CAMDI

China Association for Medical Devices Industry

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CURRENT SITUATION AND TREND OF MEDICAL DEVICE MARKET IN CHINA

International Medical Device Industry Development Status

- The output value of the global medical device accounts for 42% of the total value of the pharmaceutical industry and the market share of medical device in developed countries is up to 1:1
- In recent years it is highly valued and has become the priority to enhance the bio-pharmaceutical industry and high-end device manufacturing industry in developed countries

Data source: Foreign market research agencies, trade association calculation.

TOP 30 PUBLIC MEDICAL DEVICE COMPANIES BY SALES, 2015

No.	Company Name	Total Revenue, Last 12 Months (SUSDmm, Historical rate)	Market Capitalization (\$USDmm, Historical rate)	No.	Company Name	Total Revenue, Last 12 Months (\$USDmm, Historical rate)	Market Capitalization (\$USDmm, Historical rate)
1	Johnson & Johnson	\$25,836.0	\$258,689.9	16	Abbott Laboratories	\$5,223.5	\$59,453.7
2	Medtronic plc	\$23,127.0	\$98,839.9	17	Olympus Corp.	\$4,811.5	\$11,085.3
3	General Electric Co.	\$18,030.0	\$280,909.2	18	Smith & Nephew plc	\$4,669.0	\$15,823.2
4	Fresenius Medical Care AG & Co.	\$16,982.3	\$24,506.3	19	Zimmer Biomet Holdings Inc.	\$4,630.9	\$19,114.3
5	Baxter International Inc.	\$16,326.0	\$17,604.5	20	Terumo Corp.	\$4,114.6	\$10,686.3
6	Siemens AG	\$14,600.4	\$79,439.8	21	Toshiba Corp.	\$3,509.9	\$11,367.1
7	Cardinal Health Inc.	\$11,395.0	\$25,685.7	22	Getinge AB	\$3,432.3	\$5,457.0
8	Novartis AG	\$10,485.0	\$226,977.7	23	Varian Medical Systems Inc.	\$3,093.4	\$7,445.2
9	Koninklijke Philips N.V	\$10,402.5	\$23,226.2	24	DENTSPLY International Inc.	\$2,781.6	\$7,368.2
10	Stryker Corp.	\$9,818.0	\$35,742.9	25	Bayer AG	\$2,672.5	\$107,846.5
11	Becton, Dickinson and Co.	\$9,410.0	\$28,298.1	26	Hologic Inc.)	\$2,640.9	\$10,559.1
12	Boston Scientific Corp.	\$7,272.0	\$22,269.4	27	Danaher Corp.	\$2,505.3	\$63,641.4
13	Essilor International SA	\$7,015.3	\$26,427.6	28	Edwards Lifesciences Corp.	\$2,432.5	\$15,515.6
14	St. Jude Medical Inc.	\$5,566.0	\$17,603.4	29	Intuitive Surgical Inc.	\$2,257.3	\$17,013.9
15	3M Co.	\$5,475.0	\$109,657.2	30	Paul Hartmann AG	\$2,129.3	\$1,488.6

Data source: S&P Capital IQ, company data.

Medical Device Industry Development Status in China

National Medical Device Output Value in 2015

Sample enterprises above MIIT statistics scale:

Industry	Main business income (100 million)	Year-on-Year increase (%)	
Medical device and apparatus manufacture	2382.49	10.27	
Medical consumables and medicinal product manufacture	1858.94	10.68	

Data source: MIT

A total of 424.14 billion RMB

Industry-wide output value estimated by the trade association: over 500 billion RMB

The Quantity of Enterprises

By the end of 2015:

- 14,151 manufacturers including 5,080 Class I medical device manufacturers, 9,517 Class II medical device manufacturers and 2,614 Class III medical device manufacturers.
- 186,269 medical device enterprises with licensed management (Class II, III).

Data source: CFDA

Imports and Exports

Medical device total trade amounted to \$38.5 billion in 2015

- Imports amounted to \$ 17.3 billion, a year-on year increase of 9.8%.
- Exports amounted to \$ 21.2 billion, a year-on year increase of 5.7%.

Data source: China Customs

Distribution of Listed Medical Device Companies in China (As of October 2015)

- 41 listed manufacture companies, including 25 in Mainland China (excluding NEEQ) and 16 overseas.
- In less than 5 years from 2010 to 2015, 24 domestic medical device companies land in the capital markets of Mainland China, Hong Kong and the United States. More than half of the listed medical device companies contribute to the centralized listings. For a moment a swelling tide of medical devices rises in the capital market.

The Domestic Medical Device Industry has Huge Development Potential

	Developed countries	China	
GPD contributed by the medical industry	More than 10%	Less than 5%	
Device and pharmaceutical markets	About 1:1	About 1:3-4	
Global market share	72% (US, Europe, Japan)	About 14%	
Domestic market share	70%	30%	
Market concentration	High	Low	
GPO level	High	Low	

All Departments Consider the Medical Device Technology Industry as the Supporting Priorities

State Council	Promoting the Development of Health Service Industry Guo Fa [2013] No. 40		
	Tromoting the Development of Treath Service industry Guo La [2013] No. 40		
General Office of the State Council	Outline for the Planning of the National Medical and Health Service System (2015-2020)		
National Development and Reform Commission	Three-Year Action Plan to Improve the Core Competence of Six Manufacturing Sectors(2015-2017)		
State Council	Made in China 2025		
General Office of the State Council	Guiding Opinions on Promoting the Healthy Development of the Pharmaceutical Industry[2016] No.11		

Reconstruct the innovation system, build the core competitiveness

- Enterprise-oriented, in collaboration with universities and hospitals
- Orderly fund allocation: post subsidy
- Talent scheme and human capital
- Ownership of inventions and patents



Supporting policy on innovative products

- Accelerate registration through green channel
- Expand procurement share and market
- Encourage financial leasing
- Promote the productive service industry like R&D and design and industrial design
- Promote the achievement transformation, strengthen property rights protection
- Preferential fiscal and taxation policies for research expenditures

Speed up industrial upgrading and transformation

- The rapid development of international cooperation and innovation
- Overseas merger
- Integration of technology and capital accelerates
- Industry group and industry chain form: Shenzhen - images, Jiangxi, Jiangsu - polymer supplies, Suzhou - electronic precision instruments and nanotechnology, Tonglu and Yuhuan (Zhejiang) professional products
- Park features reveal
- Enterprises trend to benign differentiation, mergers and acquisitions rise







The emergence of new types of operation

- Technology service industry
 - Third-party R&D / third-party testing / open laboratory
 - Industrial design / consigned development / lease
 - Technology transfer / achievement transformation / patent services
 - Industrial design / consigned design / consigned processing, OEM / technical sales
- Logistics / third-party operations, maintenance / upgrading
- Hospital engineering / integrated proposal, GPO/ Pharmaceutical Exchange

Investment and M & A continue rising- the new trend of mergers and acquisitions

- Unlike the past mergers and acquisitions of local medical device companies by multinational and domestic pharmaceutical listed companies, local outstanding enterprises kick off overseas mergers and acquisitions, to take the international and diversified path
- Mindray takes over US ultrasound giant ZONARE. Fosunpharma acquires Israeli company Alma into the cosmetic device market. MicroPort purchases US Wright Medical orthopedics, etc.

Cause analysis for the continuous rising of investment and M & A

- Over-crowded segments with smaller market for each one
- The only way for enterprises to grow
- One of the most concerned industry segments by private equity and venture capital
 Short development cycle, fast return on investment and low risk factor
- Indirect impact from the new regulations on promoting the division of labor

Recent major policies

- On February 17, 2016, State Council meeting established five policies in order to encourage state-owned research institutions and universities to shift scientific and technological achievements to enterprises or other organizations by means of transfer, licensing or evaluation investment.
- On February 18, 2016, General Office of the State Council issued *Guidance on* Accelerating Economic Restructuring and Upgrading through Maker Space's Development of Services Entities, which encourages leading enterprises and academic institutions in key industry fields such as biotechnology, high-end equipment manufacturing, medicine and health to create national innovation platforms and dual innovation base and enhances international cooperation.
- On May 30, 2016 of National Conference on Science and Technology (the third session), Xi Jinping pointed out that China will become an innovative country until 2020, many important scientific and technical projects and works will be put into operation. We should focus on major national strategic needs, and strive for core technological breakthroughs so that people can enjoy a more comfortable environment, better health services, more reliable food and drug. We should develop and implement policies to encourage technological innovation of enterprises, and strengthen the support efforts of technological innovation to middle and small-sized enterprises. We should also develop a large number of entrepreneurs and talents who are good at innovation.
- In June, 2016, the State Council's *Guidance on Promoting and Regulating Application and Development of the Big Medical Data (Guo Ban Fa [2016] No. 47)* pointed out that artificial intelligence technology related to health care, 3D printing technology, medical robots, large medical equipment, health and rehabilitation assistant devices, wearable devices and related micro sensor devices, and traditional Chinese Medicine function detection and health care equipment will become the focus of national support.

CURRENT SITUATION AND TREND OF MEDICAL DEVICE MARKET IN CHINA 05

- On May 8, 2015, the State Council announced the "Made in China 2025", clearly pointing out the vigorous promotion of the breakthrough development in ten key areas including highperformance Medical Device.
- On June 4, 2015, Chinese Premier Li Keqiang chaired a State Council executive meeting, deploying to promote the healthy development of social medical, simplify the review and approval of medical institutions setup to explore ways like state-owned establishments run by private owners and private establishments with governmental support to establish regional test & examination centers.
- The revised Law of the People's Republic of China on Promoting the Transformation of Scientific and Technological Achievements was formally implemented as of October 1, 2015, aiming to increase and speed up the transformation rate of the results of universities and research institutions to business and society, transformation efficiency and transformation interest allocation mechanism.

Specific measures: public release of R&D achievement information; transformation of government functions, the abolition of review and approval; establish interest mechanism, motivate researchers' enthusiasm; strengthen the main role of enterprises in the transformation of scientific and technological achievements; the government shall set up a public service platform, with which comes suitable tax and policy environment.

• Policies of NHFPC and NDRC

- Reform of public hospitals multiple sites practicing by physicians, grading of diagnosis and treatment, social capital running hospitals (post approval for private medical institutions)
- Carry out Healthy China Cloud Service Plan
 smart medical services, health big data
 applications
- Increase proportion of national medical device
 procurement
- Relax large device configuration permits
- Clinical examination item charge policy
- Suspend price limit for high value consumables
- On May 5, 2015, multiple departments jointly issued Opinions on Promoting Drug Price Reform. Since June 1, 2015, it is required to abolish most pharmaceutical governmental pricing, improve drug procurement mechanism, strengthen the role of the health insurance cost control, strengthen the health care conduct supervision and strengthen supervision of pricing behaviors.

CFDA policies

- Special Review and Approval Procedures for Innovative Medical Device (trial) have come into force as of March 1, 2014
- On June 1, 2014, CFDA issued the newly revised Regulation on the Supervision and Administration of Medical Devices, encouraging product innovation in enterprises. Five supporting regulations (CFDA orders 4, 5, 6, 7 and 8) also came effective as of October 1, 2014.
- The "Five Rectification" special action for medical devices
- On July 20, 2015, Regulations on the Accreditation of Medical Device Clinical Trial Institutions were published to strengthen the standardized management of clinical trial institutions.

The overall effect of newly revised regulations

Positive, a basis for another glorious decade

- CFDA involvement of industrial planning and development is clear
- Conform to domestic and foreign industry trends and changes
- Reduce administrative licensing, simplify administrative procedures
- Accelerate product registration and renewal
- Production enterprises (hospitals) as the responsible body
- Strengthen the process supervision and withdrawal mechanism
- *Refine penalties to make it workable*

The specific impact of the new regulations on the industry

- Basically establish CFDA as the regulatory body of the medical device industry, and it participates in industry and trade development
- *Reverse the previous regulatory pattern of difficult entry but easy exit*
- Overall promote industry innovation and development
- Promote enterprise collaboration and division of work - transformation of part manufacturers and enterprises, professional R&D design, emerging and gradually increasing consigned enterprises, active technological innovation, increasingly frequent mergers and acquisitions





Drug review reform

 On August 18, 2015, the State Council issued Opinions on Reforming Review & Approval System for Drugs and Medical Devices (State Council No. [2015] 44), clearly proposing speeding up the review and approval for much-needed innovative drugs, reforming the review and approval method for medical device, improving review quality control system, comprehensively exposing review and approval information of drugs and medical devices.

The impact of reform on medical device industry

- Delegate part registration and approval responsibilities to the provincial food and drug administration departments
- Increase and establish registration charge standard for drugs and medical devices, which shall be adjusted every five years; give appropriate preferential registration fee for small innovative enterprises
- Give priority to the core technology patents and innovative medical devices with significant clinical value in the review and approval
- Improve the adoption rate of international standards for medical device

• Recent Main Policies for Circulation

The Specific Rectification of Medical Consumable Materials

• On May 20, 2016, National Health and Family Planning Commission held the Eighteenth Ministerial Meetings in order to correct unhealthy tendencies in medicine purchase, consumption and medical service, where the specific rectification of medical consumable materials became an important issue. Although concrete implementation opinions have not been released, the dynamic monitoring to the rational use of medical consumable materials will become the norm.

 The fight against commercial bribery, illegal invoices and bundles of medical consumable materials and equipment will become the emphases.

The Change from Business Tax to Value-added Tax and Two-invoice System

• Circulation is forced to be shortened. Sanming in Fujian Province stipulates that hospitals can only sign contracts with manufacturing enterprises or Chinese general agents.

Affiliating Operations

• Agents at all levels will be thoroughly investigated by the local drug administrations.

Price Reduction as a Result of GPO Negotiation

 Centralized procurement model of health reform pilot provinces and cities frequently downgrades, and prices of medical consumable materials will inevitably decrease.

High Trustee Fee in Hospital

 For example, in Henan Province, 80% of secondary-and tertiary-level hospitals are trusted with narrowed profit margins of agents.

Hospitals' Cutting Down the Number of Suppliers and Distributors of Medical Consumable Materials

INTRODUCTION

Founded in 1991, China Association for Medical Devices Industry (CAMDI) is a non-profit social organization with corporative qualification. As a national medical devices industry association, CAMDI is established on a voluntary basis by organizations and individuals engaged in the research and development, production, operation, investment, product testing, certification and consultation, and training in relation to medical devices. The purpose of CAMDI is to represent and safeguard the common interests and legitimate rights of its members, and to promote the healthy development of China's medical devices industry. CAMDI abides by the State's constitution, laws, regulations and policies, observes social ethnics, and receives guidance and supervision of the State-owned Assets Supervision and Administration Commission, receives guidance of China Food and Drug Administration.

Currently, CAMDI runs 28 branches and specialized committees and has more than 4,000 members.

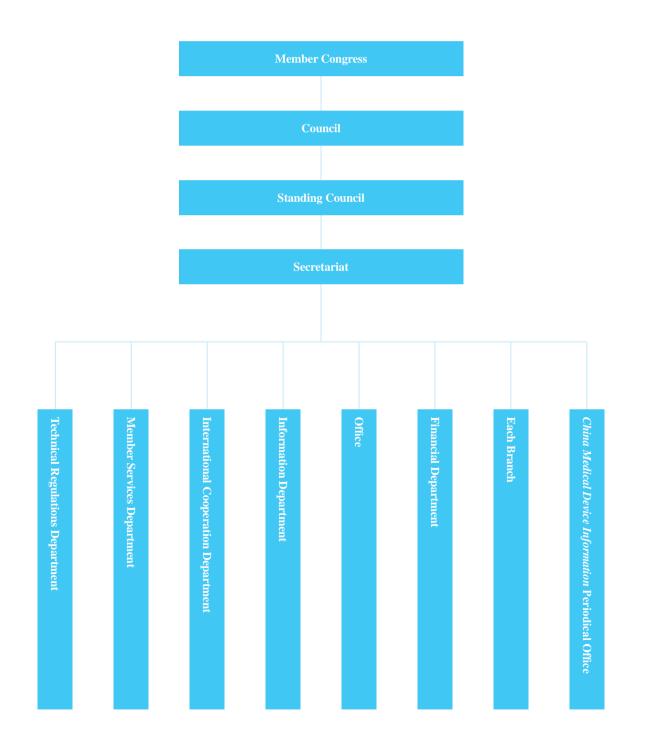
SERVICES

- * Membership Service
- * Information Service
- * Certification Consulting
- Innovation Service
- * International Cooperation

- * Special Training
- * Conference and Exhibition
- * Park Cooperation
- * Industrial Self-discipline



ORGANIZATION CHART



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BRANCHES

- * Expert Committee
- * Standard Operation Committees
- Innovation Services Committee
- * Human Resource Committee
- * Medical Data Analysis Committee
- * In Vitro Diagnosis (IVD) Branch
- The cardiac and cerebral disease Interventional therapy industry branch
- * Ophthalmic and optical Specialized Committee
- Department of orthopedics, biological materials and equipment Specialized Committee
- * Medical Device Packaging Committee
- * Vascular Devices Branch
- Gastrointestinal Endoscopy Innovation and Development Branch
- * Medical Polymer Products Branch
- * Temperature measurement Specialized Committee

- * Dental Equipment and Materials Committee
- * Medical Software Branch
- * Nursing products Specialized Committee
- * Rehabilitation Physiotherapy Branch
- * Surgical Implant Committee
- * Smart and Mobile Healthcare Branch
- * Surgical Instrument Committees
- * Hygienic Material Committees
- * Infection and Control Technology Committee
- * Medical Optical Instrument Committees
- * Medical Health Care Product Committees
- * Medical X-ray Equipment Branch
- Aesthetic Plastic Surgical Devices and Materials Committee
- * Double Innovation Industrial Cooperation Branch

KEY MEMBERS

	Abbott		BAIRD	😵 BD	Scientific
Carestream	<i>D</i> DANAHER MOTION	EDAN	② 福隆控股 FLON HOLDINGS	FOSUN 复星诌断	(FE)
② JINGJING 京積医行设备	Johnson-Johnson		Medtronic 美教力	MicroPort	mindray迈瑞
OLYMPUS	Roche	ZHINVA	SIEMENS	SIUI	SonoScape 开立
Sysmex	UNITED KE U 用心改变	WEGO顧高	yuwell 鱼跃 [。]	して して して して して して して して して して	D ZIMMER BIOMET



KEY DEPARTMENT AND THEIR FUNCTIONS

Technical Regulations Department

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- 1. Organizing experts and enterprises to participate in the research and formulation of national laws and regulations, macroeconomic regulation and control policies, and industrial policies related to medical devices
 - Giving comments and suggestions in respect of policy and legislation to relevant government authorities.
 - Actively completing all projects assigned by the State and local government authorities.
- 2. Organizing relevant parties to formulate and revise industrial standards for products



- (1) Training on medical devices regulations and standards.
- (2) Special training on quality management system.
- (3) Business management and skills training.
- 4. QMS Certification and Consulting service
- 5. Organizing academic forums, seminars, business meetings and exhibitions on laws and regulations related to medical devices



the Chairman of CAMDI, Madam Yixin Zhao



the Executive Chairman & CEO of CAMDI, Dr. Feng Jiang

Member Services Department

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1. Member Service

Strengthening contact with the members and establishing a smooth working network; listening to and representing the members' requests and safeguarding their lawful rights and interests; holding professional forums and meetings; organizing industrial enterprises participating medical device exhibitions; mailing industry periodicals to the members and providing publicity platform for them.

2. Member management

Developing members, manage their membership, and updating and completing member registration information; collecting membership fees, and preparing and issuing membership certificates.

3. Industrial Self-discipline

Drafting industry regulations and standardizing enterprises' behaviors, maintaining fair competition in the industry and promoting industry self-discipline.

4. Branches Communication

Coordinating and liaising with the branches and guiding their activities.

5. Proof of issue

Verifying and issuing industrial proof materials required for enterprise declaration of national and local programs.

International Cooperation Department

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- 1. Liaising with the trade organizations of different countries and the commercial departments of their embassies in China, and promoting academic and industrial cooperation and comunication with foreign countries.
- 2. Taking an active part in coordinating international laws and regulations, and organizing international cooperation projects.
- Actively exploring the overseas market, organizing the member enterprises to participate in worldrenowned exhibitions, and holding forums at international exhibitions.
- 4. Organizing and coordinating international business visits for domestic enterprises, providing industrial cooperation opportunities, and providing services for domestic enterprises to expand overseas markets.





Information Department

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- 1. Industrial statistics and analysis
 - Organize and implement collection and sorting of industry data, establish and improve CAMDI's database.
 - (2) Make development analysis and predictive studies of industry and various fields, prepare industry development report.
- 2. Industry development planning

Taking part in the planning of national or regional development strategies in the field of medical devices and offering consultation services.

3. Customize consultation service

According to corporate requirements, conduct investigation and survey on products and market and provide oriented consulting services for pre-market product market status and trend.





China Strategic Alliance Office of Medical Device Innovation (CSAMDI)

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CSAMDI was proposed and approved by MOST (Ministry of Science and Technology) in July 2009 and initiated by more than 400 units, including multiple large medical devices enterprises, famous universities and scientific and research institutions such as Tsinghua University, Peking University and CAS (Chinese Academy of Sciences) and social organizations such as CAMDI. Led by enterprises, oriented by market, aimed at improving technology innovation capacity of medical devices industry and guaranteed by legally binding agreements, the CSAMDI is developed into an open technologyinnovated organization which emphasizes complementary advantages, joint development, interest sharing, risk sharing and integration of industry, university, research and institution. The tasks of the CSAMDI include establishing a strategic plan of medical devices sci-tech industry, integrating innovation elements and superior resources in medical device sci-tech industry, promoting the sci-tech and industrial innovation of medical devices and assisting MOST to select, review, fund and follow up brilliant researches and development projects, which amounts to over CNY 200 million regarding state-fund capital. The CSAMDI Office is settled in the CAMDI where Jiang Feng, the Executive Chairman & CEO of the CAMDI, serves as the president. The CSAMDI subordinates 10 branches such as imaging, in vitro diagnosis and innovative service. With several times of rating as A-level alliance, it is qualified to recommend proper enterprises to apply for state funds and plays an increasingly important role in many aspects such as leading, organizing and servicing national medical devices industry innovation.

MEDIA PUBLICITY

CAMDI website

Website: www.camdi.org

Introduction: CAMDI website contains General Information, About CAMDI, Window of Membership, News Room, Services, Legislation and Standard, Branches, Publications, Contact Us and other columns.

the CAMDI website is a web service platform facing the industry, releasing key works, regulatory dynamics, international business opportunity, industrial information and exhibition, product, enterprises and other industrial information, tracking the latest industrial dynamics, satisfying the demand for enterprise information search, providing faster and more valuable service for members.





CAMDI WeChat

WeChat of CAMDI was officially launched in January 2016, and it has attracted many attentions from industrial colleagues since its release. The CAMDI WeChat focuses on related Chinese policies and regulations, regulatory information of competent authorities, industrial news, CAMDI dynamics, member information and device industrial development trend at home and abroad, etc.; based on practicability and development, trade exchange at home and abroad, upstream-downstream industries and innovative technology and other information was added; grasping the rhythm of information release, the WeChat will also push industrial important activities and exhibition information.

Follow the CAMDI WeChat, follow the more authoritative and comprehensive platform, you will receive the latest news and excellent service!



CAMDI WeChat:

Method 1: scan the QR code left;

Method 2: click "add" in the WeChat address list and search "CAMDI".

MEDICAL DEVICES INNOVATION COMPREHENSIVE SERVICE PROVIDER FOR MEDICAL DEVICE INNOVATION

www.innomd.org



www.innomd.org is a new media operated jointly by several famous domestic innovative service institutions and technology parks relying on China Strategic Alliance of Medical Device Innovation (CSAMDI) and Innovation Services Committee of CAMDI. It is intended to provide high-level and professional services on medical device innovation, including product proposal analysis, design or production outsourcing, R&D expenditures application, product testing and animal (or clinical) test, product registration, regulatory services and business development at home and abroad.



WeChat official account:

Method 1: scan the QR code up; Method 2: click "add" in WeChat address list and search "innomd" or "Medical Device Innovation" Sina/Tecent Weibo: @ Medical Devices Innovation

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ASSOCIATION PUBLICATION

China Medical Device Information

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Founded in 1995, the China Medical Devices Information is a national and comprehensive medical device information semimonthly journal in the charge of CFDA, and sponsored by CAMDI, coorganized by Society of Clinical Medical Engineering, and supported by CIE Life Electronic Society. The magazine aims to meet the requirements of clinical engineering management, technical staff and medical equipment development, spreading the latest medical device science and technology, market policies and regulations at home and abroad, promoting the development of medical device and medical health in China. In twenty years, the magazine has been developing strongly, playing an active role in respect of industrial development information reflection, advanced technology spreading and market development guidance, and its target audience covers medical device R&D, production, marketing, clinic and maintenance.

China Medical Device Information presents high quality print and rich contents with high coverage, accurate audiences, strong governmental and industrial background, comprehensive supporting service, and the average circulation for each issue is 50,000, and the main audiences are hospital and medical device enterprises, accounting for 60% and 30% respectively, while government departments take 6%. The magazine has been available in second-class and third-class hospitals and over 80% of medical device enterprises in China. There are decision makers from over 8,000 hospitals and 7,000 medical device enterprises reading the magazine for each issue.

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