INTERNATIONAL TRADE ADMINISTRATION

# 2016 Top Markets Report Medical Devices Country Case Study

## Germany

**Germany has a long history of producing high quality medical equipment, with a particular emphasis on diagnostic imaging, dental products and optical technologies. Not only is Germany the third largest market in the world after the United States and Japan, but is also by far the largest European market, twice the size of the French market and three times as large as those of Italy, the United Kingdom and Spain.**

**Overall Rank**

**1**

Germany has a strong healthcare system in terms of infrastructure, hospital beds and trained staff. There are 500,671 beds in 1,996 hospitals (around 596 public hospitals, 706 non-profit and 694 private hospitals), 2,000 medical supply stores, 1,187 rehabilitation centers, 21,062 pharmacies and 150,000 doctors' offices. Well-established infrastructure makes the healthcare industry the largest employer in Germany with currently 6.2 million employees. Another 4 million jobs depend on the healthcare sector. One out of five jobs in Germany is linked to the healthcare sector.

Accordingly, German healthcare expenditures are comparatively high but also increasingly cost-contained. In 2013, total expenditures increased 4 percent to EUR 314.9 billion, roughly 11.2 percent of GDP. In *per capita* terms, expenditure is estimated at EUR 3,910, exceeded only by Denmark, the United States, Switzerland and Norway.

Approximately 76.8 percent of healthcare spending is sourced from the public sector, mostly from statutory health insurances. As public health insurance funds continue to record deficits averaging

EUR 3.3 billion and public hospitals operate at a loss, health reforms and cost-cutting measures keep the market tight with increased pressure on prices. Hospitals in the public sector are pressed to maintain existing equipment rather than investing in new

*Country Highlights*
*Capital:* Berlin
*Population:* 83.8 million (2013)
*GDP:* $3.4 trillion (2013)
*Currency:* Euro (EUR/€)
*Language:* German
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units. Private hospitals, now at 30 percent of total hospitals in Germany, as well as the more than 60 university hospitals with specialized departments, seek price-competitive, state-of-the-art technologies and equipment offering proven cost savings.

Taking into account the heightened scrutiny on spending within certain sectors, the German healthcare industry offers high growth potential and provides opportunities for U.S. medical technology exports. The Federal Ministry of Economics anticipates that by 2030, an additional 2 million people will be employed in the healthcare industry. Current austerity measures are likely to hit the pharmaceutical industry harder than the medical device industry, which continues to be a job engine

and is expected to achieve steady growth over the next five years with annual growth rates of 3 to 4 percent. In 2012, over 51 percent of German healthcare technology manufacturers reported to have created new jobs with a very positive outlook for future growth.

According to the German Advanced Medical Technology Association (BVMed), the medical devices industry employed 195,000 persons with a market valued at EUR 25.19 billion in 2014. The German market accounts for 40 percent of the entire EU market for medical devices.

For general statistical information published by the German Federal Statistics Office, please visit ***destatis.de/EN***.

**Market Entry**

Distribution Practices

Most medical equipment imported into Germany is either sold directly through a local subsidiary with a field sales force, through medical distributors with an established distribution network or through appointed agents or manufacturer representatives. Local representation or market presence is essential when considering differing standards and certifications, warehousing costs, maintenance, accessibility and local marketing/sales preferences/discussions. An agreement for a representative party or agent is often a cost effective mechanism to enter the market, but under German law—even if the agent's performance is not satisfactory—it can be difficult and costly to terminate the agreement, particularly under an exclusive arrangement. A representation or distributorship agreement may be harder to arrange, but the German associate will generally purchase the product which is to be sold, thus sharing the marketing risk. Finding a mid-size distributor covering all of the German, or German-speaking, market has become more difficult because large manufacturers have increasingly acquired experienced distributors to gain access to established distribution channels rather than developing those themselves. For example, GE Healthcare has acquired Medicalis and Idel, and Donjoy has acquired Ormed, among others. As Germany's healthcare market is decentralized and regional, it may therefore be a viable alternative to seek regionally active and well-established dealers or distributors for northern, southern and eastern Germany with defined territories.

In addition to complying with standards, U.S. companies must meet additional criteria to assure product acceptance recognition and marketability when trying to enter the German market. For example, product information and technical data sheets must be provided in German.
Companies should also provide operation and instruction manuals in German to ensure proper understanding and usage of equipment, as well as provide reliable after-sales servicing and product support or select qualified agents or distributors who are capable of providing quality service. U.S. companies should maintain close contact and good feedback with agents and dealer/distributors in Germany in order to stay informed about market developments, trade issues, regulations and laws concerning their products.

Product Standards

The German market for medical devices is regulated by German and EU directives, standards and safety regulations. The requirements are complex and based on environmental, consumer health, safety and social concerns. Not all standards are mandatory, but compliance greatly enhances a product's marketability. Advice on the requirements and compliance certification in the case of a specific product should be sought from the below referenced sources.

The German Medical Devices Act (MPG) of 1994 was amended in August 2015. It applies to all equipment, instruments, devices and materials used on or in the human body and is applicable when seeking approval for a device to enter the German market. Exceptions include those devices that achieve their intended effect pharmacologically. About 400,000 different medical products fall under this legislation. The MPG implements EU directives covering medical and diagnostic products. Devices complying with the MPG or its equivalent laws in other EU countries must carry CE Marking. Devices with CE Marking have the advantage of being permitted on the market anywhere in the EU without further certification requirements.

Packaging and Labeling

The European Union does not set packaging and labeling requirements in general, only setting them in very specific high-risk product related cases. In the absence of any EU-wide rules, the exporter has to consult national rules or inquire about voluntary agreements among forwarders, which affect packaging and labeling of containers and outer packaging. The importer or freight forwarder is the first point of contact for shipping documents and outer packaging/labeling. EU customs legislation only regulates administrative procedures, such as type of certificate and the mention of rule of origin on the customs forms and shipping documents.

Payment and Financing Practices

In Germany, the period allowed for payment is between 30 and 60 days. Early payments are often credited with a 3 percent discount, and supplier credits in the form of LoCs are common. Practices regarding financing, availability of capital and payment schedules are comparable to those in the United States. There are no restrictions or barriers on the movement of capital, foreign exchange earnings or dividends. Most major U.S. banks are represented in Frankfurt, the country's financial hub. Similarly, a large number of German banks, including some of the partially state-owned regional banks, maintain subsidiaries, branches and/or branch offices in the United States. Germany is not eligible for support from OPIC, TDA or similar agencies.

Tariffs and Import Regulation

There is no import duty on medical devices; a 19 percent import turnover tax is payable at the port entry. For customs clearance, a product description is required describing the use, origin and value of the product. The cost of the import-turnover tax is usually offset by ultimately passing it on to the end-user in later distribution stages in the form of a Value-Added Tax (VAT), which is known in Germany as Mehrwertsteuer (MwSt).

**Current Market Trends**

The current German government has proposed several new health plans to improve and ensure the quality of hospitals and doctor offices and provide the best healthcare to patients of any age group. As of January 2015, it is mandatory for each insured person to have an electronic health card, which stores personal patient data. The new Care Provision Strengthening Act (Versorgungsstärkungsgesetz) creates incentives for doctors to open their offices in rural areas due to a demographic aging among medical staff and resulting shutdowns of general practitioners' offices. In addition, the Hospital Structuring Act (Krankenhausstrukturgesetz) stipulates quality standards for hospitals and their review and screening. Large scale cost savings and further hospital efficiencies and consolidation are expected as a result.

**Main Competitors**

The German market for medical devices is sophisticated and well-served. Germany has a handful of large producers, headed by Siemens, B. Braun and Fresenius. Ninety-five percent of the German medical technology industry is characterized by small and mid-sized (SME) companies or sub-groups of larger companies. Almost 1,200 SME companies employ over 125,000 people, and 11,300 smaller companies employ around 75,000 people. Ninety-five percent of all companies employ less than 250 employees, and rarely does one company represent more than 2 percent of the entire sector. In addition, foreign industry giants such as Philips® (Netherlands), Hitachi® (Japan) and Toshiba® (Japan) are well entrenched in the market. GE Healthcare Technologies®, Medtronic®, Agilent®, 3M Healthcare®, Hollister®, Johnson & Johnson® and Medline® are only a few of the many German subsidiaries of U.S. medical device suppliers.

As a developed market, the German medical technology industry relies on export markets for continued growth. On average, German medical technology companies export between 60 percent and 65 percent of their products. In 2014, foreign sales rose by 2 percent, and the exports reached 68 percent of local production. Around one-fifth of these exports went to the United States. Next to this strong German manufacturing base, imports supply around three-quarters of the German medical market ($16.7 billion). Between 2007 and 2011 medical device imports recorded a CAGR of 6.6 percent in Euro terms and 7.0 percent in dollar terms. U.S. medical device exporters to Germany continue to hold a 27 to 30 percent import market

share, depending on the product. U.S. suppliers of innovative and price-competitive products especially can compete strongly on the German market.

**Current Demand**

There is a stable demand for high quality advanced diagnostic and therapeutic equipment, innovative technologies and minimally invasive equipment in vascular surgery, urology, gastroenterology, dermatology and neuro-surgery. Major trends are wearable and wireless medical technologies. At the same time, the demand for specialized software to protect wireless medical devices and healthcare systems against cybercrime and malware is expected to increase. Furthermore, the German medical market experiences a clear trend toward personalized medicine based on individual patient requirements. This reflects on medical packaging with increased demand for flexible and compact packaging machines.

The trend is toward miniaturization of electro-medical equipment and nanotechnology products. New technologies in emergency and first responder care along with computer-assisted surgery are widely discussed among the German medical community. Germany is also proactive in coming up with solutions to address the aging population; therefore, there will be an uptick in demand for diagnostic equipment to detect chronic diseases in their early stages in order to prevent higher costs. It will also spur the demand for specialized wound care and easy-to-use homecare products for diabetes, orthopedic appliances and dialysis equipment. Third, big data technology is in high demand in all segments and in the context of evaluating data for new therapies and cost-containment measures as well as healthcare prevention.

**Registration Process**

The EU Commission, appointed in November 2014, is expected to consider a fundamental revision of the regulatory framework for medical devices after 2018 or 2019.

CE Marking is a legal requirement for a wide range of equipment manufacturers in Germany. CE Marking signifies that a product fulfills all necessary EU regulatory requirements. Certification requirements for use of CE Marking vary depending on the product. For some, such as those in the MPG low risk class I, the manufacturers (or importer/ authorized representative, if the product is manufactured outside the EU) may self-certify compliance with EU requirements and affix the mark. For others the certification of a "notified body" (an accredited certification agency such as TUV) will be required. For the medical aids sector, the workability and safety of a product is now considered satisfied by CE Marking. CE Marking is a visible indication that the manufacturer signed a "Declaration of Conformity" that requires it to perform all assessment testing prior to affixing the symbol, claiming compliance with all relevant CE Marking directives in force.

All electro-medical equipment in Germany must be suitable for use with 220 Volt, 50 cycle electrical current and should have VDE or TUEV approval. A UL approval is not a substitute but is helpful to obtain "GS/VDE," or GS/TUEV" approval in Germany. "GS" stands for "*gepruefte Sicherheit*" (safety tested). Although "GS" and the "VDE" (or "GS and TUV") marks are not required by law, they are highly recommended for marketing electro-medical goods in Germany.

The U.S. Product Safety Testing Institute, Underwriters Laboratories (UL), the VDE Testing and Certification Institute and TUV Product Service have formed a strategic alliance for testing of electromagnetic compatibility (EMC), which has resulted in the globally recognized EMC test mark. For manufacturers of electrical and electronic products, this cooperation has led to a substantial simplification of EMC testing. Through a single test carried out by one of these three partners, a product can now be awarded an international EMC mark, which replaces the national test marks in the major world markets of Europe, the United States and Japan.

**Barriers**

Companies exporting medical devices to Germany will not encounter any direct trade barriers or quotas. Non-tariff, indirect trade barriers could include the complex German reimbursement system or the need for additional registration procedures, for example, in the case of medical assistive technologies or products sold in pharmacies, with the requirement to apply for HMV or PZN codes, respectively. For Class 2 medical products, the

German medical products law requires manufacturing and distribution control/quality control documentation.

**Trade Events**

*BIOTECHNICA*
October • Hanover, Germany • **biotechnica.de** Europe's leading trade fair for biotechnology, life sciences and laboratory equipment. More than 600 exhibitors.

*REHACARE*
September–October • Düsseldorf, Germany • **rehacare.de** Europe's premier rehabilitation and care event. Open to the public. Approximately 50,000 visitors and 805 exhibitors from 32 countries.

*A+A (Safety + Health at the Workplace)*
October • Düsseldorf, Germany • **aplusa-online.de** The world's largest and most important specialist trade fair for all aspects of safety and security. Includes safety, security and health management, including prevention and therapy of work-related illnesses. More than 55,000 visitors and more than 1,600 exhibitors.

*MEDICA with Compamed*
November • Düsseldorf, Germany • **medica.de** • **compamed-tradefair.com** Considered the world's most important and largest international fair for medical equipment. Medica attracts 147,000 trade visitors from more than 70 countries and over 4,500 exhibitors from 80 countries. Compamed, the marketplace for suppliers to the medical manufacturing industry, attracts 600 exhibitors from 40 countries.

*FIBO*
April • Cologne, Germany • **fibo.de** The world's leading trade show for fitness, wellness and health. More than 80,000 visitors from 100 countries and more than 650 exhibitors from 38 countries.

*OTWorld*
May • Leipzig, Germany • **ot-leipzig.de** Innovative technology, new products and high quality professional training. The orthopedic and rehabilitation industry's leading event worldwide. More than 19,500 international visitors and 537 exhibitors.

*IDS (International Dental Show)*
March • Cologne, Germany • **english.ids-cologne.de** The world's leading trade show for the dental industry, including dental practices, dental labs and the specialist dental trade. More than 125,000 visitors from 150 countries; more than 2,000 exhibitors from 56 countries.

**Additional Market Research**

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*BVMED Annual Report (2014–15)*
https://www.bvmed.de/print/de/bvmed/publikationen/jahresberichte/bvmed-annual-report-2015

*Ernst & Young Medical and Biotech Reports*
http://www.ey.com/GL/en/Industries/Life-Sciences