exports **diagnostic imaging and patient aid devices** to Singapore

Source: Open data, Deloitte Analysis

Popular Target Market – Singapore (3/4)

Medical Device Regulatory System

Medical Device Regulator

Health Sciences Authority (HSA)

HSA oversees medical devices in Singapore, and its responsibilities include registered device change notification, advertising and promotion, adverse event reporting, on-site safety corrective measures, and dealer licensing

Registration Policy

4-tier Classification

- **Class A: Low-Risk Devices** *Examples: wheelchairs. Class A medical devices are exempted from product registration*
- **Class B: Medium-to-Low-Risk Devices** *Examples: hypodermic needles or suction instruments*
- **Class C: Medium-to-High-Risk Devices** *Examples: ventilators or bone fixation plates*
- **Class D: High-Risk Devices** *Examples: heart valves or implantable defibrillators*

Medical Device Registration Pathways

Evaluation Route	Applicable Class	Conditions
Full	**B,C,D**	• Class B, C and D devices that have not been approved by HSA must be registered via the full evaluation route • **Priority Review Scheme**: A medical device can be registered through the Priority Review Scheme route if it belongs to one of the five focused healthcare areas: cancer, diabetes, ophthalmic diseases, cardiovascular diseases, and infectious diseases, or it is a breakthrough technology with an edge over existing technology. The turnaround time (TAT) for Priority Review Scheme is 25% shorter compared to the TAT for a standard full route
Abridged	**B,C,D**	• Priorly approved by at least one of HSA's **overseas reference regulatory agencies** (in Canada, the EU, Japan, the U.S., etc.)
Expedited	**B**	• EBR-1: Approved by at least one of HSA's overseas reference regulatory agencies and **marketed for at least three years in the aforesaid reference regulatory agency's jurisdiction** • EBR-2: Approved by at least two of HSA's overseas reference regulatory agencies and no rejection/withdrawal
	C,D	• ECR-1: Approved by at least one of HSA's overseas reference regulatory agencies and **marketed for at least three years in the aforesaid reference regulatory agency's jurisdiction** • ECR-2/EDR: Approved by at least two of HSA's overseas reference regulatory agencies and no rejection/withdrawal
Immediate	**B,C**	• Approved by at least one of HSA's overseas reference regulatory agencies; no safety issues globally • No rejection/withdrawal from HSA or any of HSA's overseas reference regulatory agencies; solely a standalone medical **mobile application**

Marketing Policy

- All medical device dealers must apply for **a medical device dealer's license** before importing, manufacturing, and supplying devices in Singapore
- HSA will evaluate whether the dealer conforms to the requirements of the **Good Distribution Practice for Medical Devices** (GDPMDS) before licensing

Source: Open data, Deloitte Analysis

Popular Target Market – Singapore (4/4)

Major Market Entry Models of Chinese Companies

Local subsidiaries

- **Andon Health** and Xiaomi Corporation established iHealth Inc. and its Singaporean subsidiary to wholesale and distribute medical devices and conduct medical research and experiments
- **BGI Genomics** set up a wholly-owned subsidiary in Singapore for licensing and marketing

Academic cooperation

- **Mindray** signed an academic exchange and cooperation agreement with Singapore Health Services to strengthen personnel and academic exchanges and promote medical innovation together

Local partnership

- **BGI Genomics** signed a cooperation agreement with INEX Innovations Exchange, a health diagnosis company in Singapore, to establish a genomic sequencing center and carry out molecular genetic testing projects in Singapore

Local M&A

- **Bluesail Medical** acquired Biosensors International to enter the cardiac stent segment

Major Challenges in Singaporean Market

Hampered registration

- For high-risk devices, the HSA may require **clinical trials** and usually encourages local clinical trials. However, the **small number of patients** in Singapore will make clinical trials and registration more difficult

Talent shortage

- The healthcare talent shortage in Singapore may make medical device companies entering Singapore suffer the short-term difficulty in high-end talent recruitment, but the Singaporean government is accelerating healthcare talent cultivation through the "**Helix Immersion Programme**", an on-job-training programme for biomedical research and academic professionals, and the **Singapore Therapeutics Development Review** (STDR) implemented by the Agency for Science, Technology and Research (A*STAR)

Reliance on channels

- Singapore's medical device demand comes from public and private hospitals and clinics, and the **Ministry of Health** is the largest consumer, accounting for nearly **75%** of local demand. Therefore, it is critical for Chinese medical device companies to establish and maintain channels with the Ministry of Health

Source: Open data, Deloitte Analysis

Contents

Common Challenges Faced by Chinese Medical Device Companies

Strategy

Unclear Self-awareness

- Chinese medical device companies have insufficient knowledge of their capabilities, sources, and needs, and lack systematic planning for endogenous growth and extensional expansion, which results in a vague global strategy.

Unstable Market

- As affected by geopolitical risks, economic and monetary policies and other factors, it is difficult for Chinese medical device companies to predict the changes in local market regulation and access, as well as the acceptance of medical institutions and insurers, which increases the layout risk.

Insufficient Knowledge of the Competition

- Chinese medical device companies lack an understanding of the competitive landscape of overseas markets and the strengths and weaknesses of competitors, making it challenging to formulate strategies and goals and determine the region and products.

Business and Operation

Chinese Brand Recognition

- Under the localization trend in countries, it is not likely for overseas users to recognize and accept Chinese products in a short term, which challenges device companies to build and stabilize marketing and sales channels.

Supply Chain Improvement

- A resilient global supply chain helps enterprises to improve management and operation efficiency and overall competitiveness. However, constructing overseas production and supply systems is complicated and requires large investments, which is difficult to manage.

Local Optimization

- The changing business environment and competition landscape, diverse business culture, different procurement preferences for medical devices and other factors require domestic enterprises to continuously optimize and adjust the operation systems in target overseas markets.

Core Function Building

Challenging to Design Organizational Structure

- Chinese medical device companies may face challenges of culture integration, cross-regional power and responsibility division, and corporate culture and change management. Designing organizational structures and management models is challenging.

Hard to Manage Overseas Talent

- Developed markets have higher labor costs, and some countries lack medical device professionals. It is harder for Chinese medical device companies to attract, train, retain and employ talent.

Difficult to Share Information and Data

- Chinese medical device companies face higher requirements for sharing sales data, customer demand and other information. They need to improve the construction and application of digital capabilities.

Source: Deloitte Analysis

Key Success Factors for Chinese Medical Device Companies to Go Global

Strategic Guide (*"Grand Vision"*)

Self-analysis and Goal Setting

- Objectively and systematically analyze the current domestic development and existing sources, and assess the necessity and feasibility of going global to define the direction and goals for domestic and international business development.
- Gradually realize brand internationalization through greenfield investment, collaboration, JV, M&A, etc., based on company's own characteristics.

Track Changes and Avoid Risks

- Regularly pay attention to changes in the international landscape to identify potential risks (geopolitics, device access, finance and tax). Closely follow policy changes and adjust the global strategy and priorities in a timely manner to avoid risks effectively.

Market Research and Positioning

- Obtain an overview of the overall and segment markets in target countries through research, and benchmark with top players to identify their strengths and weaknesses to well position international development.

Stable Operation (*"Steady Pace"*)

Create Differential Advantages and Define Keys to Success

- Identify their competitive advantages and disadvantages and create a differential positioning of technology, product design, channels, prices, services, etc., according to the characteristics of overseas markets to gradually establish a service ecosystem. Define the key to success and continuously enhance the brand's competitiveness.
- Maintain the competitive advantage of product innovation and enhance brand image by continuous innovation and industry-university-research cooperation.

Improve Supply Links, Reduce Costs and Increase Efficiency

- Device companies can gradually improve their supply systems, reduce operating costs and enhance influence through many ways, such as building production bases, acquiring local device companies, and cooperating with other companies according to their capabilities and the process of going global.

Optimize Operations and Locally Integrate

- Understand the business environment of target countries and strengthen communication with local hospitals, device companies, insurers and other stakeholders. Establish cross-cultural project management teams and adjust and optimize operations according to local conditions to quickly integrate locally.

Functional Building ("*Strong Support*")

Reshape Organizational Structure and Improve Operational Efficiency

- Establish a strategic positioning-oriented organizational structure to improve operational efficiency, avoid ineffective communication, multiple reporting, unclear powers and responsibilities, and other problems, and improve local operational efficiency.

Cultivate Talent Ecosystems and Enhance Enterprise Attractiveness

- Enhance enterprises' attractiveness to overseas talents, using talent cultivation as a significant measure to promote the high-quality development of international business. Gradually establish a talent ecosystem through remuneration and benefits design and corporate culture construction in combination with other methods.

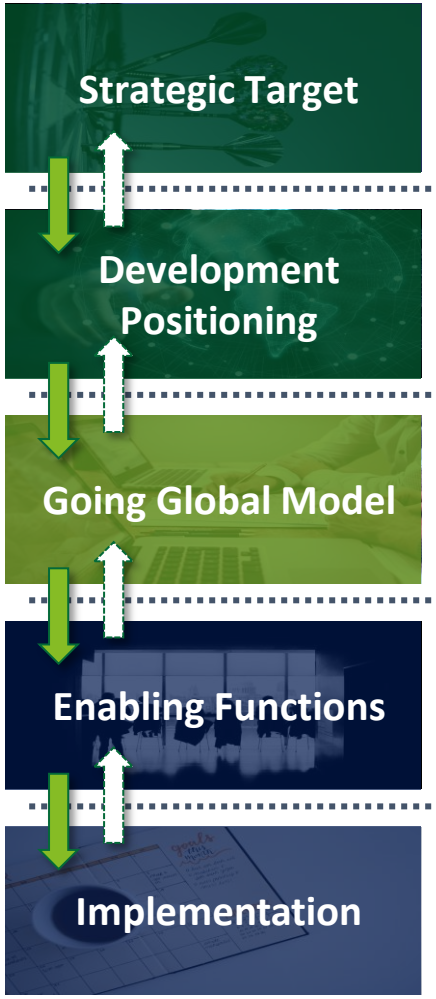
Build Digital Capabilities and Empower Modern Management Practices

- Establish an enterprise-wide full-process digital management system and optimize the operational management and functional synergy throughout the value chain to improve the effectiveness of global data sharing and overseas business and empower modern management practices.

Source: Deloitte Analysis

Planning-to-Implementation Framework Going Global

Five-step Framework and Key Questions to be Addressed



- What is the **long-term vision**? (Global reputation, market leadership)
- What is the **target** of going global (Revenue, profit, etc.)
- What is the **strategic objective** of going global? (Customer, branding, ecosystem)

- What is the **business focus** of going global? (Core business, innovative business)
- What is the **geography focus** of going global? (Europe, America, APAC)
- What is the **ecosystem focus** of going global? (Commercial, supply-chain, R&D)

- What is the going-global model based on **characteristics of target market and current market, and strategic objectives** of the company? (Export trade, cross-border M&A, greenfield investment)
- What is **the roadmap and business model** design?

Illustrative 1 | Illustrative 2 | Illustrative 3

- What are the **core capabilities** that need to be developed for the going-global initiative? What is the enhancement plan?
- What is the **talent mobilization structure and management structure** to support the capabilities development?

Illustrative 4

- Prioritized measures and **specific implementation solution.**
- Defined **performance measurement** standards and methods.

Source: Deloitte Analysis

Illustrative 1

Overseas Medical Device Market Compliance Key Area of Focus

Relevant Overseas Supervision, Analysis of Compliance Demands

1 Business of medical devices export is facing product entry supervision

e.g.:
- EU CE Certification
- US FDA Registration
- Singapore HAS Registration
- Malaysia MDA Registration

2 Business of medical devices is facing data supervision

e.g.:
- Cyber and Data Security
- Protection of Personal Info
- Protection of Personal Privacy
- Human Genetic Resource

3 Medical devices export is facing trade protection

e.g.:
- Tariff Change
- Anti-Trust and Anti-Dumping

4 Overseas labor is facing supervision

e.g.:
- Labor's Right
- Payment of Expatriates' Social Insurance
- Special Working Hours

5 Business of medical devices Importer/Producer supervision

e.g.:
- Korean License for Import and Operation, KGMP
- Thailand Food and Drug Administration License
- Taiwan Medical Device License

6 Business of medical devices is facing bribery supervision

e.g.:
- Worldwide Supervision and Punishment for Corruption and Bribery
- Avoid intimacy with local officers
- Pay close attention to giveaway

Key Areas of Overseas Compliance

Business Process	Work Content	Compliance Obligation	Risk Identification	Description of Non-Compliance Outcomes	Main Departments	Supporting Departments
Preliminary Project Study	Identify Product Type, Price Range and Estimated Sales	Relevant Policies in Target Country's Medical Devices Industry, Technical Standard; Market Safety Regulations;	Technical Risks, Policy Risks, Market Risks	Economic Loss, Reputation Loss, Administrative Penalty	Sales Department, Finance Department, Technical Department	Compliance, Law Department, etc.
Qualification Application & Product Verification	Apply for Qualification of Export Medical Devices……	Relevant Export Policies in Producing Country; Relevant Policies in Target Country's Medical Devices Industry, Technical Standard; Market Safety Regulations; Intellectual Property Compliance Demands;	Policy Risks, Technical Risks	Economic Loss, Reputation Loss, Administrative Penalty	Technical Department, Import & Export Division	
Order Acceptance & Placement	Confirm The Order……	Market Transactions & Contract Compliance Demands;	Policy Risks, Market Risks	Economic Loss, Reputation Loss, Administrative Penalty	Sales Department, Finance Department	
Production	Accept The Order……	Field Environment, Personnel Safety, Standard Requirements for Safety Production; Supply Chain Compliance Management;	Policy Risks, Technical Risks, Market Risks	Personal Harm, Environmental Damage, Economic Loss, Reputation Loss, Administrative Penalty	Purchasing Department, Production Headquarters	
Product Distribution	Distribution & Storage, Transportation, Usage……	Regulations for Quality Management of Medical Devices Distribution and Storage, Regulations for After-Sale Service (Maintenance, Repair, etc.), Adverse Reaction Management	Policy Risks, Technical Risks	Policy Risks, Technical Risks, Reputation Loss	Sales Department, Technical Department, Storage Logistics Department, Medical Department	

Source: Deloitte Analysis

Illustrative 1

Selective Overseas Medical Device Regulatory Authorities and Key Regulations

Relevant Overseas Medical Equipment Regulatory Authorities and Regulatory Basis

European Medicines Agency(EMA)

Medical Device Classification Regulation : Class I, Class II a, Class II b and Class III (risk from low to high)

✓ Main regulations:
EU 2017/745

Thailand Food and Drug Administration(TFDA)

Medical Device Classification Regulation : 1,2,3,4 four categories (risk from low to high)

✓ Main regulations:
1. Medical Device Act B.E. 2551 (2008)
2. Medical Device Act/Ordinance B.E. 2562 (2019)

Hong Kong Medical Device Branch

Medical Device Classification Regulation : Ⅰ, Ⅱ, Ⅲ, Ⅳ four categories (risk from low to high)

✓ Main regulations:
1. Medical Device Administrative Control System (MDACS) (listed system such as trader package system: local responsible person, local manufacturer, importer, distributor, etc.)

Health Sciences Authority(HSA)

Medical Device Classification Regulation : A, B, C, D four categories (risk from low to high)

✓ Main regulations：
1. Health Products Act 2007
2. Health Products (Medical Devices) Regulations 2010
3. ASEAN Medical Devices Directive (AMDD)

Medical Device Authority(MDA) , Ministry of Health Malaysia (MoHM)

Medical Device Classification Regulation : Category A, B, C, D (risk from low to high)

✓ Main regulations:
Medical Device Act (2012)

U.S. Food and Drug Administration (FDA)

Medical Device Classification Regulation : Class I, Class II, Class III (risk from low to high)

✓ Main regulations:
1.Federal Food, Drug, and Cosmetic Act
2.Medical Device Amendments
3.Medical Device Regulations

Source: Deloitte Analysis

Illustrative 2

Tax Considerations Impact on the Method and Structure of Overseas Investment

Tax Treaty Network

- ✓ Breadth of the tax treaty network in the home jurisdiction of entities in the investment structure (including intermediate holding companies)
- ✓ Applicable tax treaty benefits and compliance rules

Tax Regulation of the Target Country/Region

- ✓ Tax categories and collection rules in the business life cycle
- ✓ Applicable tax incentives in the home country/region
- ✓ Overseas tax credit/Offshore income tax regulation

Investment Structure and Model

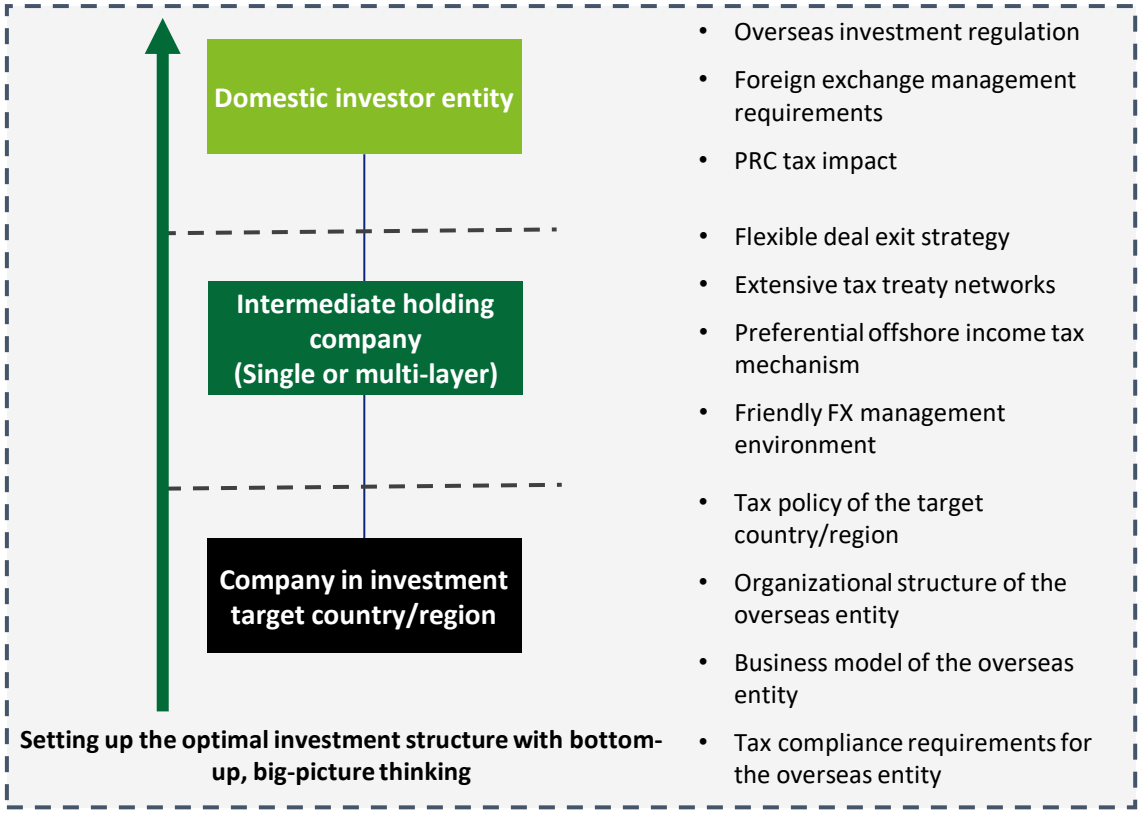
- ✓ Different overseas investment models may involve different tax considerations or impact
- ✓ Investment structures' tax impact on overseas financing and cash repatriation
- ✓ Investment structures' impact on the ease and cost considerations for future structural modification or deal exits

"Pillar Two": Global Minimum Tax

- ✓ Implementation in the target country/region
- ✓ Pillar Two rules and top-up tax calculation
- ✓ Additional tax compliance costs

Future-proof design of an optimal overseas investment structure

- Exporting products alone may no longer meet the needs of medical device companies trying to expand their global presence given the current market environment, and companies are finding it necessary to invest overseas or establish production/sales bases abroad.
- For domestic Chinese medical device manufacturers seeking to invest overseas, it is important to first design a future-proof overseas investment structure. An appropriate structure will not only make it easier for companies to mobilize funds and exit a deal, but can also help reduce tax liabilities when repatriating earnings and ramp up investment returns for shareholders.



Setting up the optimal investment structure with bottom-up, big-picture thinking

Source: Deloitte Analysis

Tax Management for Global Operations and Cross-border M&A Tax Due Diligence

Tax management for global operations

As businesses continue to deepen their presence globally, companies must establish tax management mechanisms that cater to their global operations, including but not limit to business model optimization, building internal reporting mechanisms and tax risk management systems for cross-border finance and taxation, tax compliance/risks for daily operations of overseas entities, transfer pricing risk management, taxation, compliance requirements and potential risks of moving funds across borders, strategy and implementation for intangible assets across borders.

Routine tax compliance and risk management of overseas entities

- Ensuring overseas entities' routine tax compliance is an important part of corporate tax management. It is necessary to establish a tax compliance process that is local to the entity's home market while putting together an appropriate local tax team.
- The parent company must also consider establishing a cross-border tax reporting mechanism and a risk management system to make sure the head office can understand and manage the tax risks of overseas entities as they arise.

Global strategy and implementation for intangible assets

- As industry competition intensifies, medical device manufacturers must continuously develop new products and innovate technology. As businesses globalize production, sales, and R&D, it is important for medical device manufacturers to formulate appropriate global intangible asset strategies to optimize the tax impact of the development and use of intangible assets while ensuring asset safety and security.

Tax compliance and risk management of cross-border fund allocation

- Cross-border capital allocation is an important aspect of corporate financial management in global operations. Cross-border capital allocation involves complex foreign exchange and tax compliance requirements in various jurisdictions, requiring businesses to establish targeted tax risk management mechanisms.

Global business model optimization and transfer pricing risk management

- Given the intricate international tax landscape, transfer pricing risk management plays an important part in tax management for businesses. By diversifying risks across different entities' functions and tailoring local business models for different entities, businesses can manage the entities' transfer pricing risks while optimizing the tax efficiency of the business as a whole, thus boosting investor return.

Tax due diligence: Ensuring the success of cross-border M&A

Cross-border M&A has become an essential vehicle for domestic medical device manufacturers seeking to invest overseas. Acquiring the assets/equity of an overseas target can help reduce overseas market access risk and scale up overseas operations quickly.

Tax risks are an important consideration for cross-border mergers and acquisitions, which can make or break a deal. **Tax due diligence** is an important tool for companies trying to manage the tax risks of cross-border M&A.

With tax due diligence during the deal evaluation phase, companies can survey key tax policies of the target country/region, tax burdens, major historical tax issues of the target company, and the impact on future operations, which helps domestic medical device companies understand the full extent of the tax landscape and potential tax risks of the target company during M&A negotiations, before clearly defining ways to resolve such risks in an agreement before committing to the deal, incl. . Common solutions may entail:

- ✓ Legal precautions defined in an agreement;
- ✓ Deal price adjustments;
- ✓ Remedy and compensation for tax risks;
- ✓ Payment method and remedies for deferred payment.

Source: Deloitte Analysis

Illustrative 4

Global Talent Mobilization and Cross-border Mobility

Business globalization takes collaborative efforts across different teams, the success of which is founded on global talent mobilization and management. Human resources, finance and business teams must work together to make global talent mobilization and cross-border talent mobility possible. Chinese companies will face diverse challenges and confusions in different stages of globalization regarding talent strategies and global talent management, including issues of strategic planning, policy and protocol design, international payroll, and human resource compliance and management.

All-around integrated global talent strategies and cross-border talent mobility management involve multidimensional considerations:

Before global implementation of talent strategy | **During implementation** | **Beyond implementation**

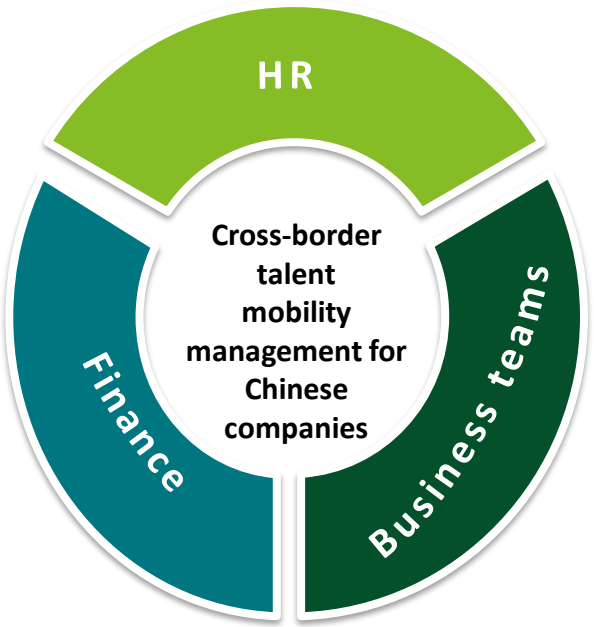
International human resources considerations
- Screening and evaluating premium international talent • Job design and staffing of key overseas positions • Identifying key performance indicators for expatriated employees • Improving overseas HR management capabilities • Overseas returnee management consulting

Immigration and visa considerations
- Providing immigration and visa support for senior overseas talents relocating to and from overseas
- Interpreting the immigration and visa requirements of different destination countries/regions

International income tax and social security considerations
- Compliance reporting of income tax and social security in the origin and destination countries/regions
- Better control over cross-border tax cost for businesses and individuals based on international tax treaties, etc.

International integration and expatriation management considerations
- Estimating the cost of talent expatriation
- Planning an expatriation program
- Providing technology platform support to effectively manage expatriated employees
- Establishing and improving the expatriate management system and protocol
- Introducing third-party providers (e.g., relocation, wages, expense reimbursement, etc.), and engage with providers as the main coordinator
- Advising the impact of labor laws of the destination country/region on employment contracts
- Analyzing the international labor law landscape facing recruitment and expatriation of talents

International compensation and benefits considerations
- Designing an international compensation and benefits structure
- Tailoring the compensation and benefits structure for special individuals
- Assisting expatriates and local employees in calculating, reporting and issuing remittance
- Customizing employee incentive mechanisms to provide a comprehensive turnkey solution for incentive services, including program design, tax analysis and planning, accounting cost estimation, employee seminar and engagement, etc.



Source: Deloitte Analysis

Contents

Deloitte China Life Sciences & Health Care Team Contacts

Survey & Authors

Carrie Xiao
China Life Sciences Sector Leader
China Life Sciences & Health Care Consulting Leader
carriexiao@deloitte.com.cn

Jeff Qiang
Consulting Director
China Life Sciences & Health Care
jqiang@deloitte.com.cn

Anne Chen
Consulting Manager
China Life Sciences & Health Care
anneschen@deloitte.com.cn

Additional contacts

Jens Ewert
Industry Leader
China Life Sciences & Health Care
jensewert@deloitte.com.cn

Scott Sun
Consulting Deputy Leader
China Life Sciences & Health Care
scottsun@deloitte.com.cn

James Zhao
Tax Advisory Leader
China Life Sciences & Health Care
jazhao@deloitte.com.cn

Travis Zhu
Risk Advisory Leader
China Life Sciences & Health Care
trazhu@deloitte.com.cn

Helen Ha
Global Employer Services Leader
China Life Sciences & Health Care
hha@deloitte.com.cn

David Yu
Assurance & Audit Leader
China Life Sciences & Health Care
davyu@deloitte.com.cn

Bill Yang
Financial Advisory Leader
China Life Sciences & Health Care
bilyang@deloitte.com.cn

Medical Device Classification

Category	Subcategory	Particulars
Medical Consumables	Medical Dressing	• Medical dressings (with adhesive), medical dressings (without adhesive), etc.
	Suture Materials	• Suture materials, etc.
	Syringes, Needles and Catheters	• Syringes (with/without needles), tubular metal needles/needles for suturing, needles of other types, catheters, cannulas, etc.
	Other Consumables	• Blood grouping reagents, first aid kits, ostomy related products, surgical gloves, etc.
Imaging Diagnosis	Electronic Diagnostic Equipment	• EKG, ultrasound, MRI, scanners, other related devices, etc.
	Radiation Meter	• CT scanners, other medical X-ray equipment, A,B,C-ray devices, etc.
	Imaging Components and Accessories	• Medical X-ray film (flat), medical X-ray film (rolled), X-ray tubes, contrast imaging equipment, other imaging components and accessories, etc.
Dental Devices	Equipment	• Dental drills, dental chairs, dental X-rays, etc.
	Others	• Dental adhesives, dental moulds, artificial teeth, other dental accessories, etc.
Orthopedics Devices and Prosthetics	Orthopedics Devices and Prosthetics	• Fixed devices, artificial joints, other artificial body parts, etc.
Patient Aids	Removable Devices	• Hearing aids, cardiac pacemakers, other portable/removable devices, etc.
	Therapy instruments	• Respiratory therapy instruments, etc.
Other Medical Devices	Wheelchairs	• Mechanical wheelchairs, automatic wheelchairs, etc.
	Ophthalmic Instruments	• Ophthalmic equipment, etc.
	Hospital Equipment	• Surgical chairs, surgical beds, etc.
	Ultraviolet Devices	• Infrared and ultraviolet devices, etc.
	Others	• Other related medical devices

Note: In this material, the scale and growth rate of each medical device segment market are measured based on the above classification.

Deloitte.

德勤

About Deloitte

Deloitte China provides integrated professional services, with our long-term commitment to be a leading contributor to China's reform, opening-up and economic development. We are a globally connected firm with deep roots locally, owned by our partners in China. With over 20,000 professionals across 31 Chinese cities, we provide our clients with a one-stop shop offering world-leading audit & assurance, consulting, financial advisory, risk advisory, tax and business advisory services.

We serve with integrity, uphold quality and strive to innovate. With our professional excellence, insight across industries, and intelligent technology solutions, we help clients and partners from many sectors seize opportunities, tackle challenges and attain world-class, high-quality development goals.

The Deloitte brand originated in 1845, and its name in Chinese (德勤) denotes integrity, diligence and excellence. Deloitte's global professional network of member firms now spans more than 150countries and territories. Through our mission to make an impact that matters, we help reinforce public trust in capital markets, enable clients to transform and thrive, empower talents to be future-ready, and lead the way toward a stronger economy, a more equitable society and a sustainable world.

Deloitte refers to one or more of Deloitte Touche Tohmatsu Limited ("DTTL"), its global network of member firms, and their related entities (collectively, the "Deloitte organization"). DTTL (also referred to as "Deloitte Global") and each of its member firms and related entities are legally separate and independent entities, which cannot obligate or bind each other in respect of third parties. DTTL and each DTTL member firm and related entity is liable only for its own acts and omissions, and not those of each other. DTTL does not provide services to clients. Please see www.deloitte.com/about to learn more.

Deloitte Asia Pacific Limited is a company limited by guarantee and a member firm of DTTL. Members of Deloitte Asia Pacific Limited and their related entities, each of which is a separate and independent legal entity, provide services from more than 100 cities across the region, including Auckland, Bangkok, Beijing, Bengaluru, Hanoi, Hong Kong, Jakarta, Kuala Lumpur, Manila, Melbourne, Mumbai, New Delhi, Osaka, Seoul, Shanghai, Singapore, Sydney, Taipei and Tokyo.

This communication contains general information only, and none of DTTL, its global network of member firms or their related entities is, by means of this communication, rendering professional advice or services. Before making any decision or taking any action that may affect your finances or your business, you should consult a qualified professional adviser.

No representations, warranties or undertakings (express or implied) are given as to the accuracy or completeness of the information in this communication, and none of DTTL, its member firms, related entities, employees or agents shall be liable or responsible for any loss or damage whatsoever arising directly or indirectly in connection with any person relying on this communication.