Demand for innovative medical technology solutions continues to grow as we live longer, healthier lives. In 2017 spending on medical technology in Germany reached an estimated record high of EUR 36 billion. This creates growth opportunities for the medical technology industry, which in Germany is made up almost entirely of small and medium-sized companies. The positive outlook in the domestic market, combined with strong exports of “Medtech Made in Germany,” resulted in a 4.8 percent domestic industry revenue increase. The following information is designed to help international manufacturers understand how to expand in the German healthcare sector as well as outlining the range of support services provided by GTAI.

Medical Technology

Europe’s Biggest Market

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The Medical Technology Industry in Germany

Germany is the world’s third largest manufacturing nation with a share of 9.3 percent of worldwide medical technology production. More ▶

Fact Sheet: Medical Technology Cluster in Germany | © GTAI
Medical Technology Clusters in Germany
The publication provides a countrywide overview of more than 30 specialized medical technology clusters. Germany’s clusters provide benefits along the entire value chain. More

Facts & Figures

THE GERMAN MEDICAL TECHNOLOGY INDUSTRY IN NUMBERS (2017)

<table>
<thead>
<tr>
<th>Category</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sales</td>
<td>30.6 bn</td>
</tr>
<tr>
<td></td>
<td>4.8% increase in 2017</td>
</tr>
<tr>
<td></td>
<td>Lead market in Europe</td>
</tr>
<tr>
<td>Exports</td>
<td>64% (19.08 bn) of the production are exported, 2.5% increase in 2017. Target markets:</td>
</tr>
<tr>
<td></td>
<td>• European Union 41.6%</td>
</tr>
<tr>
<td></td>
<td>• Europe (non-EU) 9.3%</td>
</tr>
<tr>
<td></td>
<td>• North America 19%</td>
</tr>
<tr>
<td></td>
<td>• Asia 18.6%</td>
</tr>
<tr>
<td>R&amp;D Expenditure</td>
<td>9% of annual turnover in 2017</td>
</tr>
<tr>
<td>Employees</td>
<td>≥ 200.000; 15% in R&amp;D</td>
</tr>
<tr>
<td>Companies</td>
<td>Structure: approx. 1.250 manufacturers, dominated by SME’s</td>
</tr>
</tbody>
</table>

Manufacturing and Innovation Clusters in Germany

Medical Technology in Germany: Manufacturing and Innovation Clusters | © Markus Datenbank, Bureau van Dijk
Innovative Strength

The German medical technology industry generates one third of its turnover from products less than three years old. The approximately 1,250 manufacturers (each with more than 20 employees) active in the medical technology sector invest around nine percent of their turnover in R&D. However, this is only one indicator for the high level of Germany’s innovative strength. In terms of all European patent applications in medical technology in 2017, Germany is on the first place within the European Union. From a global perspective, Germany was second only to the US in terms of number of medical technology patent applications in 2017.

Research and Product Development

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. 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). Many collaborative projects are coordinated by medical technology cluster organizations with centralized management and project management staff: Germany is home to more than 30 innovation clusters in 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.

- Fact Sheet: Medical Technology Clusters in Germany

Market access: CE Marking and Reimbursement

Mandatory Conformity Marking

International companies serving the German market are required to meet German and European health and safety legislation requirements. Specific German regulations (MPG) must be complied with in addition to European medical device directives (MDD) and 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: 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.

Reimbursement Benefits

After 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.

Reimbursement Strategies

The innovation-friendliness of the national health systems largely influences their uptake levels of new technologies and 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.

Business Information
Interested in general guides about the German business location? This section gets you started:

- Investment Guide
- Incentives in Germany
- Investor’s Basics [pdf-download]

Gabriel Flemming | © GTAI

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✉️ Submit your question

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