Medical Technology

Europe’s Biggest Market

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.

Germany’s Medical and Research Actors Respond to Corona Crisis

The German medtech market is the largest in Europe with record spending of around EUR 38 billion in 2019. With increased demand being created by the Covid-19 pandemic, this figure will be surpassed in 2020 and subsequent years.

Hospitals to double number of ICU beds

Although a number of industry sectors will experience significant to minimal foreign direct investment decline as a result of the ongoing crisis, the healthcare sector will record an increase according to forecasts.

Germany’s two thousand hospitals currently have a 500,000 bed capacity. Intensive care unit capacity has been increased from 12,000 beds to 40,000 beds in recent weeks. German federal and state governments intend to further double the number of ICU beds in a joint effort and require hospitals to take immediate action in an effort to prepare for worst case pandemic scenarios.

Increased manufacturing capacity through diversification and partnering

Ventilators and personal protective equipment (PPE), specifically masks and gowns, are among those products most desperately needed in hospitals. Current demand exceeds available supply even though many global players including Drägerwerke, B. Braun and Siemens Healthineers are German in origin, and have significant on-site manufacturing capacity (as do international players including Johnson&Johnson, Hamilton et al). The European Commissioner for the Internal Market has called for quick action beyond the traditional medtech industry, urging manufacturers to increase and diversify production. Positive examples include textile and shoe manufacturers who have begun producing masks and gowns.

In Germany, textile manufacturers and even automobile industry suppliers have proven to be capable of diversification by adapting their production lines to make new products like filtering face piece (FFP) masks. MAHLE, a specialist for combustion engine technology and car air conditioning, is working with underwear maker Triumph to this end, forecasting short-term output of 1.5 million FFP3 masks a month.

Medtech clusters to set up special corona networks

Bringing together industry partners has been a key capability of Germany’s network of 30 medtech cluster networks across the country. In the face of the Covid-19 epidemic, this infrastructure has proven invaluable. MedicalMountains in Tuttlingen has set up the “Corona Dreh scheibe” (Corona Hub), an online partnering platform specifically designed to coordinate regional demand and supply, purchasing agencies and manufacturing capacities. The national medtech in-
Industry association BVMed and SPECTARIS – covering optical, photonic, analytics and medtech industries – are also hosting Covid-19 specific information and partnering services.

**New European Medical Device Regulation (MDR) to be postponed**

EU and German legislators have taken immediate steps to guarantee uncomplicated procedures of conformity assessment with the European Medical Device Directive MDD and national Medical Device Law MPG. On March 30, EU Commissioner Stella Kyriakides announced the intention to postpone the more scrutinious European Medical Device Regulation MDR for one year until May 2021, the initiative yet to be confirmed and legalized by EU Commission and EU Parliament. Industry associations and manufacturers had previously voiced concerns at being able to comply with the new regulation, thereby putting supply and patient safety at potential risk.

**Exemption of conformity assessment for masks and ethanol disinfectants**

As well as putting the more strict legal system of conformity assessment for medical devices MDR on hold, very specific steps have been taken to ease restrictions on related products including FFP2 and FFP3 masks which are not legally considered medical products. PPE with regulatory compliance in countries including Canada, China, USA, and Japan may now be marketed in Germany without undergoing the standard non-medical CE conformity assessment procedure. Germany’s testing institutes DGUV (IFA) and DEKRA have installed an alternate quick testing process to provide momentary exemption of CE-marking obligation where certified products are unavailable. Ethanol-based hand disinfectants have also been exempted from conformity assessment entirely, allowing pharmacies and manufacturers to immediately market such products after notifying the appropriate agency (BAuA).

**Centralized PPE procurement**

Protective mask and gown procurement of the German federal government has been put under centralized management by the Federal Ministry of Health. A general call for offers has been put in place online in an "open house" format with fixed pricing, date and means of delivery all being mandatory elements for offers (priority granted for products made in Germany).

For further information on medical technology in Germany please contact our industry specialists.

**Video: Smart Hospitals in Germany**

With aging populations and increasing demand for medical services, AI and other digital innovations are going to become a crucial part of the healthcare of the future.
Industry Overview: The Medical Technology Industry in Germany

Germany is the world’s largest manufacturing nation with a share of 9.9 percent of worldwide medical technology production.
MedTech Radar

#2/2018: Digital und intelligent

Fact Sheet: 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.

Facts & Figures

THE GERMAN MEDICAL TECHNOLOGY INDUSTRY IN NUMBERS (2017)

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<thead>
<tr>
<th>Sales</th>
<th>30.6 bn</th>
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<tr>
<td>% increase in 2017</td>
<td>4.8%</td>
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<td>Lead market in Europe</td>
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### MEDICAL TECHNOLOGY

<table>
<thead>
<tr>
<th>Exports</th>
<th>64% (19.08 bn) of the production are exported, 2.5% increase in 2017. Target markets:</th>
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<tbody>
<tr>
<td></td>
<td>• European Union 41.6%</td>
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<tr>
<td></td>
<td>• Europe (non-EU) 9.3%</td>
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<tr>
<td></td>
<td>• North America 19%</td>
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<td></td>
<td>• Asia 18.6%</td>
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<tr>
<th>R&amp;D Expenditure</th>
<th>9% of annual turnover in 2017</th>
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<tr>
<td>Employees</td>
<td>≥ 200,000; 15% in R&amp;D</td>
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<th>Companies</th>
<th>Structure: approx. 1,250 manufacturers, dominated by SME's</th>
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**Manufacturing and Innovation Clusters in Germany**
MEDICAL TECHNOLOGY IN GERMANY

Manufacturing and Innovation Clusters

Number of Companies
- 10 – 20
- 20 – 40
- 40+

Innovation Cluster HQ

www.gtai.com
www.health-made-in-germany.de

Source: Markus Dethlenfeld, Barnea van Dijk