INDUSTRY OVERVIEW

The Medical Technology Industry in Germany

ISSUE 2020
Europe’s Biggest Healthcare Market

“Germany is an extremely important market for Aerogen, and we look forward to continuing to strengthen our commitment here. With an in-country office, and an experienced team we are working closely with our customers and partners to meet their individual needs and grow together.”

John Power
CEO and Founder | Aerogen

**EUR 30 bn**
sales generated by Germany’s medical technology industry in 2018

**EUR 387 bn**
total annual health expenditure in 2018 – more than 11% of GDP

**~100%**
of Germany’s 82 million residents are covered by health insurance

**EUR 2/3**
of medical technology sales in export markets in 2018

**EUR 60 bn**
domestic out-of-pocket healthcare market in 2018

**88%**
of Germans are enrolled in a public health insurance plan

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 devices 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. This is especially the case in the medical device sector. In 2018, almost 70 percent of medical technology products made in Germany were exported to international markets.

Domestically, more than 99 percent of the country’s 82 million residents are covered by health insurance. German health insurers cover around two thirds of Germany’s total annual health spend of EUR 387 billion (or 11.4 percent of GDP). The out-of-pocket market is worth around EUR 60 billion.

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 1,500 billion.
The Medical Technology Industry in Numbers

Medical Technology Made in Germany
The German medical technology industry, made up almost entirely of small and medium-sized enterprises, is highly innovative and generates a significant share of its revenues from exports. In 2018, the approximately 1,300 medical device manufacturers (>20 employees) and their 140,000 employees generated more than EUR 30 billion in sales – an increase of more than four percent over the previous year. Export markets are particularly important to German companies – around two thirds of sales in 2018 were generated outside the domestic market. Exports grew nearly six percent to a total of more than EUR 20 billion in 2018. Germany is the world’s largest manufacturing nation and enjoys 9.9 percent share of worldwide medical technology production. This is in second place behind the USA (38.9 percent) and before Japan (8.9 percent) and China (8.1 percent) respectively.

Growing Export Demand
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 actually stays within Europe. Approximately 42 percent of German exports go to EU member states and another nine percent to other European countries. Nineteen percent of exports are shipped to North America and Asia respectively.

Setting International Standards
Close collaboration between science and industry has helped establish Germany’s medical technology sector as an international beacon of quality, performance and safety standards. A number of institutions – including the German Joint Federal Committee (JFC) and notified bodies like TÜV and DEKRA – are responsible for ensuring the safety and reliability of medical technology products and services produced in Germany. The industry is also subject to EU directives and regulations governing certification and marketability. Implementing essential industry norms including ISO 13485 (regulation of quality management systems) and ISO 14155 (clinical evaluation of medical technology) are common practice. All of this leads to medical technology developed and made in Germany that meets the highest quality standards.

Innovative Cluster Networks
Germany is home to more than 30 specialized cluster networks focusing on medical technology. Their goal is to achieve continuous innovation in research and development as well as in manufacturing by connecting companies, hospitals, universities, and other research institutions. Dedicated cluster management teams help obtain funding for joint R&D projects, provide share facilities, and organize educational training programs for their members.

*estimat
Source: German Medical Technology Association (BVMed) 2019

German Medical Device Manufacturer Revenue Development
in EUR billion

<table>
<thead>
<tr>
<th>Year</th>
<th>Revenue generated abroad</th>
<th>Revenue generated inland</th>
</tr>
</thead>
<tbody>
<tr>
<td>2014</td>
<td>9.0</td>
<td>16.4</td>
</tr>
<tr>
<td>2015</td>
<td>10.0</td>
<td>17.6</td>
</tr>
<tr>
<td>2016</td>
<td>10.6</td>
<td>18.6</td>
</tr>
<tr>
<td>2017</td>
<td>10.8</td>
<td>19.1</td>
</tr>
<tr>
<td>2018</td>
<td>11.25</td>
<td>20.25</td>
</tr>
</tbody>
</table>

*estimat
Source: German Medical Technology Association (BVMed) 2019

German Medical Technology Exports by Destination 2017
in percent

<table>
<thead>
<tr>
<th>Destination</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>European Union</td>
<td>42</td>
</tr>
<tr>
<td>North America</td>
<td>19</td>
</tr>
<tr>
<td>Asia</td>
<td>19</td>
</tr>
<tr>
<td>Europe (non-EU)</td>
<td>9</td>
</tr>
<tr>
<td>Other</td>
<td>11</td>
</tr>
</tbody>
</table>

Source: BVMed 2019
Healthcare in Germany

Healthcare Expenditure
Healthcare expenditure in Germany totaled EUR 387 billion in 2018, representing a more than three percent increase on the previous year’s spending level. The amount is equivalent to 11.4 percent of GDP or approximately EUR 4,600 per capita.

Health Insurance
With around 88 percent of the German population enrolled in a public health insurance plan, the public health insurance system plays the dominant role in the allocation of healthcare funds. Eleven percent of the population opt for private health insurance, with less than 0.2 percent of the population having no insurance cover.

Public health insurance providers covered EUR 221 billion or approximately 57 percent of total healthcare expenses in 2018. Private health insurance companies reimbursed an additional EUR 32 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
In 2017, outpatient care accounted for more than 50 percent of annual health expenditure. The most significant outpatient facilities include doctor’s offices (EUR 55 billion) and pharmacies (EUR 49 billion). Inpatient and partial inpatient institutions account for EUR 13.4 billion of total expenditure, of which EUR 94.7 billion was incurred by hospitals.

Hospital Care
In Germany, 1,942 hospitals – with total capacity of more than half a million beds – treated more than 19 million patients in 2017. The average hospitalization period was 7.3 days. The country also had approximately 1,142 preventative care and rehabilitation facilities with nearly 165,000 beds treating around two million patients. The average rehabilitation stay was 25.4 days. In order to build up the necessary infrastructure, more than 1000 ambulatory healthcare centers (Medizinisches Versorgungszentrum - MVZ) have been established on campus by hospitals in Germany. According to the German Hospital Federation, hospitals also provide specialized ambulatory care in some 20 million cases each year.

International Patients
Some 10 percent of German hospitals have a specifically international focus and existing services dedicated to patients from abroad. Doctors with outstanding qualifications, highly specialized nursing staff, excellent diagnostics facilities, and a superb medical infrastructure together ensure that German hospitals offer the highest quality medical care.

Key Market Data 2018
- More than 99 percent of Germany’s 82 million residents are covered by health insurance
- Total annual health expenditure: EUR 387 billion (11.4% of GDP)
- Hospital expenditure: EUR 94.7 billion
- Outpatient expenditure: EUR 95.5 billion
- Number of hospitals: 1,942 (one third private ownership)
- Number of hospital beds: 497,200
- Diagnosis Related Group (DRG) System (hospital sector): 1,292 DRGs, 205 additional remuneration titles
- Number of active medical doctors: 392,400
- Number of dentists: 64,925

Total Annual Health Expenditure 2018
in EUR billion

<table>
<thead>
<tr>
<th>Country</th>
<th>Total Expenditure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Germany</td>
<td>EUR 387 billion</td>
</tr>
<tr>
<td>France</td>
<td>EUR 263 billion</td>
</tr>
<tr>
<td>UK</td>
<td>EUR 207 billion</td>
</tr>
<tr>
<td>Italy</td>
<td>EUR 155 billion</td>
</tr>
<tr>
<td>Spain</td>
<td>EUR 107 billion</td>
</tr>
</tbody>
</table>

Source: OECD 2019
Medical Technology Trends

**Germany’s Hidden Champions**
German medical technology is cutting edge. A diversity of companies – nearly all of them small and medium-sized – develops and commercializes innovative devices across the range of more than 500,000 individual products within the medical technology spectrum. Many specialize in very specific fields of application and product types. While these companies may focus on niche markets, they are often global leaders in their respective fields. Germany’s medical technology R&D infrastructure is highly valued as a resource that allows these innovative companies to adapt quickly to global market trends.

**Demographic Change**
Germany’s over-65 population will increase to 24 million by 2035. As such, 65-year-olds will represent a third of the domestic population – with people aged 50 years and older accounting for half of the total population. Long neglected as consumers of private consumer goods and services, yesterday’s senior citizens have become today’s “golden agers.” Companies who establish a foothold in Germany’s forerunner “silver economy” are well positioned to launch into European and international markets.

**Telemedicine**
Telemedicine is making further inroads into the German healthcare system. This is a development that could result in annual savings of EUR 5.6 billion according to McKinsey & Company. Seven of Germany’s 16 federal states already permit remote medical treatment by digital means, giving rise to a growing number of telemedicine service providers.

**Cara Care**
The Berlin-based start-up offers a digital therapy that alleviates the symptoms of digestive disorders for 86 percent of the patients who use its service. This consists of an app-based questionnaire and “food diary” as well as individual analyses and consultations with nutrition advisers via video chat.

**Teleclinic**
This Munich-based start-up allows people with private health insurance to consult doctors via smartphone app, video call, chat and normal telephone call. The costs are already covered by some insurance providers in the same way as a traditional visit to the doctor’s office. Additional health insurance providers are expected to follow suit in the near future.

Industry Spotlight – Germany is Europe’s Dental Land

Many segments within the German medical technology sector reflect changing trends relatively quickly. Germany’s dental sector is a particularly relevant example for early innovation adoption. Around half of all medtech manufacturers in Germany are active in the dental sector in addition to orthopedics, digital imaging, disposables etc. The “dental” sector occupies second place – behind X-ray equipment – in the country’s medical technology manufacturing sector. More than 60 thousand different products cover the complete spectrum of dentistry – from diagnostics through preventive medicine to tooth restoration. Germany spends more on dental health per capita than any other country in the European Union, with some EUR 27 billion of overall health spending of EUR 384 billion in 2018 occurring in Germany’s dental practices.

Europe’s biggest dental market is expected to keep expanding thanks to growing dental health awareness among the population – with an increasing willingness and ability to pay for preventative and corrective treatments alike. The gap in unmet medical and cosmetic treatment need continues to rise as the population ages and has access to an increasing range of dental technology solutions. Price-sensitive patients and dental health consumers also benefit from the new economies of scale that are being created – especially in the lower price dental implant segment. Fully integrated CAD/CAM systems with 3D scanning technology, used both intraorally and in dental labs, together with novel ablative and additive manufacturing systems have accelerated the manufacturing process significantly.
MARKET OPPORTUNITIES

European and German Medical Device Regulation

CE Marking
International companies serving the German market are required to meet German and European health and safety legislation requirements. Specific German regulations must also be complied with in addition to European medical device directives (MDD) which from May 2020 is replaced by the European medical device regulation (MDR). Medical device manufacturers are required to declare conformity to European Union legislation (Conformité Européenne - "CE") for all devices with an intended medical purpose. The CE mark can be applied to the device once conformity has been declared.

MDD Conformity Assessment
Medical devices, unlike pharmaceuticals, are not certified by governmental institutions but by notified bodies working on their behalf. There are some 60 such notified bodies throughout Europe, of which 10 are headquartered in Germany (e.g. TÜV SÜD and DEKRA). In the case of low-risk products, the manufacturer can declare conformity with EU regulation without involving a notified body. The risk classification criteria are provided in Annex IX of the European Medical Device Directive 93/42/EEC which, together with the intended use, are the basis for risk classification in the individual case.

In addition to the fundamental legal framework provided by the EU, additional German regulation is in place for the following:

- Use and upkeep of medical products
- Prescription requirement and pharmacy requirement for medical products
- In-house-manufacturing of medical products
- Refurbishment of medical products
- Safety manager and medical products

New MDR Conformity Assessment
The European Commission initiated a revision of the existing regulatory framework for medical devices in 2012. The goal was to align the rules with the technological progress achieved since the early 1990s when the existing directives were put in place. It was also intended to harmonize national interpretations and to increase transparency for all involved stakeholders.

A transition time of three years was put in place effective from May 5, 2017, when the MDR text was published in the Official Journal of the European Union. From May 2020 onward, new medical devices can be certified only under the new European Medical Device Regulation (MDR - Regulation (EU) 2017/745). Given the maximum validity of a CE marking of four to five years, this leads to the disappearance of MDD CE markings by approximately 2025. Selected key revisions of the new MDR are:

- New risk classification rules according to Regulation (EU) 2017/745, Article 51, Annex VIII
- Specific risk reclassifications (some class I into class II, IIb into class III)
- Implant conformity assessment procedure for class IIb implants identical to class III
- Introduction of new risk class I "r" for reusable surgical devices. Unlike rest of class I products, self-certification is ruled out as notified body must be involved for conformity assessment
- Some devices without an intended medical purpose are treated as medical products. These are considered as being similar to medical devices in functioning and risk-profile. Annex XVI of the Regulation contains the list of the group of devices concerned.
- Enforcement of unannounced (supplier) audits for higher risk products
- Unique Device Identification (UDI) database with 21 elements of information per device
- Individual clinical trials necessary for class III
- Clinical information to be published in public EUDAMED database
- Notified bodies to produce clinical trial report
- New EU expert committee (Medical Device Coordination Group) may issue scientific statement based on clinical trial report of notified body
- Notified bodies to incorporate scientific statement (may provide certification with restrictions)
- Obligation for implementation of post-market surveillance systems

Medical devices made in Germany receive the CE mark indicating conformity with European standards.
Reimbursement in Europe and Germany

The first steps to accessing the European market usually include the declaration of conformity in compliance with the European Medical Device Regulation. However, having been approved for the European market, international manufacturers are then faced with national healthcare and cost reimbursement systems.

In Germany, manufacturers are confronted with a system that is characterized primarily by statutory health insurance and, to a lesser degree, private health insurance. Both statutory and private health insurance are financed through insurance premiums (paid jointly by the insured person, their employer, the national pension fund etc.). While most EU countries have a DRG system in place for the inpatient sector, there are a number of different institutions, financing and reimbursement systems in place across the 28 member countries in the union.

Innovation friendly DRG System

The innovation friendliness of the respective national health systems largely influences their uptake levels of new technologies or commercialization of new products. Germany’s inpatient system is especially innovation-friendly in terms of product safety requirements and the availability of immediate reimbursement. The German DRG system allows for any CE-certified medical device to be reimbursed under existing procedures and their DRG codes (unless prohibited in the individual case). While German authorities are merely executing a prohibition right in the inpatient sector, reimbursement of a novel technology in the outpatient sector is subject to approval in each product’s case.

Reimbursement for Inpatient Innovations

Pre-existing DRG codes and the corresponding fixed lump-sum budgets based on established technologies are not always sufficient to cover innovative device spending. Where this is the case, the German system offers the NUB procedure (Neue Untersuchungs- und Behandlungsverfahren - Novel Diagnosis and Treatment Procedures). With NUB status granted and individual OPS (Operations and Procedures Code) codes put in place, reimbursement can be increased significantly and a sustainable business case secured by the manufacturer. In 2016, the German health authorities introduced an additional scrutiny procedure within the Health Care Strengthening Act introducing § 137h Social Code Book (SGB) V. This reflects in part the stricter stance of the new European MDR aimed specifically at medical devices of increased risk class IIb and III or active implants with an especially invasive character. The G-BA (German Joint Federal Committee) is now required to perform benefit assessments for devices using a novel scientific-theoretical concept whenever an NUB procedure is initiated.

Outpatient Sector Reimbursement

There are two independent general agreements for the private health insurance and statutory health insurance systems in the outpatient sector, based on which a nationwide billing system for approved and paid services has been agreed. The Uniform Evaluative Standard ("EMB") is applicable for the statutory health insurance sector. According to § 135 Social Book Section 1 SGB V, the G-BA is required to assess and confirm the diagnostic or therapeutic benefit of novel diagnosis and treatment methods as well as the medical need for use and the product’s economic viability before a new method may be adopted in the EBM. Alternatively, individual contracts can be concluded between insurers and manufacturers for products not covered by the statutory health system.

Germany’s reimbursement system supports product innovation

German Market Access after CE Certification and Clarification of Reimbursement Status

<table>
<thead>
<tr>
<th>First step to take at EU level</th>
<th>CE certification (MDD/MDR)</th>
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</thead>
<tbody>
<tr>
<td>Second step to take at national level</td>
<td>German Act on Medical Devices (MPG) and reimbursement legislation Social Code Book 1 SGB V</td>
</tr>
<tr>
<td>In-patient sector</td>
<td>Reimbursability granted as long as basic principles of quality of care and/or efficiency are not violated</td>
</tr>
<tr>
<td>Out-patient sector</td>
<td>Reimbursability is subject to approval</td>
</tr>
</tbody>
</table>
Medical Technology Landscape in Germany

Industry Hotspots
Germany’s medical technology industry stretches across the entire country, with the town of Tuttlingen in the southwest perhaps being the most well-known of the country’s numerous medtech hotspots. The sheer density of device manufacturers there is often explained in terms of the local precision manufacturing heritage and, more specifically, cuckoo clock production. Different medical technology segments are dotted around the country, with medical optics, for example, being well represented in the eastern German city of Jena, with some globally leading manufacturers still bearing the city name in their own company names.

Promoting Partnership
The small and medium-sized company nature of most German medtech manufacturers makes cooperation with academic, scientific and other manufacturer partners a common element of company strategies. Pooled resources allow advantageous synergy effects to be effectively realized and research and product development costs to be cut through joint purchasing initiatives. The close proximity of medical universities, research institutions and large manufacturers to each other often constitutes the nucleus of local medtech clusters that support the industrial value chain at the local level. Today those medtech cluster networks, funded by national and regional governments, are equipped with staff and budgets of their own and represent the most significant landmarks in Germany’s medtech industry landscape.

European Cluster Excellence Initiative
The European Cluster Excellence Initiative (ECEI) was launched by the EU Commission in 2009 as part of the European Union’s efforts to foster growth and creation of world-class clusters across the EU. The European Secretariat for Cluster Analysis (ESCA) was subsequently established in order to offer practical advice to Europe’s cluster management organizations. Today, ESCA is a network of cluster experts from more than 30 countries that consults cluster policy makers and promotes cluster management excellence through benchmarking and quality labelling of clusters and their management organizations. In Germany, 10 cluster networks with activities in the medical technology sector have already been ECEI certified.

go-cluster Initiative
The Federal Ministry for Economic Affairs and Energy “go-cluster” excellence program brings together more than 100 innovation clusters from across Germany. Cluster members are at the cutting edge of innovation and represent the technological diversity within the country’s industry and technology sectors. The initiative provides financial stimulus – in the form of support for innovative services and funding for novel solutions – to optimize cluster management allowing member clusters to position themselves as highly effective and visible international clusters. Membership provides numerous advantages to innovation clusters, actors and partners.

Digital Hub Initiative
The Digital Hub Initiative, developed by the Federal Ministry for Economic Affairs and Energy, seeks to support the establishment of digital hubs in Germany. The underlying idea of establishing 12 digital hubs across the country is that cooperation between companies and business start-ups within a confined area will boost innovation in the digital age.
Medical Technology in Germany: Manufacturing Clusters

City or Area of Cluster Location
- 10-20 Companies
- 20-40 Companies
- 40+ Companies

Source: GTAI 2017 based on Marcus Datenbank, Bureau van Dijk
Europe’s Talent Pool

Engineering Tradition
Germany enjoys a long and successful tradition in mechanical medical engineering and high quality manufacturing. Medical technology companies and their employees alike can rely on Germany’s unique education system, which produces the largest pool of talents and skilled people in Europe. Most students enroll in the public university system, which is practically free of charge.

High Academic Uptake
According to the German Federal Statistical Office, Germany has a particularly high academic uptake rate. In the academic year 2018/2019, some 2.9 million students were enrolled at more than 426 institutions of higher education. Germany’s share of university students in the sciences, mathematics, computer sciences, and engineering is significant with 200,000 additional students in those fields of study in 2018. In the region of 40 percent of these students are pursuing courses in fields relevant for the medical technology industry, with over 500 individual university programs throughout the country related to medicine. There are more than 140 bachelor and masters programs for students to choose from in the medical technology field alone.

Dual Education System: Medical Technicians
Germany operates a dual vocational training system - combining the benefits of classroom-based and on-the-job training over a period of two to three years. A total of 323 different recognized trades can be learned with regard to medicine; with specific advanced training courses available to enable metal or electronics specialists to achieve status as recognized medical technicians. In close cooperation with the German government, the German Chambers of Industry and Commerce (IHKs) and the German Confederation of Skilled Crafts (ZDH) ensure that exacting standards are rigidly adhered to, guaranteeing the quality of training provided across Germany.

One in five German companies take part in the dual vocational training system, thereby turning apprentices into specialists who fit each company’s needs. Most apprentices receive an employment contract after training. More than 70 percent are taken on as employees in production-based industries underlining the importance of the training system. More than 1.3 million young people are currently in vocational training in Germany.

Competitive Labor Costs
High productivity rates and steady wage levels make Germany an extremely attractive investment location. The labor cost gap between Germany and its eastern European neighbors has been significantly reduced. In fact, Germany has gained the labor-cost edge in recent years.

Since 2005, wages in the manufacturing sector have risen in most European countries (EU-28), with the growth rate averaging 2.7 percent. While some countries – particularly in Eastern Europe – experienced a rise of more than five percent, Germany recorded one of the lowest labor cost growth rates (2.3 percent) in the manufacturing sector within the EU. This has been another decisive argument in favor of Germany as a premium business location. 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 globally active businesses.

Employee Distribution in the Medical Technology Industry in Europe 2017

<table>
<thead>
<tr>
<th>Country</th>
<th>Distribution in thousands</th>
</tr>
</thead>
<tbody>
<tr>
<td>Germany</td>
<td>200</td>
</tr>
<tr>
<td>France</td>
<td>85</td>
</tr>
<tr>
<td>UK</td>
<td>100</td>
</tr>
<tr>
<td>Italy</td>
<td>76</td>
</tr>
<tr>
<td>Spain</td>
<td>24</td>
</tr>
</tbody>
</table>

Source: Statista 2019
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 that 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).

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.

Incentives in Germany

<table>
<thead>
<tr>
<th>Funding purposes</th>
<th>Investments</th>
<th>Working Capital</th>
<th>Research &amp; Development</th>
<th>Specific Purposes</th>
<th>Personnel</th>
</tr>
</thead>
<tbody>
<tr>
<td>Financing supported by any of the following public funding instruments (combinations of instruments usually possible)</td>
<td></td>
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</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Public funding instruments</th>
<th>Grants</th>
<th>Loans</th>
<th>Guarantees</th>
<th>Equity Capital</th>
<th>Mezzanine Capital</th>
</tr>
</thead>
</table>
SUCCESS STORY

Best Practice Example: Aerogen

Germany Trade & Invest (GTAI) provides a range of inward investment-related services to international investors. After careful consultation with the individual investor, a support program of consultancy and information services – including market analysis, tax and legal information as well as partner and site selection – is provided to help set the stage for investment success.

Company Information
Founded in Galway, Ireland in 1997, Aerogen is one of the world’s leading medical device company specializing in the design, manufacture and commercialization of aerosol drug delivery systems. The company has partnered its technology with the world’s leading mechanical ventilation companies. More than eight million patients in over 75 countries benefit from more effective and efficient medical treatment made possible by the company’s innovative aerosol drug delivery technology.

Product Information
The company’s patented vibrating mesh technology turns liquid medication into a fine particle mist, gently and effectively delivering drugs to the lungs of critically ill patients of all ages. Aerogen’s products significantly improve aerosol drug delivery; resulting in better patient care across hospital intensive care and high-dependency units, emergency departments and wards as well as neonatal and pediatric departments. Delivering more than six times as much medication as traditional nebulizers, the aerosol drug delivery system effectively speeds up recovery times and reduces hospital admission rates.

Project Information
Aerogen established German subsidiary company, Aerogen GmbH, in November 2017. Since establishing its German presence, the company has expanded its international sales activities from its DACH market base, increasing its sales division to 12 employees.

Aerogen GmbH currently supplies over 350 hospitals in Germany, with the number increasing to 800 hospitals when accounts supported alongside premium OEM partners are included. The company has recorded year-on-year growth of 44 percent, generating EUR 14 million turnover in Germany. Strategic partnerships with leading companies in the mechanical ventilation sector play an important role in market acceptance of Aerogen’s nebulizer technology for application in aerosol drug delivery. A strong engagement of the Aerogen team in Germany and close collaboration with premium OEM partners has resulted in Aerogen achieving 30 percent growth on the previous year’s results on end-user sales in partners’ exclusive hospital accounts.

Market Expansion
Aerogen is seeking to consolidate its position in Germany by establishing its products as the gold standard across intensive care units (ICUs) in Germany, while growing its business from ICUs to wards for spontaneous patients, with particular focus placed on special treatment of illnesses including asthma and chronic obstructive pulmonary disease. The company’s core international business will continue its upward progression with high-growth opportunities targeted in new markets in Europe and beyond.

“We plan to continue to grow Aerogen as the gold standard across intensive care units in Germany. Additionally, we will grow our business from ICUs to wards for spontaneous patients, where we will focus on special treatment of illnesses such as asthma and COPD.”

Alyas Mussa, National Sales Manager, Aerogen GmbH
Industry Associations and Organizations

Germany Trade & Invest works closely together with the respective German industry associations to provide support to foreign medical technology companies seeking to settle in Germany.

Industry associations function as the local interest groups of business operators within a specific industry. They realize more than just the general functions of professional associations for their members. They also promote and represents the combined interests of the industry and trade companies; carry out active lobbying work by representing the interests of the company in their activities with municipal, state, and federal government authorities; offer various working groups as platforms for dialogue and exchange; and organize events and continuing education and training.

The associations also provide information about the local economic framework conditions in Germany and specific regions in the world. All members are also able to draw on the comprehensive advice and services of the responsible association. They are generally the first point-of-contact in the event of day-to-day business problems. Within Germany there are two associations dedicated to the medical technology sector.

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 160 companies in the industrial goods and appliances sector – predominantly small to medium-sized enterprises are positioned within the sectors of industrial goods and medical appliances. The medical technology trade association provides its members with support and information in various business areas and topics including financing, hygiene and processing, compliance, regulatory affairs, HTA, market access, research funding, and public affairs.

www.spectaris.de

BVMed
BVMed represents more than 220 industry and trade companies. Among the members of the association are 20 of the largest medical device manufacturers worldwide in the consumer goods sector. Its scope comprises the entire sector of medical dressings, technical aids such as ostomy and incontinence products or bandages, plastic disposable items such as syringes, catheters and cannulae as well as the implants sector of intraocular lenses, hip, knee, shoulder and spinal implants, heart valves and defibrillators and even artificial hearts. Homecare services and biotechnology procedures, such as tissue engineering, are further member fields of activity.

www.bvmed.de

"Health - Made in Germany“ Export Initiative
The “Health – Made in Germany” export initiative is the first address for international partners looking to discover how they can gain access to and benefit from Germany’s longstanding commitment to innovation, quality and reliability in health care. The Federal Ministry for Economics and Technology (BMWi) initiative bundles key information and provides vital business contacts to new and fruitful cooperation.

www.health-made-in-germany.com

Germany Trade and Invest would like to thank both associations for the support and information provided for the making of this publication.
Our services

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. Our 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.

Our support services for your investment project

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For questions on how to establish your business in Germany, please contact Gabriel Flemming at gabriel.flemming@gtai.com

For more information about the medical technology sector in Germany, please visit our website: www.gtai.com/medtech

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About Us
Germany Trade & Invest (GTAI) is the economic development agency of the Federal Republic of Germany. The company helps create and secure extra employment opportunities, strengthening Germany as a business location. With more than 50 offices in Germany and abroad and its network of partners throughout the world, GTAI supports German companies setting up in foreign markets, promotes Germany as a business location and assists foreign companies setting up in Germany. All investment services and related publications are free of charge.

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