



MARKET STUDY ON THE CHINESE MEDTECH INDUSTRY



This initiative is part of the MAGIA project, the European Strategic Cluster Partnership (ESCP) on medical technologies, which has received funding from the European Union's COSME Programme (2014-2020).

MedTech Alliance for Global Internationalisation

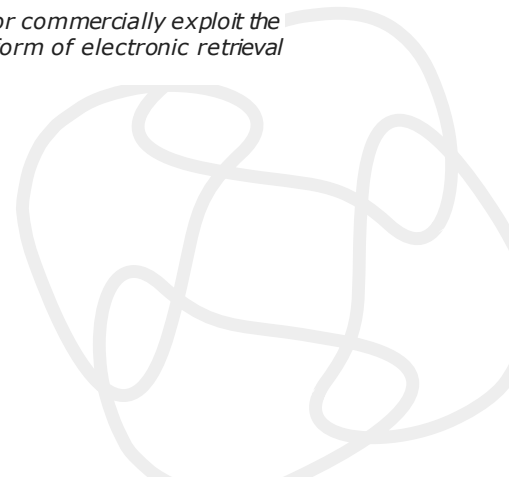


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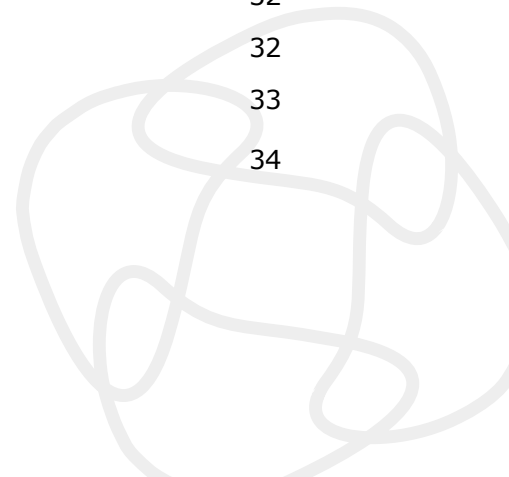
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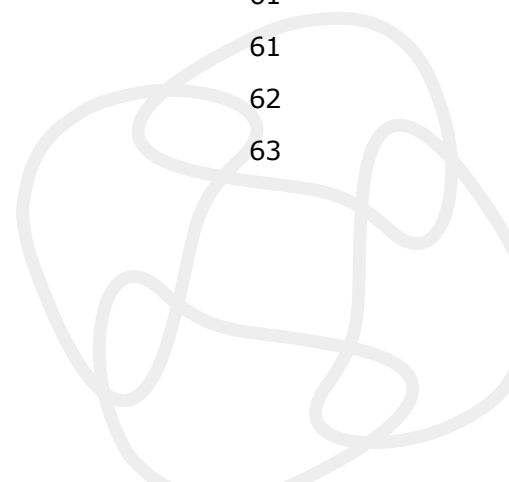


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1. Introduction

China is one of the largest markets for medical devices worldwide and therefore an attractive export target market for European medical device manufacturers.

At the same time, China can be a challenging and intransparent market, e.g. if compared to the European Union. European medical device exporters face a multitude of open and hidden market-entry barriers when trying to access the Chinese market. The challenges include: finding out, if the own medical devices are in need in the Chinese healthcare market, the functioning of the Chinese healthcare system itself, the medical device registration process, finding and managing distributors, logistics and import processes etc. The challenges are especially difficult for Small and Medium-Sized Companies, which are the backbone of the European medical device industry.

Therefore, the objective of the EU-funded "Market Study on the Chinese MedTech Industry" is to offer the European medical device SME from the four "MAGIA – MedTech Alliance for Global Internationalisation"-Life Science Clusters an in-depth overview in regards to the Chinese healthcare market, its regulatory environment, CFDA registration procedures as well as insights into potential market access and business development strategies.

The MAGIA – MedTech Alliance for Global Internationalisation Life Science Cluster includes:

- BioPMed / Italy
- BioWin/ Belgium
- Lyonbiopole/ France
- Life Science Nord/ Germany

In preparation of the market study the Life Science clusters have identified four key areas, in which their companies have strengths and which are of special interest for them:

- Cardiovascular
- Dentistry
- Oncology
- Orthopedics

The market study will provide a general overview of the medical device market in China, provide an insight into the regulatory framework and give an outlook on how to navigate in the market.



2. General China Market Overview

2.1 General Political, Social, Economic System and Technological Developments in China

2.1.1 Political System

The People's Republic of China is - by its own definition - a socialist state, governed by the communist party of China.¹

In China, 5-year plans provide a complex framework within which the government operates and which state major policy goals in China. Currently, the valid-5 year plan is "China's 13th Five Year Plan (2016-20)"², which explicitly states ambitious development goals for a wide range of topics, including healthcare.

As in many healthcare markets also in China, the state is one of the key stakeholders in the healthcare system and the state steers the system via a wide range of means, including the National Development and Reform Commission (NDRC), China's Planning Commission, which for example can set fixed mandatory prices for certain hospital services.

China's major policy goals in regards to the improvement of the healthcare system are currently:

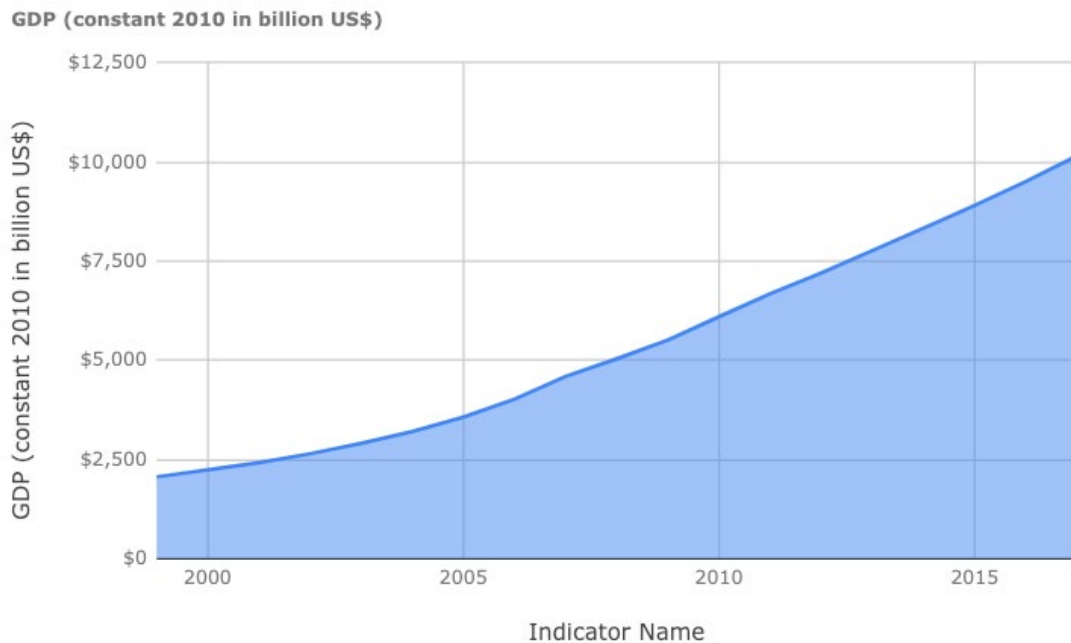
- Extending universal health coverage
- Enhancing the primary Healthcare System
- Abolishing poverty (in certain rural areas)
- Creating an overall healthy environment
- Boosting Innovation and Research

¹ <http://english.cpc.people.com.cn/206972/206981/8188424.html>, retrieved 31.12.2018, "The Ideological and Theoretical Basis of the Communist Party of China (CPC)" from 29.03.2013

² http://www.xinhuanet.com/english/photo/2015-11/04/c_134783513.htm, "Highlights of proposals for China's 13th Five-Year Plan" retrieved 31.12.2018

2.1.2 Economic System

China's economy has seen an extended period of growth since the start of the opening-up reforms in 1978, which further accelerated since its WTO accession in 2001.

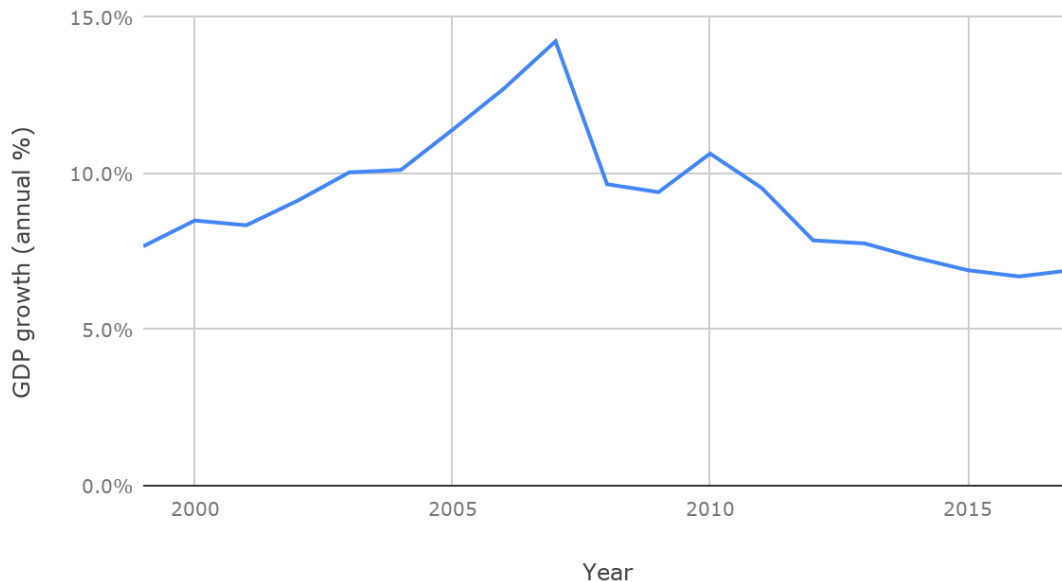


The GDP rose from \$2,424 billion USD in 2001 to \$10,161 billion USD in 2017, which relates to a compounded average GDP growth rate of 9.4%.

The GDP growth rates have become slower in recent years, but with more than 6% remain high, e.g. when compared to EU growth rates.



GDP growth China (annual %)



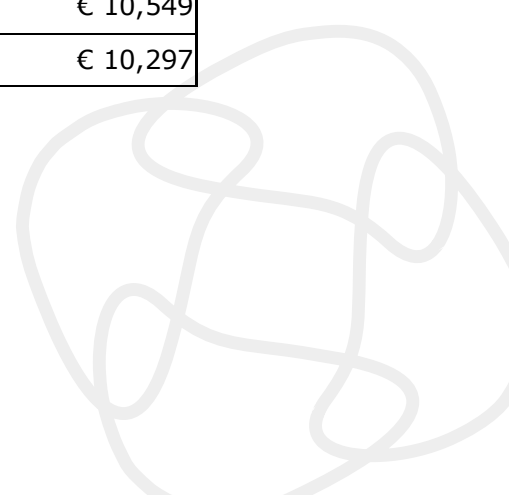
China has started to join the ranks of the high-income nations in the world, by United Nations standards. The average GDP per capita in China is €7648.72. The GDP per capita varies from €15375.38 in Beijing, which has the highest local GDP, to Gansu, which has € 3,642 GDP per Capita.³ Below a list of the 10 regions with the highest GDP per capita in China, their population and their average GDP per person in Euro:

10 Regions with the highest GDP per capita in China⁴

Region	Population in million	GDP per person in Euro
Beijing	21.7	€ 16,544
Shanghai	24.2	€ 16,242
Tianjin	15.6	€ 15,274
Jiangsu	80.3	€ 13,711
Zhejiang	56.6	€ 11,732
Fujian	39.1	€ 10,549
Guangdong	111.7	€ 10,297

³ China Statistical Yearbook 2018, including own calculation

⁴ China Statistical Yearbook 2018, including own calculation



Shandong	100.1	€ 9,306
Inner Mongolia	25.3	€ 8,160
Chongqing	30.8	€ 8,099

These 10 regions represent a total of 505 million inhabitants, roughly the size of the EU, and had an average GDP per capita of 11.289 Euros, i.e. similar to Hungary or Poland, which each had GDP per capita of 11.300 Euros in 2017.⁵

For high-end healthcare services and products, the above 10 areas possess an interesting, affluent medium to high-income class in its urban areas, which by its purchasing power can be compared to certain areas in Europe.

In order to start business activities in China, the 10 regions are a good point to start, especially the clusters Beijing/Tianjin in the North of China, Shanghai/Jiangsu in the East, Guangdong/Fujian in the South and Chongqing in the West of China.

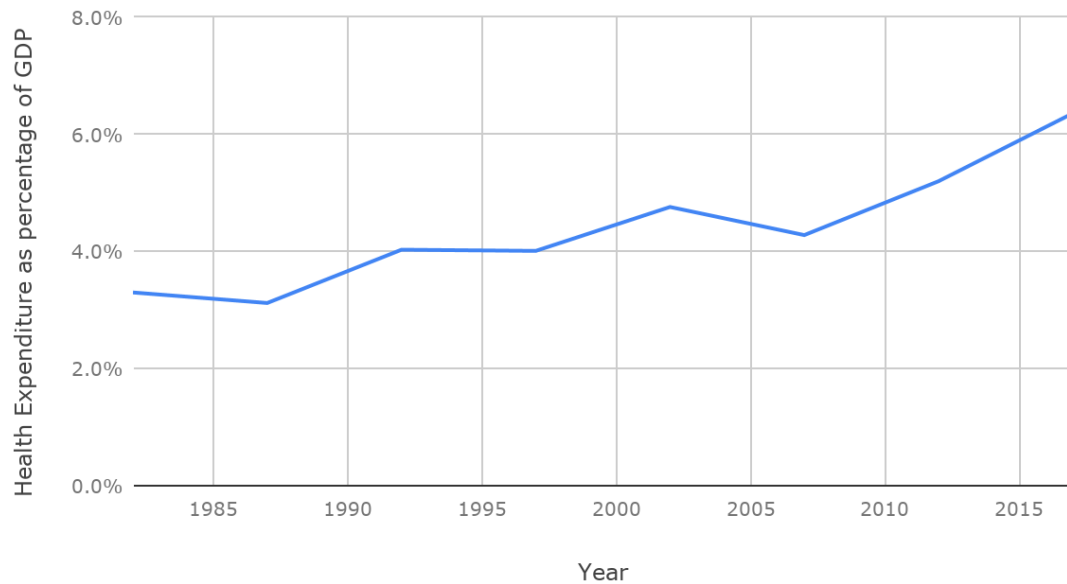
The total expenditure for Public Health was 674 billion Euro in 2017, and China spent 6.4% of its GDP on health in 2017. The level of health care spending measured as part of the GDP has seen increasing rates in the last years, especially since a wave of healthcare reforms since 2009 which were aimed at building a universal healthcare coverage system for its vast population.

Though the overall rate of healthcare spending as part of the GDP remains below OECD average, China managed to cover nearly all of its citizens in some form of public health insurance, albeit on different coverage levels depending on the rural or urban residence status, with the latter having higher coverage rates.

⁵https://ec.europa.eu/eurostat/tgm/table.do?tab=table&init=1&language=en&pcode=sdg_08_10&plugin=1



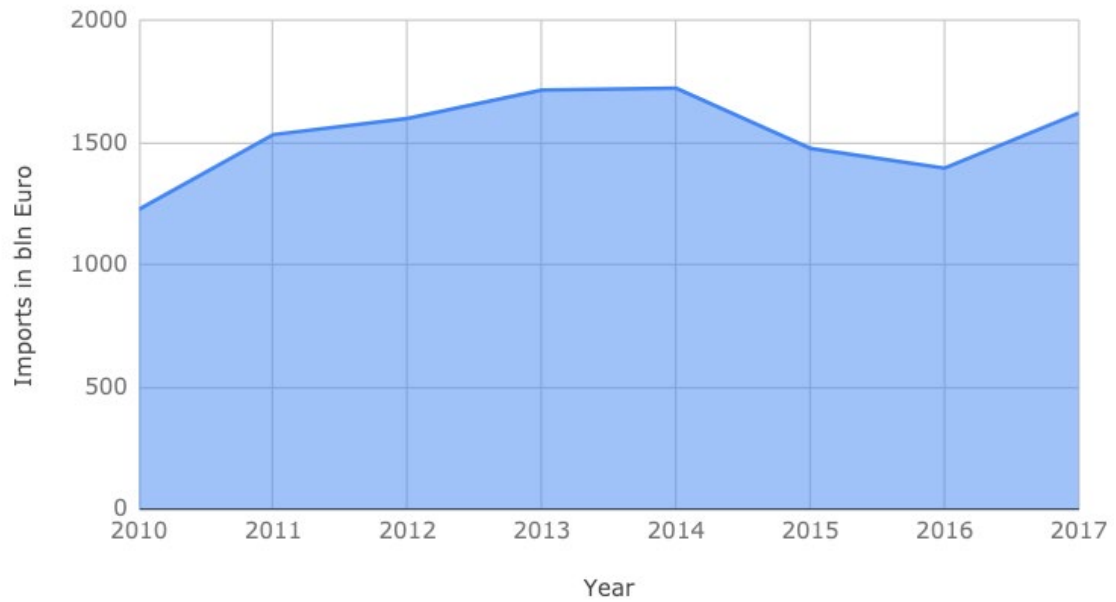
Health Expenditure as percentage of GDP vs. Year



The imports of Medical Devices to China will be analyzed in later chapters in detail. In general, despite the steady, positive economic growth rates of the economy in the last years as laid out above, the total value of imports of goods into China, did not increase in the same rate as the GDP, as can be seen in the following chart:



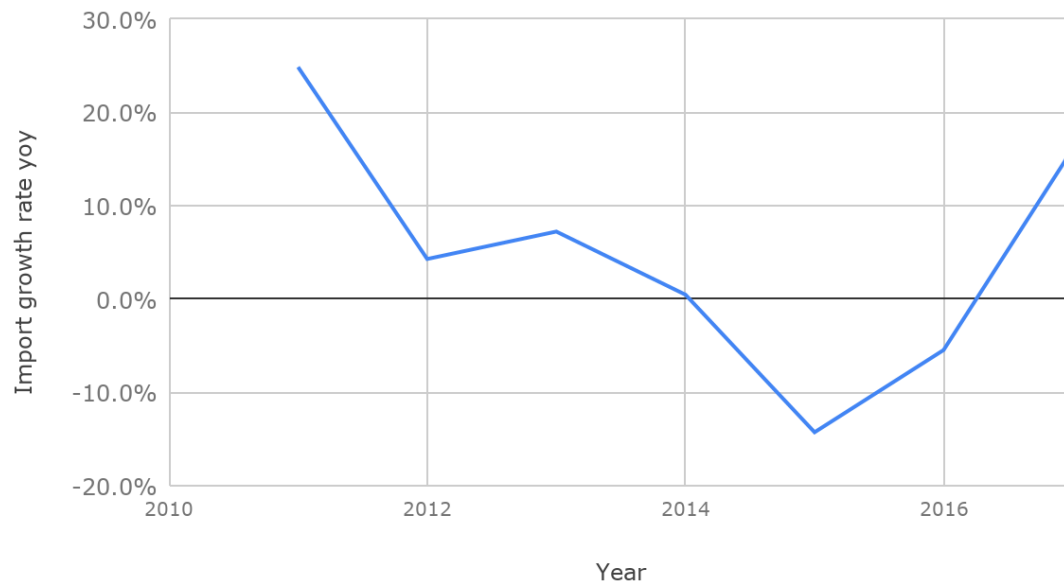
Imports China in bln Euro



Instead, the total imports of China have seen periods of growth and decline in recent years.



Import growth rate yoy



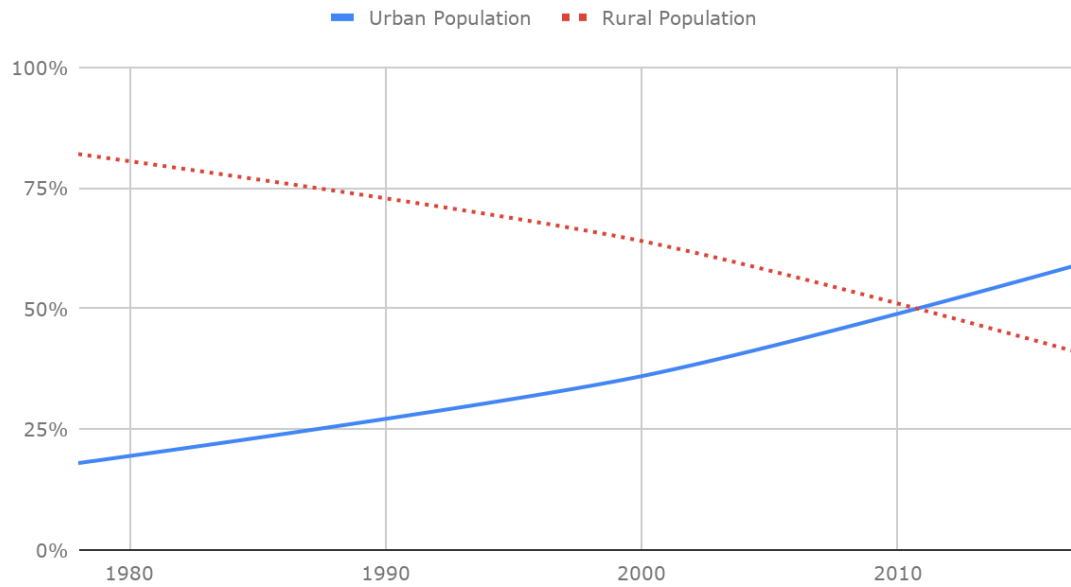
Therefore, each exporter to China has to analyze its market positioning and growth rates for his industry. A steadily increasing GDP does not necessarily mean that each export segment for European exporters to China is growing with the same rates. The medical devices market will be further analyzed in chapter IV.

2.1.3 Social System

In regards to the social system one of the main transitions that China is undergoing currently, is the transition from a major rural society to a society with a major urban population.



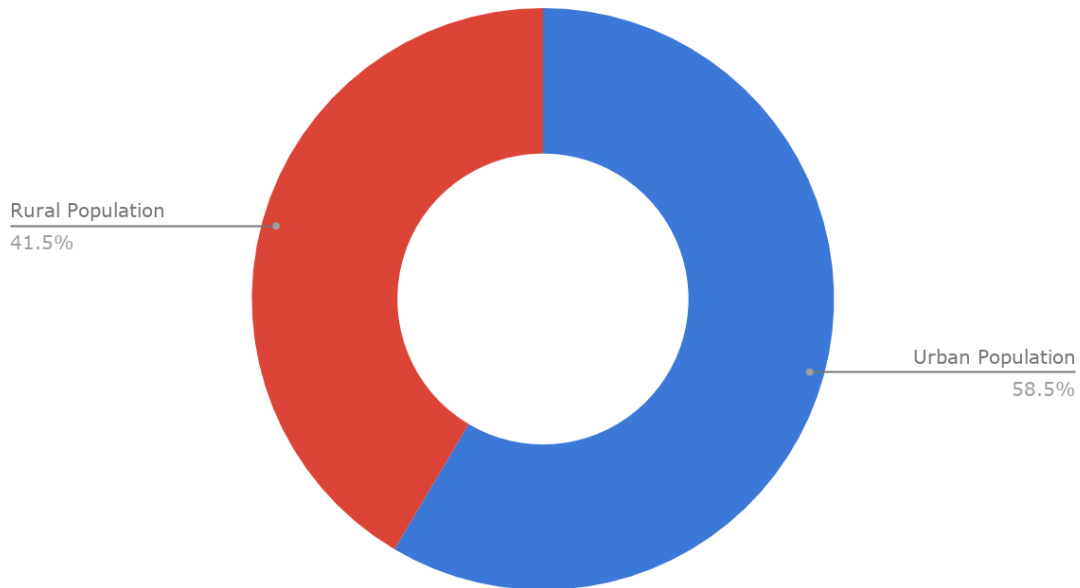
China Urban Rural Population



In 1978, the urbanization rate was 18%, it has reached 58.5% by 2017, and the rate is predicted to increase to 71% by 2030.



Urban Rural Population China



Urbanization has a significant influence on lifestyle patterns, which in turn has notable effects on individual health and public health, as well as the healthcare system. In general, higher urbanization leads to lower levels of physical activity and to changes in dietary habits, e.g. more western fast-food style food intake, which then in turn lead to a higher burden of disease. Unsurprisingly, non-communicable diseases, e.g. cardiovascular diseases, are on the rise.

On the positive side, higher urbanization rates also bring with it a more health conscious and wealthy city elite, which in tendency demands higher-level healthcare services, including self-financed health services.

The urbanization trend was steady in recent years, but also limited due to the "hukou" system in China. Traditionally, China has a hukou-system, which is fixing the residence of its people either to urban or rural residency status. One of the aims of the system is to limit the growth of the cities to somehow manageable levels for the government. In regards to access to the healthcare system, the hukou status defines, where a resident gets access to social services, e.g. in which urban area or in which rural area.

2.1.4 Technological System

Technologically China advanced significantly since the opening up reforms. One core focus of the Chinese government is promoting Research and Development in China. It is constantly increasing government funds as well as is creating a favorable policy environment for R&D in companies, including health sciences and MedTech. The aim of the government is to advance the manufacturing capability of its economy and to

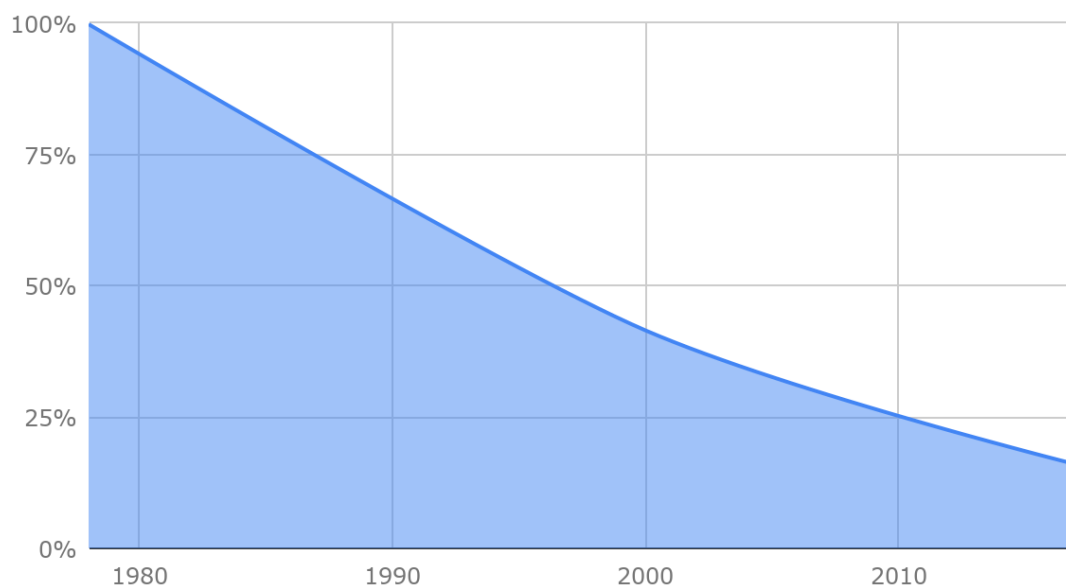
move it higher levels on the value-added chain, which allows for higher income creation via exports and less reliance on expensive high-end imports.

2.2. History of Chinese Healthcare System (short overview)

Since the P.R. China was founded in 1949 the overall life expectancy could be raised from just 36 years⁶ to 77.2 years for females and 74.2 years for males.⁷

Before 1978 -the year when the opening-up reforms started- the main provider of healthcare coverage and services were the working units, i.e. state-owned enterprises (SOEs). The working units often had their own hospitals, which provided the relevant In- and Out-patient services for its workers and employees.

Rate of Employment in SOEs and Collective owned units



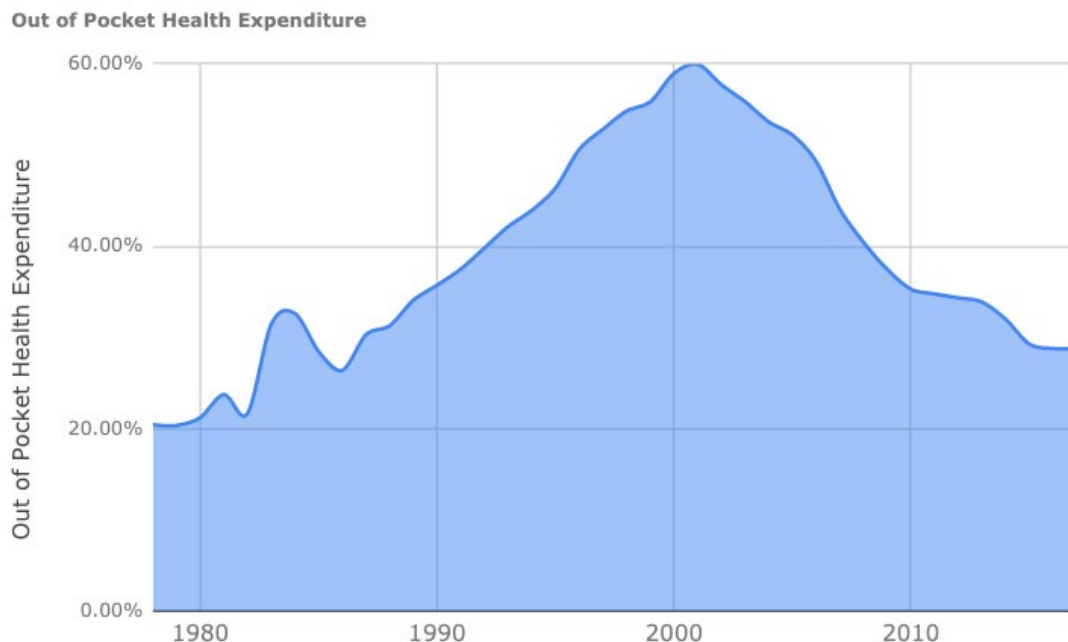
In 1978, 98% of all employees were employed by such SOEs or collective owned units. In the 1980s and 90s, the SOEs were reformed, and the overall rate of

⁶ Kantha S., Nutrition and health in China, 1949 to 1989, Prog Food Nutr Sci. 1990;14(2-3):93-137.

⁷ United Nations Data, <http://data.un.org/en/iso/cn.html>

employment decreased from slowly from over 98% then to 16% in 2017. The main provider of employment has become the private sector.

Since one of the main providers of health services and coverage were the working units, the transition of the working-unit-hospitals was a challenge for the public health system. The working unit hospitals which were basically “non-profit” before 1978, often had to become “for-profit” in cases, where the SOE was closed and therefore the funding source of the hospital (the working unit) disappeared. Since the demand for health services existed by patients independent of funding, the provision of services against out-of-pocket-payments became the main source of income for the previous working unit hospitals. In the following years, the out-of-pocket health expenditures increased steadily and they peaked in 2001 with 60%.⁸

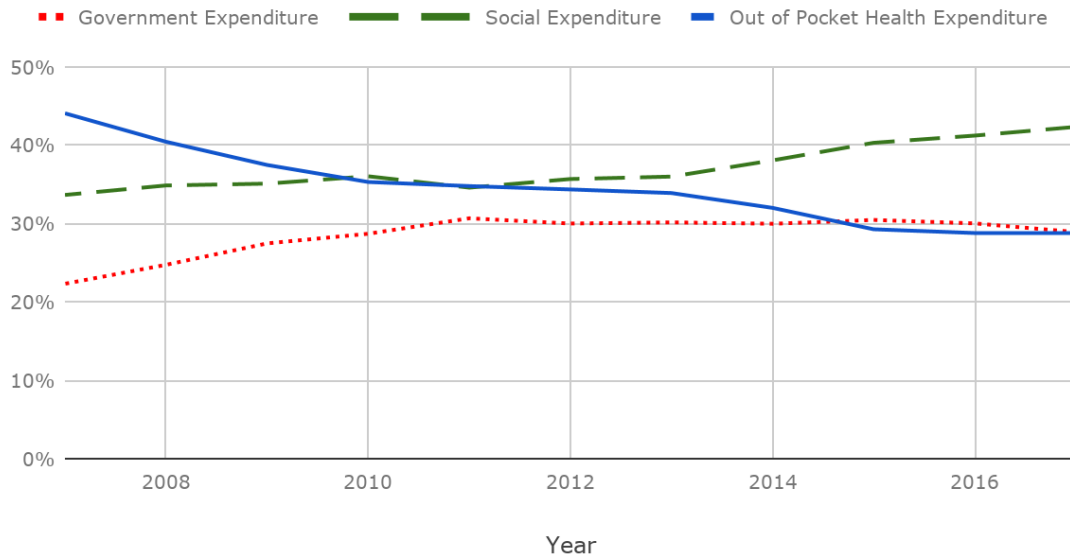


Since then, various health reforms have led to a lower rate of out-of-pocket expenditures for the patients. Further to this, a social insurance system was built up and the government expenditures were raised significantly. In 2017 the Government expenditures were 29%, the social expenditures were 42% and the out-of-pocket expenditures were lowered to 29% according to China’s Statistical Yearbook:

⁸ [China Statistical Yearbook 2018](#)



Government Expenditure, Social Expenditure and Out of Pocket Health Expenditure as Percentage of Total Health Expenditure in China



In order to increase investments in the healthcare sector, the hospital sector was opened for private investments since the health reforms in 2009. The rate of private hospitals raised to 49% in 2014. In parallel, the financial support for the hospital sector was raised from 61.8 billion Euro in 2009 to 135.6 billion Euro in 2014.⁹

2.3. Healthcare related government Initiatives

In 2018, major healthcare related priorities of the chinese government were as follows:¹⁰

- Enhancing capability and capacity in eHealth, Big Data and Artificial Intelligence
- Improvement of the prevention and treatment of major diseases, such as cancer, e.g. by expanding research facilities
- Deepening of the hospital and healthcare insurance reforms
- The attraction of foreign investment
- Increasing the subsidy levels for basic health insurance
- Continued support for Traditional Chinese Medicine (TCM)
- Increasing the regulatory efficiency

⁹ Li, S., The impacts of marketization and subsidies on the treatment quality performance of the Chinese hospitals sector, *China Economic Review*, <https://doi.org/10.1016/j.chieco.2018.10.007>

¹⁰ Government work report: 2018 Medical Reform Key Tasks determined, 政府工作报告：2018医药改革重点任务确定

In addition to the “China’s 13th Five Year Plan (2016-20)”, major overarching government policy goals were laid out in the following two government initiatives:

- Healthy China 2030 and
- Made in China 2025

The “Healthy China 2030” Program aims at enhancing the ability of local manufacturers to develop and manufacture high-end medical devices amongst others. It encourages local enterprises into further investments in the medical devices sector and provides more government support incentives in that area in order to be able to substitute more and more imported high-end devices with local manufactured medical devices.¹¹

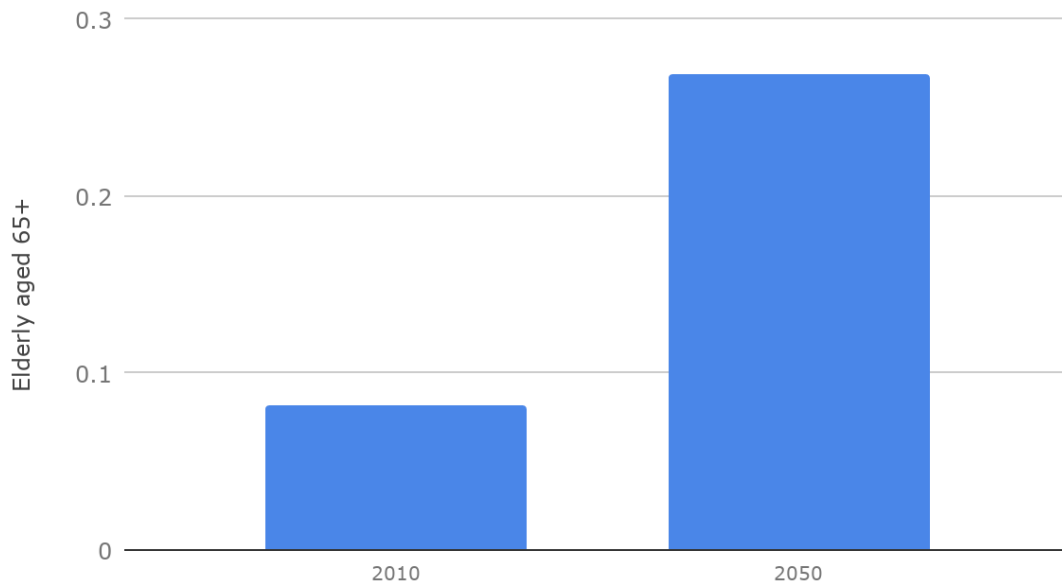
One of the major goals of the “Made in China 2025” initiative of the Chinese government is to increase the percentage of domestically procured medical devices in (public) hospitals to 50% in 2020 and to 70% in 2025,¹² equally by improving the research and development eco-system for domestic companies. Focus areas of the initiative that were mentioned explicitly as examples were medical robot systems and stents.

¹¹ “Promoting the development of domestically-made innovative medical devices” “促进国产创新医疗器械发展”系列报道之三 医疗器械国产替代风头正劲, <http://www.camdi.org/news/7686>

¹² <http://www.camdi.org/news/7231>

2.4. Demographics and general burden of disease in China

% of Elderly population aged 65+ in China



China has an aging population. In 2010, the rate of elderly over 65 years was 8.2% of the total population. According to predictions, this rate will increase to 26.9% by 2050, and in total, over 150 million people will be aged over 80 years.

The ratio of people in the working age, between 15 and 64 years, compared to those aged over 65 years, is expected to decrease from a ratio of 9 people in 2010 to just 3 in 2050.¹³

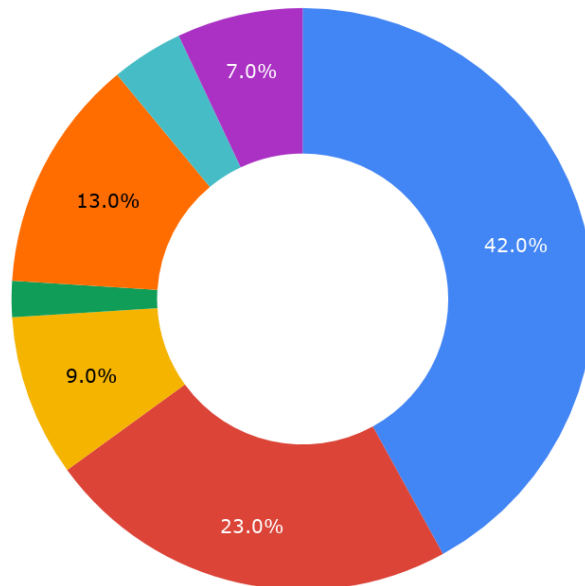
An aging society leads to several of challenges for China, since with aging society the overall burden of diseases increases with age, and with comes rising overall healthcare costs, as well as the need of adjusting the pensions system.

¹³ Evandro Fei Fanga et.al., A research agenda for aging in China in the 21st century, Ageing Research Reviews 24 (2015) 197–205



Proportional Mortality in China

- Cardiovascular diseases
- Cancers
- Chronic respiratory diseases
- Diabetes
- Other in Non communicable diseases
- Communicable, maternal, perinatal and nutritional conditions
- Injuries



In China in 2016, 89% of the deaths were related to non-communicable diseases.

The main reasons for the growing prevalence of non-communicable diseases in China were:

- The demographic shift to an aging society
- Changes in the general environment (e.g. air and water pollution)
- Overall lifestyle changes and alterations in regards to the dietary intake:
 - Lower levels of activity
 - Unbalanced diets with high sugar and salt intake
 - Smoking and alcohol consumption habits in parts of the population (mainly males)

Since 2010s cancer became the leading cause of death and disability in China.¹⁴

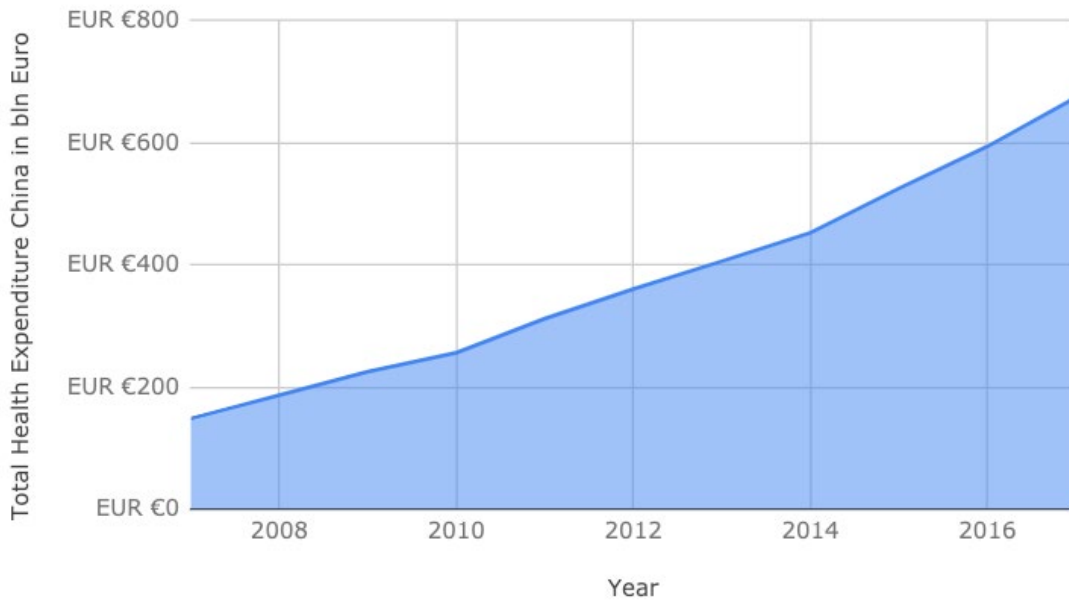
51% of the male population over 15 years of age were smokers in 2016. 21% of the total population over 18 years of age has a raised blood pressure, a raised blood glucose level occurred in 9% of the total population in 2014. 12% of the adolescents in the age between 10 and 19 were obese.¹⁵

¹⁴ Lancet T. China through the lens of health in 2018 and beyond Editorial. The Lancet. 2018;391(10125):999. doi:10.1016/S0140-6736(18)30563-4.

¹⁵ WHO, NCD Country Profile China, 2018



Total Health Expenditure China in bln Euro



The total health expenditures in China increased constantly from 148 billion Euros in 2007 to 674 billion Euro in 2017. The aging population and the rising level of income are the main reasons for a continued trend of rising healthcare costs in the coming years.

2.5. Health Care Providers

The following table provides an overview of the main healthcare providers in China:

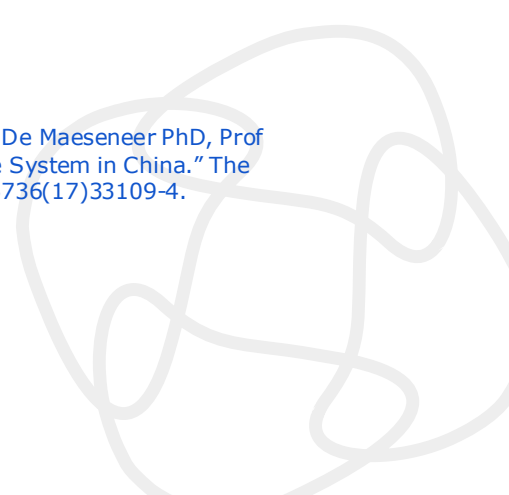
Healthcare Providers in China	Explanation / Comments
Physical Examination Centers	Physical Examination Centers provide general, mainly annual physical check-ups and can be found mainly in urban centers, they are often private-run, often large chains
Public Primary Healthcare Centers	There is a vast network of primary health-care centers, in urban and rural areas, which provide generalist clinical care and basic public health services, government tries to strengthen the gatekeeper "family doctor" function of primary

	healthcare centers
Hospitals Out-Patient	In the P.R. China there are virtually no small scale private specialist doctor clinics, e.g. a cardiologist who runs his or her own small-scale clinic in a small town, the P.R. China has -like many socialist countries - a poli-clinic system: the hospitals - whether public or nowadays also private - are the main provider of out-patient services
Hospitals In-Patient	In-patient services, e.g. cardiac surgeries, are provided by public and private Hospitals. Besides "western medicine", many hospitals, including university clinics, also provide Traditional Chinese Medicine (TCM) health services and procedures
Dental Clinics	The exception to the general rule that there are virtually no small-scale specialist medical practices in China, is dentistry clinics, many towns host several private-run specialist clinics, further to this large national high-end dentistry clinics, including foreign investments have evolved in recent years
Rehabilitation and Elderly Centers	The rehabilitation and elderly care sector is in a period of fluent development, several government initiatives aim to strengthen the rehabilitation and elderly care sector, in order to prepare for the coming wave of an overall aging population, private investments in this sector was encouraged in recent years

2.5.1 China's Primary Healthcare System

In 2016 China's Primary Health Care Centers and organizations provided 55% of all out-patient services and conducted 18% off inpatient services. In total numbers, they received 4.4 billion outpatient visits by patients and there for 41.7 million discharges after In-patient services.¹⁶

¹⁶ PhD, Xi Li, Jiapeng Lu PhD, Shuang Hu PhD, Prof KK Cheng PhD, Prof Jan De Maeseneer PhD, Prof Qingyue Meng PhD, Prof Elias Mossialos PhD, et al. "The Primary Health-Care System in China." *The Lancet* 390, no. 10112 (December 9, 2017): 2584–94. doi:10.1016/S0140-6736(17)33109-4.



Historically, the Primary Health Care Centers were a success in providing basic health care services to the people, especially in the countryside.

Nowadays, the primary health-care system is facing several structural challenges and the government is addressing these issues via a wave of reforms that aim to strengthen and vitalize this sector. The measurements include better funding as well as procuring more and better equipment.

However, participating in the expected growth of this sector is a challenge, mainly due to the severe budget constraints and the focus on highly cost-efficient solutions.

2.5.2 China's Secondary and Tertiary Healthcare System

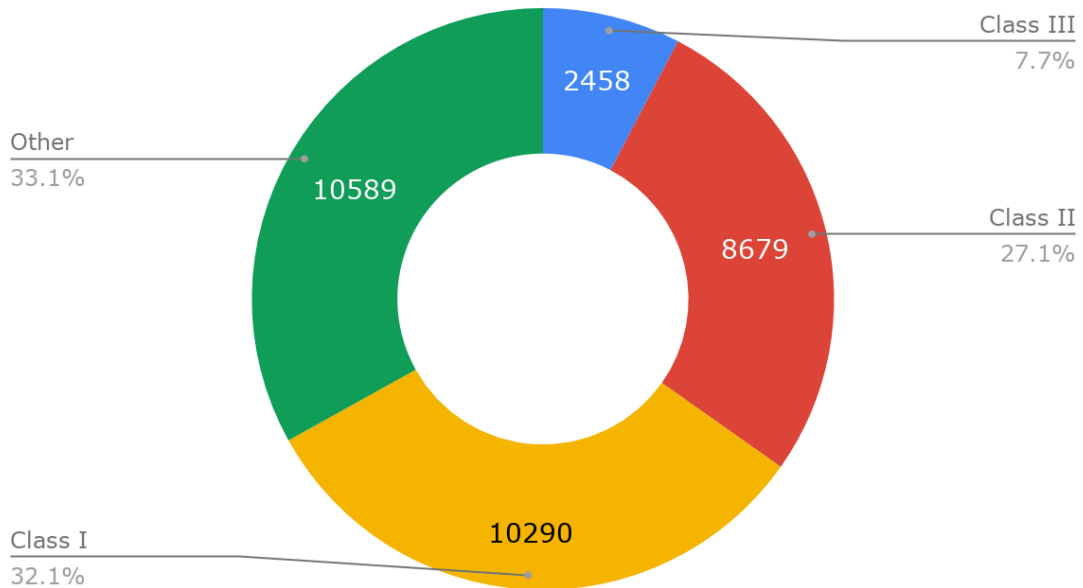
In 2018 there were a total of 32,016 hospitals in China, which provided both In-patient and Out-patient services. In 2017 the hospitals had over 175 million In-patient visits with an average duration of stay of 8.8 days. All healthcare institutions in China combined (including primary health centers) took care of 8 billion Out-patient visits.

Hospital in China are divided into three levels:

- Class I hospitals provide mainly basic Medical Health Care Services as well as Prevention Services
- Class II hospitals provide comprehensive medical and healthcare services, they also cover minor education and research tasks within the healthcare system.
- Class III provide specialist medical and healthcare services, in general, they have several specialty departments. Class III hospitals are also mainly in charge for the education health professionals, comparable to European University Clinics. Class III hospitals with more than 1000 beds are not uncommon in China's major cities.



Number of Hospitals in China



There were 2458 Class III hospitals in China¹⁷ which, in general, in the hospital sector are the main recipient of imported high-end medical device equipment.

The list below contains an overview of the distribution of hospitals in China in the different regions, including population sizes and the local GDP per capita:

Region	Population in million	Number of hospitals	GDP per capita in Euro
Beijing	21.7	649	€ 16,544
Tianjin	15.6	422	€ 15,274
Hebei	75.2	1890	€ 5,799
Shanxi	37.0	1378	€ 5,378
Inner Mongolia	25.3	801	€ 8,160
Liaoning	43.7	1340	€ 6,869
Jilin	27.2	705	€ 7,052

¹⁷Source: <http://www.nhc.gov.cn/mohwsbwstjxxzx/s7967/201811/e1c2f8699eb848f6b9908c4bfcab6be5.shtml>

Heilongjiang	37.9	1099	€ 5,381
Shanghai	24.2	360	€ 16,242
Jiangsu	80.3	1797	€ 13,711
Zhejiang	56.6	1254	€ 11,732
Anhui	62.6	1129	€ 5,538
Fujian	39.1	620	€ 10,549
Jiangxi	46.2	694	€ 5,549
Shandong	100.1	2540	€ 9,306
Henan	95.6	1779	€ 5,975
Hubei	59.0	990	€ 7,707
Hunan	68.6	1339	€ 6,336
Guangdong	111.7	1506	€ 10,297
Guangxi	48.9	613	€ 4,861
Hainan	9.3	221	€ 6,178
Chongqing	30.8	784	€ 8,099
Sichuan	83.0	2332	€ 5,711
Guizhou	35.8	1298	€ 4,849
Yunnan	48.0	1254	€ 4,373
Tibet	3.4	154	€ 4,987
Shaanxi	38.4	1160	€ 7,321
Gansu	26.3	575	€ 3,642
Qinghai	6.0	213	€ 5,627
Ningxia	6.8	215	€ 6,473
Xinjiang	24.5	905	€ 5,706

Due to the different levels of healthcare services provided and the more expensive equipment in Class III hospitals, the In- and Out-Patient Costs differ significantly.¹⁸

Average Out-Patient Treatment Cost in Class III Hospital in China	€ 40.69
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¹⁸ Source: www.nhc.gov.cn/mohwsbwstjxxzx/s7967/201811/

Average Out-Patient Treatment Cost in Class II Hospital in China	€ 25.94
Average In-Patient Treatment Cost in Class III Hospital in China	€ 1,697.82
Average In-Patient Treatment Cost in Class II Hospital in China	€ 767.78

Class III hospitals often include VIP sections, that provide high-end medical services for private patients, who pay their own medical bills independently from the public health insurance system.

2.5.3 Dental Care System

The dental care system is independent from the regular hospital system. Though there are major public stomatology hospitals, which have a status as University-Clinic and which are teaching clinics for future stomatologists/dentists, the majority of the dental clinics are private-run dentistry clinics - in-part independent clinics, in-part large clinic chains.

The number of licensed dental clinics is over 40.000 in China. On the hand side a comparably large number in absolute terms, but still comparably low, when compared on a per capita basis with other OECD countries.

A significant part of the dental treatment costs are not covered by the public health insurance and the patients have to pay major parts of the treatment costs by themselves. Further, the clinics are in essence "for-profit" and have to cover the main costs via private-patient fees income. Therefore, many of the clinics are permanently on the lookout to professional dentistry add-on services and products that they can provide their patients. Also, the procurement process of private clinics is not tender-based, unlike in public hospitals.

For the coming years, a significant increase of the market for Dental Care is expected for China.¹⁹

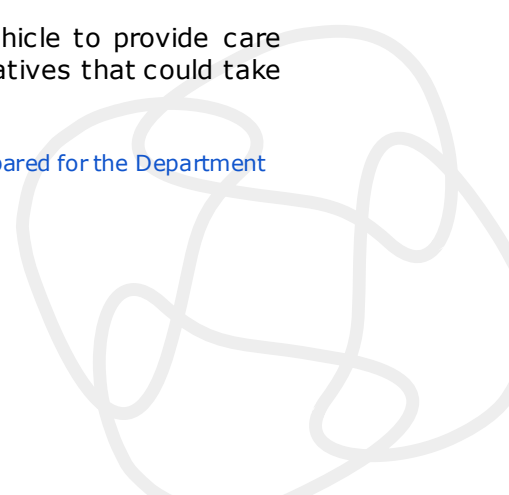
2.5.4 Elderly Care System and Rehabilitation

The three main kinds of elderly-care services facilities in China are:

- Public social welfare facilities
- Nursing homes
- Residential Care Facilities

Traditionally, public social welfare facilities were the main vehicle to provide care services for elderly welfare recipients, e.g. persons without relatives that could take

¹⁹ KPMG, Commercial Opportunities in the dental care market in China, prepared for the Department for International Trade, UK, 2016



care of them. These facilities were mainly government-run and rely on public subsidies.

There are both public- and private-run nursing homes in China. In general, these facilities include health professional as staff members, and provide up to rehabilitation services.

In China, Residential Care Facilities have seen a large growth in the last years, mainly driven by private investments and encouraged by supportive government policies in combination with a wide array of government incentives.²⁰

In general, Rehabilitation Services are one of the healthcare sectors, that are still underserved in China. Around 85 million people are permanently or temporarily disabled in China, e.g. after a stroke, and 90% of them have rehabilitative needs, but just 10 million people could receive rehabilitative care according to a recent study. Consequently, the area of rehabilitative services is a healthcare segment that is predicted to grow significantly in the upcoming years.²¹

2.5.5 Medical Workforce and Medical Workforce Education System

Since a medical reform in 2013 and in order to ensure a country-wide minimum base level of medical education for licenced doctors, the minimum education comprises of 5 years of undergraduate medical study and three years of residency. Further to this a lifelong learning is encouraged and for several medical specialties regular tests are required in order to maintain one's medical licence.

In 2014, there were 2.4 million licensed doctors and 0.5 million licensed assistant doctors in China.²² The number of newly-licensed doctors increased from 160.000 doctors in 2005 to 220.000 doctors in 2015 annually.²³

2.5.6 Privatization Trend in the Chinese Healthcare System

Since the latest wave of major Healthcare reforms in China, which started in 2009, the number of private hospitals in the healthcare system increased significantly. The majority of the hospitals in China, 62.1%, are now private hospitals.

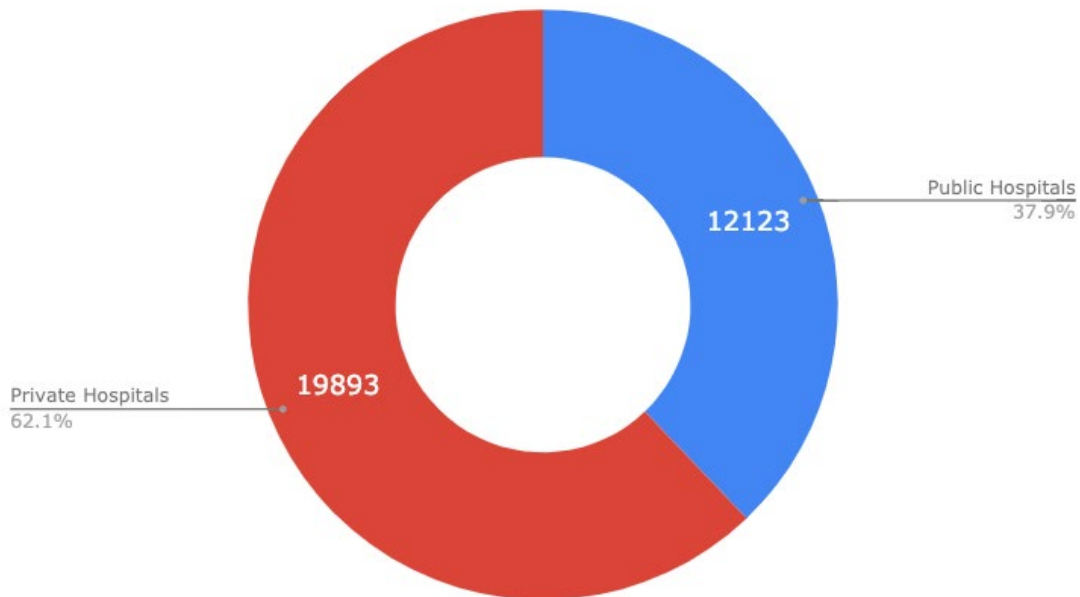
²⁰ Glinskaya, E., Feng, Z., Options for Aged Care in China, Building and Efficient and Sustainable Aged Care System, World Bank Group, 2018.

²¹ Yue Xiao et.al., Integrated medical rehabilitation delivery in China, Chronic Diseases and Translational Medicine 3 (2017) 75-81.

²² Zhu, Jiming, Wenkai Li MD, and Lincoln Chen MD. "Doctors in China: Improving Quality Through Modernisation of Residency Education." *The Lancet* 388, no. 10054 (October 15, 2016): 1922–29. doi:10.1016/S0140-6736(16)00582-1.

²³ Tang, Chengxiang, and Daisheng Tang PhD. "The Trend and Features of the Doctor Workforce Supply in China After the National Medical Licensing System Reform From 2005–15: a Longitudinal Analysis." *The Lancet* 390, no. 4 (December 6, 2017): S46. doi:10.1016/S0140-6736(17)33184-7.

Number of public and private hospitals in China



Private hospitals- unlike public hospitals - can make independent procurement decisions based on criteria like service, effectiveness, price, safety etc. In general, these criteria are major decision criteria for public hospitals, too, but public hospitals have to tender, and the tendering system for public hospitals is influenced by government policies and regulations, namely the Healthy China 2030 and Made in China 2025 policies.

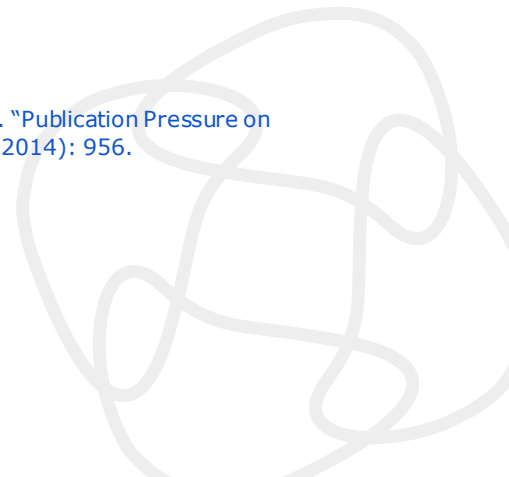
Generally, large class III hospitals still remain the main market for high-end imported medical devices, e.g. in MRI imaging, due to their comparably high volume of patients.

2.5.7 Research and clinical trials in Class III hospitals

International research and cooperation in high-level medicine is highly encouraged by the Chinese government. There is a significant pressure to publish (international) medical research in China for doctors, if they want to advance within the public university hospital system²⁴.

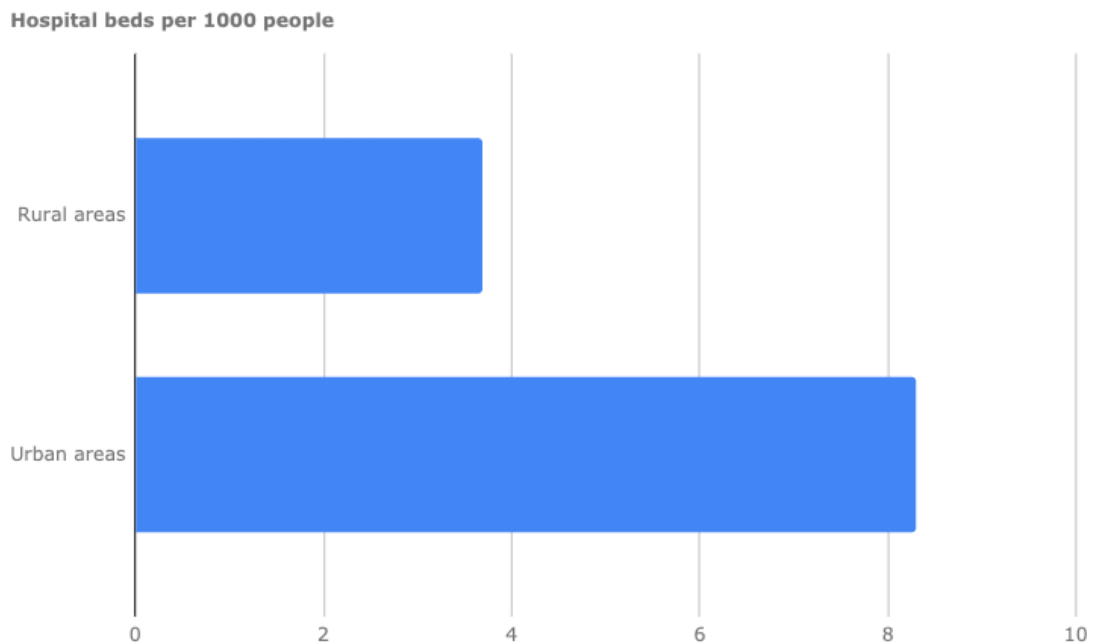
For European Medical Device companies that are research-orientated, this brings potential opportunities to collaborate with Chinese hospitals and to develop technology, which is needed by the local healthcare market.

²⁴ Chen, Shanquan, Yao Pan, Qiang Yao, Lan Yao, Zhiyong Liu, and Li Xiang. "Publication Pressure on Chinese Doctors— Another View." *The Lancet* 384, no. 9947 (September 13, 2014): 956. doi:10.1016/S0140-6736(14)61630-5.



2.5.8 Urban-rural healthcare system divide

In general, 75% of healthcare spending occurs in urban areas, e.g. there are 8.3 hospital beds per 1000 people in urban areas versus 3.7 in rural areas.



It is one of the government policy goals to narrow this gap between the urban and the rural healthcare sector in China.

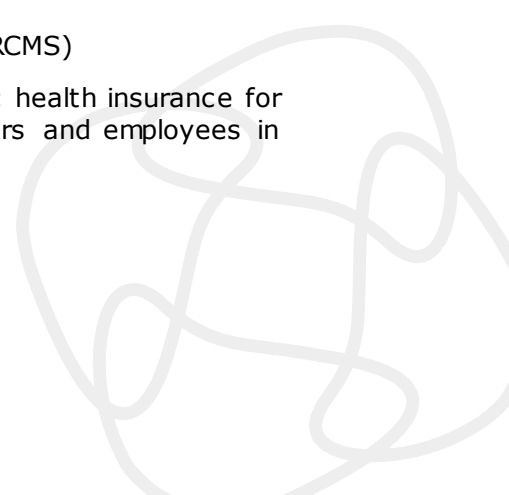
2.6. Healthcare System Financing

2.6.1 (Public) Health Insurances

In 2018, nearly the whole population in China is insured by either one of the following public health insurance schemes:

- Urban employee basic medical insurance (UEBMI)
- Urban resident basic medical insurance (URBMI)
- New rural Cooperative medical insurance scheme an (NRCMS)

The urban employee basic medical insurance is the main public health insurance for employees in the urban areas. The enrollment of the employers and employees in urban areas into the UEBMI is mandatory in China.



In general, for the UEBMI the insurance contributions are divided into two accounts, an individual account (for each person) and a social account for social pooling. Around 6% the wages are collected as a payroll tax from the employer and around 2% are collected as an employee contribution.

The 2% of the employee and one part of the employer's contribution are collected in a personal account, which funds accumulate over the years. The remainder of the contributions goes into a social pooling fund.

The individual account pays for out-patient services and drug costs, whereas the social account mainly covers for In-patient costs within a range of predefined services and coverage rates. Although the In-patient costs are covered to a large extent, individual out-of-pocket contributions as a fixed percentage of the overall hospital bill are mostly necessary for each hospital stay.

As a result, individuals in China are aware of the occurred costs of each hospital visit and to a certain extent have to further provide out-of-pocket-payments during each hospital visit.^{25 26 27}

2.6.2 Hospital Financing (Revenue) System and Government Subsidies

The two main sources of revenues for hospitals in China are:

- medical service provisions, e.g. surgeries
- drug sales via hospital pharmacies

Drug sales constitute over 40% of the hospital revenue, government subsidies around 9% and the rest stems from medical service provisions.²⁸

2.7. Special Insight: Trends and burden of disease in regards to

2.7.1 Cardiovascular diseases

In China there are 290 million people with cardiovascular diseases in China and around 3.7 million people die of cardiovascular disease each year.

²⁵ Dong K. Medical insurance system evolution in China. *China Economic Review*. 2009;20(4):591-597. doi:10.1016/j.chieco.2009.05.011.

²⁶ Yu H. Universal health insurance coverage for 1.3 billion people: What accounts for China's success? *Health Policy*. 2015;119(9):1145-1152. doi:10.1016/j.healthpol.2015.07.008.

²⁷ Hu J, Mossialos E. Pharmaceutical pricing and reimbursement in China: When the whole is less than the sum of its parts. *Health Policy*. 2016;120(5):519-534. doi:10.1016/j.healthpol.2016.03.014.

²⁸ Hu J, Mossialos E. Pharmaceutical pricing and reimbursement in China: When the whole is less than the sum of its parts. *Health Policy*. 2016;120(5):519-534. doi:10.1016/j.healthpol.2016.03.014.

The demand for cardiovascular devices and interventions is likely to rise steadily in China, due to the overall aging society in combination with rising income levels.

The market for high-level medical devices in the cardiovascular area, such as stents and pacemakers, is still dominated by large multinational companies from outside China, who can provide reliable, safe high-quality products and have invested heavily in the market build-up in previous years. These multinationals account up to 80% of the market share for stents and pacemakers. However, several local companies from within China are catching up.²⁹

In general, the annual demand for stents in China is above 450.000 per year and the growth rate is around 40% annually. The import value for cardiac pacemakers was 109.74 million USD in 2017, but the import market decreased steadily from 2014 to 2017, mainly due to a larger amount competition from domestic competition, and against an overall increasing total market size for pacemakers in China.³⁰

2.7.2 Oncology diseases

In 2015 occurred 4.3 million new cancer cases and 2.8 million cancer deaths in China. The cancers with the highest mortality in China are lung cancer, gastric cancer, liver cancer, esophageal cancer and colorectal cancer.³¹

Currently, there is an overall gap between excellent treatment methods that are available outside of China, e.g. in Europe, and those that are available within China. The average mortality rate due to malignant tumors is predicted to remain higher in China when compared to certain OECD countries.

Market research is advisable for medical device manufacturers, in order to identify areas, in which imported medical devices provide a significant benefit compared to local competitors.³²

2.7.3 Orthopedics diseases

The market for orthopedic devices is one of the major sub-sectors within the medical device market in China and accounts for around 6% of the total market for medical devices. As one example: The demand for artificial joints has risen significantly in recent years and the market size is increasing in double-digits year on year.

Innovative areas of interest in the orthopedic area are 3D printing solutions combined with biomaterials as a potential market for future growth.³³

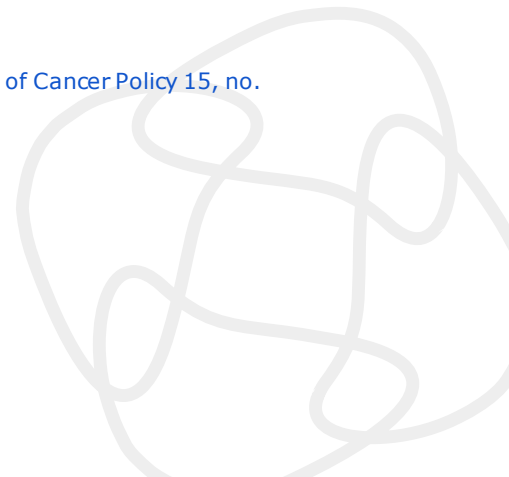
²⁹ <http://m.camdi.org/news/mvx5da.html>

³⁰ <http://www.camdi.org/news/6956>

³¹ Xu, Tingting, and Jing Wu. "Financial Toxicity of Cancer in China." *Journal of Cancer Policy* 15, no. Part B (May 1, 2018): 96–99. doi:10.1016/j.jcpo.2018.02.007.

³² <http://m.camdi.org/news/mvx5da.html>

³³ <http://m.camdi.org/news/mvx5da.html>



Due to the aging society, the overall demand for orthopedic solutions is predicted to increase.

2.7.4 Dentistry diseases

Caries and related diseases are a significant burden of health in China. As example, during a survey in Sichuan province the prevalence of deciduous caries was 55.9% for children under 5 years in 2015. This rate increased by 16.2% compared with the level in 1990. The rate of caries was 24.3% among 5 to 14 year old children in Sichuan.³⁴

During another study, which was conducted in Shanghai between adults aged in between 35 and 44 years of age, the prevalence of (previous) caries experience was 91.4% and the prevalence of decayed or filled root indices was 30.3%.³⁵

Though the prevalence rates are relatively high, the overall treatment rates are still comparably low, when compared to OECD countries, indicating an overall long-term increase in demand for services, solutions and devices in China.³⁶

³⁴ Prevalence and Years of Life Lost due to Disability from Dental Caries among Children and Adolescents in Western China, 1990-2015, *Biomed Environ Sci*, 2017; 30(10): 701-707

³⁵ Dental caries status and risk indicators of dental caries among middle-aged adults in Shanghai, China. Wei Xu a, Hai-Xia Lu b, Cun-Rong Li a*, Xiao-Li Zeng a
Journal of Dental Sciences (2014) 9, 151e157

³⁶ KPMG, Commercial Opportunities in the dental care market in China, prepared for the Department for International Trade, UK, 2016

3. Regulatory Affairs

3.1. NMPA (CFDA) registration process

Before Medical devices can be sold in China, they have to be registered. What constitutes a medical device in China and therefore which product has to be registered, is defined in the “State Council Order No. 680” in Chapter VIII, article 76”:

“Medical devices are instruments, equipment, in vitro diagnostic reagents [...] and other similar or related products, that are used directly or indirectly in and on the human body -including the required computer software-; whose utility is mainly obtained via physical means and not obtained by pharmacological, immunological or metabolic processes[...], and which purpose is the:

- (1) Diagnosis, prevention, monitoring, treatment or relief of diseases;
- (2) Diagnosis, monitoring, treatment, mitigation or functional compensation of injuries;
- (3) Testing, substitution, adjustment or support of physiological structures or physiological processes;
- (4) Support or maintenance of life;
- (5) Pregnancy control;
- (6) Providing information for medical or diagnostic purposes, by examining samples from the human body.

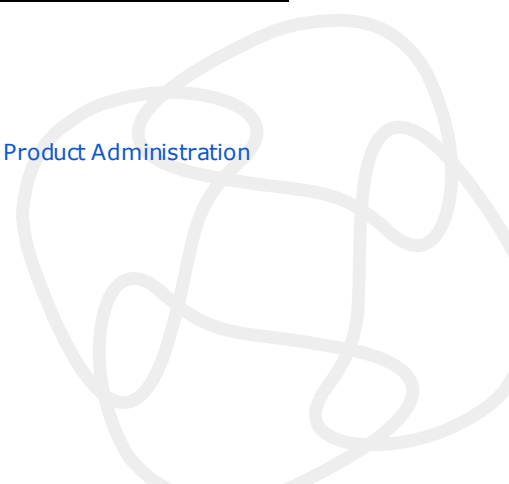
[...]”

In China, the [China] National Medical Products Administration (NMPA) is in charge of medical devices registrations. The NMPA is a newly established authority. Up until 2018, the China Food and Drug Administration (CFDA) was in charge for the medical device registration process in China.

The NMPA has the following major departments that are relevant in regards to medical devices:³⁷

Policy, Law, and Regulations	Medical Device Registration:	Medical Device Supervision and Administration
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³⁷ The US-China Business Council information sheet “China National Medical Product Administration (NMPA), 2018.



<p>Publishes relevant laws (e.g. Orders from the State Council, China’s highest legislative body), administrative rules (e.g. further specifications how to implement the State Council Orders) as well as technical norms and standards (e.g. the Chinese correlate to IEC standards)</p>	<p>Drafts standards for medical device registration and manages the medical device registrations</p>	<p>Administers the implementation of the quality management standards as well as further rules and regulations, carries out inspections, investigates and punishes violations</p>
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The two main regulations (laws) governing the Medical Device Registration and Management process within China are:

- “State Council Order No. 650” on Medical Device Supervision and Administration Regulations³⁸
- “State Council Order No. 680” on amending Medical Device Supervision and Administration Regulations³⁹

In addition, there is a wide range of further regulations detailed aspects of the NMPA registration process.

The regulations are mainly in Chinese, which can make a quick check difficult, but the regulations are specific and should be consulted during the registration process. The main chapters of “State Council Order No. 680” are for example:

Chapter I General Provisions

Chapter II Registration and Filing of Medical Device Products

Chapter III Medical Device Production

Chapter IV Medical Device Management and Use

Chapter V Treatment of Adverse Events and Recall of Medical Devices

Chapter VI Supervision and Inspection

Chapter VII Legal Penalties

Chapter VIII Supplementary Provisions

³⁸ http://www.gov.cn/zhengce/2014-03/31/content_2651127.htm

³⁹ http://www.gov.cn/zhengce/content/2017-05/19/content_5195283.htm



In 2017, the NMPA(CFDA) accepted a total of 6,834 applications for

- medical devices registrations
- renewal registrations (after 5 years of the initial registration)
- and medical devices licensing changes (e.g. after a medical device upgrades)

Compared with 2016, the number decreased by 23.4%.

In regards to imported medical devices in the class II category, 2057 applications were accepted, a decrease of 33.5% compared with 2016. Among these were 1283 applications for medical devices registrations and 774 applications for in vitro diagnostic reagents. 16.1% of the applications were first time applications, 47.9% re-registrations and 36.0% in regards to medical device registration changes.

In regards to imported medical devices in the class III category, 2320 applications were accepted, a decrease of 17.7% compared with 2016. Among these were 1853 applications for medical devices registrations and 467 applications for in vitro diagnostic reagents. 13.0% of the applications were first time applications, 50.4% renewal-registrations and 36.6% in regards to medical device registration changes.

In total, the NMPA (CFDA) approved 5632 medical device registrations in 2017 for imported products, a decrease of 2.3% when compared with 2016.

73.9% of the medical device registrations for imported products were from the following 5 countries:⁴⁰

- United States
- Germany
- Japan
- United Kingdom
- South Korea

3.1.1 NMPA (CFDA) classification system

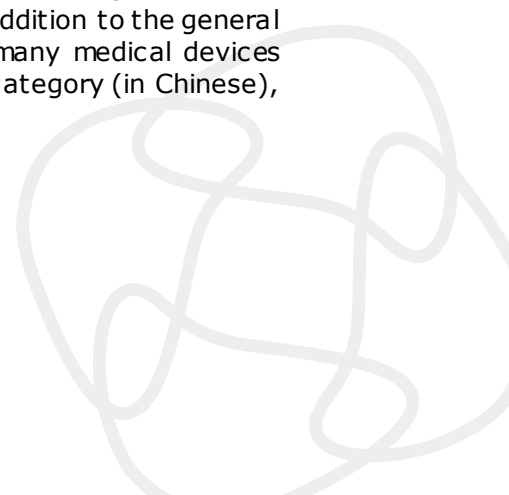
Medical Devices are divided into three categories in China, depending on the risk they pose to the patient:⁴¹

Class I	Class II	Class III
medical device poses a low level of risk	medical devices pose moderate risks	medical devices pose high risks

As a further clarification, the NMPA has developed a detailed catalog of medical devices since the first publication of the State Council Order, in addition to the general definition of the general risk categories. In the detailed catalog, many medical devices are named and classified explicitly into their corresponding risk category (in Chinese),

⁴⁰ <http://www.nmpa.gov.cn/WS04/CL2197/324951.html>

⁴¹ Article 4, "State Council Order No. 680"



which helps in finding the correct risk category. The risk class and sub-category then defines the correct medical device registration procedure, amongst others.

The “Medical Device Classification Catalogue” consists of 206 primary product categories and contains a listing of 6609 typical product names for medical devices.⁴²

3.1.2 CFDA registration procedure

The medical device registration for Class I medical devices is -simply speaking - mainly paper-based and straight-forward and can be achieved within a few months and with comparably limited financial effort.

The medical device registration for Class II and III medical devices is time and resource consuming and mostly requires sincere professional preparations. For the medical device registration of Class II and III medical devices the following documents have to be prepared (in Chinese) and to be submitted to the NMPA:

1. Medical Device risk analysis report;
2. Medical Device technical requirements and applied standards (e.g. during CE application);
3. Medical Device Test reports (e.g. IEC reports);
4. Clinical evaluation data / Clinical Trial reports;
5. Medical Device user manuals, detailed specifications and Medical Device product samples (for additional technical testings in China);
6. Quality management system documentation, in relation to the product development and production;
7. Further material and documents, in order to prove that the product is safe and effective

In regards to No. “4. Clinical evaluation data / Clinical Trials”:

In general, all Class III medical devices need to provide Clinical Trial data for the medical device registration⁴³ in China. There exist detailed provisions, which specify, which kind of clinical trial data is accepted from outside China. In practice however, the acceptance of clinical trial data from overseas is often limited due to a variety of reasons. One reason is often the required minimum number of included patients, e.g. a requirement of 100 or more patients that have to be included in Clinical Trials according to the Chinese regulations are not seldom. This can be a major hurdle for European SMEs, because in Europe Clinical Trial Data of such a high amount of patients is not so often (for medical device registration). Further, according to the Chinese regulations the Clinical Trials have to be conducted with the medical device that seeks registration in China, not with technical similar devices, albeit from a

⁴² <http://www.camdi.org/news/7268>

⁴³ http://www.gov.cn/zhengce/content/2017-05/19/content_5195283.htm

competitor. As a result, for most class III devices and many class II devices, clinical trials have to be conducted in China. Clinical Trials in China are - as in many countries - time and resource consuming, and a duration of 1 to 2 years and (extra) costs over 300.000 Euro for a clinical trial that need to be conducted is not uncommon.

Medical Device registrations are valid for a period of 5 years in China, and then can be re-registered via the NMPA.

3.1.3 CFDA Testing Center(s)

The medical devices have to comply with local norms and standards. During the NMPA registration process, the medical devices will be tested according to their conformance with these norms, e.g. in regards to:

- biocompatibility
- sterility
- electromagnetic compatibility etc.

There are several testing centers in whole China, that are accepted by the NMPA, e.g. in Beijing, Tianjin, Shanghai, Guangzhou etc. In general, the registration agent will recommend a testing center.

3.1.4 CFDA registration fees (government)

The NMPA charges government fees for the NMPA registration:⁴⁴

Class II	Initial Medical Device registration	EUR €27,038
	Amendments to the medical device registration	EUR €5,385
	Continuation of the Medical Device registration (after 5 years)	EUR €5,231
Class III	Initial Medical Device registration	EUR €39,590
	Amendments to the medical device registration	EUR €6,462
	Continuation of the Medical Device registration (after 5 years)	EUR €5,231
	Clinical Trial application fee	EUR €5,538

⁴⁴ <http://samr.cfda.gov.cn/WS01/CL0087/120201.html>



These fees do not include agent fees, which are used regularly for preparation of the NMPA process. Therefore, for Class III medical devices the overall registration costs can be estimated more than 70.000 Euros, if the medical device is on the clinical trial exempt list or clinical trials are somehow not necessary because of other exemptions. This does not include sample costs, because for technical testings samples have to be tested in the testing centers, e.g. for electromagnetic compatibility (EMC) tests in case of electrical medical devices, and in case of large-scale medical devices further costs have to be calculated into the budget, because the sample(s) might be destroyed in the course of the testing procedure. If clinical trials are necessary during the course of a NMPA registration, the total medical device registration costs can easily be more than 500.000 Euros, mainly due to the expensive clinical trials. A time frame of 3 years or more for the overall registration time until approval can be expected⁴⁵. Without Clinical Trial the time for a class III device registration can be estimated 1.5 to 2 years in regular cases. The time to obtain a class II medical device registration is similar. Class I device registrations can be obtained within one year.

The NMPA has published a Catalogue of Medical Devices Exempted from Clinical Trials, which lists a total of 855 medical devices (as of at the end of 2018), for which no clinical trial is needed for the NMPA registration.⁴⁶

3.2 Introduction into medical device standards (system)

In addition to the overarching State Council decrees (laws), a total of 1599 medical device standards were issued, including 449 mandatory standards and 1148 recommended standards, e.g. in regards to general electrical requirements to specialty requirements for medical devices like pacemakers.

In general, the proportion of mandatory standards for medical devices is declining in China, from 48% in 2010 to 28% in 2018.⁴⁷

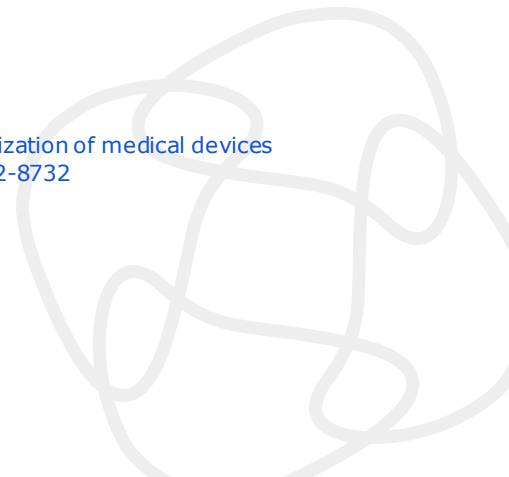
China has established an own standard system for medical devices, which is founded on international standards, but deviations occur for certain standards. National Standards are "GB standards", whereas industry standards are "YY standards", e.g. correlate to IEC standards.⁴⁸ For medical device registrations in China, it is best to put great emphasis on checking, which standards apply to the medical devices, whether they are similar to the international standards - which would make a registration easier - or in which cases specialty national standards apply, which can make a registration more cumbersome and challenging.

⁴⁵ Matthes, Urs, *The Chinese Medtech Sector*, Switzerland Global Enterprise

⁴⁶ <http://www.biodiscover.com/news/politics/731443.html>

⁴⁷ <http://www.camdi.org/news/7650>

⁴⁸ Zhang, Weifan, Lui, Rebecca and Chatwin, Chris (2016) *Marketing authorization of medical devices in China*. *Journal of Commercial Biotechnology*, 22 (1). pp. 15-22. ISSN 1462-8732



Some medical devices still need the China Compulsory Certification (CCC) mark for product safety, such as medical diagnostic X-ray equipment, electrocardiograph, pacemaker, etc.

3.3. Labeling and packaging

Medical devices that are imported to China must have Chinese instructions for use in the package. The labelling of the device must be according to the Chinese regulations, e.g. include a manufacturing date, warning and precautions in Chinese as well as manufacturers contact information etc. The packaging must also provide relevant declarations in Chinese, e.g. via an added sticker that fulfills the requirements.

3.4. Import

Each time medical devices are imported into China, the customs checks whether the NMPA registration is valid for the imported goods, e.g. the Shanghai Entry-Exit Inspection and Quarantine Bureau disclosed on the 19th that in 2017, a total of 33,704 medical devices were imported from Shanghai, amounting to US\$430.58 million, an increase of 18.84% and 22.43% respectively over the same period of last year. The unqualified detection rate increased by 10% compared with 2016.

It found that 8863 batches were unqualified, and 106 batches were returned and destroyed. The reasons for the failure include the failure of the Chinese label specification and the quality defects.⁴⁹

3.5. Further relevant regulations

3.5.1 Innovative NMPA registration process

For innovative devices the NMPA has opened a "green channel". However, the requirements are high, e.g. in 2017 completed 323 reviews for special approval for innovative medical devices and determined that 63 products are allowed to enter the special approval channel for innovative medical devices.⁵⁰

In the first half of 2018, the NMPA released another statistics, and according to that a total of 23 innovative medical devices were approved with the green channel, of

⁴⁹ <http://www.camdi.org/news/6655>

⁵⁰ <http://www.nmpa.gov.cn/WS04/CL2197/324951.html>



which 19 were domestic medical devices.⁵¹

3.5.2 Patents and IP protection

In general, there are three kinds of patents in China:

- Invention Patents
- Utility model patents
- Design Patents

The filing process can consume significant financial resources and time.

For invention patents, the time frame from application to successful receipt of the patent can be 3 to 5 years, after that the protection period is 20 years. The filing process for utility patents takes around one year and the protection period is 10 years. The filing for design patents is similar and the protection period is 10 years.⁵²

The IP protection mechanism for medical devices was improved in the last years in China, though it is still difficult to obtain its rights after patent or IP violations.

3.5.3 Fines and Punishments

Violations to laws and regulations can have severe consequences in China, e.g. in cases like selling medical devices without the proper medical device registrations, or making false or misleading statements in order to obtain a medical device registration. Articles 63 to 75 of the “State Council Order No. 680” list legal punishments for violations of the medical device laws and regulations in China. The catalog of punishments includes fines as high as 5 to 6 times of the illegal income, and prison terms in case of grave violations, not only for local agents but also including for medical device exporters.

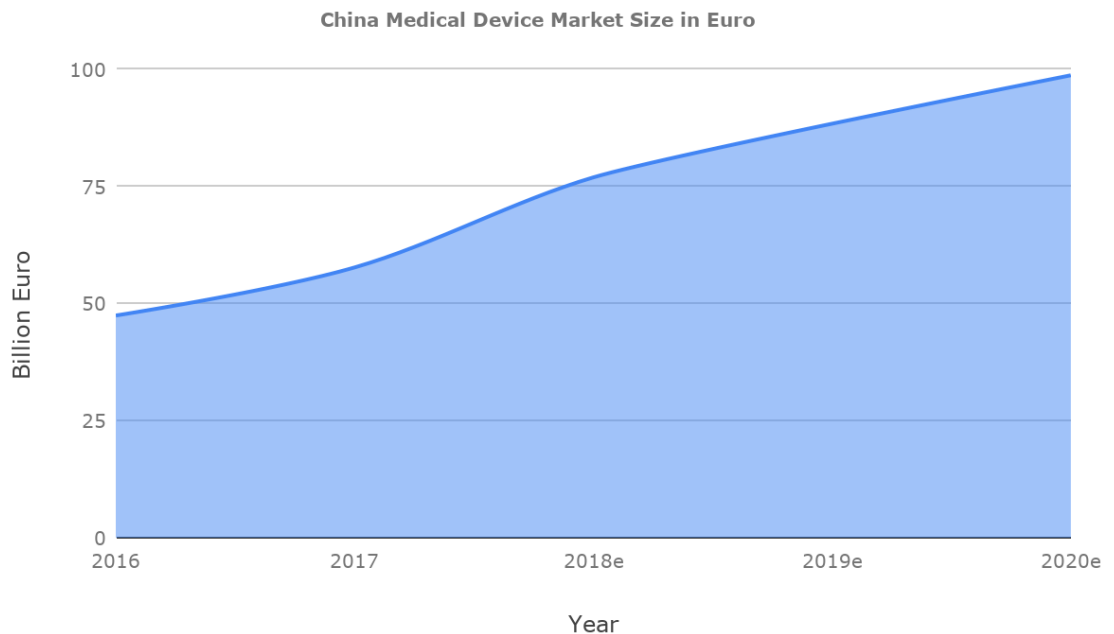
4. Market Access and Business development

4.1 The market for medical devices

⁵¹ <http://www.camdi.org/news/7671>

⁵² Jing Fang, Hui He, and Nan Li, China’s Rising IQ (Innovation Quotient) and Growth: Firm-level Evidence, IMF Working Paper





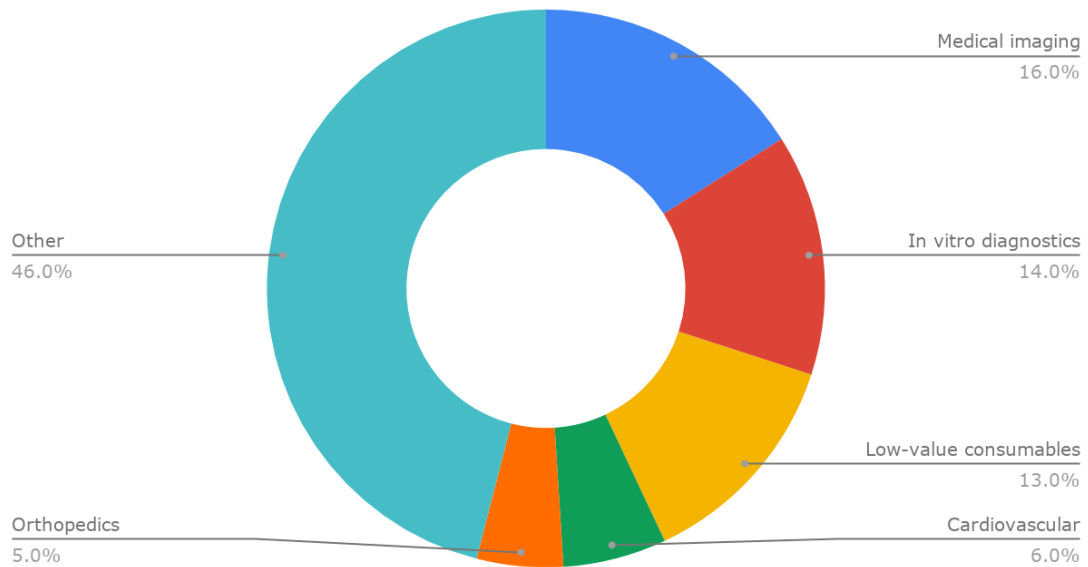
According to Chinese Statistics, the total market size for Medical Devices was 57 billion Euros in 2017, up from 46.8 billion Euros in 2016. The average growth rate was in between 20% to 25% in recent years and is expected to maintain its growth in the 20% bandwidth in the coming years, so the market is expected to reach 97.6 billion Euros in 2020.⁵³

China's top five medical device market segments are Medical Imaging, In vitro diagnostics, Low-value consumables, Cardiovascular devices and Orthopedic devices, which combined constitute around 54% of the total Medical devices market in China:

⁵³ <http://www.camdi.org/news/7671>



Medical Devices Market Structure China

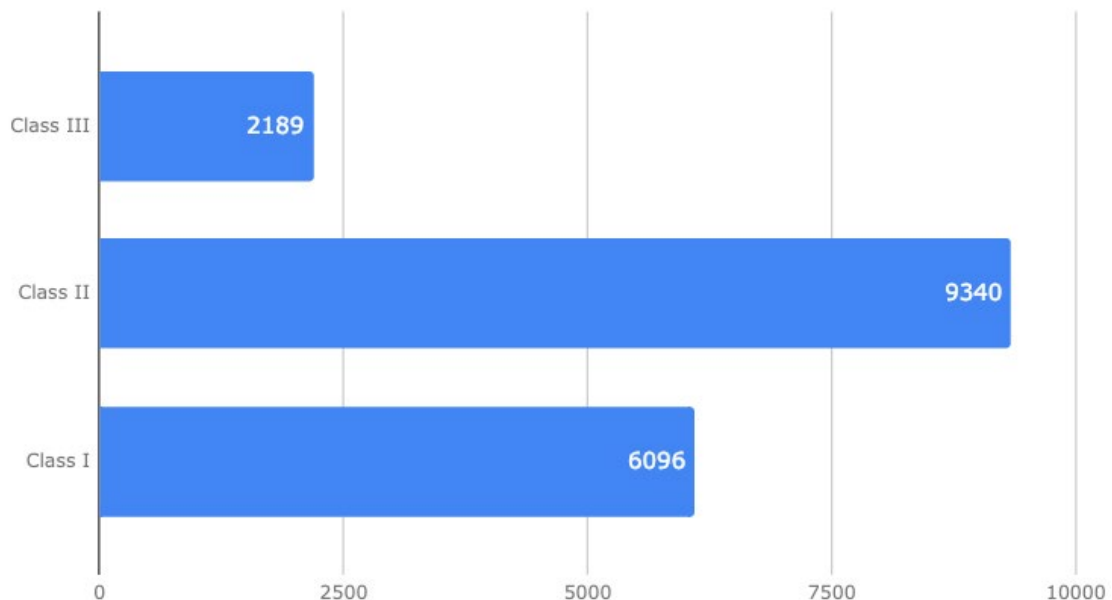


At the end of 2017, there were around 16,000 medical device manufacturers registered in China, 90% of which were Small and Medium Sized Companies. The focus of the majority of these companies is manufacturing Class II and Class I devices according to the NMPA.⁵⁴

⁵⁴ <http://www.camdi.org/news/7671>



Chinese Companies able to manufacture Class I to III Medical Devices



Of these 16.000 Medical Device manufacturers 2.000 companies have a licence to export.

In China, 80% of the Medical devices are manufactured in one of the three regions:⁵⁵

- Pearl-River Delta (Shenzhen / South China)
- Yangtze River Delta (Shanghai / East China)
- Beijing-Tianjin-Bohai (North China)

In general, the strength and focus of the Chinese Medical Device manufacturers is mass manufacturing and marketing Medical Devices, that are comparably low Research and Development (R&D) intensive.

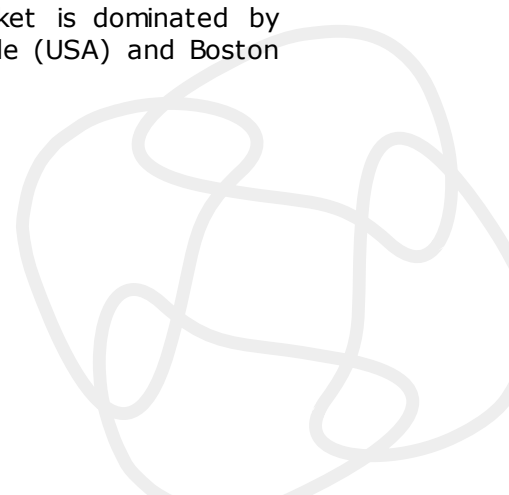
The market for high-end, R&D-intensive Medical Devices in China is dominated by large multinational companies.⁵⁶ For example, the high-end market for MRI (Magnetic Resonance Imaging) equipment is - from the chinese perspective - dominated by foreign companies, around 90% of the market Share goes to Siemens (Germany), General Electric (USA), Philips (Netherland), Canon (Japan), whereas the rest 10% of the market are filled by local players like Neusoft (China).⁵⁷

As another example, more than 95% of the pacemaker market is dominated by multinational companies like Medtronic (USA/Ireland), St. Jude (USA) and Boston

⁵⁵ <http://www.camdi.org/news/7664>

⁵⁶ <http://www.camdi.org/news/7671>

⁵⁷ <http://www.camdi.org/news/7072>



Scientific (USA).⁵⁸ In this market - and other markets - China has started to support domestic medical champions. One of the reasons is to lower to lower price ranges, e.g. chinese pacemakers tend to be 20% to 30% cheaper than pacemakers from the multinational companies.⁵⁹ Consequently, local competitors catch up in their abilities and the imports of cardiac pacemakers is decreasing, although the overall market is increasing.⁶⁰

In general, Chinese competitors in the Chinese market rely heavily on their cost-efficiency as general sales strategy, and focus first on conquering the vast market of low- to medium range hospitals, i.e. Class I and II hospitals, and just in a second step upgrade their capacity in Research and Development. Once they have a significant capital base, they try to gain a foothold in Class III hospitals with newly developed higher level products.⁶¹

However, there are four general weaknesses of the domestic medical device industry, according to the "2018-2020 China Health Industry Investment Research Report"⁶²:

- Focus on low-cost bidding strategies in combination with absence of strategic marketing, which leads to high-volume, low-margin manufacturing, and limited Research and Development
- Lack of medical device technology platforms for launching new products, general shortage in long-term investment in training and development of customers
- Deficits in detail-orientation and sophistication when developing high-end products
- General Medical Device safety, efficiency and life-cycle management, when compared to international competitors

In order to evaluate the Medical Device Market in China for European SME as *export* Market, an analysis of the Chinese *imports* for Medical Devices based on HS Code categories is feasible. The HS Code system classifies internationally traded goods into different categories for customs purposes. Within the different HS Code categories, a total of 12 HS Codes can be linked to Medical Devices. Below there is a table with a breakdown of Chinese Medical Devices Imports for the years 2016 and 2017 based on Chinese Customs Statistics⁶³:

HS Code	Product Group	2016	2017	Change
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⁵⁸ <http://www.camdi.org/news/7054>

⁵⁹ <http://www.camdi.org/news/7054>

⁶⁰ <http://www.camdi.org/news/6956>

⁶¹ <http://www.camdi.org/news/7591>

⁶² 《2018-2020 中國大健康產業投資研究報告》

⁶³ GTAI, Corinne Abele, Branche kompakt: China will bei Medizintechnik im High-End-Segment aufholen, 2018



90181	Electrodiagnostic apparatus and devices	EUR €1,849	EUR €1,945	5.2%
90220	X-ray machines etc.	EUR €2,781	EUR €2,899	4.2%
84192	Sterilizers	EUR €66	EUR €56	-14.6%
87130	Wheelchairs	EUR €5	EUR €5	-11.7%
90184	Dental instruments	EUR €142	EUR €200	41.1%
90183	Syringes, Catheters, etc.	EUR €1,487	EUR €1,741	17.0%
90185	Ophthalmological instruments	EUR €386	EUR €467	21.0%
90189	Other instruments and apparatus	EUR €2,072	EUR €2,167	4.6%
9019 & 9020	Therapy devices, breathing equipment	EUR €326	EUR €413	26.6%
94020	Medical furniture etc.	EUR €110	EUR €111	1.3%
90210	Orthopaedic technology, prostheses	EUR €2,559	EUR €2,860	11.8%
	Total	EUR €11,783	EUR €12,863	9.2%

The total value of Medical Device Imports increased by 9.2%, which is a solid growth, but less than the 20% to 25% total Medical Device Market growth. Therefore, the potential export market growth outlook for exporters seems to be positive, but *lower* than the overall Medical Devices Market growth in China.

For a deeper analysis, a further breakdown can be made. Below there is an overview about the total Medical Device Exports to China from the European Union⁶⁴ and the Medical Device Imports to China⁶⁵:

HS Code	Category Group Description	Medical Device Imports to China (in million Euro)	Medical Device Exports to China from EU 28 (in million)	Medical Device Exports to China from 4 MAGIA countries	Exports from MAGIA countries as % of total
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⁶⁴ Eurostat Data

⁶⁵ GTAI, Corinne Abele, Branche kompakt: China will bei Medizintechnik im High-End-Segment aufholen, 2018

			Euro)	(in million Euro)	Medical Device Imports to China
90181	Electrodiagnostic apparatus and devices	EUR €1,945	EUR €508	EUR €246	13%
90220	X-ray machines etc.	EUR €2,899	EUR €1,078	EUR €725	25%
84192	Sterilizers	EUR €56	EUR €18	EUR €6	11%
87130	Wheelchairs	EUR €5	EUR €1	EUR €1	18%
90184	Dental instruments	EUR €200	EUR €80	EUR €54	27%
90183	Syringes, Catheters, etc.	EUR €1,741	EUR €517	EUR €270	16%
90185	Ophthalmological instruments	EUR €467	EUR €184	EUR €171	37%
90189	Other instruments and apparatus	EUR €2,167	EUR €616	EUR €483	22%
9019 & 9020	Therapy devices, breathing equipment	EUR €413	EUR €123	EUR €82	20%
94020	Medical furniture etc.	EUR €111	EUR €33	EUR €25	22%
90210	Orthopaedic technology, prostheses	EUR €2,860	EUR €841	EUR €452	16%
	Total	EUR €12,863	EUR €4,000	EUR €2,514	20%

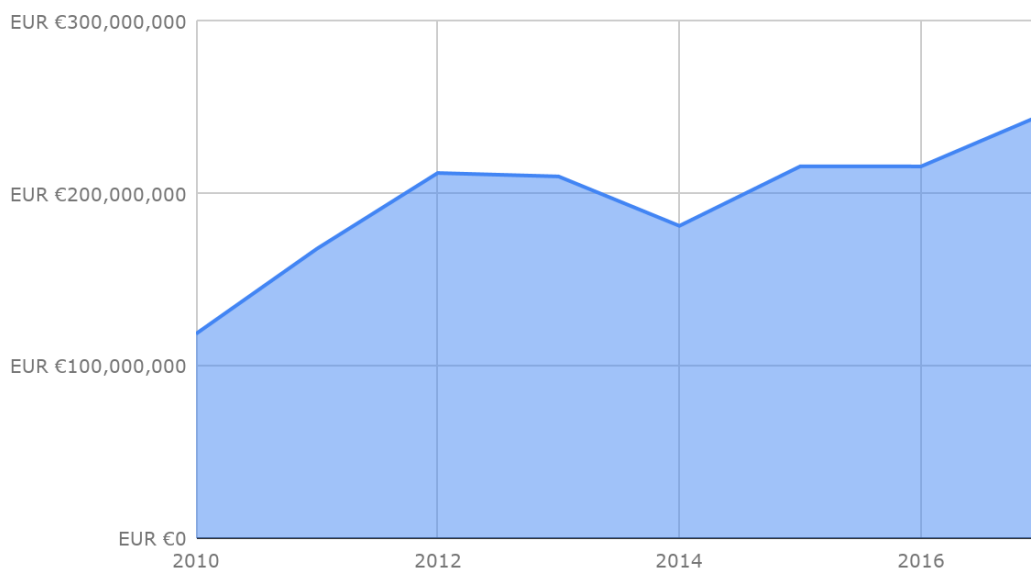
The total import value of Medical Devices in 2017 was 12.9 billion Euro in total from all countries, according to the Chinese Import Statistics.

The European Union (EU28) exported a total of 4 billion worth of Medical Devices to China, or 31% of the total Chinese imports in Medical Devices. The four MAGIA

countries (Belgium, France, Germany, Italy) exported a total of 2.5 billion Euro worth of Medical Devices to China, or a fifth of all Medical Device imports of China.

In order to gain deeper insight, for each Medical Device HS code category a 2010 to 2017 comparison of the export statistics for the MAGIA countries was compiled:

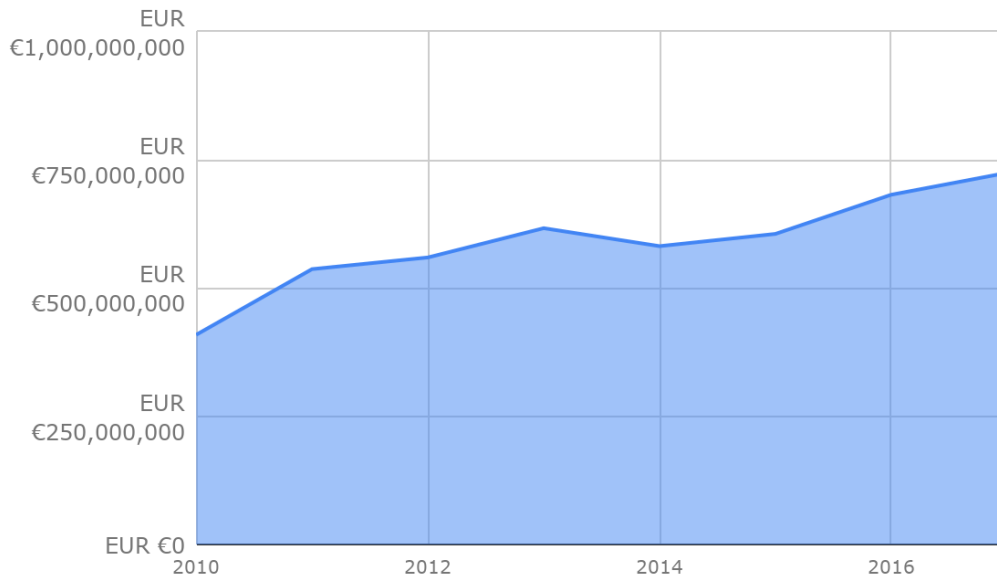
Electrodiagnostic apparatus and devices



For electrodiagnostic apparatus and devices the average annual growth rate for the years 2010 to 2017 of exports from MAGIA countries to China was 11.0%, for 2015 to 2017 6.7%.

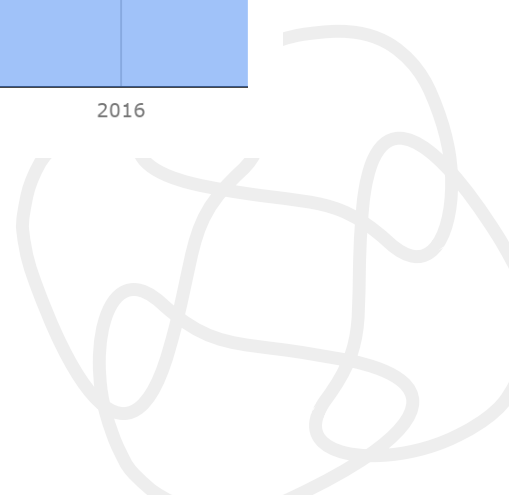
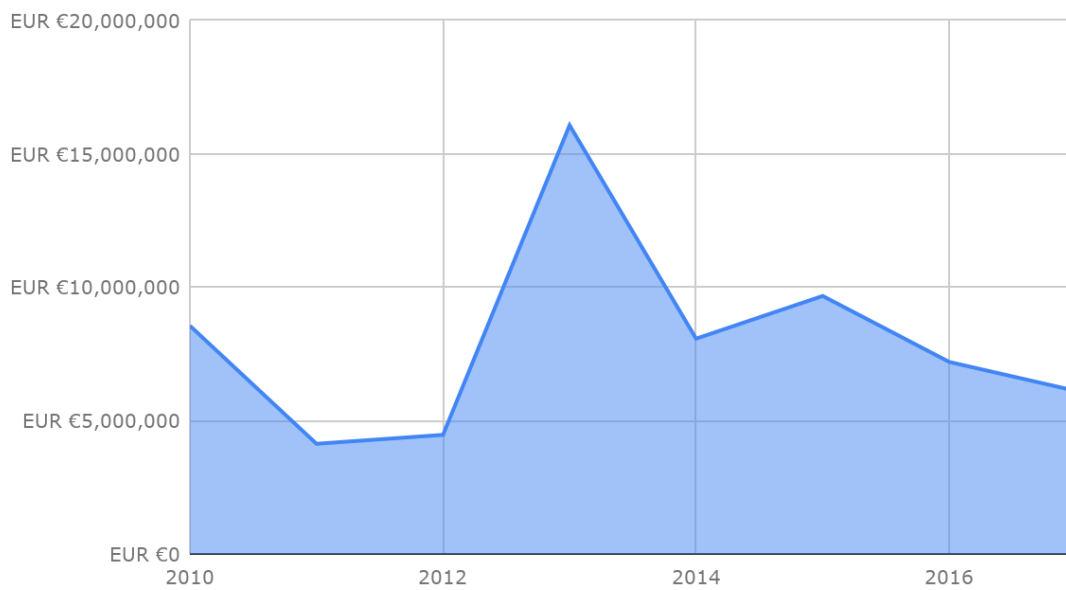


X-ray machines

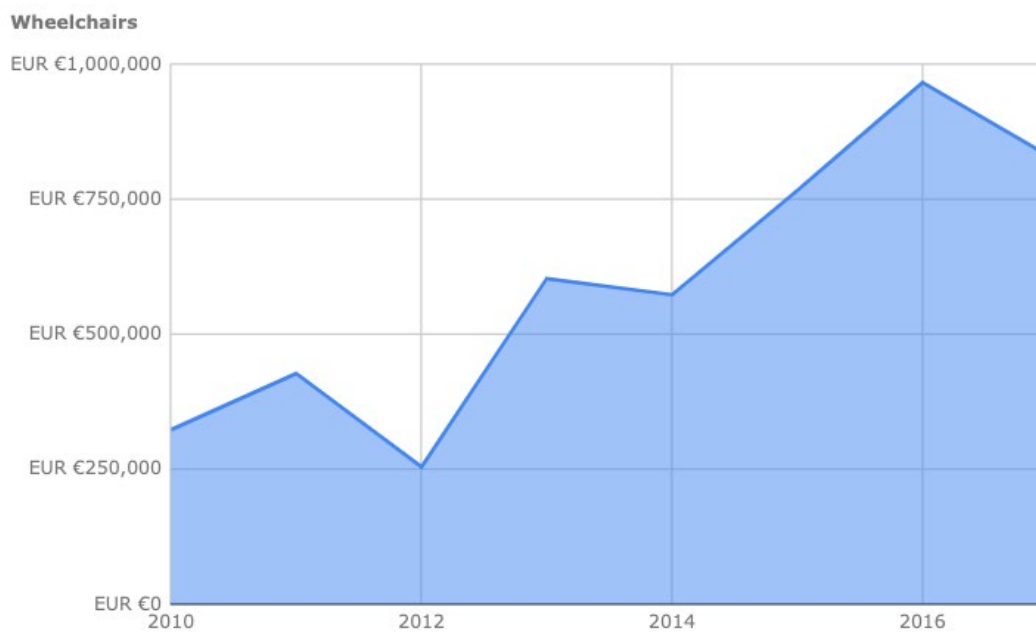


For X-Ray machines the average annual growth rate for the years 2010 to 2017 of exports from MAGIA countries to China was 8.5%, for 2015 to 2017 9.4%.

Sterilizers



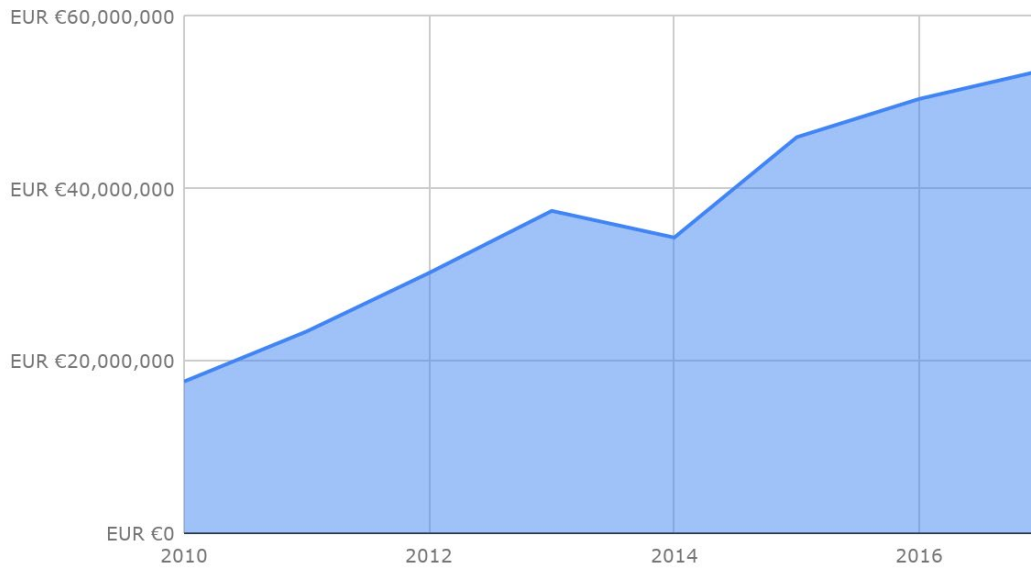
The exports of sterilizers from MAGIA countries to China declined in average by 4.7% annually in the years from 2010 to 2017 and peaked in 2013. In the years from 2015 to 2017 the exports decreased by 20.5% in average.



For Wheelchairs the average annual growth rate of exports from MAGIA countries to China for the years 2010 to 2017 was 14.5%.

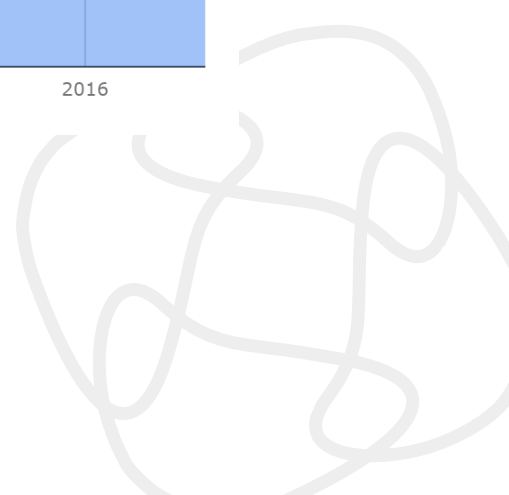
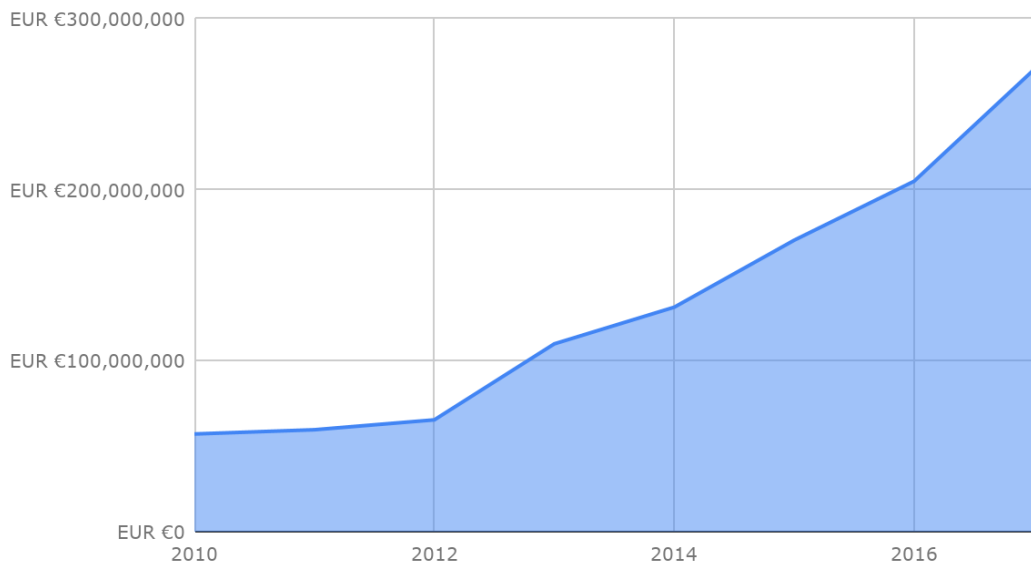


Dental instruments



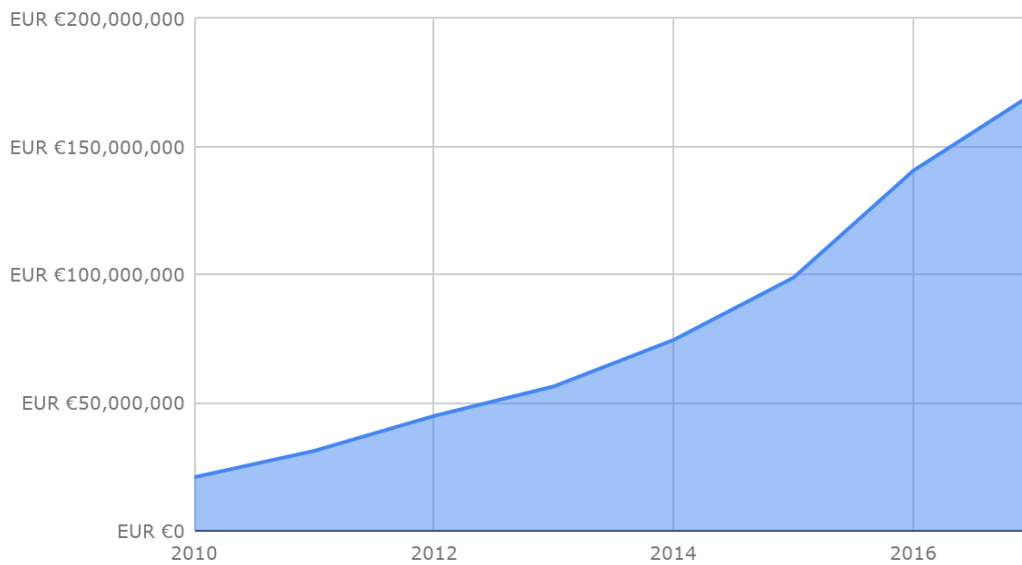
For Dental Instruments the average annual growth rate of exports from MAGIA countries to China for the years 2010 to 2017 was 17.3%, for 2015 to 2017 8.1%.

Syringes, Catheters, etc.



For Syringes, Catheters, Needles for sutures etc. the average annual growth rate of exports from MAGIA countries to China for the years 2010 to 2017 was 24.9%, for 2015 to 2017 25.9%.

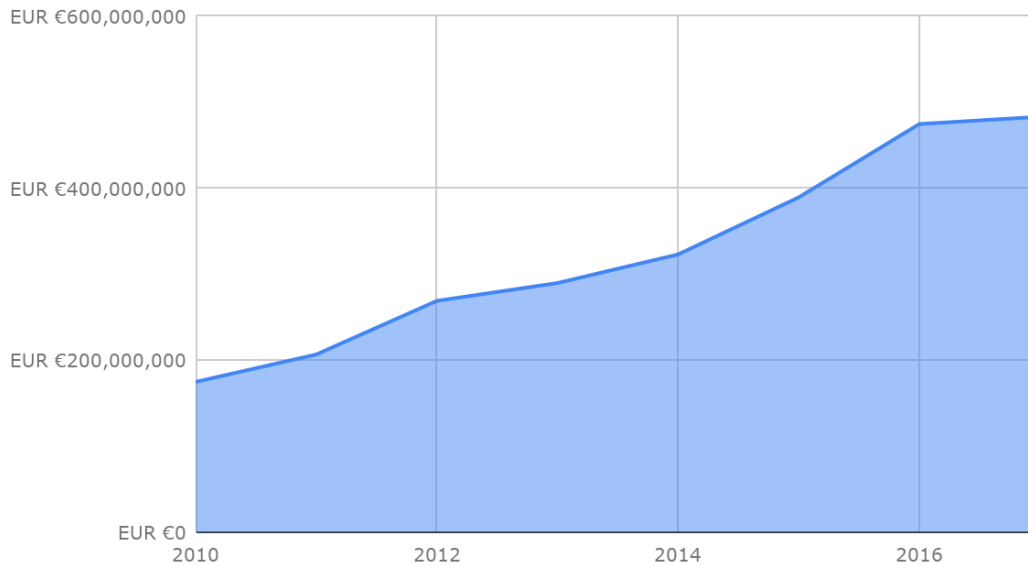
Ophthalmological instruments



For ophthalmological instruments the average annual growth rate of exports from MAGIA countries to China for the years 2010 to 2017 was 35.0%, for 2015 to 2017 31.4%.



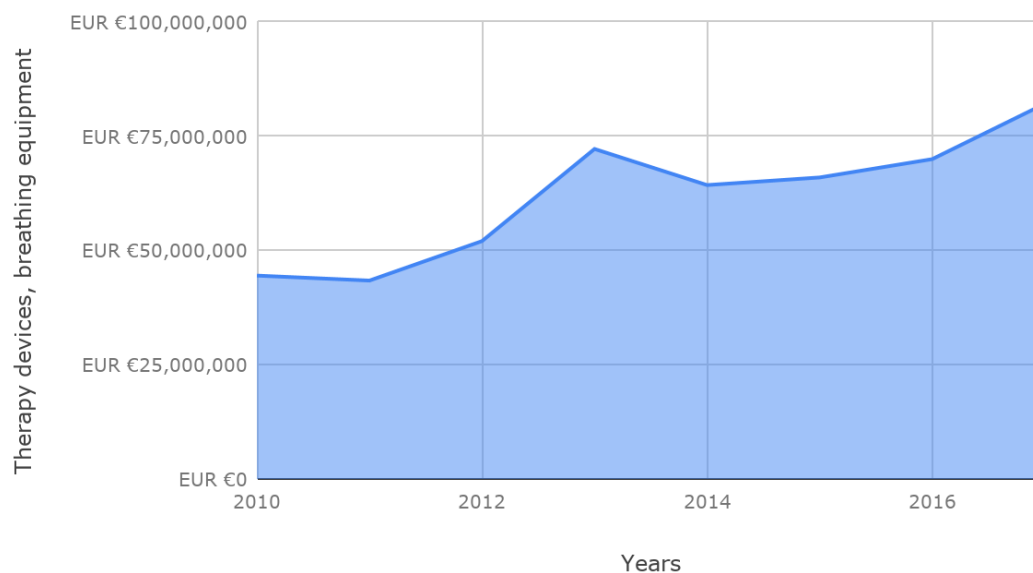
Other instruments and apparatus



For "other instrument and apparatus" the average annual growth rate of exports from MAGIA countries to China for the years 2010 to 2017 was 15.6%, for 2015 to 2017 11.4%. The category "other instrument and apparatus" includes electro-surgical instruments and appliances as well as dialysis instrument and apparatus for example.



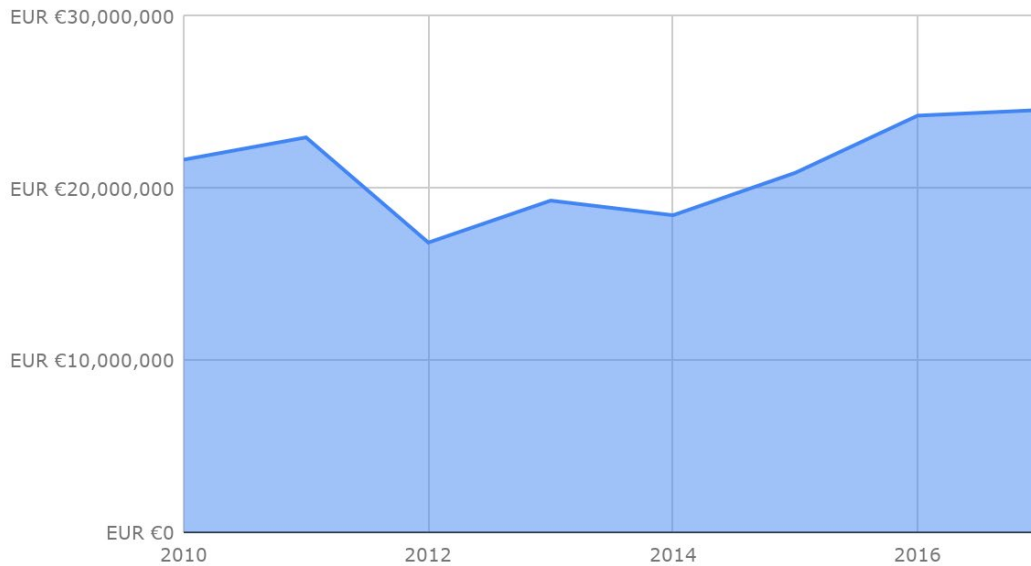
Therapy devices, breathing equipment



For the HS Code category “Therapy devices, breathing equipment” the average annual growth rate of exports from MAGIA countries to China for the years 2010 to 2017 was 9.1%, for 2015 to 2017 11.5%.



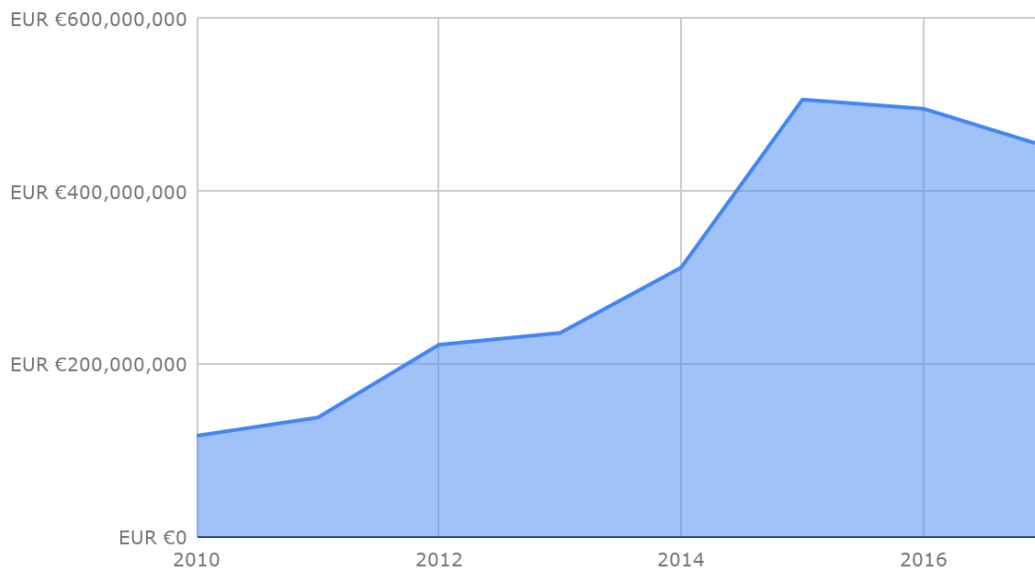
Medical furniture etc.



For the HS Code category "Medical furniture etc." the average annual growth rate of exports from MAGIA countries to China for the years 2010 to 2017 was 1.8%, for 2015 to 2017 8.4% annually.



Orthopaedic technology, prostheses

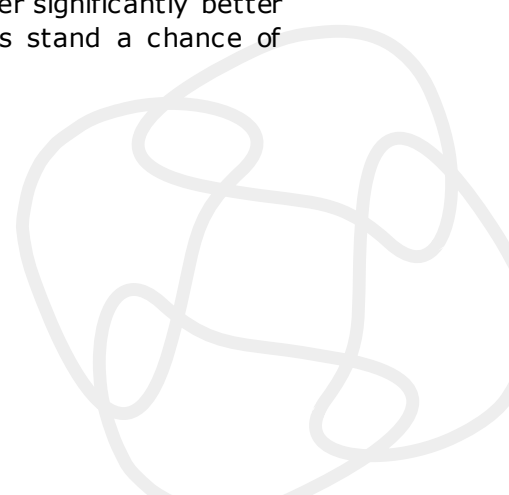


For the HS Code category “Orthopaedic technology, prostheses” the average annual growth rate of exports from MAGIA countries to China for the years 2010 to 2017 was 21.3%, but in the years 2015 to 2017 the exports declined by 5.5% annually.

4.2 The tender process in hospitals / Hospital Procurement

Public hospitals in China must procure via public tenders in order to purchase medical equipment or devices. These tenders are openly visible (in Chinese) for potential bidders. In order to participate in a bid, a bidder must be registered in China and have the relevant certificates for medical device distribution in China, meaning exporters from Europe have to participate a tender process via local distributors unless they have a subsidiary in China with all relevant medical device distribution licenses.

In general, in China the procurement of domestic medical devices is encouraged, meaning domestic manufacturers or international companies with local medical device manufacturing are at an advantage in the public bidding process. However, if demand exists for high-end medical features or devices that offer significantly better treatment outcome for its patients, imported medical devices stand a chance of succeeding in the bidding process.



4.3 Medical Device Marketing in China

4.3.1 Localisation

For marketing the medical devices to a wider audience in China - once the NMPA certificate has been received - a specific market analysis of the target group is advisable, e.g. dentists, in order to further localize the marketing materials of the European medical devices. In general, the market landscape in China is different than in Europe, e.g. competitors are different, standard operating procedures are divergent etc., and this is best reflected also in localized marketing materials, instead of 1:1 translations.

When trying to find a potential distributor in China, e.g. via medical device exhibitions, it is important to have Chinese translated marketing material on the exhibition booth from the first day. Most of the visitors on the exhibition speak just Chinese and by having English marketing materials the potential audience for a product can be severely limited. High-end medical devices with sophisticated features and superior efficacy stand the best chance of positive reception on the exhibition by having a well-made, translated marketing material at hand. Conversely, without Chinese marketing material the success of the exhibitor depends on the English level of the potential distributor.

4.3.2 Advertisement

Advertisement materials need to be examined and approved by the NMPA in the Chinese province, in which the distributor or the subsidiary is located, before they can be circulated widely. For example, the advertisements are not allowed to contain false or misleading statements. In this regards it is important to also check advertisement from distributors, if they disseminate advertisement material on behalf of the manufacturer.⁶⁶

4.4. Two Invoice-System

Several provinces have started a "two-invoice system" while creating a centralised procurement system for their public hospitals (1 Invoice: Manufacturer-Distributor; 1 Invoice: Distributor-Hospital) in order to limit the number of intermediaries between the medical device manufacturer and the hospitals.

The origin of the two-invoice system stems from the procurement of pharmaceuticals for public hospital pharmacies, where 7 to 8 distributors between the manufacturer and the hospital pharmacies were not unseen.⁶⁷

⁶⁶ State Council Order 680

⁶⁷ <http://www.camdi.org/news/7435>



One of the major goals of the “two-invoice system” is to achieve price reductions for the public hospitals during the procurement process.⁶⁸

The impact on the overall hospital procurements remains to be seen. It is noteworthy that the system has not been rolled out country-wide and applies to public hospitals only. The main impact of the system on the market for imported medical devices remains to be seen, since the focus of the system is medical consumables for hospitals, not high-end equipment purchases.

4.5. Finding the right partner

Unless the exporter wants to open a subsidiary company in China for own direct participation in the marketplace, a local business partner needs to be found. There are several ways to find local business partner companies, among them are:

- Consult MAGIA project managers
- Contact your chamber of commerce in China
- Contact the European Chamber of Commerce in China
- Participate or exhibit on exhibitions and fairs
- Visit medical conferences and their fairs and check for potential distributors of non-competing medical device products

Typical business partners are distributors or commercial agents.

4.5.1 Distributor

Many SME exporters of medical devices seek Chinese distributors in order to access the Chinese market for healthcare. Typically, after a distribution contract has been signed and the NPMA registration been obtained, distributors purchase medical devices from the manufacturers and then market the devices in China via their own company or via further sub-distributors to hospitals or other end-customers.

One of the advantages of successfully seeking and finding a distributor is the limitation of financial risks, compared with the opening of an own subsidiary. One of the disadvantages, however, is, that a manufacturers export success depends on the performance of a third-party, the distributor. A thorough due diligence of the distributor is therefore advisable.

4.5.2 Commercial Agents or Representatives

Commercial Agents / Commercial Representatives represent a medical device manufacturer in China, find local sub-distributors and manage the sub-distributors on behalf of the manufacturer and work for a commission of the sales volume.

⁶⁸ <http://www.camdi.org/news/7675>



4.5.3 Subsidiary/Local Sales Representative Office

A medical device exporter can open its own subsidiary, typically a Representative Office or a Wholly Foreign Owned Enterprise (WFOE).

In China, a Representative Office (RO), also called 'Liaison Office', is allowed to facilitate communication to potential customers, do market research, promote the medical device company etc.

However, the entity of a Representative Office has its limitations in China, because the RO is not allowed to earn income in China, i.e. is a vehicle mainly for marketing purposes. But as such, the Representative Office can be a useful tool to support a distributor in China in cases where a medical device manufacturer wants to keep the branding and advertisement under better control.

The opening of a WFOE allows for own distribution of medical devices, if -amongst others - a medical device distribution licence has been applied for. One of the disadvantages of the WFOE can be the high set-up and running costs - when compared to the "distributor-model" -, which can be prohibitive for a SME, especially if there is not already a customer or sales base, which can cover the costs.

4.5.4 Search strategies and decision criteria

When choosing a distributor a through due diligence is important, because once a distributor is chosen, it is hard to change the distributor. Criteria for choosing the right distributor can be:

- Competence
- Experience
- Reputation
- Financial ability
- Sales Experience
- After-Sales Experience

4.6. Major Medical Device manufacturers from China

There are over 16.000 medical device manufacturers in China. The following are the 10 largest medical device manufacturers from China:⁶⁹

⁶⁹ <http://www.camdi.org/news/7635>



English Company Name	Name in Chinese	Webpage
Dian Diagnostics	迪安诊断	www.dazd.cn
Glory Medical	尚荣医疗	http://www.glory-medical.com.cn/en/
Lepu Technology	乐普医疗	http://en.leputechnology.com/
Medical System	美康生物	http://www.nb-medicalsystem.com/
Microport	微创医疗	http://www.microport.com/en/
Mindray	迈瑞医疗	http://www.mindray.com/cn/about.html
Runda Medical	润达医疗	www.rundamedical.com
Shinva	新华医疗	http://www.shinva.com/
Wego	威高股份	http://www.weigaogroup.com/
Yuwell	鱼跃医疗	www.yuyue.com.cn

4.7. Important Associations and Internet Links

European Union Chamber of Commerce in China

<http://www.europeanchamber.com.cn/en/home>

EU SME Centre

<http://www.eusmecentre.org.cn/>

Belgian-Chinese Chamber of Commerce (BCECC)

<https://bcecc.be/>



French Chamber of Commerce and Industry in China (CCIFC)

<http://www.ccifc.org>

China-Italy Chamber of Commerce

<http://www.cameraitacina.com/>

German Chamber of Commerce - AHK Greater China

<https://china.ahk.de/>

National Health Commission

<http://www.nhfpc.gov.cn>



State Administration for Market Regulation (SAMR)

<http://eng.cfda.gov.cn>



Center for Medical Device Evaluation (CMDE)

<http://www.cmde.org.cn>

China Association for Medical Devices Industry (CAMDI)

<http://en.camdi.org/>

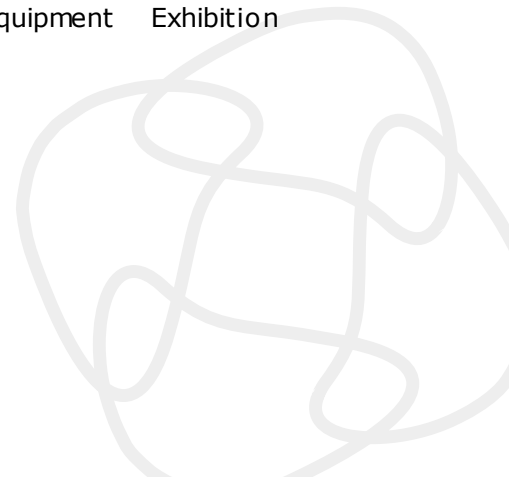
4.8. Important Medical Fairs in China in 2019

4.8.1 Medical Devices

22.03.-24.03.2019

CHINA MED - International Medical Instruments and Equipment Exhibition
Beijing, China, People's Republic

<http://www.chinamed.net.cn/>



14.05.-17.05.2019

CMEF Spring - China Medical Equipment Fair, Shanghai, China, People's Republic

<http://www.cmef.com.cn/>

26.09.-29.09.2019

CMEH - The Beijing International Medical Devices Exhibition, Beijing, China, People's Republic

<http://www.bjmed.net/>

October 2019 CMEF Autumn - China Medical Equipment Fair, not yet determined, China, People's Republic

<http://www.cmef.com.cn/>

4.8.2 Dental Devices

03.03.-06.03.2019

Dental South China Expo & Conference - South China International Dental Equipment & Technology Expo & Conference, Guangzhou

<http://www.dentalsouthchina.com/>

24.04.-27.04.2019

Dental Show West China - West China International Exhibition & Symposium on Dental Equipment, Chengdu, China, People's Republic

<http://www.wcise.com/en>

09.06.-12.06.2019

Sino Dental - International Exhibition on Dental Equipment, Technology and Materials, Beijing, China, People's Republic

<http://www.sinodent.com.cn/>

September 2019

CDS - China Dental Show, Shanghai, China, People's Republic

<http://www.chinadentalshow.com/cn/index.htm>



30.10.-02.11.2019

DenTech China - International Exhibition for the Dental Industry, Shanghai, China, People's Republic

<http://www.dentech.com.cn/>

4.8.3 Rehabilitation and Assistive Devices

31.03.-02.04.2019 RC&O - Rehacare & Orthopedic Canton, Guangzhou, China, People's Republic

<http://www.cantonrehacare.com/>

17.04.-19.04.2019

CIHIE - China International Home Medical HealthCare Recovery Products & Instruments Expo & Chinese domestic medical device industry status quo and future deve, Beijing, China, People's Republic

<http://en.jianbohui.com/>

4.8.4 Medical Device manufacturing

25.09.-27.09.2019

MEDTEC China - The exhibition dedicated to medical device design & manufacturing, Shanghai, China, People's Republic

<http://www.medtecchina.com/en-us/>

4.9. Listing of major relevant hospitals, clinics,



research

centers

4.9.1 General hospital List

Since 2010, Fudan University Hospital Management Research Institute has launched the "Chinese Hospital Specialist Reputation Ranking" and "Chinese Hospital Rankings". The review is based on expert opinions from the Chinese Medical Association and the Physician Society, involving 37 clinical specialties. A questionnaire was sent to 4,173 experts and received 2,657 valid receipts.

Top List of Hospitals in China according to Fudan University:

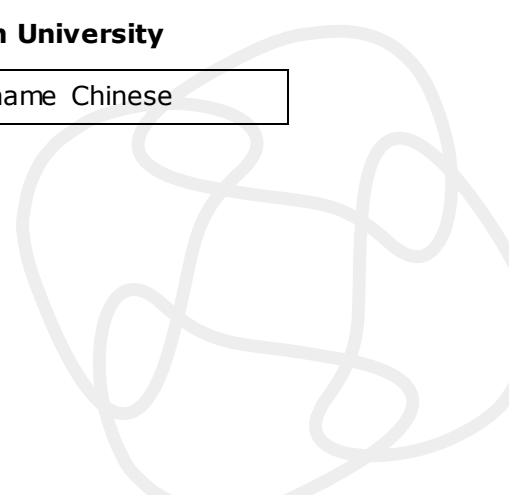
1	Chinese Academy of Medical Sciences Peking Union Medical College Hospital	中国医学科学院北京协和医院
2	West China Hospital of Sichuan University	四川大学华西医院
3	General Hospital of the Chinese People's Liberation Army	中国人民解放军总医院
4	Ruijin Hospital Shanghai Jiao Tong University School of Medicine	上海交通大学医学院附属瑞金医院
5	Air Force Military Medical University Xijing Hospital	空军军医大学西京医院
6	Zhongshan Hospital, Fudan University	复旦大学附属中山医院
7	First Affiliated Hospital of Sun Yat-sen University	中山大学附属第一医院
8	Huazhong University of Science Tongji Hospital, Tongji Medical College	华中科技大学同济医学院附属同济 医院
9	Huashan Hospital, Fudan University	复旦大学附属华山医院
10	Peking University Third Hospital	北京大学第三医院
11	Peking University First Hospital	北京大学第一医院
12	First Affiliated Hospital of China Medical University	中国医科大学附属第一医院

13	Union Hospital of Tongji Medical College, Huazhong University of Science and Technology	华中科技大学同济医学院附属协和医院
14	Central South University Xiangya Second Hospital	中南大学湘雅二医院
15	First Affiliated Hospital of Zhejiang University School of Medicine	浙江大学医学院附属第一医院
16	Peking University People's Hospital	北京大学人民医院
17	Southern Medical University Southern Hospital	南方医科大学南方医院
18	Renji Hospital, Shanghai Jiaotong University School of Medicine	上海交通大学医学院附属仁济医院
19	Second Affiliated Hospital of Zhejiang University School of Medicine	浙江大学医学院附属第二医院
20	Southwest Military Hospital, Army Military Medical University	陆军军医大学西南医院
21	Central South University Xiangya Hospital	中南大学湘雅医院
22	Jiangsu Provincial People's Hospital (the First Affiliated Hospital of Nanjing Medical University)	江苏省人民医院（南京医科大学第一附属医院）
23	Qilu Hospital of Shandong University	山东大学齐鲁医院
24	Naval Military Medical University Changhai Hospital	海军军医大学长海医院
25	First Affiliated Hospital of Zhengzhou University	郑州大学第一附属医院

4.9.2 Cardiovascular diseases

Top Cardiovascular Hospitals in China according to Fudan University

No.	Hospital name English	Hospital name Chinese
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1	Chinese Academy of Medical Sciences Fuwai Hospital	中国医学科学院阜外医院
2	Zhongshan Hospital affiliated to Fudan University	复旦大学附属中山医院
3	Beijing Anzhen Hospital, Capital Medical University	首都医科大学附属北京安贞医院
4	Guangdong Provincial People's Hospital	广东省人民医院
5	Shenyang Military Region General Hospital	沈阳军区总医院
6	Second Affiliated Hospital of Zhejiang University School of Medicine	浙江大学医学院附属第二医院
7	Beijing University First Hospital	北京大学第一医院
8	The Second Affiliated Hospital of Harbin Medical University	哈尔滨医科大学附属第二医院
9	Ruijin Hospital, Shanghai Jiao Tong University School of Medicine	上海交通大学医学院附属瑞金医院
10	West China Hospital of Sichuan University	四川大学华西医院

Top Cardiac Surgery Hospitals in China according to Fudan University

No.	Hospital name English	Hospital name Chinese
1	Chinese Academy of Medical Sciences Cancer Hospital	中国医学科学院肿瘤医院
2	Fudan University Cancer Hospital	复旦大学附属肿瘤医院
3	Sun Yat-sen University Cancer Center	中山大学肿瘤防治中心
4	Tianjin Medical University Cancer Hospital	天津医科大学肿瘤医院
5	Peking University Cancer Hospital	北京大学肿瘤医院
6	Shandong Cancer Hospital and Shandong Cancer Research Institute	山东省肿瘤医院暨山东省肿瘤防治研究院

7	Zhejiang Cancer Hospital	浙江省肿瘤医院
8	West China Hospital of Sichuan University	四川大学华西医院
9	Affiliated Tumor Hospital of Nanjing Medical University (Jiangsu Provincial Cancer Hospital)	南京医科大学附属肿瘤医院 (江苏省肿瘤医院)
10	Chinese Academy of Medical Sciences Peking Union Medical College Hospital	中国医学科学院北京协和医院

4.9.3 Oncology

Top Oncology Hospitals China according to Fudan University

No.	Hospital name English	Hospital name Chinese
1	Chinese Academy of Medical Sciences Cancer Hospital	中国医学科学院肿瘤医院
2	Fudan University Cancer Hospital	复旦大学附属肿瘤医院
3	Sun Yat-sen University Cancer Center	中山大学肿瘤防治中心
4	Tianjin Medical University Cancer Hospital	天津医科大学肿瘤医院
5	Peking University Cancer Hospital	北京大学肿瘤医院
6	Shandong Cancer Hospital and Shandong Cancer Research Institute	山东省肿瘤医院暨山东省肿瘤防治研究院
7	Zhejiang Cancer Hospital	浙江省肿瘤医院
8	West China Hospital of Sichuan University	四川大学华西医院
9	Affiliated Tumor Hospital of Nanjing Medical University (Jiangsu Provincial Cancer Hospital)	南京医科大学附属肿瘤医院 (江苏省肿瘤医院)
10	Chinese Academy of Medical Sciences Peking Union Medical College Hospital	中国医学科学院北京协和医院

Top Nuclear Medicine Hospitals China according to Fudan University

No.	Hospital name English	Hospital name Chinese
1	Chinese Academy of Medical Sciences Peking Union Medical College Hospital	中国医学科学院北京协和医院
2	Union Hospital of Tongji Medical College, Huazhong University of Science and Technology	华中科技大学同济医学院附属协和 医院
3	Chinese People's Liberation Army General Hospital	中国人民解放军总医院
4	West China Hospital of Sichuan University	四川大学华西医院
5	Zhongshan Hospital affiliated to Fudan University	复旦大学附属中山医院
6	Air Force Military Medical University Xijing Hospital	空军军医大学西京医院
7	The First Affiliated Hospital of China Medical University	中国医科大学附属第一医院
8	The First Hospital of Shanxi Medical University	山西医科大学第一医院
9	Ruijin Hospital, Shanghai Jiao Tong University School of Medicine	上海交通大学医学院附属瑞金医院
10	Renji Hospital, Shanghai Jiaotong University School of Medicine	上海交通大学医学院附属仁济医院

4.9.4 Orthopedics diseases

Top Orthopedic Hospitals China according to Fudan University

No.	Hospital name English	Hospital name Chinese
1	Beijing Jishuitan Hospital	北京积水潭医院
2	Chinese People's Liberation Army General Hospital	中国人民解放军总医院
3	Peking University Third Hospital	北京大学第三医院
4	Shanghai Sixth People's Hospital	上海市第六人民医院

5	Chinese Academy of Medical Sciences Peking Union Medical College Hospital	中国医学科学院北京协和医院
6	West China Hospital of Sichuan University	四川大学华西医院
7	Naval Military Medical University Changzheng Hospital	海军军医大学长征医院
8	The Third Hospital of Hebei Medical University	河北医科大学第三医院
9	Peking University People's Hospital	北京大学人民医院
10	Air Force Military Medical University Xijing Hospital	空军军医大学西京医院

4.9.5 Dentistry Hospitals

Top Stomatology Hospitals China according to Fudan University

No.	Hospital name English	Hospital name Chinese
1	Peking University Stomatological Hospital	北京大学口腔医院
2	West China Stomatological Hospital of Sichuan University	四川大学华西口腔医院
3	The Ninth People's Hospital, Shanghai Jiao Tong University School of Medicine	上海交通大学医学院附属第九人民 医院
4	Air Force Military Medical University Stomatological Hospital	空军军医大学口腔医院
5	Wuhan University Stomatological Hospital	武汉大学口腔医院
6	Affiliated Stomatological Hospital of Guanghua School of Stomatology	中山大学光华口腔医学院附属口腔 医院
7	Beijing Stomatological Hospital, Capital Medical University	首都医科大学附属北京口腔医院
8	Affiliated Stomatological Hospital of Nanjing Medical University	南京医科大学附属口腔医院
9	Affiliated Stomatological Hospital of China Medical University	中国医科大学附属口腔医院

10	Nanjing Stomatological Hospital	南京市口腔医院
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General Comments

The conversion rate from Euro to RMB is 1 Euro to 7.8 RMB throughout the report.

The conversion rate from Euro to USD is 1 Euro to 0.88 USD throughout the report.

