

INDUSTRY OVERVIEW

The Medical Technology Industry in Germany

Issue 2014/2015



GERMANY
TRADE & INVEST

EUROPE'S BIGGEST MARKET

Global demand for innovative medical technology solutions continues to grow as we live longer, healthier lives. "Medical devices made in Germany" make a significant contribution to enhancing patient health care and quality of life around the world. Medical technologies developed in Germany benefit from a world-class research and business environment, with the sector's predominantly small and medium-sized companies enjoying an international reputation as innovators and market leaders. Internationally, the "Made in Germany" seal continues to be held up

as a guarantee of quality; nowhere more so than in the medical device sector. In 2012, global demand for German quality saw almost 70 percent of medical technology products being exported to international markets. Domestically, more than 99 percent of the country's 80 million residents are covered by health insurance. Annual health care expenditure in Germany accounts for EUR 294 billion. In addition to expenses reimbursed by health insurance providers, Germans spend an estimated EUR 60 billion for health care out of their own pockets.

With its state-of-the-art infrastructure and its central location in Europe, Germany is also an ideal location for serving surrounding European countries with an additional potential market volume of more than EUR 1,300 billion.



GERMANY'S HEALTH CARE SYSTEM

HEALTH CARE EXPENDITURE

Health care expenses in Germany totaled EUR 294 billion in 2011, an almost two percent increase over the previous year. The amount is equivalent to 11.6 percent of GDP or EUR 3,590 per capita. Medical device spending accounted for EUR 27 billion (2010).

HEALTH INSURANCE

With around 88 percent of the German population enrolled in a public health insurance plan, the public health insurance system plays the major role in the allocation of health care funds. Eleven percent of the population opt for private health insurance and less than 0.2 percent are without any insurance.

Public health insurance providers covered EUR 168.5 billion or approximately 57 percent of total health care expenses in 2011. Private health insurance companies reimbursed an additional EUR 27.7 billion of medical expenses. The remaining amount is covered by government budgets, state-mandated long-term care insurers, the social pension fund, state-mandated accident insurance providers, employers, and private households.

IN- AND OUTPATIENT CARE

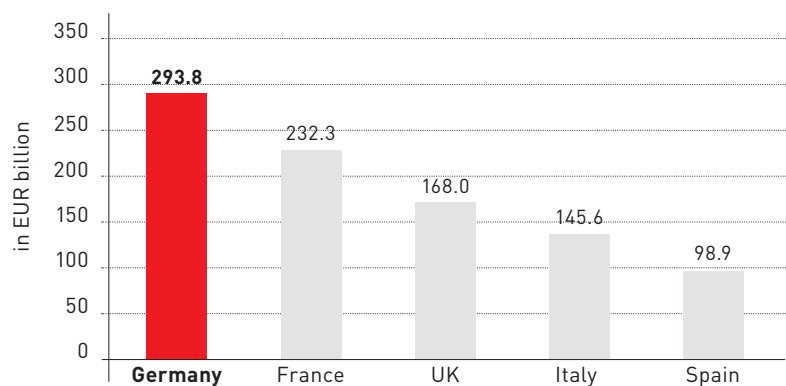
Outpatient care accounts for nearly 50 percent of annual health expenses. The most significant outpatient facilities included doctor's offices (EUR 43 billion) and pharmacies (EUR 41 billion). Inpatient and partial inpatient institutions accounted for more than EUR 104 billion of total expenditure, of which more than EUR 74 billion were incurred by hospitals.

GERMANY'S HEALTH SYSTEM FACTS AND FIGURES (2012)

More than 99 percent of Germany's 80 million residents are covered by health insurance.

- Annual health expenses: EUR 294 billion (11.6% of GDP)
- Hospital treatment expenses: EUR 62 billion
Outpatient treatment expenses: EUR 28 billion
- Number of hospitals: 2,017 (1/3 private)
- Number of hospital beds: 501,500
- Diagnosis Related Group (DRG) System (hospital sector):
1,187 DRGs, 155 additional remuneration titles
- Over 60% of hospital material demand provided by group purchasing organizations (GPOs)
- Number of active medical doctors: 348,000

Total Annual Health Expenditure in 2011



Source: OECD 2013

HOSPITAL CARE

In Germany, 2,017 hospitals (2012) with a total capacity of more than half a million beds treat 18 million patients annually. The average hospitalization period is 7.6 days. The country also has approximately 1,212 preventative care and rehabilitation facilities with nearly 169,000 beds (2012) that treat around two million patients each year. The average rehabilitation stay is 25.5 days.

THE MEDICAL TECHNOLOGY INDUSTRY IN NUMBERS

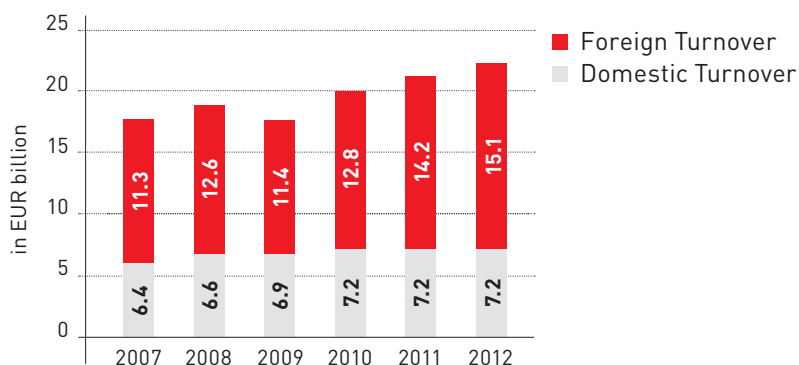
The German medical technology industry consists almost entirely of small and medium-sized enterprises, is highly innovative, and generates a large portion of its revenues through exports. Around 11,000 companies employ more than 170,000 people. In 2012, the approximately 1,200 medical device manufacturers with more than 20 employees each generated EUR 22.3 billion in sales – an increase of more than four percent over the previous year. Export markets are particularly important to German companies – about two thirds of sales in 2012 were generated outside their home country. Exports grew nearly seven percent in 2012 to more than EUR 15 billion.

The SPECTARIS industry association expects another four percent growth for the German medical technology industry in 2013. Key drivers include the innovative strength of the sector, the solid financial basis of most companies, and a stable level of demand in major health care markets.

MEDICAL TECHNOLOGY EXPORTS CONTINUE TO GROW

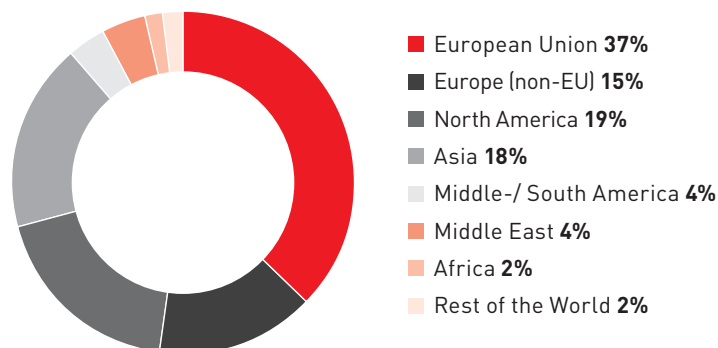
Medical technology “Made in Germany” is highly valued around the world. Although the US remains the largest single market and demand from China continues to grow, the largest share of German exports stays within Europe. Approximately 38 percent of German exports go to EU member states and another 15 percent to other European countries. North America accounts for 19 percent of exports while 18 percent are shipped to Asia.

German Medical Device Manufacturer Revenue Development



Source: SPECTARIS, German Statistical Office 2013

German Medical Technology Exports by Destination



Sources: SPECTARIS 2013

In 2012, the greatest growth rates in demand came from Russia (+44 percent), the UK (+19 percent), Japan (+18 percent), China (+17 percent), and Austria (+16 percent). The “Health Made in Germany” export initiative was created in order to make it easier for German companies to enter new markets.

MEDICAL TECHNOLOGY TRENDS

German medical technology is cutting edge. Hundreds of companies – nearly all of them medium-sized – produce medical technology innovations across the entire spectrum of products. Many specialize in very specific fields of applications or types of products. While these companies may focus on niche markets, they are often world market leaders in their respective fields.

Thanks to close cooperation between universities, the private sector and hospitals, German medical technology is developed with patients and users directly in mind. Companies continuously strive to improve their existing products. One in three products on the market has been developed within the last three years. However, medical devices are not the only focal point for continuous improvement. German medical technology companies also offer package and system solutions. These comprehensive packages cover everything from delivery and set-up to briefings, maintenance, and beyond.

Another noticeable trend is the personalization of health care. The success of medical treatments can be greatly enhanced through diagnostic tests that identify patients most likely to be helped or harmed by a new medication or therapy. The combination of therapeutics and diagnostics known as “theragnostics” is successfully applied in a wide range of areas, including in-vitro diagnostics and molecular imaging.

SIGNIFICANT MEDICAL TECHNOLOGY TRENDS AND DEVELOPMENTS

PROSTHESES AND IMPLANTS

The use of new materials has made it possible to produce gentler, longer-lasting endoprostheses and implants. Thanks to modern prosthetics amputees can enjoy near-normal mobility.

IN-VITRO DIAGNOSTICS

In-vitro diagnosis (IVD) consists of instruments and apparatus which are used together with reagents for the laboratory or on-site examination of human samples. Innovative sub-areas include lab-on-a-chip (LOC) technology, molecular diagnostics, immunodiagnostics, decentralized diagnostics, and individualized medicine.

IMAGING SYSTEMS

The industry has made great innovative leaps in areas such as positron emission tomography (PET). Close integration of diagnostics and therapy makes treatment easier for many patients and also helps to reduce costs. A single whole-body PET/CT (computer tomography) or PET-MR (magnet resonance tomography) examination can be used to pinpoint tumors and plan radiation therapy.

E-HEALTH

A rapidly aging population and decreasing numbers of specialized medical practitioners in rural areas make it difficult for rural communities to receive comprehensive medical care. Telemedicine can help to fill these gaps and to provide better care at lower cost. Another example is “ambient assisted living” (AAL). With the aid of a wide range of remote support services senior citizens are enabled to live self-sufficient lives at home.

DEVICE AND SYSTEM NETWORKING

With the increasing presence of technology in the operating room, the need for improved interconnectivity and coordination has also grown. The development of products for the connection of different operation tools has accordingly increased. Modern operation and documentation software, for example, uses checklists to help prevent errors and eliminates additional work by automatically generating operation logs.

OPTIMIZED HOSPITAL PROCESS MANAGEMENT

In the past, individual hospital departments conducted their own planning and work was managed individually. To improve efficiencies, disciplines are now becoming more integrated. As a result, processes not only have to be planned appropriately, but all necessary data must also be available at the right time and at the right place.

THE CE MARKING SYSTEM

MANDATORY CONFORMITY MARKING

Any medical device intended for the German market must bear a CE marking before it can be sold or put into service. The CE marking is affixed to certain products intended for sale within the European Economic Area (EEA) to indicate conformity with the essential health and safety requirements set out in European directives. CE marking is the declaration by the manufacturer (and acceptance by an assessment body) that a product complies with relevant directives. The fulfillment of all legal requirements is determined in a formal conformity assessment procedure called the *Medizinproduktegesetz* (MPG – “Law on Medical Devices”).

MEDICAL DEVICE CE MARKING

There are three European CE marking directives that specifically apply to medical devices manufacturers:

- The Medical Devices Directive (MDD) applies to all general medical devices not covered by the Active Implantable Medical Devices Directive or the In Vitro Diagnostics Directive (93/42/EEC)
- The Active Implantable Medical Devices Directive (AIMDD) applies to all active devices and related accessories intended to be permanently implanted in humans (90/385/EEC)
- The In Vitro Diagnostics Directive (IVDD) applies to all devices and kits used away from the patient to make a diagnosis of patient medical conditions (98/79/EC)

The German Healthcare System: CE Certification of Medical Devices

Definition of Medical Devices:

All products e.g. instruments, apparatus, materials, software or other items that are designed for diagnosis, prevention, surveillance, treatment or compensation of human illnesses, injuries or handicap

Class I

- Medical instruments
- Crutches
- Wheelchairs
- Surgical beds
- Bandaging

Class IIa

- Dental filler
- Diagnostic ultrasonic devices
- Hearing aids
- Contact lenses
- Tooth crowns
- Muscle and nerve stimulation

Class IIb

- Anesthetic devices
- Respiration devices
- X-rays
- Blood bags
- Defibrillators
- Dialysis devices
- Condoms
- Contact lense cleaner
- Dental implants

Class III

- Heart catheters
- Endoprotheses
- Coronary stents
- Absorbable surgical sutures
- Breast implants
- Heart valves

Please note that there are no general classifications by national law or EU rules. Each product is categorized individually with reference to the intended use.

Source: MED Cert

MEDICAL DEVICE CE MARKING CLASSES

Medical devices, with the exception of in vitro diagnostic medical devices and active implantable medical devices, are divided into four classes (I, IIa, IIb, and III) according to European directives. Depending on the class of product, conformity can be established by the manufacturer or with the involvement of a notified body. Such intervention is necessary for all active implants (in accordance with Council Directive 90/385/EEC), for in vitro diagnostic medical devices (in accordance with Annex II of Council Directive 98/79/EC or for

self-administration), as well as for other medical devices of classes III, IIb, or IIa and class I products which are placed on the market in a sterile condition or which have a measuring function.

SELF-CERTIFICATION

Medical devices with minimal risk can take advantage of the self-certification process whereby the manufacturer provides a declaration of conformity before affixing the CE marking to the product. Medical devices with greater risk require voluntary certification by a notified body.

R&D FRAMEWORK

INNOVATIVE STRENGTH

The German medical technology industry generates one third of its turnover from products less than three years old. However, this is only one indicator for the high level of Germany's innovative strength. In terms of all European patent applications made in 2012, Germany holds a share of around 18 percent of the 148,494 patent applications registered at the European Patent Office (EPO). With 10,412 patent applications in 2012, the medical technology sector is leading Germany's sectors from the front. From a global perspective, Germany was second only to the US in terms of number of medical technology patent applications in 2012.

RESEARCH AND PRODUCT DEVELOPMENT

The approximately 1,200 companies (each with more than 20 employees) active in the medical technology sector invest around nine percent of their turnover in R&D.

Close cooperation between Germany's R&D institutes and equipment manufacturers, not to mention a plethora of in-house R&D facilities, helps to maintain an internationally unparalleled competitive edge. R&D is considered to be among the most important areas for the development of the German economy. R&D projects can count on numerous types of financial support in the form of grants, interest-reduced loans, and special partnership programs, some especially created for small and medium-sized enterprises (SMEs).

CENTRAL INNOVATION PROGRAM SME - BEST PRACTICE EXAMPLE A NEW RUNNING EXPERIENCE – ADAPTIVE JOINTS FOR KNEE AND FOOT PROSTHESES

One cooperative project received EUR 557,824 in funding over a two-year period for the development of new adaptive joints for knee and foot prostheses through the ZIM program. Project participants included the Institute of Composite Structures and Adaptive systems of the German Aerospace Center, the Faculty for Electronics, Informatics and Mathematics (www.dlr.de/fa) of the University Paderborn (www.eim.uni-paderborn.de), iXtronixs GmbH (www.ixtronixs.com) in Paderborn, and OTW Orthopädietechnik Winkler GmbH (www.winkler-ot.com) in Minden. This project resulted in a new prosthesis product promoting the natural and effort-saving motion sequence of the users. By implementing this cooperation project all partners were able to create a unique selling proposition for the product developed, thereby creating new opportunities in international markets. The project also led to the formation of the HAPS Technology GmbH, which is currently setting up a high-tech production line for lightweight and biomechatronic elements in Paderborn.

R&D PROGRAMS FOR SMEs IN THE MEDICAL TECHNOLOGY SECTOR

As part of the High-Tech Strategy, the federal government provides extra support to innovative SMEs in order to maximize their potential. In 2009, the Federal Ministry of Education and Research (BMBF) and the Federal Ministry of Economics and Technology (BMWi) provided SMEs with over EUR 950 million in technology funding. Two governmental support programs are of particular interest in the medical technology sector.

KMU-INNOVATIV ("INNOVATIVE SME")

The BMBF has introduced the *KMU-innovativ* ("Innovative SME") scheme to significantly improve SME access to research funding including simplified credit risk assessment. A special call for medical device projects was started within this incentives program at the end of 2011.

CENTRAL INNOVATION PROGRAM SME

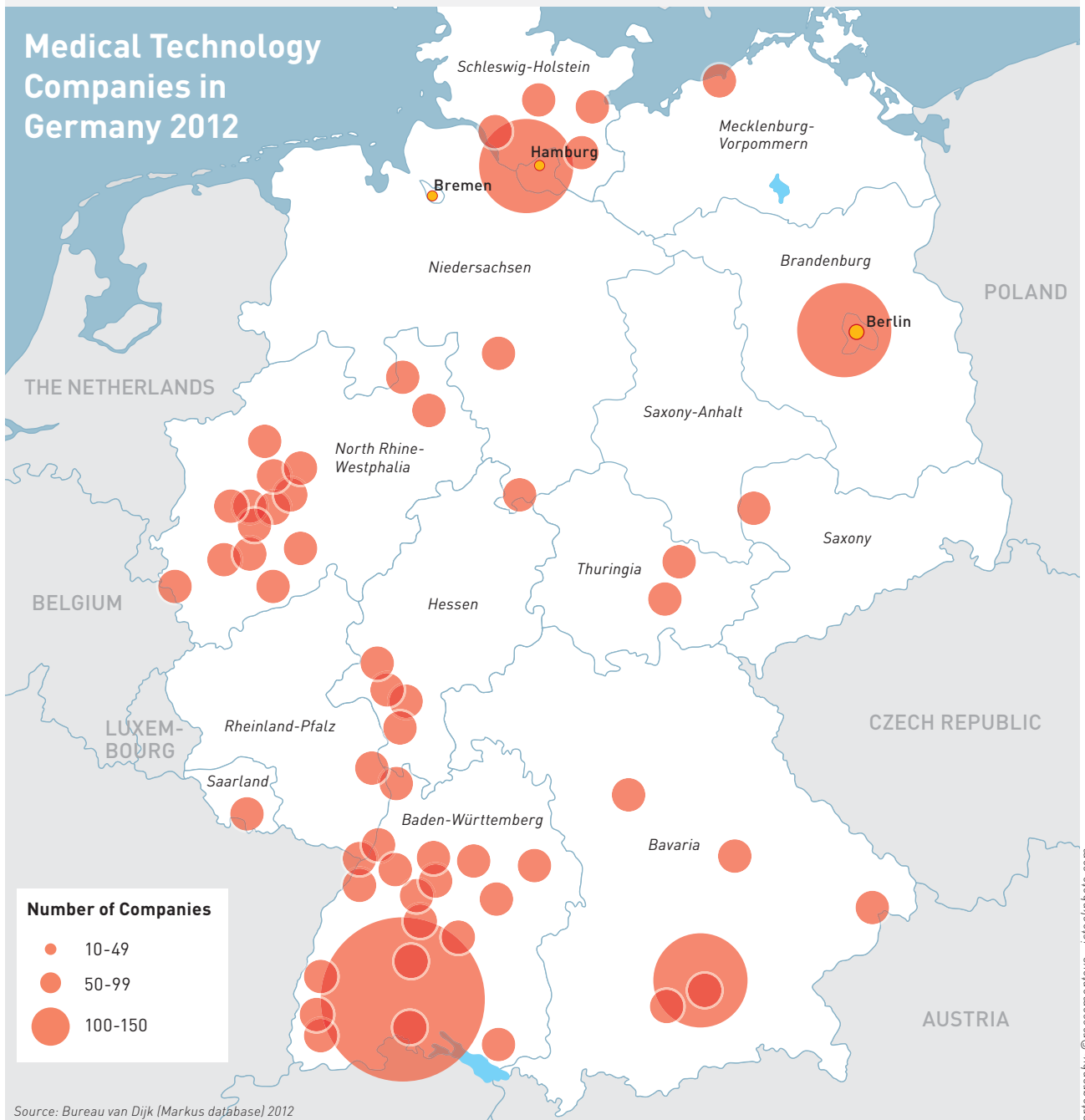
The BMWi's Central Innovation Program SME (ZIM) is a nationwide funding program for SMEs and partner research establishments. The program has been open to all industry branches and technological sectors as a source of support for innovation efforts since 2008. Total grants available through 2014 are roughly half a billion euro. The maximum grant per applicant is EUR 350,000.

CUTTING-EDGE MEDICAL TECHNOLOGY IN GERMANY

Germany is home to an extensive network of medical technology companies. Highly interdisciplinary and research oriented in nature, the medical technology sector is characterized by highly innovative small and medium-sized enterprises.

Leading-edge medical technology clusters provide ideal conditions for technology transfer between scientific institutions and private sector companies.

Medical Technology Companies in Germany 2012



WORKFORCE

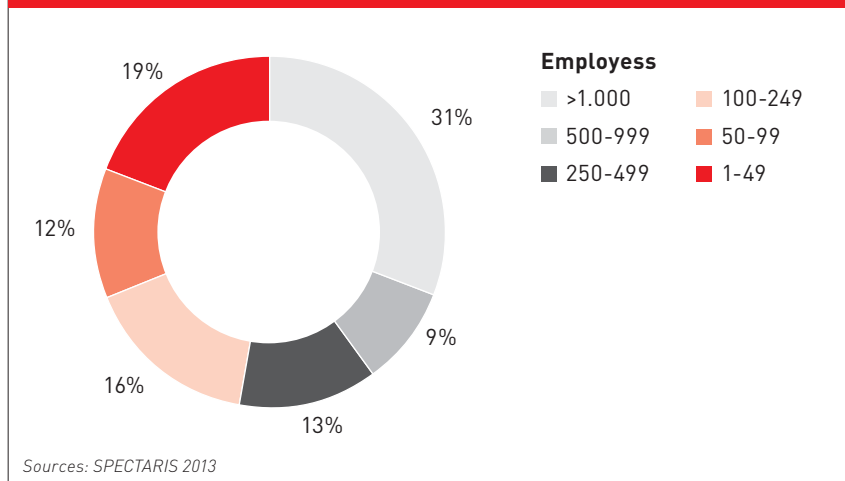
WORLD-CLASS EDUCATION STANDARDS

Germany's world-class education system ensures that the highest standards are always met. Eighty-four percent of the German population have been trained to university entrance level or possess a recognized vocational qualification – well above the OECD average of 67 percent. The country's dual education system – unique in combining the benefits of classroom-based and on-the-job training over a period of two to three years – is specifically geared to meet industry needs. The German Chambers of Industry and Commerce (IHK) ensure that exacting standards are adhered to, guaranteeing the quality of training provided across the country. Germany provides direct access to a highly qualified and flexible labor pool to meet industry needs while ensuring that skilled and unskilled workers are well prepared for the workplace.

DIVERSIFIED EDUCATION IN MEDICAL TECHNOLOGY

Academic training in the medical technology sector in Germany is of the highest caliber. In order to maintain and enhance the country's excellent medical technology R&D standards, key skills in engineering and natural sciences – and especially in information technology – are taught in medical technology training. Knowledge transfer and the continuous flow of researchers between public and private research institutions is one way of staving off the shortage of emerging young academic talent. In recent years the total number of students in German universities has been increasing, as has the share of students in natural sciences and engineering.

Employee Distribution by Company Size 2012



Numerous interdisciplinary courses for the training of medical technicians exist. Having obtained a vocational qualification in the metal or electrical industry, it is possible to gain further qualifications in medical technology. A number of universities also offer advanced courses as a supplement to the traditional technical fields of study. Individual programs in biomedical and clinical engineering are also available in universities of applied sciences.

THRIVING SME SECTOR

The German medical technology sector is largely made up of small and medium-sized enterprises. Ninety-seven percent of all medical technology firms in Germany employ less than 500 employees and 20 percent of all employees work in businesses with less than 50 employees. Big companies with more than 500 employees account for roughly 60 percent of total turnover in this sector. The small companies (less than 50 employees) account for around seven percent of total turnover.

With an average of 101 employees per company in 2012, the medical technology industry is typically more small and medium scale than is the case for German industry by and large - with an average employee number of around 134 in 2013. Based on the number of companies, sales, and total employment, it counts as a smaller industry within the manufacturing industry that has developed in dynamic fashion. However, in marked contrast to the overall manufacturing sector which has seen employment levels decline over the past decade, the medical technology industry workforce continues to grow.

INVESTMENT STABILITY

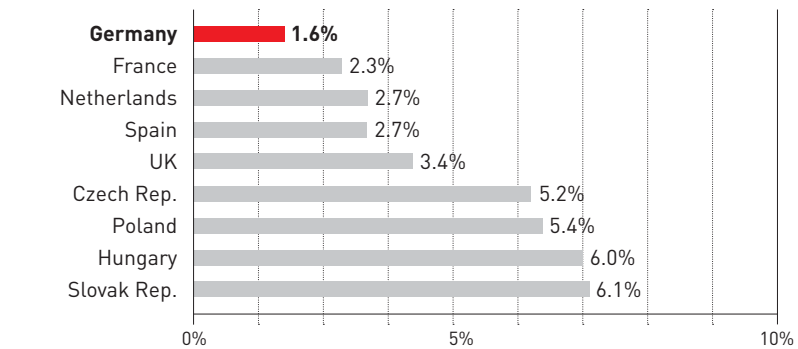
OPEN AND TRANSPARENT MARKETS

German law generally makes no distinction between German and foreign nationals regarding investments, available incentives or the establishment of companies. The legal framework for foreign direct investment in Germany favors the principle of freedom of foreign trade and payment. There are no restrictions or barriers to capital transactions or currency transfers, real estate purchases, repatriation of profits, or access to foreign exchanges.

RELIABLE LOGISTICS INFRASTRUCTURE

Germany's infrastructure excellence is confirmed by a number of recent studies including the Swiss IMD's World Competitiveness Yearbook and various UNCTAD investor surveys. The 2011-2012 Global Competitiveness Report of the World Economic Forum (WEF) ranked Germany second for infrastructure in the world; singling out Germany's extensive and efficient infrastructure for highly efficient transportation of goods and passengers for special praise. Accumulated in this score for Germany are high marks for the quality of roads and air transport, excellent railroads and port infrastructure, as well as its communications and energy infrastructure.

Labor Cost Growth in Total Economy 2003-2012



Annual average growth expressed as percentage of industry, construction and services.
Source: Eurostat 2013

COMPETITIVE LABOR COSTS

High productivity rates and steady wage levels make Germany an extremely attractive investment location. Labor cost increase levels have been the lowest in Europe in recent years. German productivity rates are more than five percent greater than the average of the EU's 15 core national economies, and more than one quarter higher than the OECD average. Highly flexible working practices such as fixed-term contracts, shift systems, and 24/7 operating permits contribute to enhance Germany's international competitiveness as a suitable investment location for internationally active businesses.

In economically challenging times, a safe and attractive investment like medical technology proves particularly attractive to investors. As a comparatively low-risk investment, the medical industry requires stable policy frameworks and sufficient legal stability. Germany is world renowned for its highly developed economic, legal and political frameworks which provide investors – in all industry sectors – with the necessary security for their business investments.

INTERNATIONALLY COMPETITIVE TAX CONDITIONS

Germany offers one of the most competitive tax systems of the big industrialized countries. For corporations the average overall tax burden is just below 30 percent. Significantly lower rates are available in certain German municipalities – up to eight percents less. The overall corporate tax burden can therefore be as low as 22.83 percent. Moreover, Germany provides an extensive network of double taxation agreements (DTA) ensuring that double taxation is ruled out, e.g. when dividends are transferred from a German subsidiary company to the foreign parent company.

FINANCING & INCENTIVES

In Germany, investment projects can receive financial assistance through a number of different instruments. These instruments may come from private sources or consist of public incentives programs available to all companies – regardless of country of provenance. They fit the needs of diverse economic activities at different stages of the investment process.

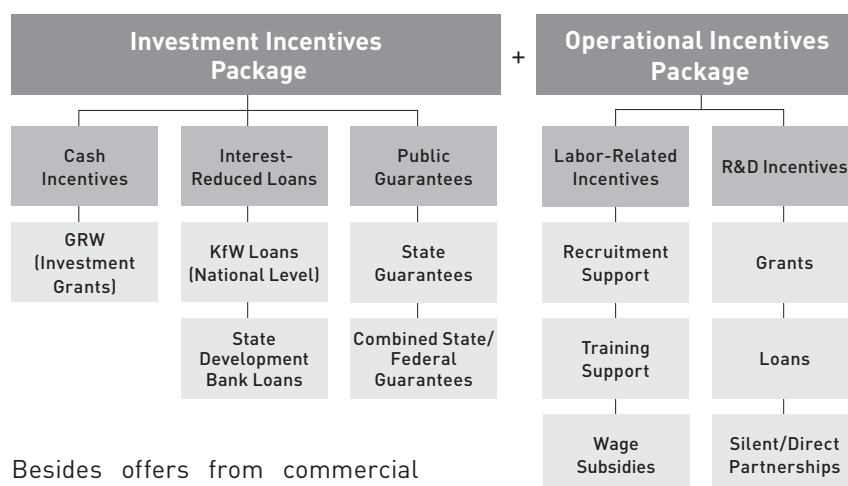
EARLY STAGE INVESTMENT PROJECT FINANCING

Technologically innovative start-ups in particular have to rely solely on financing through equity such as venture capital (VC). In Germany, appropriate VC partners can be found through the German Private Equity and Venture Capital Association (BVK). Special conferences like the German Equity Forum provide another opportunity for young enterprises to come into direct contact with potential VC partners. Public institutions such as development banks (publicly owned and organized banks which exist at the national and state level) and public VC companies may also offer partnership programs at this development stage.

LATER STAGE INVESTMENT PROJECT FINANCING

Debt financing is a central financing resource and the classic supplement to equity financing in Germany. It is available to established companies with a continuous cash flow. Loans can be borrowed for day-to-day business (working capital loans), can help bridge temporary financial gaps (bridge loans) or finance long-term investments (investment loans).

Types of Incentives in Germany



Besides offers from commercial banks, investors can access publicly subsidized loan programs in Germany. These programs usually offer loans at attractive interest rates in combination with repayment-free start-up years – particularly to small and medium-sized companies. These loans are provided by the state-owned KfW development bank and regional development banks.

INVESTMENT CASH INCENTIVES

When it comes to setting up production or service facilities, investors can count on a number of different public funding programs. These programs complement the financing of an investment project. Most important are cash incentives provided in the form of non-repayable grants applicable to co-finance investment-related expenditures such as new buildings, equipment or machinery.

LABOR INCENTIVES AND R&D PROJECT GRANTS

Once the location-based investment has been initiated, companies can receive further subsidies to help put together a workforce or for deployment in R&D projects. Labor-related incentives play a significant role in reducing the operational costs incurred by new businesses. The range of programs offered can be classified into three main groups: programs focusing on recruitment support, training support, and wage subsidies respectively. R&D project funding is made available through a number of different incentives programs targeted at reducing the operating costs of R&D projects. Programs operate at the regional, national, and European level and are wholly independent from investment incentives. At the national level, all R&D project funding has been concentrated in the High-Tech Strategy to push the development of cutting-edge technologies. Substantial annual funding budgets are available for diverse R&D projects.



“HEALTH - MADE IN GERMANY”

Health – Made in Germany is where partners from abroad should look first to discover how they can gain access to and benefit from Germany’s commitment to innovation, quality and reliability in health care. The initiative provides information, links partners, and paves the way to applying German know-how to serving people around the globe. Especially small and medium-sized companies can benefit from a wide range of services to support their international business activities. The website www.health-made-in-germany.com is the place to start looking for the latest information about Germany’s health care industry and what it can do for you – it provides an overview of the industry as well as information about international markets and industry events.

The initiative is designed to meet the industry’s specific needs with a focus on pharmaceuticals, medical technologies, medical biotechnology, telemedicine, and health care services.

“Health - Made in Germany” is an initiative by the Federal Ministry of Economics and Technology.



SPECTARIS

SPECTARIS is the German industry association for the high-tech medium-sized business sector and representative body in the areas of medical technology, optical technologies and analytical, biological, laboratory, and ophthalmic devices. Innovation and growth characterize the different industry sectors. Technologies developed here are used in almost all branches of industry, making them an important motor for the German economy.

In the medical technologies sector, SPECTARIS represents around 150 German capital goods and auxiliary aid companies who mostly produce high-tech products and have a pronounced export orientation. Member companies cover an extensive research and applications environment which includes medical products for diagnostic and surgery purposes to supply systems and anesthesia and intensive care devices. The association also represents manufacturers of ophthalmic devices, large and small sterilisators, medical functional room equipment, respiratory home therapy, rehabilitation aids, and orthopedic technology.



BVMed

BVMed, the German Medical Technology Association, represents about 220 manufacturers and service providers of medical devices. The medical technology industry in Germany amounts to EUR 23 billion and employs about 170,000 people.

BVMed represents the entire range of medical technologies, including wound management products, technical aids such as ostomy and incontinence products or bandages, plastic disposable items such as syringes, catheters and cannulae, as well as the implant field of intra-ocular lenses, hip, knee, shoulder and spinal implants, pacemakers and defibrillators and even artificial hearts. Homecare services and biotechnology procedures, such as tissue engineering, are further fields of activity.

Germany Trade and Invest would like to thank its partners for their support and information provided for this publication.

GERMANY TRADE & INVEST HELPS YOU

Germany Trade & Invest's teams of industry experts will assist you in setting up your operations in Germany. We support your project management activities from the earliest stages of your expansion strategy.

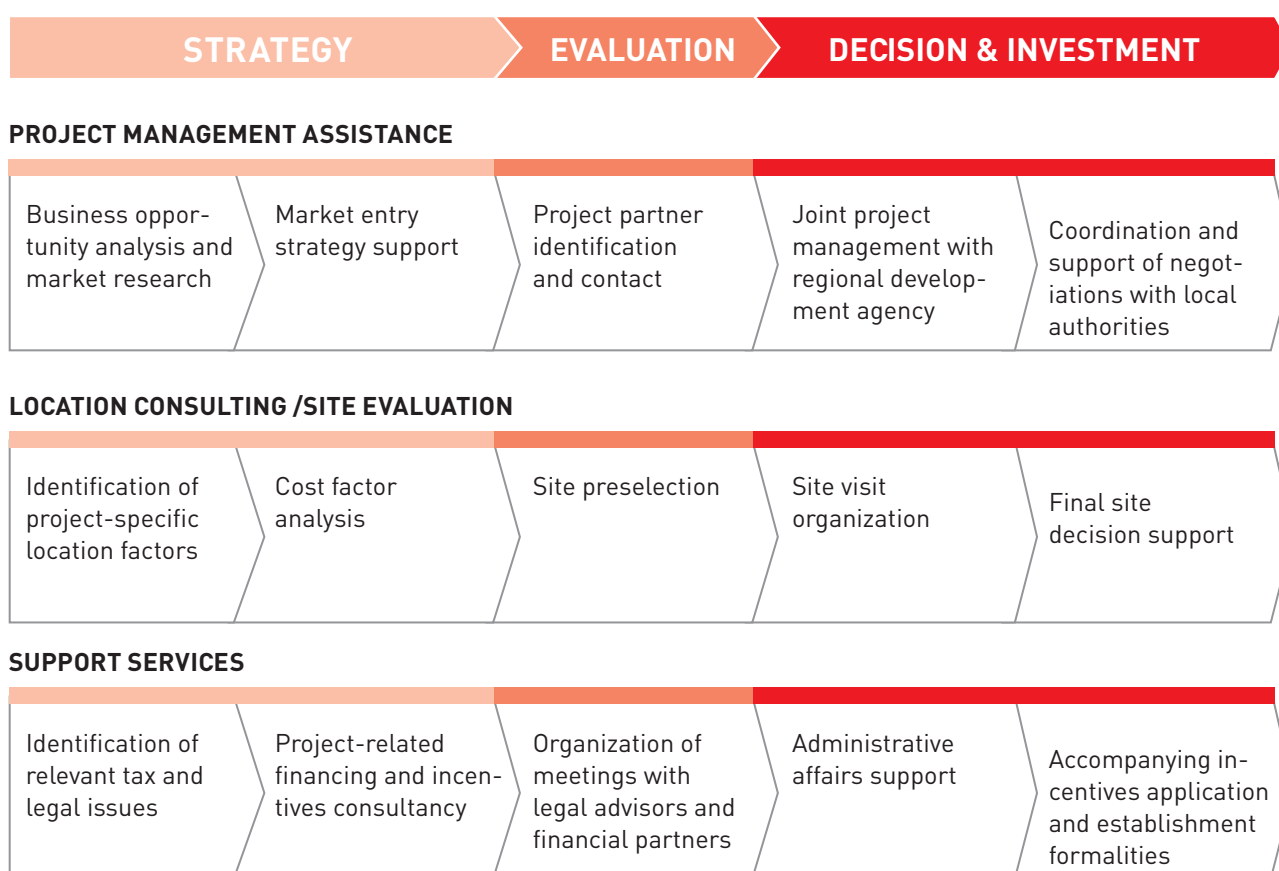
We provide you with all of the industry information you need – covering everything from key markets and related supply and application sectors to the R&D landscape. Foreign companies profit from our rich

experience in identifying the business locations which best meet their specific investment criteria. We help turn your requirements into concrete investment site proposals; providing consulting services to ensure you make the right location decision. We coordinate site visits, meetings with potential partners, universities, and other institutes active in the industry.

Our team of consultants is at hand to provide you with the relevant background information on Germany's tax and legal system, industry regulations, and the domestic labor market. Germany Trade & Invest's

experts help you create the appropriate financial package for your investment and put you in contact with suitable financial partners. Incentives specialists provide you with detailed information about available incentives, support you with the application process, and arrange contacts with local economic development corporations.

All of our investor-related services are treated with the utmost confidentiality and provided free of charge.



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