Highly innovative with strong exports – medical technology “Made in Germany” enjoys great popularity across the globe and has an excellent reputation. Many of these medical technologies are cutting-edge and are thus important economic drivers. They make a significant contribution to Germany’s position as an industrial centre. German medical technology companies invest around 10% of their revenue in research and development – more than double the amount of the average German industrial company. The medical technology industry also plays a crucial role in helping us to master challenges like demographic change. More than virtually any other industry, medical technology relies on a very diverse range of key enabling technologies: the sector makes good and proactive use of the opportunities deriving from Germany’s high-tech capabilities.

Innovations in medical technology are increasingly the result of interdisciplinary collaboration between different technologies and scientific disciplines. In many forward-looking areas, such as regenerative and bespoke health, as well as telehealth and e-health, the industry’s players are reaching out into uncharted areas of medical technology. I therefore believe it is crucial to use our funding instruments to continue supporting, in a differentiated and target-orientated manner, the innovative capacities and research activities of our companies. Our support goes not least to start-up companies, small and medium-sized enterprises and the funding of advances in technology.

The most significant factors influencing the medical technology industry at present are probably digitalisation and artificial intelligence. Digitalisation of medical supply and production processes is in full swing; more and more operations are being carried out with the use of robot-assisted systems. Micro-robots are injected into the bloodstream to measure blood pressure, and machine learning allows for greater precision in analyses of imaging data. Adaptive systems support laboratory employees and physicians in fields where computers outperform humans: in the analysis of large data quantities, recognition of patterns, and the cross-referencing of a large number of symptoms. In the end, this results in greater security for the physician and the patient.

We will continue to support our companies as they master challenges like these. Germany’s Artificial Intelligence Strategy is designed in an adaptive manner, to be continuously and collaboratively updated by science, business, and civil society: we want to display courage and creative drive as we develop artificial intelligence which serves the interests and well-being of mankind.

On this note, I wish you and all of us continued economic success and hope that the articles in this publication will stimulate your thinking and discussions.
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The German medical technology industry is growing. Drivers in the background are the innovative force of the sector and demographic change. Growth is, however, slowing down significantly. In spite of all lip service paid to the strengthening of Germany as an industrial centre, which is in many respects the foundation on which our international success story is built, a rising number of regulatory burdens are impeding further growth. Growth and innovation go hand in hand with new and additional opportunities for the diagnosis and treatment of patients, who depend on this progress. Medical technology helps us heal. We see it as our obligation to open up new market opportunities for both users and patients.

As SPECTARIS, we represent the interests of the German medical technology industry, which is still shaped by many small and medium-size enterprises. The new European Regulation on medical devices will enter into full effect six months from now. Implementing the new framework will require great effort and equally sizeable resources. Companies are will have to invest large percentages of their annual revenues into implementing the Medical Device Regulation (MDR). A study by the Swiss Federal Office of Public Health and the State Secretariat for Economic Affairs forecasts a total of 9.3% of EU revenues each year. This negatively impacts innovative projects. Niche products will disappear from the market, together with the companies serving these niches. This above all affects small and medium-sized enterprises (SMEs). An exemplary company developing and marketing eye implants for the visually impaired has already ceased operations together with other market participants. Other companies move abroad or have their products initially or solely approved for the US market. By now, access to the US market is easier than accessing the European home market. This sends a fateful signal to Germany’s innovative capacities.

As an association, we focus on the interests of our member companies, on the interests of the German medical technology industry. The regulatory environment will continue to become more restrictive after the MDR. On a national as well as international scale. Before any market processes manage to sort out the situation, we need to design our processes in a more efficient manner to meet mounting regulatory pressure. Let’s also take these challenges as an opportunity. We will grow more powerful if you share your expertise and examples from everyday business with us.

Our contribution to the political discussion is particularly valued so much because we, SPECTARIS, explore and represent interests in a well-founded manner. The trust you as a member place in our association is shared by our partners in politics and public administration.

Our yearbook again explores the key issues and topics in the MedTech industry, with the MDR being just one of many diverse challenges. I hope you enjoy reading through this edition and would be delighted to welcome you as a fellow campaigner for better framework conditions for our medical technology industry.

I would like to thank all members, supporters, and partners for their constructive cooperation, built on trust.

Dr Martin Leonhard
Chairman
Medical Technology in the German Industry Association SPECTARIS
The medical technology industry in Germany

The German medical technology is a job motor; growth threatened by over-regulation

A report of the Federal Statistical Office showed that the 1,350 German producers of medical technology generated overall revenues of 30.3 billion euros in 2018. This calculation equates to a 1.2% growth over the previous year. As a result of changes to the calculation basis, the values of 2017 and 2018 can only be compared to a certain extent, with actual growth probably somewhat higher. Domestic revenues were 10.5 billion euros, with foreign revenues amounting to 19.8 billion euros. The industry is highly innovative and shaped by SMEs: Over 93% of companies in the industry have fewer than 250 employees. The R&D ratio, i.e. the share of expenditures for research and development relative to the overall revenue, is at 9%. Similarly to previous years, the number of employees increased in 2018, by 3.9% to around 143,200. The industry above all sees itself confronted with increasing over-regulation, particularly as a result of the new ordinance on medical devices. Many companies expect this to jeopardise further revenue and employment growth and already today see the first signs of this development.

Employees and companies

2017 – 2018

Employees

2017 » 137,857 → +3,9% 2018 » 143,178

Companies

2017 » 1,310 → +3,2% 2018 » 1,352

The industry benefits from trends in society, but has difficulties finding skilled employees

On the other hand, there are opportunities as a result of demographic changes, particularly in the mature economies, as well as opportunities opened up by sizeable health investments in many emerging economies. The growing importance of good health, as well as technological innovations and further development, are market drivers. Digitalisation currently has the greatest impact on the sector. The health economy is undergoing a phase of rapid change. Digitalisation is already now influencing all areas of care, and the business model of producers is changing as a result: from the classical device technology providers of the previous decade to solutions providers in the current decade, up to providers of digital and comprehensive health solutions in the coming decade.

Source: SPECTARIS, Federal Statistical Office

» Source: SPECTARIS, Federal Statistical Office
The high-tech industry at a glance

Revenues 2017–2018

2018

Overall revenue

€30.28 billion

2018

Export rate

65.4%

2017 » 63.7%

2018

Domestic revenue

€10.49 billion

2017 » €10.85 billion

2018

Foreign revenue

€19.79 billion

2017 » €19.08 billion

» Source: SPECTARIS, Federal Statistical Office

Notes:

» The figures refer to companies with 20 or more employees
» Including small companies: €32.73 billion, 11,600 companies, 198,000 employees (2016)

To make sure that the full potential of this change can be exploited, the framework conditions of Germany as a leading market must be optimised and the problem of a lack of qualified personnel countered purposefully.

Trade barriers hinder international business

With an export rate of over 65%, foreign business is of great importance. Around 42% of German medical technology exports were to countries of the European Union in 2018. As such, the robust development of demand from these countries was a key pillar of industry growth. However, Brexit is already casting its shadows over business with the UK – exports in 2017 fell 7% short of the previous year. In 2018, exports again decreased slightly. With a look to the coming year, it is also expected that revenue growth will lose some of its traction as a result of the new Medical Device Regulation. Demand from North America again grew in 2018, but growth was comparatively weak at 3%. On the other hand, the development of exports to China was very positive, with a high increase of 12%. After exports to Russia increased by almost 28% in 2017, growth was a bit weaker in 2018, but still positive at 4%.

The global market for medical technology continues to grow

The market drivers explained above give producers fairly positive expectations for the coming years; revenue is expected to grow in 2019 and 2020 as well, even with the possibility of growth slowing against the backdrop of economic development as well as the illustrated over-regulation. Experts forecast average annual growth of the world market for medical technology of around 5.6% over the coming years. The market size should reach 595 billion US dollars in 2024. German medical technology – with its high innovative force, good positioning, and international competitiveness – will continue to benefit from this development.
Medical technology benefits from international business

Revenues 2011 – 2018 (in billion €)

SMEs shape the sector

When looking at the distribution of German medical technology producers by size categories, it becomes apparent that the industry is shaped by SMEs. The 1,262 companies with fewer than 250 employees offered almost 66,000 jobs in 2018, realising revenues of 8.4 billion euros.

<table>
<thead>
<tr>
<th>Size Category</th>
<th>Companies</th>
<th>Revenue (in billion €)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 50 employees</td>
<td>26,731</td>
<td>€2.31 billion</td>
</tr>
<tr>
<td>50 – 99 employees</td>
<td>16,254</td>
<td>€2.00 billion</td>
</tr>
<tr>
<td>100 – 249 employees</td>
<td>22,911</td>
<td>€4.08 billion</td>
</tr>
<tr>
<td>250 and more employees</td>
<td>77,282</td>
<td>€21.89 billion</td>
</tr>
<tr>
<td>Total employees</td>
<td>143,178</td>
<td>€30.28 billion</td>
</tr>
</tbody>
</table>

» The figures refer to companies with 20 or more employees.
» Source: SPECTARIS, Federal Statistical Office
Federal states invest in medical technology

When looking at the regional distribution of companies active in the production of medical technology, it becomes clear that Baden-Württemberg holds the top spot as regards the number of producers and revenue. The state is joined at the top by Bavaria, Hesse, Schleswig-Holstein, and North Rhine-Westphalia.

Most federal states already recognised the massive potential of medical technology long ago and initiated measures to actively promote the establishment of new companies in this sector.

» The figures are for the year 2018 and for companies with 20 employees or more. For reasons of confidentiality, the data of some federal states do not include Economic Class 26.6. (Production of Radiation and Electrotherapy Devices).

» Source: SPECTARIS, Federal Statistical Office
International comparison of healthcare expenditure

In an international comparison of healthcare expenditure, relative to the national gross domestic product, Germany and France are among the three highest spenders, with 11.2% each. Only the USA (16.9%) and Switzerland (12.2%) spend an even higher share on healthcare. For comparison: This value was still at 10.2% in 2005. The OECD average was 8.8% in 2018.

Health expenditure of selected countries as a % of the gross domestic product in 2018

Source: OECD Health Data
Medical technology in Europe

Germany is ahead of the curve

German medical technology companies assume the leading position in Europe. Of all revenues realised by the industry within the EU – around 78 billion euros in 2016 –, 40% are generated by German producers. There are a total of 68,000 European companies active in medical technology (including small enterprises), and they employ around 530,000 people. These figures clearly illustrate how important the medical technology sector is not just for Germany, but the European economy as a whole.

<table>
<thead>
<tr>
<th>Country</th>
<th>Revenue¹ (in millions)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Germany</td>
<td>32,729</td>
</tr>
<tr>
<td>2. France</td>
<td>11,360</td>
</tr>
<tr>
<td>3. Italy</td>
<td>9,797</td>
</tr>
<tr>
<td>4. United Kingdom</td>
<td>7,189</td>
</tr>
<tr>
<td>5. Sweden</td>
<td>2,274</td>
</tr>
<tr>
<td>6. Denmark</td>
<td>2,245</td>
</tr>
<tr>
<td>7. Spain</td>
<td>2,094</td>
</tr>
<tr>
<td>8. Austria</td>
<td>1,733</td>
</tr>
<tr>
<td>9. Netherlands</td>
<td>1,568</td>
</tr>
<tr>
<td>10. Belgium</td>
<td>1,475</td>
</tr>
<tr>
<td>11. Poland</td>
<td>1,170</td>
</tr>
<tr>
<td>12. Hungary</td>
<td>1,118</td>
</tr>
<tr>
<td>13. Finland</td>
<td>954</td>
</tr>
<tr>
<td>14. Czech Republic</td>
<td>832</td>
</tr>
<tr>
<td>15. Portugal</td>
<td>379</td>
</tr>
<tr>
<td>16. Slovakia</td>
<td>265</td>
</tr>
<tr>
<td>17. Romania</td>
<td>194</td>
</tr>
<tr>
<td>18. Iceland</td>
<td>146</td>
</tr>
<tr>
<td>19. Slovenia</td>
<td>144</td>
</tr>
<tr>
<td>20. Other EU countries</td>
<td>492</td>
</tr>
</tbody>
</table>

¹ In 2016 or the last year with figures available; including small enterprises
» Source: SPECTARIS, Eurostat
Note: The figures refer to the respective overall revenue of local producers in 2016 or the last year with figures available (including small enterprises).

Source: SPECTARIS, Eurostat
The importance of emerging markets continues to grow, Europe still the most important trade partner.
The most important export region for German medical technology in 2018 was the European Union, with 42% of exports relevant to the industry made to EU countries. Add to this the exports to other European countries (9.6%), and over half of exports of medical technology goods was made to another European state. Almost 19% of exports were delivered to both North America and Asia. European Union countries also dominated in terms of imports, accounting for a 33% share of all German imports, followed by North America (share: 26.7%) and Asia (19.9%).

**KEY:**
- **Export:** Share of the overall German medical technology exports in 2018 (in brackets: export growth/decrease)
- **Import:** Share of the overall German medical technology imports in 2018 (in brackets: import growth/decrease)

»» Source: SPECTARIS, Federal Statistical Office
The global market for medical technology continues to offer great potential

The market research company EvaluateMedTech expects the global market for medical technology and in-vitro diagnostics (IVD) to show average annual growth of 5.6% up to 2024, to reach a volume of 595 billion US dollars. The consultancy company Frost & Sullivan estimates the global market volume of medical technology (without IVD) to amount to 422 billion US dollars and expects the market to grow by 5.6% to 446 billion US dollars.

The global medical technology market in 2019 by segment

- Orthopaedics: 12.2%
- Cardiology: 9.4%
- Ophthalmology: 8.4%
- Wound care: 5.3%
- Patient monitoring: 5.1%
- Respiratory/Anaesthesia: 4.6%
- Audiology: 4.3%
- Robotic assistance systems: 1.9%
- Neurology: 2.7%
- Aesthetic medicine: 1.8%
- Urology/Gynaecology: 1.8%
- Other segments: 25.3%

Source: Frost & Sullivan
The global medical technology market in 2019 by region

- Europe: 27.0%
- North America: 39.2%
- Asia and the Pacific: 25.9%
- Central and South America: 4.6%
- The rest of the world: 3.3%

445.5 billion USD

» Expected overall market growth for 2019: +5.6%

» Source: Frost & Sullivan, EvaluateMedTech
MEDICA – World Forum for Medicine

Where all global players in medicine meet to discuss health market trends

Medical technology industry is facing the future, more dynamic, digital, and connected than ever before. One must keep up with current developments to meet the challenges of tomorrow. Companies, opinion leaders, decision-makers, and medical as well as business and research experts need a shared platform for dialogue and international business.

Medica has been this platform for almost 50 years. The world’s largest and leading medical trade fair welcomes exhibitors, visitors, and press representatives from across the globe to Düsseldorf each year in November. It serves as the yardstick of global goings-on: three-quarters of all exhibitors, regularly over 5,000 of them in the previous years, are international. The over 120,000 specialists who visit the trade fair come from more than 150 countries.

The supplier trade fair COMPAMED has shown similarly strong growth since the first edition in 1992. It takes place simultaneously with the MEDICA in Düsseldorf, and has developed into the uncontested hotspot for complex high-tech solutions. In addition, it has become the internationally leading event in its industry as well, with the last edition drawing 800 exhibitors and around 20,000 visitors.
Everything – in a nutshell

The key driver behind the success of the trade fair, in addition to its unrivalled international character, is the range of topics covered at MEDICA. It not only spans the individual subsegments of the market in a clearly structured and focussed manner, but also complete processes of outpatient and inpatient care. Key areas are electromedicine and medical technology, digital health (incl. m-Health, e-Health, IT for medical practices and clinics), laboratory technology and diagnostics, physiotherapy and orthopaedic technology, medical products, as well as medical furniture.

The COMPAMED fair, which takes place at the same time, rounds off this offer, turning the event into a permanent fixture where all players along the entire value-added chain meet and discuss medical technology devices, instruments, and products each year. This creates the perfect framework conditions for producers of medical technology, as well as their users and suppliers, to enter into new partnerships and work towards the success of shared projects.

Providing trendsetters with impulses

Those who consider themselves trendsetters in an already particularly innovation-driven industry must be creative and constantly reinvent themselves – just like MEDICA. New programme elements are developed time and again, expanded into indispensable components of the event in close collaboration with renowned industry partners.

Digitalisation? That’s not just a hyped trending topic, but part of everyday operations at MEDICA. Still-sceptical physicians already attended a special exhibition on a first IT offer for physician practices in the 1980s. This initially developed into the MEDICA MEDIA, which then became the MEDICA HEALTH IT FORUM dialogue platforms – with a trailblazing mix of stage events, expert discussions, and exhibition areas.

Connectivity? That’s only now picking up steam in Germany. With a look to global trends, MEDICA has already been providing the right orientation assistance for years – with the MEDICA CONNECTED HEALTHCARE FORUM and the integrated MEDICA App COMPETITION as the central pitch for the best global mobile health solution.

Entrepreneurial spirit? As the industry’s most important sources of ideas, digitally driven start-ups are given a permanent stage each year at the MEDICA START-UP PARK. Other exhibitors have by now recognised the potential of this concept, copying it in “friendly recognition” of MEDICA, along with the MEDICA App COMPETITION. This only proves that the global number one is on the right track!

MEDICA is and remains the original trade fair, with many exhibition highlights, integrated forums, and accompanying conferences.

Information can be found online at:
https://www.medica.de
https://www.compamed.de

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German medical technology is in demand – even as it faces growing challenges on world markets

Medical technology from Germany is in demand across the globe. Successes in collaborations with other countries are substantiated by the industry figures: With an export rate over 65%, the most important markets are situated outside of the home market, whereby the EU countries traditionally account for the lion’s share of export activity at over 40%. North America and Asia take up the next spots, both with shares of almost 19%. Asian companies realised growth of almost 5% in 2018. Furthermore, Latin American markets have recovered a bit, once again showing growth of around 5% over the previous year.

The trade conflict between the large US and Chinese markets is however dampening the positive trends somewhat and resulting in greater compliance expenditures for companies. The USA has withdrawn from the Joint Comprehensive Plan of Action (JCPOA), which has resulted in US sanctions, above all against foreign financial institutions. Business with Iran has for the most part ground to a halt for many German producers of medical technology, in spite of exception regulations in place. The remaining parties to the JCPOA have not yet managed to find an effective countermeasure. The establishment of INSTEX – Instrument in Support of Trade Exchanges – is only forecast to compensate for the major withdrawal of foreign financial institutions from doing business with Iran in the medium to long term. The current leitmotif pursued by the USA, “America first”, is furthermore reflected in various new legislative initiatives to intensify US sanctions against the Russian Federation as well as to impose potential sanctions against EU products. The volatility of US trade and customs policy as well as “Brexit”, which was still pending by the copy deadline, carry with them great insecurity and risks for companies. With its comprehensive range of information and by representing interests at the German, European, and US level, SPECTARIS attempts to exert influence on the current political developments and to counteract punitive duties as well as further intensification of US sanctions.

At the same time, successes have become apparent in the area of free trade agreements, which can have a positive effect on exports of German medical technology. The Economic Partnership Agreement between Japan and the EU, the most comprehensive free trade agreement ever negotiated by the EU, took effect on 1 February 2019. The agreement has achieved decisive improvements to non-tariff trade barriers. For example, Japan agreed to further liberalise access to public tenders, among other things allowing European companies to participate in tenders for 51 universities, 25 hospitals, and 11 industry and industrial research centres.

Consensus was reached on new free trade agreements with Vietnam and the Mercosur states in June 2019. The free trade agreement with the Mercosur states forms part of a more comprehensive association agreement between the EU and the four Mercosur states Argentina, Brazil, Paraguay, and Uruguay. The final version is expected soon. The agreement with Vietnam is slated to take effect at the end of 2019 or beginning of 2020. Free trade agreements are currently being negotiated with Australia and New Zealand as well.

The negotiations between the EU and USA on a trade agreement, as well as to solve the trade conflict, picked up steam again after the EU member states gave their consent to the European Commission to start formal negotiations on an agreement on conformity assessment and to abolish tariffs on industrial products.
Structured support on the potential in developing and emerging markets helps German medical technology SMEs

Taking into consideration the potential offered by emerging countries, with their progressing economic markets, investments in future markets are even more worthwhile. The countries continue to show promising growth, with their potential in growing demand for modern healthcare infrastructure providing good market opportunities for German exporters in the area of hospital expansion and equipment.

At a larger scale, emerging countries will continue to play a key role for German medical technology exports, also outside of Asia. IW Cologne has found that by now over 20% of all German exports of medical devices and materials are delivered to emerging countries, with an upward trend. These markets, with their rapidly expanding digital infrastructure and great willingness to adopt e-health applications, additionally show demand for new digital business models, which might prove decisive in future market shares. African countries are increasingly assuming a more important role here.

Therefore, the Federal Government wants to address the economic potential of Africa in a more targeted manner, striving for far-reaching relationships with the African states and doing justice to the political and economic importance of Africa and its potential. The relationships should at the same time respect the considerable regional diversity and complexity of Africa and serve German and European interests. That’s not an easy task with an economic structure of such heterogeneity. Various approaches should thus result in structured support in tapping the potential of the African states – above all by working together more intensively with the “Compact with Africa” countries. Here, SPECTARIS is involved in various activities together with the Federal Government. To name an example, we support the “Africa Business Guide” of Germany Trade and Invest, which clearly summarises information on opportunities presented by the continent, sorted by industry. In addition, the Africa Business Network of the Federal Ministry of Economics strives to support companies in their African activities. SPECTARIS is also closely involved in this project and will accompany a special pilot project in Morocco for the health sector. The topic of “Global Health” is addressed together with the Federal Ministry of Health.

Emerging countries: Brazil, Russia, India, China, Chile, Colombia, Mexico, Peru, Egypt, Qatar, South Africa, United Arab Emirates, Indonesia, Korea, Malaysia, Philippines, Taiwan, Thailand, Turkey

Source: IW Cologne
International markets | German medical technology is in demand – even as it faces growing challenges on world markets

Here, SPECTARIS supports the activities of the network with its expertise in medical technology. The great relevance of health topics and the engagement of medical technology companies is recognised by the Federal Ministry for Economic Cooperation and Development, which is why a EZ (Development Cooperation) Scout has been active at SPECTARIS again since March 2019. The EZ-Scout can provide targeted support to the business activities of companies in Africa and developing and emerging countries on other continents.

A EZ-Scout supports members in their activities in developing and emerging countries

As development in the developing and emerging countries continues to push forward, their markets for first-class and high-tech products also mature. These countries are thus becoming increasingly interesting for export-oriented economies, especially also for the industries represented by SPECTARIS. In turn, these countries are increasingly dependent on modern, state-of-the-art technology for the further development and improvement of their own performance. By connecting development cooperation (EZ) with foreign trade, Germany’s partner countries offer very interesting opportunities. This above all applies to medical as well as analysis, bio-, and laboratory technology in the developing healthcare systems.

Since March 2019, Dr med. Franz von Roenne has been active in the Foreign Trade department as a EZ-Scout. As a delegate of the Gesellschaft für Internationale Zusammenarbeit (GIZ) GmbH (Association for International Collaboration), his deployment is part of a programme by the Federal Ministry for Economic Cooperation and Development (BMZ) for the targeted promotion of collaboration between business and programmes for state development cooperation. There are EZ-Scouts at 17 umbrella and industry associations, in three state associations, at 11 chambers of industry and commerce, as well as in craft and association institutions.

The SPECTARIS EZ-Scout connects interested members with development cooperation programmes and networks and their links with foreign trade funding instruments. They offer individual consulting and provide bespoke information on request, as well as organising topical information events. They take care of networking with the Agency for Economy and Development at the BMZ, other EZ-Scouts, as well as similar positions at German chambers of industry and commerce (ExperTS) and to countries with a German Desk to link up German foreign trade (Global Business Network). By making connections to bilateral and multilateral development cooperation programmes and their networks, they help establish specific contacts.

The EZ-Scout systematically supports the interlinking of foreign trade and development cooperation, particularly on site and as needed. There is an important reason for this: Healthcare, including its design, planning, and financing, is organised by public authorities across the globe. Effective care, however, relies to a large extent on state-of-the-art, tailored technologies as supplied by private business. Intensive cooperation is required to optimally attune supply and demand, long before common market mechanisms start to result in actual business. The EZ-Scout at SPECTARIS therefore above all looks for an exchange with interested members on the design and use of optimised business models. During the first six months of his activity, numerous members who are active in developing and emerging markets have shown an interest in using, expanding, and sharing their experiences. The EZ-Scout is available to answer any questions related to the various topics and offers surrounding development cooperation.

Contact:
Dr med. Franz von Roenne
EZ-Scout of the Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) GmbH on behalf of the Federal Ministry for Economic Cooperation and Development (BMZ)

Phone: +49 (0)30 414 021 55
Mobile: +49 (0)170 54 14 357
Email: ez-scout@spectaris.de
SPECTARIS partnership project in East Africa – initial successes and prospects for the second phase

Since 2016, SPECTARIS has been involved in a project funded by the Federal Ministry for Economic Cooperation and Development (BMZ), through sequa, to develop the health industry in East Africa. Target countries are all member states of the East African Community (EAC): Burundi, Kenya, Rwanda, Tanzania, Uganda, and since 2018, Southern Sudan.

A look back to the first phase

The first project phase, designed with a duration of three years, focused on strengthening the local health sector, stimulating regional integration, and establishing initial contacts to German producers of medical technology. Our local partner is the East African Healthcare Platform (EAHP), which was founded as the central opinion-forming institution to support all regional health industry stakeholders. During the project, East African companies visited trade fairs such as the MEDICA in Düsseldorf and analytica in Munich, where they first came into contact with German producers. The progress of the project was assessed on-site in the early summer of 2019, with a positive report on the attainment of goals and recommendation to continue the project.

A look forward to the second phase

SPECTARIS is currently assessing the continuation of the project. In the next phase, stronger focus should be placed on concrete business and cooperation opportunities, among other things, that offer various options for companies to participate. These could be created through the development of market expertise, by sharing market analyses, as well as through the initiation of business contacts to local users and distributors in the health industry. German companies active in medical and laboratory technology will have the opportunity to actively explore the market by participating in delegation trips, study trips, and local conferences. Furthermore, there are prospects of investing in a pilot project in the private health industry and the opportunity to carry out sponsored workshops and training courses on the company’s own equipment. The partnership with the East African Health Platform opens up the opportunity to gain deeper insight into the East African market and gain long-term access to it. With the EAHP, SPECTARIS has a reliable partner to safeguard and expand future market opportunities for our member companies.

Contact: Krasimira Maryanska
SPECTARIS e.V.
Russian market for medical technology continues to grow

Government intensifies import substitution of foreign medical products

Moscow (GTAI) – Russia to invest 24 billion euros in its healthcare system until 2024. Intensification of import substitution regulations pushes foreign medical technology producers to develop local production.

As part of the national project “Healthcare”, the government is to invest around 23.6 billion euros in national healthcare until 2024. Focus is placed on the treatment of cardiovascular disease and cancer. This should improve the average life expectancy of the Russian population by 5 years by 2024.

The Ministry of Industry expects the Russian market for medical technology to grow to around 4 billion euros in 2019 (295 billion roubles). In 2018, the market grew by around 10% to approx. 3.8 billion euros (281 billion roubles, ECB annual average exchange 2018: 1 euro = 74.04 roubles). Around 80% of purchases were made by public health institutions.

Strong growth of the market for private medicine

Russia’s market for medical services has expanded by 11.6% over the previous year in 2018, to around 41 billion euros. The largest share is attributable to benefits under the obligatory state insurance (OMS). The share of private medicine amounts to 15.8%.

The private health market is among the most promising market segments in Russia. In 2018, the value of legally provided private medical services increased by 10.8% to 6.5 billion euros. The consulting firm KPMG expects the market to grow to approx. 8 billion euros by 2012. As they are subject to less stringent regulation, private clinics can continue to procure foreign medical technology without any restrictions.

The market for telehealth (e-health) continues to offer good business opportunities. In 2018, the market volume amounted to approx. 100 million euros. Until 2030, this market could grow to 1.2 billion euros; however, legislative obstacles and immature regulation still impede industry development. Currently, diagnoses via online consultations are not yet allowed.

Government supports domestic producers

The approx. 400 Russian producers had a revenue share of the domestic market for medical products of approx. 23%. With the “Strategy to Develop the Medical Industry by 2030”, the Ministry of Industry strives to increase the production volume of Russian medical technology producers by a factor of 3.5 over the course of 2017 (910 million US dollars), with a more than tenfold increase of exports (to 1 billion US dollars). At least 100 new medical products “Made in Russia” are to be approved each year.

The Federal Antitrust Agency has identified a lack of compatibility between medical products. According to the agency, this makes it harder for domestic producers to access the market while keeping prices high. Standardisation catalogues should resolve this issue. The Ministry of Healthy strives to work out such a catalogue by the end of 2019.

Market access to become harder for foreign producers

The Ministry of Industry endeavours to reduce import dependency of 111 medical products by 2020. With Directive No. 813, enacted on 26 June 2019, the government added 14 items to the list of foreign medical products and devices on which restrictions are imposed with public procurements, including otoscopes, tonometers for the measurement of intraocular pressure,
respirators, ultrasound scanners, and intraocular lenses. If at least two Russian producers participate in a public procurement tender with their products, similar foreign products are excluded.

Prime Minister Dmitry Medvedev signed a directive in June 2019 restricting the freedom of public institutions to act in procuring medical technology through competition proceedings. In these, quality criteria can be included in addition to the price; however, for X-ray machines, optical microscopes, dental and ophthalmological instruments, sterilisers, and other medical products, the price is now the decisive factor.

Russia starts digital labelling of rehabilitation technology

Russia is also expanding the obligation to digitally label goods to encompass medical technology, and particularly rehabilitation technology. This should allow for seamless tracing of products from the manufacturer to the end user. The start is marked by a pilot project to label wheelchairs, running from 1 September 2019 until 1 June 2021. During a first phase, wheelchairs with manual drive are affected, after which this will be extended to wheelchairs with a motor or other mechanical moving devices. The Centre for the Development of Promising Technologies (ZRPT), which is part of the business empire of oligarch Alisher Usmanov, in entrusted with implementing the project.

Single market requires new registration

In the wake of the establishment of a single medical technology market in the Eurasian Economic Union (EEU), all medical devices are subject to new registration by the end of December 2021. The Association of Medical Technology Producers Medizinskie Resursy estimates that this would take at least 20 years. As a result, the industry association warns that medical technology bottlenecks could start from 2022 onwards. The deadline might eventually be postponed, but foreign producers should already now carefully examine the new requirements of the EEU.

German medical technology producers expand their presence in Russia

To retain access to public orders in spite of all obstacles, German companies are investing in the creation or expansion of local production. The medical technology producer Sarstedt laid the foundation for a factory to produce disposable blood collection systems in July 2019. A total of around 31 million euros will be invested in the project until 2022. The medical supply manufacturer B. Braun is investing around 40 million euros in the construction of a logistics centre and the expansion of the production plant in the Twer region until 2022. Fresenius Nephrocare is building three dialysis centres in the Rostov area by 2020, at a cost of around 6 million euros.

The localisation of production has already paid off for medical technology producer Otto Bock. Along with three other providers, the Russian representative office Otto Bock Mobility was selected to provide 39,000 wheelchairs of the “Start” model to public health institutions.

Even with intensification of import substitution politics, Russian imports of medical technology are on the rise. German producers’ exports to Russia grew by around 3.9% over the previous year in 2018, amounting to around 640 million euros. Russia accounts for 2.7% of the overall export revenue, ranking tenth on the list of the most important purchasing countries of German medical technology.
The Brazilian medical technology market is booming

With over 210 million inhabitants, Brazil ranks among the ten most populous countries in the world; with a GDP of 2.14 trillion US dollars (2018), it is the ninth-largest economy. From a health perspective, the rapid ageing of society is relevant: With the share of over-65-year-olds still falling short of 10% in 2019, it is set to rise to approx. 17% by 2040 and double to over 25% by 2060. Moreover, life expectancy is set to rise from the current age of 76.5 to 81 years in 2060. This will pose many challenges to the country, which in turn offer opportunities to German medical technology companies as a result of increasing demand for medical technology.

The Brazilian economy is slowly recovering, and with approval of the pension reform in mid July 2019, growth is expected to accelerate. The government of President Jair Bolsonaro, who has been in office since January 2019, endeavours to not just ease pressure on the national federal budget, but has also initiated various reforms to open up the market. Moreover, anti-corruption efforts have intensified with measures such as Operation Lava Jato.

In 2018, 528,000 formal jobs were created on the Brazilian labour market, 18% of these in the health industry. With the national health system SUS, the country currently has the eighth-largest health market in the world and the fourth-largest medical population with 2.18 physicians per 1,000 inhabitants. In 2018, health expenditures amounted to 637 billion Brazilian real, 57% were spent on private health insurance or private costs, and public funds made up the remaining 43%.

The MT market grew by 13.5% in 2018, amounting to 10.5 billion US dollars. In 2019, growth is expected to be five to 7%. Over the course of the year (2018), imports increased by 21.8% to a total of 5.4 billion US dollars, and national production (51.5% of the overall industry volume) grew by 5.6% to 5.7 billion US dollars. This increase is attributable to investments in electro-medical and electrotherapeutic as well as radiation devices and fixtures.

Germany takes second place in the Brazilian import ranking of medical technology, at 10.4%, topped only by the USA with 32.7% (2018). Directive RDC no. 208/2018 has simplified the procedure for importing products subject to health monitoring. Moreover, risk management and freight parameterisation procedures were introduced, speeding up the analysis and approval processes of imported goods and reducing processing times. This has made German medical technology companies significantly more competitive.

The partnership established by the health authority ANVISA and InMetro (duration of five years) in 2015 to protect public health is making a significant contribution to solving complex tasks, such as improving the quality of medication, medical devices, and prostheses.

<table>
<thead>
<tr>
<th>Imports (million USD)</th>
<th>Exports (million USD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical equipment</td>
<td>843.25</td>
</tr>
<tr>
<td>Implants &amp; prostheses</td>
<td>188.65</td>
</tr>
<tr>
<td>Laboratory equipment</td>
<td>981.39</td>
</tr>
<tr>
<td>Durables</td>
<td>1,186.01</td>
</tr>
<tr>
<td>Dental technology</td>
<td>147.97</td>
</tr>
<tr>
<td>Medical imaging equip.</td>
<td>566.4</td>
</tr>
<tr>
<td>Rehabilitation equip.</td>
<td>448.99</td>
</tr>
<tr>
<td>Overall</td>
<td>4.36 billion</td>
</tr>
</tbody>
</table>

Source: ABIMO
To name an example, this resulted in a significant reduction (or even elimination) of product registration backlogs, strengthened the analysis capacities of laboratories, and created greater transparency as well as efficiency in communication between stakeholders. This was partially achieved through greater use of process automation technology.

Hospitals have been restructured in a more vertical manner for a few years, which ensures cost reductions and high-quality care. Health insurers are investing in their own networks, and on the other hand, hospitals are establishing their own health insurance. Related to this process, there were 107 mergers and acquisitions in the Health, Hygiene, and Aesthetics segment in 2018.7 While domestic investors outpaced foreign investors, more foreign investors are expected over the coming years. Among others, investments are coming from the Cura Network for Diagnostic Care, contributing 300 million Brazilian real to open new laboratories, and Fleury is investing 170 million real, purchasing the Laje network of clinical analysis labs in Rio de Janeiro. Sabin, the fifth-largest company in this industry, acquired six laboratories from October 2018 to February 2019 and is planning to invest 170 million real in this expansion. Gelfond and competitors such as Allier want to grow with their own services for health insurers, with their own network of hospitals and clinics such as Notre-Dame Intermédica and Hapvida. These operators achieve above-average performance through better cost control.8 Hapvida acquired the São Francisco Group in 2019 for 5 billion Brazilian real and is the health insurer with the largest number of customers, with 5.8 million policyholders of (dental) care plans. The group has net revenues of 6 billion Brazilian real. German companies can benefit from opportunities in medical imaging procedures, which require high equipment investments and specialised staff. Diagnostics companies are investing heavily in technology and the development of new examinations. Dasa, the industry leader with 250 million examinations carried out annually, is investing 30 million Brazilian real in artificial intelligence (AI), digitalisation, and genetic tests.

On a larger scale, the trade agreement between the EU and Mercosur also provides new drivers through the simplification of bilateral trade. German medical technology companies benefit from the use of international standards and the alignment of technical regulations to the needs of micro businesses and SMEs, from the transparency provided through the free provision of relevant information, as well as from Mercosur accepting compliance with technical provisions. This facilitates market access, removes (bureaucratic) obstacles, and creates new business opportunities. Assuming quick approval of the agreement in the relevant national parliaments, the agreement is predicted to take effect in approximately five years.

The German-Brazilian Foreign Chamber of Commerce and Industry (AHK) in São Paulo also strives to draw investments to the region, reinforce bilateral trade, and promote cooperation between the Mercosur countries and the EU as well as business of its members. As an important business platform, the AHK opens up the Brazilian market to interested partners, for example through establishing a business presence (among other services a virtual Brazilian business address, support from multilingual AHK employees). Important business relationships are made as part of the business partner arrangement service.

During a pre-market check, the market is probed in line with current trends and opportunities. Individual market entry strategies are additionally developed in collaboration with the companies, which promises good results on the booming market for medical technology.

**Current market trends**

1. **Digitalisation**
   - Ministry of Health: introduction of electronic patient files
   - Intelligent hospital beds at 9 de Julho in São Paulo

2. **Telehealth**
   - (Segment growth rate 20% p. a.; by 2022, revenue over 12.2 billion Brazilian real)10
   - Synchronous telehealth at the Albert-Einstein Hospital in São Paulo connects physicians and patients through teleconferences
   - Treating neurological emergencies, (strokes, fits, head injuries) in hospitals of the Leforte Group in São Paulo
   - The Federal State Rio Grande do Sul has reduced waiting times for ophthalmic consulting through Teleoftalmo

3. **Artificial intelligence, big data**

4. **Lending out MT devices**

**An overview of opportunities**

- Market growth prognoses range from 5–7%, clearly outpacing the Brazilian economy (0.9% GDP growth in 2019)
- Higher share of the GDP for health expenditures (9.3% in 2018)
- One of the ten most populous countries in the world, rapidly ageing population, ninth-largest national economy
- Demand cannot be covered by national production: Brazil procures around 65% of its medical technology demand abroad9

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7 DCI
8 Valor Económico
9 GTAi
10 Abimo
Medical technology in China: A lucrative, but increasingly competitive market

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The global med tech industry is booming – and China represents one of the world’s largest markets for medical technology. In 2017, it accounted for almost 19% of the global med tech market. Although the growth of China’s med tech industry has significantly slowed down, to a rate of 8.3% – compared to an annual growth rate of over 20% between 2013 to 2016 –, it still expands at almost double the pace of global growth.

From 2011 to 2017, China generated an export surplus in medical devices. The three most important product categories on the Chinese market are medical imaging (16% market share), in-vitro diagnostics (14%), and medical consumables (13%). The most important foreign suppliers of medical technology for China have been USA, Germany, and Japan.
By far the largest import product categories are diagnostics and treatment equipment as well as dental care. The need for orthopaedics devices is particularly high in China, with products “Made in Germany” in hot demand. In general, China is one of the most important markets for the German medical technology industry after the USA. In 2017, German companies realised revenues of around 1.8 billion EUR in China, an increase in export volume of almost 14% over the previous year.

**China’s demand for medical technology remains high**

The Chinese government has been investing efforts in improving the health insurance and health care systems since the 1990s – and particularly since 2009. With a growing middle class and greater health awareness, there has been a call for better quality. This is an important driver of high demand for advanced medical technology devices. Another key driver behind the need for high-quality medical technology and devices is the rapidly ageing Chinese population, with the resulting increase of chronic disease and age-related illnesses.

The Chinese government has taken measures to respond to this development, among other things through budget increases. Since 2010, China’s public health expenditure has almost tripled to approximately 1,521 billion Chinese Yuan (CNY) in 2017.\(^1\) However, China still cannot meet the domestic demand for state-of-the-art medical technology itself.

**Foreign companies still dominate the premium segment of medical technology**

The Chinese medical technology market can roughly be divided into two sectors: the low and medium-price segment and the expensive, technologically more advanced premium segment. The latter is clearly dominated by foreign companies – above all by Philips, Roche, and Medtronic. But other companies such as Siemens, General Electric, and Johnson & Johnson also rank among the foreign top companies for medical technology in China.

Chinese suppliers, in turn, dominate the low to medium-price segment. Over 80% of Chinese suppliers can be assigned to this segment. Foreign imports barely play a role here anymore. Moreover, Chinese providers are increasingly pushing into the premium segment. In 2016, no less than three Chinese producers introduced high-class PET-CT devices. This breached the de-facto import monopoly in this field. In the following year, Chinese producers already managed to take a share of around 10% of the upper segment of China’s market for medical technology devices.

In parallel to the advancing modernisation and digitalisation of the industry, the quality of medical technology products in China is improving too – among other reasons as a result of state financial support.\(^2\) In comparison to their foreign competitors, Chinese companies still invest relatively little in research and development. The performance and quality of premium medical technology products from China is still lagging behind foreign competition. As a result, Chinese producers primarily enter into price competition with international providers.

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\(^1\) 1 CNY ≈ 0.13 EUR
\(^2\) To name an example, the national government supported 25 research and development projects in digital diagnostics technology with 150 million CNY in 2018.
China’s medical technology market is increasingly competitive

The Chinese market is highly competitive: According to the US government, there were approximately 16,000 Chinese producers of medical technology devices in 2017. However, this number is set to decrease significantly as the result of many mergers on the Chinese market. The medical technology industry of China is primarily located along the coast, above all in the Beijing-Tianjin-Hebei region, and both the Yangtze and the Pearl River Delta. Interesting hubs are, however, also developing in the country’s heartland, for instance around the cities of Chongqing, Chengdu, and Wuhan.

Many Chinese manufacturers have their interests represented by the China Association of Medical Device Industry (CAMDI) – the national industry association for medical technology. These are usually smaller companies competing within a relative homogenous product range. With support of the Chinese government, however, some larger companies have also formed. Three Chinese medical technology companies already ranked among the ten largest in China in 2017: Mindray, Shinva, and WeGo. Mindray is already operating internationally as well. It is seen as one of the most promising companies of the Chinese med tech industry.

The Chinese government sees strategic merit in the development of medical technology

The medical technology industry is of great strategic importance to China. The role of innovation in healthcare and medical technology is, amongst others, emphasised in the current Five-Year Plan, the key policy document for the scientific and societal development of the People’s Republic of China (PRC). A large number of plans in support of these fields were introduced in the last four years. The “Internet+Health” initiative to accelerate the digitalisation of China’s healthcare, and the underlying “Healthy China 2030” strategy deserve special mention. The latter focuses on providing better healthcare to China’s rapidly ageing society and enhances the roles of general practitioners, local medical care, as well as private healthcare providers. Advancements should also be made in telemedicine and mobile healthcare. Initial successes can already be witnessed in the digital field: In 2015, there were only six so-called “Internet Hospitals” that rely more heavily on the use of artificial intelligence and new information technologies. By May 2019, this number had already increased to 158.

Medical technology also plays a major role in the comprehensive innovation strategy “Made in China 2025” (MIC25). High-performance medical devices are identified as one of ten core industries in which China strives to assume a globally leading position by 2049. To this end, for instance, the degree of localisation – i.e. the share of domestic solutions on the Chinese market – should be increased.

<table>
<thead>
<tr>
<th>MIC25 sets ambitious market share goals for Chinese med tech</th>
<th>By 2020</th>
<th>By 2025</th>
</tr>
</thead>
<tbody>
<tr>
<td>» Share of county-level hospitals with mid- to high-end medical equipment</td>
<td>50%</td>
<td>70%</td>
</tr>
<tr>
<td>» Domestic market share of core components (e.g. for medical use of big data and 3D printing) from Chinese producers</td>
<td>60–70%</td>
<td>85%</td>
</tr>
</tbody>
</table>

Source: NMSAC
China’s domestic market is set to reach a scale of around 168 billion USD by 2025. Moreover, significant advancements are to be made in equipment for medical imaging, implantations, clinical tests, advanced therapeutics, as well as health monitoring. To achieve this, China resorts to foreign know-how. At the same time, however, the development of internationally competitive high-quality brands is another goal set by the Chinese government.

**Preferential treatment for domestic producers is common on China’s procurement market**

The growth of the Chinese medical technology market can primarily be attributed to the procurement activities of hospitals. They are key players in China’s healthcare system, with public institutions providing the largest share of services. It is therefore important to have a basic understanding of the public procurement activities of Chinese hospitals. They are primarily governed by two laws, the “Tender and Bidding Law (TBL)” and the “Government Procurement Law (GPL)”. Products and services which fall under the GPL are listed in a central catalogue. In addition, however, local governments often introduce their own catalogues and regulations. China’s public procurement market therefore continues to be seen as non-transparent. It is also used to the benefit of Chinese competitors. After all, solely the (lower) prices of Chinese products – and not a combination of price, quality, and performance – often seem to be the decisive criterion in procurements. In addition to that, the use of domestic products is endorsed by government authorities. The GPL itself states that domestic solutions are to be preferred. Since 2014, the National Health Commission (formerly the National Health and Family Planning Commission) also lists “excellent” domestic medical products. The Chinese manufacturers included in these lists are usually preferred in tendering procedures.

**Good knowledge of local conditions is crucial to foreign companies**

In principle, the Chinese market for medical technology is highly attractive to foreign companies, not least because of the impressive growth figures and high demand for premium products. Chinese alternatives do not yet represent a strong competition in this segment. Beijing did, however, clearly state the objective to strengthen domestic solutions. The increasing decentralisation of China’s healthcare system also poses a challenge for foreign suppliers of medical technology. Smaller companies in particular might experience difficulties in taking root or defending their position on the Chinese market without a local partner. Foreign companies are thus well advised to diligently analyse the regulatory environment and strategic context of China’s medical technology industry. A well-founded and comprehensive China strategy is required to compete on the increasingly competitive domestic market of the PRC.

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3 1 USD ≈ 0.90 EUR
4 Officially, a product is considered “domestic” if it has for the most part been manufactured on Chinese territory. In practice, however, this attribute is usually understood to refer to the manufacturer’s country of origin.
With the date of application only a little over six months away – what is the state of the Medical Device Regulation?

Disclaimer: The editorial deadline of this yearbook was in October 2019; developments after this date could not be considered.

The new Regulation (EU) no. 2017/745 on medical products (or “MDR” – Medical Device Regulation) was published in the Official Journal of the European Union on 5 May 2017 and took effect twenty days after publication, with full application from 26 May 2020. The MDR will replace the currently valid guidelines 93/42/EEC for medical products (MDD – Medical Device Directive) and 90/385/EEC for active implantable medical devices (AIMDD – Active Implantable Medical Device Directive). What’s the current state of affairs, with application of the new directive in just over six months away?

Bottleneck Notified Bodies (NB)

Many requirements to actually implement the MDR are still not in place. Producers still have an insufficient number of NB. However, these are absolutely necessary for market approval of medical products. They carry out special inspections and evaluations depending on the risk class of the medical products; moreover, they certify that the so-called conformity assessment is correct. Further tasks include auditing the QM systems in accordance with EN ISO 13485:2016 as well as carrying out audits to evaluate compliance with requirements, such as those resulting from the MDSAP (Medical Device Single Audit Programme).

Producers are generally free to appoint NB and conclude an agreement with them. However, before an NB is allowed to carry out activities under the MDR, they must complete a comprehensive appointment process specified in the MDR. This process is much more complex and protracted than expected by all participants. The average duration of the entire process is 18 months.

Currently, a little over six months before the date of application of the new MDR, the approximately 27,000 medical technology companies in Europe have only 5 NB available for market approval of their products (as of the beginning of October 2019: There are currently 58 notified bodies available in the EU for the old MDD/AIMDD). Producers of medical technology from non-EU states also need an NB to sell their products on the EU market, further compounding this bottleneck effect. This low
number of available NB is alarming, particularly because several NB currently active under the MDD/AIMDD have communicated that they will not seek appointment under the MDR. The financial and bureaucratic burdens are too sizeable, and many have difficulties finding qualified professionals. The situation is furthermore exacerbated by a significant increase in the number of products to be certified under the MDR, with the resulting auditing efforts increasing.

In the future, a hard Brexit might reinforce the bottleneck, because BSI Assurance UK Ltd, one of the five previous NB, would no longer be able to carry out its activities if the UK leaves the EU without an agreement. Moreover, 70% of all companies not registered in the EU (above all from the US) currently use BS in Great Britain; these companies would have to find another solution within the EU-27 area. The European Commission is currently expecting the appointment of up to 20 NB under the MDT by the end of the year; however, even if this ends up being the case, this will still not be sufficient to have all producers and products re-evaluated by 26 May 2020.

### Medical products unavailable

This might impact product diversity in the future, and lead to certain medical products – above all niche products – becoming unavailable. The in part significantly more strict regulatory requirements placed on products will likely result in discontinuations of tried-and-tested medical products. This is always the case whenever compliance with the new requirements placed on medical products is associated with such costs that the revenues expected to be realised with the products no longer justify the expenditure. According to a Swiss study from 2018, commissioned by the Swiss Federal Office for Health and the Swiss State Secretariat for Economic Affairs, the overall costs for the implementation of the MDR and IVDR in Europe will amount to approximately 18.8 billion US dollars from 2017–2020, with producers (incl. their market players along their value-added chain) and suppliers shouldering the lion’s share of the burden (18.4 billion US dollars). The sum of annual running costs in Switzerland is calculated to be 525 million Swiss francs, or 9.3% of the annual revenue of Swiss medical technology in the EU and EFTA. The costs for conformity assessments are expected to rise by 50 to 60% on average. Producers will start thinking about streamlining their portfolio and take the necessary measures. A survey carried out by the German Chamber of Commerce and Industry (DIHK) and SPECTARIS in the summer of 2018 shows that around 80% of medical technology companies expect serious difficulties in bringing innovative products to market in the future. Around half of all surveyed companies see themselves forced to slim down their product lines, with one third planning to take products out of their range altogether.

### Legal uncertainty

Many of the legal acts, standards, and guidelines strictly necessary to implement the MDR are not yet in place. Various standards must be aligned to and harmonised with the MDR. For a few
months now, the procedure has been stuck while points of contention are worked out between the European Commission and the competent standardisation bodies. Companies suffer from this significant legal uncertainty. The European database for medical products (Eudamed) will not be completed with all modules at the announced date. The “MDR/IVDR Implementation Rolling Plan” of the European Commission states the following: “It is indicated that modules for clinical investigation and market surveillance will not be available at the time of application of the MDR due to workability issues.” Without being aware of all necessary functional specifications, companies must already now adapt their IT systems in order to meet the MDR requirements in due time. Moreover, downstream European legal acts and guidelines for implementation are still not in place, which additionally adds to the legal uncertainty companies are facing.

Even if the MDR is a European directive already effective as law in all member states, attention should be paid to national legislation. In the end, the MDR also allows for member states to draft national regulations for certain issues, which must then be observed. The Federal Ministry of Health proposed a draft bill to update the Medical Products Act on August 2019. The draft bill of 163 pages will, among other things, adapt the current Medical Products Act (MPG). In addition to this legislative proposal, the Federal Ministry of Health is preparing another products regulation to revoke, modify, and even reintroduce existing legislation on medical products law.

Already now, larger companies are faced with the tremendous challenge of keeping an overview of the numerous directives, guidelines, laws, and standards at the national, European, and international level and observing the many regulatory requirements. For SMEs, this is virtually impossible without external assistance and in some cases even threatens their very existence.

Conclusion

The main and important, objectives of the MDR, to improve patient security and quality assurance, are not attained at the current state of implementation. The future unavailability of necessary medical products is not in the interest of patients. The many, in part unclear, regulatory hurdles are posing major challenges to companies. Therefore, it is crucial to in the first place ensure the functionality of the overall system. This functionality of the overall system also comprises a sufficient number of notified bodies for product approvals, a sufficient number of expert committees and laboratory bodies for clinical trials, and the availability of a functional Eudamed database. Moreover, the requirements to be met by companies must be specified with sufficient clarity.

The MDR brings with it countless new requirements for producers of medical products, among others:
» The introduction of an additional “Scrutiny Procedure” in the clinical evaluation of implantable medical products of Class III and active products of Class IIb which are intended to deliver and/or remove a medicine to/from the body
» Introduction of an electronic European vigilance and market surveillance system with shorter reporting deadlines
» More discerning requirements on clinical evaluation and the creation of clinical data with more comprehensive equivalence inspection
» Mandatory clinical trials for implants and Class III products
» Significantly stricter documentation obligations, including a monitoring plan after bringing the product to market, regularly updated reporting on security (from Class IIa onward), a plan and evaluation report on clinical monitoring after bringing to market
» Introduction of a European traceability system, Unique Device Identification (UDI), in a phased manner depending on the product risk class
» New rules on classification; partially connected with higher classifications (e.g. products with nanomaterials, material medical products, introduction of Class IIR (reusable) for surgical instruments which can be reused)
» Producers require a “person responsible for regulatory compliance”. This person is to observe significantly more comprehensive tasks than the current Security Officer of the company

The SPECTARIS “Regulatory Affairs Forum for Medical Technology” and further working groups

To support producers, above all in this special period, SPECTARIS operates a Regulatory Affairs Forum for Medical Technology (formerly known as the Technical Commission for Medical Technology) as well as further regulatory affairs working groups, particularly geared towards the field of medical technology. Participants are given a compact overview of current regulatory developments and challenges at the national, European, and international level. The activities of the Regulatory Affairs Forum for Medical Technology (RFMT) offer valuable assistance to companies to help them understand the situation, analyse it, and carry out implementations. The RFMT and working groups open up room for dialogue and the exchange of experiences between
producers. Here, focus is placed on understanding and properly implementing regulatory requirements.

In addition to direct dialogue, the Regulatory Affairs Forum as well as the working groups impart further expert knowledge. Experts from the field are invited as guests. Experienced working group members are represented in national, international, and European expert committees and share insights on current issues, interpretations, and implementation ideas at the national as well as European level.

The association regularly informs its members on the regulatory developments in the field of medical technology and gives them the opportunity to provide input on specific legislative measures and current issues.
Successful approval of medical products in China – a road with many obstacles

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The approval of medical products in China starts with their classification following the Medical Device Classification Catalogue, the current version of which was published on 31 August 2017 by the China Food and Drug Administration (CFDA). This catalogue is clearly illustrated with a large number of examples. If a device cannot be unequivocally classified into one of the 22 specified product categories, the Rules for Medical Device Classification are to be used. In borderline cases, there exists the option of applying for official qualification with the National Medical Products Administration (NMPA, formerly CFDA). Potential risks, specific characteristics, and the use of the device must be described in the application. The producer must submit a detailed functional description and proof of classification of the device in the producer’s country of origin together with the application.

It can take months to process applications. China uses the three risk classes I, II, and III for medical technology and in-vitro diagnostics (IVD). European classifications merely serve as an indication for the class, with Chinese officials very frequently reaching a different classification. If this is the case, the European products are usually assigned one class higher. If the device is assigned to risk class II or III, the next step of the registration process comprises the creation of the Technical Requirements (formerly: Registration Standard), which map out the requirement to agree on type tests with a Chinese test laboratory. Active medical devices are subject to performance, electrical safety, and electromagnetic compatibility (EMC) inspections in China. China has its own system of standardisation. Obligatory Chinese standards are called GuoBiao (GB), which is literally translated as “national standard”. Chinese industry standards for medical devices are called YY standards. The test standard for electrical safety is called GB 9706.1-2007. It is based on IEC 60601-1: 1988, 2005, 2012. The standards are equivalent but not completely equal. The test standard for EMC in China is YY 0505-2012 and is identical to IEC 60601-1-2: 2004. Nevertheless, tests must be carried out at a test laboratory accredited by the NMPA in China.

In China, biocompatibility tests for devices which come into contact with the patient’s body are carried out in accordance with GB/T 16886.1-2011, which is in turn identical to ISO 10993-1:2009. Here, there exists the opportunity of having a test which was carried out abroad recognised if the test was performed in accordance with ISO 10993-1:2009 and the test report issued was by a test laboratory approved following Good Laboratory Practices (GLP).

Preparation of the application dossier can begin in parallel to the type tests. The type test reports and the Clinical Evaluation Report (CER) are the cornerstones of the application. Whether a clinical trial in China is required for the CER can be determined using various exclusion criteria. The NMPA has published multiple lists of medical products and IVD of Classes II and III which do not require clinical trials in China for registration. The third version of the Exception List is already available for medical technology, as is the second extended version for IVD. These lists comprise 855 exempted medical devices and 393 exempted IVD products for which a highly simplified CER suffices on application.

In other instances, clinical data which were collected in a clinical trial performed outside of China can be used to create the CER if these meet Chinese rules. If such data are not available, there still is the option of finding a predicate device approved in China and use its data. The applicant must have obtained the
clinical data in a legal manner. A clinical trial for the product is only unavoidable if these three approaches are fruitless.

Class I medical products don’t need to be put to a type test or undergo a clinical trial in China; for these, simple notification of the NMPA suffices.

The guidelines on technical lifetime examination, updated on 14 May 2019, form a new challenge in the registration of active medical products. As part of the registration process, applicants must prove the lifetime of their products. Here, the lifetime is the period during which safe operation of the product is guaranteed.

Under the NMPA provisions, only a legal person with residency in China can apply for the registration of medical technology devices. For the registration of their products, foreign producers thus require a legal representative, the NMPA Legal Agent. The producer must issue a written power of attorney for representation at the NMPA. The NMPA Legal Agent plays a decisive role in applying for, changing, and extending certificates as well as importing devices to China. Therefore, this position should be selected carefully, with the most important decision criteria being experience in dealing with regulatory matters, the relevant product standards, and the competent authorities. There are generally three options available:

» 1. The Chinese subsidiary of the producer assumes the function of legal agent.
» 2. The distributor is appointed as the legal agent; in this case, however, a company is to a large extent dependent on the distributor, who is virtually given exclusivity.
» 3. A consultancy company responsible for the NMPA registration is appointed as the NMPA Legal Agent. This has the advantage of remaining independent and being able to use as many distributors as required, as well as change them.

On 7 May 2019, the Center for Medical Device Evaluation (CMDE) announced the introduction of an electronic platform to submit the application dossier (http://erps.cmde.org.cn). The system serves electronically managed medical product registrations; in future, all documents for the NMPA registration are to be submitted through this eRPS system, with the paper form no longer being necessary.

Since 10 May 2019, it is thus possible to apply for a Certificate Authority (CA). The CA certificate is required to log into the eRPS system. With imported medical products, the NMPA Legal Agent must apply for a CA certificate on behalf of the foreign producer. The application dossier is to be submitted in complete form, together with all accompanying documents such as test reports, certificates, evidence, etc., in Chinese.

The National Medical Products Administration checks the submitted documents for compliance with the formal requirements within a week. For Class II products, the CMDE requires approximately 60 working days for the technical evaluation of the documents and 90 working days for Class III products. After this initial technical evaluation, the NMPA expert issues a Supplementary Notice. In response to this notice, the producer must make all supplementary documents available within a year and submit these to the NMPA. Then follows the final technical evaluation, which will again take around 60 working days. The NMPA requires another 30 working days for administrative approval of the registration and to issue the certificate.

Certificates for Class II and III medical products are valid for five years. Certificate extensions must be applied for at least six months before the expiration date at the latest. There is no expiration date for certificates for Class I products.

To safeguard product quality in the life science sector, the NMPA expects proactive cooperation of the local legal representative of foreign producers. The NMPA published a guideline on responsibilities—the Guideline for Imported Medical Device Legal Agent. This includes supporting the producer in the approval of its products and regulation-compliant Chinese operating instructions. From 1 January 2019, the Chinese company name of all imported Class II and III medical products must be included in the Chinese operating instructions and on the Chinese label, and the name must match the name on the NMPA certificate. This request is illustrative of the importance of a well-informed, proactive, and cooperative NMPA Legal Agent for the timely implementation of current regulations in China. Further responsibilities of the legal representative comprise monitoring and reporting adverse events in China as well as notifying the supervisory authorities and supporting the supervisory authorities in quality control.

To this end, the NMPA has released Decree No. 1 on the reporting of adverse events for medical products on 31 August 2018. The Decree states that adverse events that occur overseas must be reported to the NMPA, and a report must be created by the local legal representative in China. This regulation assigns the responsibility for controlling, proactive monitoring, and providing information on quality problems to the producer and the NMPA Legal Agent in equal parts. The system serves to improve risk management of medical products by targeting the monitoring, evaluation, and remedying of adverse events for this product group. The NMPA Legal Agent plays a much more important role than before. As the local legal representative, they are responsible for meeting requirements after the product is brought to market, without the producer having to establish its own Chinese office.

With regards to the issue of adverse events, the State Administration of Market Regulation (SAMR) published a joint declaration together with the General Administration of Customs of China (GACC) on 30 October 2018, announcing closer cooperation in the recall of defective imported goods. With this reform, the SAMR was given the main responsibility for product recalls in China, with greater focus placed on life science products and foodstuffs, such as medical products, medicines, and cosmetics, in addition to health food and infant milk. The GACC reports to
the SAMR on products identified as defective during the customs inspection. The SAMR in turn informs the GACC on infringements in the event of recalls, to allow the GACC to initiate measures against the involved companies. Moreover, producers and consumers can find information about recalls on the website of SAMR. The WeChat Messenger services of the SAMR and GACC also regularly publish information on recalls.

Further reinforcement of product safety controls was enacted in the Directive on the Administration of Medical Products and Medicine Overseas, passed on 28 December 2018. This regulation specifies that the NMPA will also carry out factory inspections for producers in other countries in the future, to guarantee the safety and effectiveness of imported medical products and medicines.

Comprehensive inspection of all producers is not envisioned; sampling will take place on the basis of risk assessments. To date, primarily Chinese producers were regularly inspected. In January and March 2019, the production sites of 24 foreign companies were already subjected to an inspection. Deficiencies were identified in all instances. The respective problems can be looked up online on the NMPA website. Producers then have 50 working days to take corrective measures.

On 23 August 2020, the NMPA announced the introduction of the UDI system (Unique Device Identification) for medical products in China. The new UDI regulation took effect on 1 October 2019. This important requirement will already affect the registration and import of medical products in China in the very near future. To date, four important documents have been published on the UDI (NMPA Announcement on Issuing the Rule of UDI System for Medical Devices, Rule for UDI System of Medical Devices in China, YY/T 1630-2018 Fundamental Requirements for the UDI and the NMPA UDI Interpretation Rule). Foreign producers of medical products must carry out the following steps:

» 1. Creation of a DI code (Device Identification) in line with the UDI code standard of the Chinese approval authority ANCC (Article Numbering Center of China) and determining the PI code structure (Production Identification)

» 2. From 1 October 2019, the applicant must submit the relevant DI code to the NMPA for applications for approval of medical products – such as new approvals, renewed approvals, and changes to the approval of medical products.

» 3. Selection of a suitable data carrier – such as a barcode, QR code, or RFID code – in accordance with the ANCC Standard and applying it to the product or packaging.

» 4. Uploading the DI code and the associated information to the UDI database for medical products before the product is imported to China. Important – this UDI database has not yet been made available by the NMPA.

» 5. If there are changes to the DI code and the associated information, the applicant must update the information in the UDI database.

Major regulatory challenges must be overcome to enter the Chinese market. Therefore, companies should schedule plenty of time and arrange for an appropriate budget. After successfully going through the required tests and creating a solid application dossier, the path into this very promising market is wide open.
### German healthcare expenditure by institution

<table>
<thead>
<tr>
<th>Institutions</th>
<th>2016</th>
<th>2017</th>
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<tbody>
<tr>
<td>Health expenditure</td>
<td>358.7</td>
<td>375.6</td>
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<tr>
<td>» Investments</td>
<td>7.0</td>
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<tr>
<td>» Ongoing healthcare expenditure</td>
<td>351.7</td>
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<td>» Health protection</td>
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<td>» Outpatient institutions</td>
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<td>» Medical practices</td>
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<td>» Dental practices</td>
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<td>» Practices of other medical professions</td>
<td>13.1</td>
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<tr>
<td>» Pharmacies</td>
<td>48.4</td>
<td>49.3</td>
</tr>
<tr>
<td>» Health trade professions/retail</td>
<td>20.8</td>
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<tr>
<td>» Outpatient care</td>
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<td>19.4</td>
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<tr>
<td>» Inpatient/short-term inpatient institutions</td>
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<td>138.4</td>
</tr>
<tr>
<td>» Hospitals</td>
<td>92.5</td>
<td>94.7</td>
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<tr>
<td>» Preventive/rehabilitation institutions</td>
<td>9.5</td>
<td>9.7</td>
</tr>
<tr>
<td>» Inpatient/short-term inpatient care</td>
<td>30.9</td>
<td>34.0</td>
</tr>
<tr>
<td>» Emergency services</td>
<td>4.5</td>
<td>4.8</td>
</tr>
<tr>
<td>» Administration</td>
<td>18.9</td>
<td>19.3</td>
</tr>
<tr>
<td>» Other institutions and private households</td>
<td>11.4</td>
<td>16.8</td>
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<tr>
<td>» Care abroad</td>
<td>1.7</td>
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* Source: Federal Statistics Office

### German healthcare expenditure by cost bearer

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<th>Cost bearer</th>
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<tbody>
<tr>
<td><strong>Total cost bearers</strong></td>
<td>375.6</td>
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<td><strong>Public budgets</strong></td>
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<tr>
<td></td>
<td>15.4</td>
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<tr>
<td><strong>Statutory health insurance</strong></td>
<td>214.2</td>
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<tr>
<td></td>
<td>221.3</td>
</tr>
<tr>
<td><strong>Long-term care insurance</strong></td>
<td>37.2</td>
</tr>
<tr>
<td></td>
<td>39.4</td>
</tr>
<tr>
<td><strong>Statutory pension</strong></td>
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<tr>
<td></td>
<td>4.8</td>
</tr>
<tr>
<td><strong>Statutory accident insurance</strong></td>
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<tr>
<td></td>
<td>5.9</td>
</tr>
<tr>
<td><strong>Private health insurance</strong></td>
<td>31.6</td>
</tr>
<tr>
<td></td>
<td>32.2</td>
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<tr>
<td><strong>Employers</strong></td>
<td>15.6</td>
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<tr>
<td></td>
<td>16.1</td>
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<tr>
<td><strong>Private households and private non-profit organisations</strong></td>
<td>50.8</td>
</tr>
<tr>
<td></td>
<td>56.0</td>
</tr>
</tbody>
</table>

* preliminary figures

* Source (introductory text and figures): Federal Statistics Office
“Hazardous substances” under the Medical Device Regulation

Nathalie Buijs, Manager Regulations & Industrial Policy
MedTech Europe

EU Regulation 2017/745 on medical devices (hereafter “Medical Device Regulation” or “MDR”) introduces new legal requirements for certain “hazardous substances” in medical devices. These requirements are established in Section 10.4. of Annex I (General Safety and Performance Requirements). Section 10.4. specifies that the use of certain chemical substances in medical device parts or materials in a concentration of 0.1% by weight or more will need to be justified in the technical file. The presence of such substances will also need to be indicated on the device label.

**Legal requirements**

**Substances and devices in scope**
The requirements of MDR Section 10.4. apply if the following conditions are met simultaneously:

» The substance is classified as carcinogenic, mutagenic or toxic to reproduction (CMR) of category 1A or 1B; or has endocrine-disrupting properties.

» The substance is contained in a device, or a part or material thereof, which is invasive and comes into direct contact with the human body; or which (re)administers medicines, body liquids or other substances, including gases, to/from the body; or which transports or stores such medicines, body fluids or substances, including gases, to be (re)administered to the body.

» The substance is contained at a concentration of 0.1% or more by weight of the device, part or material concerned.

**Manufacturer obligations**
A manufacturer of devices containing substances which fulfil the three above-mentioned conditions have two key obligations to fulfil:

» Risk justification: The manufacturer must conduct a benefit-risk assessment which proves that the benefits of using the substance outweighs the risks. This assessment must be documented in the technical file to allow scrutiny by the Notified Body. The MDR requires that the justification consists of (a) an analysis of potential exposure to the substance, being a patient or user, (b) an analysis of possible alternative substances, materials or designs; (c) the actual risk-benefit assessment comparing the current device with identified alternatives in terms of functionality, performance and risk-benefit ratio, taking into account the intended use of the device. The manufacturer must base the risk-benefit assessment on the latest relevant scientific committee guidelines. For phthalates, there will be the forthcoming Guidelines of the Scientific Committee on Health and Environmental Risks (SCHER).

» Labelling: The presence of substances in scope of MDR Section 10.4. must be labelled on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging, with the list of such substances. The acceptability of symbols to meet this labelling requirement is still to be determined (see challenges below). If the intended use of such devices includes treatment of children, pregnant, breastfeeding woman or other patient groups considered particularly vulnerable to such substances and/or materials, information on residual risks for those patient groups and, if applicable, appropriate precautionary measures shall be given in the instructions for use.

**Comparison with the Medical Device Directive**
The following table compares the new requirements in the Medical Device Regulation (MDR) with the existing requirements for certain phthalates in the Medical Device Directive (MDD). This shows that the MDR is much wider in scope than the MDD.
not only has the number of substances which are covered increased drastically, also the obligations in terms of risk justification and labelling have become more stringent.

Key challenges

The medical technology industry is strongly committed to the new Medical Device Regulation and its full and timely implementation. Medical device manufacturers are investing heavily to comply with the new requirements. However, they are likely to face several challenges when implementing the new requirements on hazardous substances:

» Difficulty to define which devices are in scope of the requirements (e.g. meaning of ‘invasive’, ‘administering substances to/from the body’).
» Challenge to establish the level (device, material, part) at which to calculate the hazardous substance concentration.
» Knowledge of which substances are present in parts or materials and at which concentration will require improved communication with and information from suppliers and/or testing by the medical device manufacturer.
» Keeping track of the list of substances classified as CMR 1A, CMR 1B and endocrine disruptors. This includes monitoring Adaptation to Technical Progress to the CLP Regulation (for CMR substances) as well as updates of the REACH Candidate list and identification of substances with endocrine-disrupting properties under the Biocidal Products Regulation (for endocrine disruptors).
» Meeting the requirements for risk justification (including assessment of potential alternatives) and ensuring that the relevant scientific committee guidelines are met. In certain cases, this may require manufacturers to implement design changes in order to keep the device compliant with the law.
» Updating the list of substances on the label. To avoid multiple label updates, MedTech Europe has developed a hazardous substance symbol which could be used instead of a substance list (which would require continuous updating of the label). This symbol is currently subject to approval for inclusion in the revised ISO 15223-1 standard and may eventually become harmonised against the MDR. MedTech Europe developed guidance on symbols under the MDR which is publicly available on our website.¹
» Potentially addressing concerns from patients and/or healthcare professionals who will, by means of device labels, be made aware of the presence of substances which have been classified as hazardous for human health, even if they do not necessarily pose a risk to the patient. The European Commission’s factsheet for healthcare professionals states in this regard that: “The MDR foresees that device labels will have to indicate the presence of CMR substances or endocrine-disrupting substances in medical devices above certain concentrations. This labelling requirement does not mean that a device is unsafe. The fact that it has been CE marked means that both the manufacturer and the Notified Body have established a positive risk-benefit ratio (MDR Annex I, Chapter II, section 10.4.1).”²
» Finally, the MDR requirements come on top of existing regulations on chemicals, several of which apply wholly or partially on medical devices, e.g. Regulation (EC) No 1907/2006 on REACH, Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products (BPR).

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Type of substances in scope</td>
<td>Pthalates which are classified as CMR, of category 1 or 2</td>
<td>All substances which are classified as CMR, of category 1A and 1B, and all substances having endocrine-disrupting properties identified in accordance with REACH or BPR</td>
</tr>
<tr>
<td>Number of substances in scope</td>
<td>11 substances</td>
<td>+ 1200 substances</td>
</tr>
<tr>
<td>Justification of the use of substances in scope</td>
<td>Justification about compliance with essential requirements, in particular risk of leaking Only if intended use includes treatment of children or treatment of pregnant or nursing women</td>
<td>Justification must consist of analysis of exposure, analysis of alternatives and risk-benefit assessment Justification always required</td>
</tr>
<tr>
<td>Labelling of the presence of substances in scope</td>
<td>To be labelled as a device containing phthalates</td>
<td>To be labelled with ‘the list of substances’</td>
</tr>
</tbody>
</table>

² CMR: Carcinogenic, mutagenic or toxic to reproduction; Category 1A: ‘Known to have CMR potential for humans’; Category 1B: ‘Presumed to have CMR potential for humans’; Category 2: ‘Suspected human CMR’
³ REACH: Regulation (EC) No 1907/2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals
⁴ BPR: Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

MedTech Europe has developed industry guidance to support manufacturers with the MDR obligations related to hazardous substances. The guidance is available to SPECTARIS members free of charge. To obtain a copy, please contact regulatory@medtecheurope.org.


SPECTARIS Yearbook 2019/2020 | Medical Technology
Connecting medical devices across manufacturers

The series of interoperability standards IEEE 11073 SDC

Digitalisation in healthcare has the objective of improving the efficiency and quality of patient treatment. Increasing cost pressure, higher service demands, as well as limited resources require the continuous development of hospitals as overall systems. A crucial part of this strategy is the IT connection of the medical technology devices of different manufacturers in order to quickly collect data at the location at which they are generated and forward them without any media disruptions. Hospitals can gain a significant cost advantage – and thus competitive advantage – by connecting to technologies involved in the value-added chain. To date, the integration of medical technology systems is implemented by the providers of proprietary systems solutions. This strategy comes with the disadvantage of giving this provider a virtual monopoly, with adjustments to the configuration up to the end of the ongoing investment cycle only possible with significant (financial) efforts. This prevents the continuous implementation of efficiency improvements, e.g. through the integration of new technologies, and massively restricts the creative freedom of hospitals. The publication of the series of standards IEEE 11073 SDC represents a milestone in the elimination of bottlenecks. The standardisation of interfaces for complex medical technology devices allows for the integration of devices from different producers into an overall system, as well as a large number of value-added features across devices (see Illustration 1).

IEEE 11073 service-oriented device connectivity (SDC)

The IEEE 11073 SDC series of standards (see Illustration 2) is maintained and developed by the user’s association OR.NET e. V. The non-profit association develops usage scenarios for connectivity-based value-added services, creates guidelines on their implementation, and offers support in the software-side implementation of interfaces.

Since the beginning of 2019, OR.NET e.V. has integrally published three core standards of the IEEE 11073 SDC series of standards which can be implemented by industry players. The core of the series is made up by the Domain, Information, and Service Model (IEEE 11073-10207). This allows for the description of each medical...
In connectivity solutions on the basis of standard hardware and software, patient safety is not possible without information security. Therefore, the IEEE 11073 SDC series contains mechanisms for the encryption of communication, authorisation and authentication of network partners, etc.

Sustainable technology with future potential

With the continuous evolution of digitalisation in healthcare, all clinical disciplines are also facing new challenges. Complex diagnostics and therapy tailored to patients place great demands on clinical personnel as regards the collection and processing of information and the controlling of supporting technical systems. As a result of the interoperability of devices across producers, data or features are no longer merely made available to the deployed systems themselves, but also to the overarching infrastructure or other devices.

To make sure that these semantically interpretable data can be shared between the various devices, the so-called Medical Devices Communication Profile for Web Services, or MDPWS (IEEE 11073-20702), was developed. It builds on the established DPWS standard and defines expansions and restrictions to meet medical requirements. Each IP-capable standard network can be used for data transmission, for example ethernet (IEEE 802.3 series) or Wi-Fi (IEEE 802.11 series). Such standard technologies reduce costs and efforts for use in hospitals.

The SDC core standards are complemented by the IEEE 11073-20701 standard. On the one hand, this defines the overall architecture on the basis of the core principles of service-oriented architecture (SOA), and on the other hand, it specifies the connection between the two other core standards and other standards. The strict separation between the data model and data transmission in the two standards makes it future-proof: If a more suitable transmission technology is established in the future, it can be used without changing the modelling of the devices. Moreover, the use of other established standards is described for aspects such as time synchronisation or Quality of Service (QoS).

In connectivity solutions on the basis of standard hardware and software, patient safety is not possible without information security. Therefore, the IEEE 11073 SDC series contains mechanisms for the encryption of communication, authorisation and authentication of network partners, etc.

Illustration 2: Interoperable, producer-independent connection of medical devices: IEEE 11073 SDC core standards

Sources: ICCAS Leipzig /Max Rockstroh
The innovative force of German medical technology producers

Around one-third of revenues realised with German medical technology stem from products which are less than three years old. The industry invests a great amount of capital and personnel in research and development (R&D). With R&D expenditures amounting to around 9% of revenue and with around 15% of employees active in R&D, the R&D intensities of producers clearly exceeded the industry average.

In 2018, the medical technology segment made the most successful patent applications with the European Patent Office: 13,795 (+5%) of a total of around 174,000 applications. Germany takes second place with 1,336 applications, behind the UAS (5,175 applications) and ahead of Japan (1,184).

European patent applications in the field of medical technology

2008–2018

Contact:
Mike Bähren
SPECTARIS e.V.

Source: European Patent Office
European patent applications in the field of medical technology

Origin of applicants 2018

<table>
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<th>Country</th>
<th>Applications</th>
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<td>USA</td>
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<td>Germany</td>
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<td>China</td>
<td>305</td>
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<td>Others</td>
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Source: European Patent Office
Cooperation agreements with medical institutions and healthcare professionals

Maria Heil, M.C.L. (Mannheim/Adelaide) attorney at law, Partner, NOVACOS Law Practice

Contact:
Email: maria.heil@novacos-law.com
www.novacos-law.com

Cooperations with medical institutions and healthcare professionals are very important to the medical technology industry. Only in this way can medical applications be tested in practice and can companies gather information from users and patients. Examples of such necessary cooperations include conducting clinical trials, studies, presentation activities, and advisory boards. Demand for close exchange with users is set to increase even further with a look to the enhanced requirements placed on clinical data before and after certification under the MDR.

Over the past years, however, several forms of cooperation have also been subjected to public scrutiny. They were in part used to grant unlawful remuneration to healthcare professionals under the guise of a cooperation. For this reason, it is now more important than ever for medical technology companies to design cooperations with healthcare professionals in a legally sound manner from the very beginning. The legal framework is provided by the prohibitions of undue benefits under the Act on advertising in the healthcare sector (Heilmittelwerbegesetz) and professional regulations, as well as criminal related to corruption (above all §§ 299a, b of the Penal Code StGB), but members of SPECTARIS are also bound by the SPECTARIS Code of Conduct since 2017.

Cooperations with medical institutions and healthcare professionals should particularly comply with the following criteria:

1. Actual need for cooperation

Remunerated cooperations are only allowed whenever medical technology companies actually have a real need on their performance. In practice, this means that companies are allowed to enter into those cooperations which are reasonable for the company in line with objective and factual standards. For example, this may apply to gathering information on further product developments, issues in patient care, as well as the collection of medical opinions in fields in which the company is active. The regulatory requirements placed on clinical product data under the MDR can particularly substantiate the objective need for cooperation. The actual need should be communicated to the outside world in a visible manner, e.g. by specifying it in the cooperation agreement or in the letter of invitation. Already during the planning phase, the concrete use of the results of the cooperation in the company should be taken into consideration. Later implementation should also be carried through and documented.

2. Concrete implementation with the selected cooperation partners

When selecting partners to support the medical technology companies, the abstract requirements placed on the partner must be defined in advance (size of the hospital, specification, physician’s qualification, etc.), in order to ensure that the company obtains useful results. Accordingly, the specific partner must be selected on the basis of the pre-defined criteria. Selection on the basis of revenue figures or similar is not permissible. The required number of partners must additionally be specified in advance. The company must, for example, ask itself how many statements from different partners are statistically required in market research in order to obtain conclusive results. Only this number of partners may actually be included in the market research. The question of how many partners are necessary may, among other things, depend on the complexity of the issues to be dealt with or the plurality of available opinions.
3. Appropriate remuneration

If there exists an actual need for cooperation and after specifically selecting the partners following the criteria specified above, the company is allowed to pay the cooperation partner an appropriate remuneration for the performed services. Various criteria can generally be used to calculate the remuneration, above all depending on the type of performance to be remunerated.

» If the performance is of a service nature, e.g. participation in an advisory board, speaking activities, etc., focus should be placed on the time required for performing the service. Speaker’s agreements regularly require a set hourly rate to calculate an appropriate remuneration. To determine the rate, criteria such as the qualification and experience of the service provider, industry reputation (national/international), the difficulty or scientific demand of the task, etc. are decisive on a case-by-case basis. Many medical technology companies have worked out various general categories and defined a matrix in advance which includes the hourly rates for service activities.

» If the service is of a more “factual” nature, e.g. sponsoring an external event for continued education, the calculation of the appropriate remuneration does not or not primarily depend on the personal criteria associated with the performing party, contrary to the services specified above. To name an example, in calculating the appropriate value of a sponsoring service, decisive factors are not the time spent and expertise required to hang up an advertising banner. Other criteria are relevant here, such as the value of the advertisement to the company, the size and importance of the event, the exclusivity of the advertisement, and so on. The company must evaluate these external factors for each project and “fill it with life”. An appropriate remuneration can then be determined on this basis. In both cases, the proper documentation of applied criteria is important to make sure that the objective and factual criteria used to calculate the remuneration can still be understood after granting the remuneration.

4. Formal requirements

A written agreement should always be concluded between the cooperation partners, mapping out the cooperation, background (company need, partner’s qualifications, etc.), the service, and above all the remuneration. Only then can unequivocal proof of the legal grounds for payment to medical institutions or healthcare professionals be provided to third parties. If the agreement is concluded with one individual healthcare professional who is an employee (for example of a hospital or medical centre), the approval of the employer for this specific cooperation is additionally required – as is the case with all economic performances. A general approval for secondary employment does not suffice. Documentation on the observance of compliance principles plays a crucial role in designing the cooperation, as it can serve as evidence in case of disputes. Therefore, companies should have a uniform electronic procedure in place for each cooperation, in which not only the written agreement, but also the need, calculation of the remuneration, etc. are laid out and substantiated in writing.

5. One-sided support payments in line with the SPECTARIS Code of Conduct

If, in exceptional cases, a medical institution is to be supported without performing a service in return, for example for research purposes, this is generally possible under German law in the form of a donation. The requirements from the SPECTARIS Code of Conduct must additionally be observed. This is governed by Chapter 4, Clause 3 on one-sided support payments for education purposes. Companies can support external continuing
education events, award grants and fellowship programmes, as well as promote disease awareness campaigns following the requirements specified therein. Chapter 4, Clause 4 covers sponsoring for research purposes. The Code allows for (material or financial) support of earmarked research contributions for clearly defined research studies initiated by third parties for clinical or non-clinical research programmes.

If the company has an interest in the results of the research, a mutual cooperation agreement with the purpose of transferring the rights to the results might be the proper solution. Here, the parties should ensure that the appropriateness of the remuneration does not depend on the financial research requirements, but should rather be in line with the value the data have for the company.

6. Bottom line

A legally sound cooperation with medical institutions and healthcare professionals is possible under observance of the applicable principles. This requires thorough planning in advance on the part of the company as well as the inclusion of departments that can capably handle the cooperation. For example, a clinical study should not be managed by the Marketing team. On the other hand, market research on new advertising statements can be planned and carried out by the Marketing department. There have not been any significant changes to the requirements placed on cooperations in the previous years. Changes to the risk profile, above all in the field of primary care (§§ 299a, b StGB), have further increased the importance of comprehensive requirement documentation; nevertheless, cooperations can be planned and carried out under observance of the framework conditions mapped out above.

Especially as a result of the relevance of clinical data to product approval and monitoring under the MDR, cooperation between the industry and users in certain areas is actually expressly promoted by the legislator.
German healthcare expenditure by service type

<table>
<thead>
<tr>
<th>Type of service</th>
<th>2016</th>
<th>2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall health expenditure</td>
<td>358.7</td>
<td>375.6</td>
</tr>
<tr>
<td>Investments</td>
<td>7.0</td>
<td>7.0</td>
</tr>
<tr>
<td>Ongoing healthcare expenditure</td>
<td>351.7</td>
<td>368.6</td>
</tr>
<tr>
<td>Prevention/health protection</td>
<td>11.8</td>
<td>12.1</td>
</tr>
<tr>
<td>Health promote</td>
<td>3.9</td>
<td>4.0</td>
</tr>
<tr>
<td>Health promotion</td>
<td>4.7</td>
<td>4.9</td>
</tr>
<tr>
<td>Early detection of diseases</td>
<td>1.9</td>
<td>2.0</td>
</tr>
<tr>
<td>Opinions and coordination</td>
<td>1.3</td>
<td>1.2</td>
</tr>
<tr>
<td>Medical services</td>
<td>95.2</td>
<td>98.0</td>
</tr>
<tr>
<td>Basic services</td>
<td>26.0</td>
<td>27.0</td>
</tr>
<tr>
<td>Special services</td>
<td>49.7</td>
<td>51.1</td>
</tr>
<tr>
<td>Laboratory services</td>
<td>9.4</td>
<td>9.7</td>
</tr>
<tr>
<td>Radio-diagnostic services</td>
<td>10.1</td>
<td>10.4</td>
</tr>
<tr>
<td>Care/therapeutic services</td>
<td>95.6</td>
<td>105.8</td>
</tr>
<tr>
<td>Care services</td>
<td>70.9</td>
<td>79.8</td>
</tr>
<tr>
<td>Therapeutic service</td>
<td>23.5</td>
<td>24.8</td>
</tr>
<tr>
<td>Maternity services</td>
<td>1.1</td>
<td>1.2</td>
</tr>
<tr>
<td>Accommodation/care</td>
<td>27.8</td>
<td>28.7</td>
</tr>
<tr>
<td>Goods</td>
<td>97.4</td>
<td>99.3</td>
</tr>
<tr>
<td>Medicines</td>
<td>55.8</td>
<td>57.3</td>
</tr>
<tr>
<td>Devices</td>
<td>19.4</td>
<td>19.6</td>
</tr>
<tr>
<td>Dentures (material/laboratory costs)</td>
<td>7.5</td>
<td>7.5</td>
</tr>
<tr>
<td>Other medical needs</td>
<td>14.7</td>
<td>14.9</td>
</tr>
<tr>
<td>Transport</td>
<td>7.1</td>
<td>7.5</td>
</tr>
<tr>
<td>Administrative services</td>
<td>16.8</td>
<td>17.2</td>
</tr>
</tbody>
</table>

Source: Federal Statistics Office
Ethical aspects in nursing bed care

The nursing bed plays a very crucial role in care. As a point of care, the nursing bed forms the foundation of maintaining what is usually someone’s last personal space, allowing for care in line with current standards and representing how our society deals with “those in need of care”. Against this backdrop, there is an ethical and moral obligation to refrain from bringing nursing beds with minimal furnishings to market out of short-term, economic considerations.

Ethics has always played a major role in care, and professional codes of conduct have been in place since the dawn of professional care. Nevertheless, principles of medical ethics have recently grown even more relevant. Not in the least because of several “care scandals”, some of which were the subject of public debate.

The rights of those in need of care and assistance are laid down in the eight articles of the Care Charter (see box). This Charter is intended to strengthen the rights of people in need of long-term care and assistance by summarising the fundamental and indisputable rights of people in need of support, care, and assistance. These rights are an expression of respect for the dignity of people, and they are thus embedded in numerous national and international legal texts. Comments on the rights are added in explanations on the articles, exploring the central aspects and situations of the lives of people in need of care and assistance. Moreover, the Charter specifies quality characteristics and objectives to be aspired to and implemented as part of good care and assistance.

The producers of nursing beds organised within the industry association SPECTARIS explicitly want to direct focus of care discussions to the nursing bed as a “point of care”, in which residents or those in need of care often spend most of their time, in line with these ethical and moral aspects. They are currently developing a declaration of commitment with the objective of illustrating how the producers of nursing beds observe and implement the ethical requirements laid out in the Care Charter in nursing bed features, to the benefit of both residents as well as care professionals and relatives.

Nursing beds are medical products that guarantee the utmost level of safety

Nursing beds are medical products that comply with the strict regulatory market approval regulations. In terms of quality and design, they are always developed to guarantee the utmost level of safety for both the care professionals as well as residents.

Nursing beds support the nursing staff and at the same time serve as a nursing aid to residents

Nursing beds are both medical product and furniture, supporting the daily work of nursing staff with their numerous functions as well as residents as a care aid. The most recent findings from nursing science on positioning, mobilisation, and decubitus prevention must be taken into consideration.

A good balance between the best possible protection against falls while at the same time allowing for the greatest freedom and self-determination

On the one hand, producers of nursing beds must always strike a good balance between offering the resident the best possible protection against falling from the bed to prevent (in part dramatic) consequences (fall consequence prevention), and on the other hand, the basic rights of residence to self-determination and freedom.
Nursing beds contribute to homeliness at the “point of care”

As a “point of care”, many patients spend most of their time in the nursing bed. Producers contribute to improvements in their quality of life by creating a comfortable ambiance through the selection of materials and with high-quality, modern designs.

Producers contribute to environmental protection

The basic ethical requirements entail that producers consider the overall lifecycle of the nursing bed, also under consideration of environmental and sustainability aspects. The selection of materials, production process, logistics, deployment, and the easiest possible disposal at the end of the lifecycle play a crucial role here. High-quality nursing beds additionally ensure that there are very few returns, and thus a low replacement and scrap rate. A fixture of the overall process is trying to minimise the burden placed on the environment. This extends far beyond the standard requirements, for example by refraining from the use of tropical timbers or only using coatings which are harmless to the environment.

Code of Conduct, professional ethics, and data privacy

Regardless of the product, the ethical approach of producers also comprises the consistently fair treatment of employees, suppliers, and customers in daily operations. Fairness, transparency, honesty, as well as – naturally – observing all legal regulations and preventing all types of discrimination, are part of day-to-day activities.

In light of the advancing digitalisation, which also impacts the field of nursing beds, data privacy plays a key role. Producers undertake to comply with all data protection requirements under the General Data Protection Regulation (GDPR) as part of the digitisation of their products.

As a member of the German Industry Association SPECTARIS, producers are also bound to the SPECTARIS Code of Conduct for cooperations in healthcare.

Care Charter:

» Article 1: Self-determination and self-help support
Everyone in need of long-term care and assistance has the right to self-help support and to assistance to enable them to live a life which is as self-determined and independent as possible.

» Article 2: Physical and mental integrity, freedom, and security
Everyone in need of long-term care and assistance has the right to protection against any physical or mental threats.

» Article 3: Privacy
Everyone in need of long-term care and assistance has the right to the safeguarding and protection of their privacy and intimate personal space.

» Article 4: Care, support, and treatment
Everyone in need of long-term care and assistance has the right to qualified, health-promoting care, support and treatment that is tailored to their personal needs.

» Article 5: Information, counselling, and informed consent
Everyone in need of long-term care and assistance has the right to be fully informed of the possibilities and opportunities available for counselling, support, care, and treatment.

» Article 6: Respect, communication, and social participation
Everyone in need of long-term care and assistance has the right to respect, interaction with others, and to participate in society.

» Article 7: Religion, culture, and beliefs
Everyone in need of long-term care and assistance has the right to live in keeping with their culture and beliefs, and to practice their religion.

» Article 8: Palliative care, end-of-life care, and death
Everyone in need of long-term care and assistance has the right to die with dignity.
Requirement for the digitalisation of the healthcare system: the further development of assessment procedures

Digital medical products are set to revolutionise healthcare. They goal is to ensure that all processes are carried out faster, better, and above all at lower costs.

Patients can better manage their illnesses, doctors can carry out remote treatments and make remote diagnoses on the basis of data transmitted by patients. They can then decide whether a patient need not worry and can stay home, or should visit the hospital instead. Data can be compiled to prevent unnecessary examinations and an overview can be given of the entire medical history of the patient, as well as their provision of medication, therapeutic products, and supporting products. Moreover, artificial intelligence can assist in making diagnoses and expedite treatment recommendations. Doctors can even discuss findings over long distances and bundle their expertise in consulting patients.

However, the emergence of this brave new world of medicine, simple yet efficient, is often obstructed, not just by ethical, professional, and legal discussions.

Above all, the requirements of the German healthcare system pose a challenge to digital medical products such as software and apps.

The German statutory healthcare system is generally divided into two segments: the inpatient and outpatient segments. Each of these care processes has its own rules for accepting a healthcare service into the reimbursement process. Many digital supply offers, however, work across industry sectors with a single process. For example, a patient collects data on their heart rhythm at home using a mobile ECG and provides them to their treating specialist for analysis, as well as a hospital physician, through an app. These then jointly make a decision on whether hospitalisation is necessary. The patient and specialist operate in the outpatient segment, whereas the hospital physician makes their diagnosis decision in the inpatient segment. The patient can also store different measurements in the app. It might give instructions on when measurements are useful and when to urgently contact a physician. The patient might feel more secure in spite of their cardiac failure and enjoy greater participation in life by even going on a trip abroad. Whenever the patient is feeling insecure about their health condition, they can collect data and send them to their German physicians who then consult with the patient and treat them from Germany. In this case, treatment not only spans various segments but also countries. Now, the question must be addressed where the service was performed for bill settlement.

Digital applications often offer benefits in the care process that exceed the typical patient benefits within the framework of a treatment.

The topic of benefit analysis is crucial to all producers of medical products whenever they want to have their products reimbursed by the statutory health insurers as part of new examination or treatment methods or the product itself represents a new examination or treatment method.

There are strict criteria in place for providing evidence of benefits. Randomised control studies (RCT) are usually required to effectively prove benefits. Here, only benefits to patients are relevant to the evaluation, as is specified in Book 5 of the German Social Code. Mortality, morbidity, and health-related quality of life are evaluated. Further benefits of a method are only taken into consideration when answering the final question of whether it can be included for reimbursement as an alternative to existing examination and treatment methods.

The requirements described here, however, do not constitute specific challenges in the evaluation of methods based on digital medical products – they apply to the entire industry.

Special features of digital care offers on the one hand result from the “innovation cycles” of digital medical products, such as apps and software for therapy or diagnosis. These are subject to much more rapid change than classical medical products, because experiences made with the product can instantly be taken over in a new version. Apps and software are continuously updated and their quality developed further during use. The product does not have one set functional status which is used as part of the method. The identified user learning curve, which makes it harder to evaluate medical products as part of a medical method, is joined by the “improvement curve” of the digital product.
On the other hand, products also adapt to usage behaviour, generate outcomes and recommendations – depending on the available data – which they can use in combination with user data. As the product is used more and more, the quantity of data from which decision recommendations can be calculated for this individual patient increases.

In short, the product available at the beginning of the study is no longer the same at the end of the study.

New evaluation methods must be created to account for these special features, new study designs which pay tribute to the characteristics of continuous further development.

Often, however, process changes are the most important benefits offered by a digital product. Patients are only asked to visit the physician if the transmitted data change. Examinations by robotic physician assistants of course come with the benefit of having them carried out at home, in the patient’s familiar environment. Physicians must no longer be motivated to move their practice to rural areas to ensure local care or only seldomly have to pay house visits to people with reduced mobility. Treatments might become less onerous for patients, but the same high quality is still guaranteed.

This also means that a method assessment must be replaced by a process evaluation. A first approach can be found in the draft of the planned Digitalisation Act, in which “positive care effects” to be proven are mentioned.

However, the development of adequate assessment procedures for digital care offers is and remains necessary. The special characteristics of study design, new categories of benefits, and short innovation and product lifecycles must be taken into account here.

What’s more, providers of digital care offers must be informed and consulted in a binding manner on options to access the reimbursement system, to make sure that good and innovative ideas do not fail because of the selection of the wrong access option.

If Germany wants to use digital care offers to the benefit of insured persons, not only individual players must be involved, but all stakeholders should all work together on new concepts as partners – and not just for assessment.

Access paths should be clearly defined and evaluation methods explained and developed collaboratively during an exchange. Patients must be better included into the process of further development of the health system. After all, a risk-benefit analysis for patient care always takes place at the end of an assessment process. They should therefore be given a voice.
Digitalisation and lack of skilled labour

Almost 8 million employees, or around one-fifth of all employees subject to make social security contributions, are faced with the risk of their jobs being rendered either completely obsolete or at least changing fundamentally by 2025. This is the conclusion of a study conducted by the Boston Consulting Group. Headlines such as this one shape the perception of advancing digitalisation and create unease in the general public at first glance, with people perceiving an acute threat for their own jobs.

In this context, we struggle to reconcile this insight with the apparent contradiction of digitalisation being massively slowed down by a lack of skilled labour. The Association of German Engineers (VDI) reports that the German job market depends heavily on experts from the fields of engineering and computer science to keep pace with international competition when it comes to digitalisation. The SPECTARIS study “Health 4.0” draws similar conclusions for the German healthcare industry. It paints a picture of an industry still only realising a minor share of revenue with digital products and services, lagging in an industry and international comparison. The main reason given for this is a lack of suitable employees with the right digital qualifications who could help design the transformation. We can confirm this observation from our daily operations in executive search. The search for excellent managers with digital expertise, who can push forward digitalisation for our healthcare clients, now forms a significant and continuously growing share of our business.

The authors of the “Health 4.0” study assert that a significant net plus of jobs can be created over the coming years by remedying this obstacle to growth. This could amount to around 10,000 additional jobs. Even if there are great worries about the state of digitalisation in Germany, the positive conclusion can be drawn that the health industry can continue to serve as a job motor for overall economy in the future as well – if suitable measures are taken, already laying the foundation for long-term success today.

Let’s start by looking at the current and immediate need for action. Difficulties already arise from the fact that the “Health 4.0” study indicates that less than 40% of medical technology companies have defined an express
Digitalisation strategy. These contrasts to the observation that most companies seem to agree that digitalisation is the future and “something has to be done” in this field. Many companies fail to properly implement these insights, however, experiencing difficulties with grasping the specific issues at hand, dividing them into manageable chunks, and deriving specific fields of action from them. Nevertheless, this should be at the beginning of the entire process. Only in this way companies can start establishing firm foundations as part of their strategic staff planning today in order to use their digital key competences to draw employees to their company on the highly competitive specialised job market of the future, thus gaining decisive competitive advantages.

This “laying the tracks for long-term success” is unfortunately not sufficiently emphasised in public discussions. In light of the fundamental changes digital transformation will bring about, also on the job market, looking for properly qualified employees externally and winning their commitment to the company is no longer enough. In fact, competences will be required in the future which are not yet widely available on the job market in this combination and form. The German Stifterverband provides a good overview with their “Higher Education Report 2020”, differentiating between three types of “future skills”. On the one hand, these include technological skills such as complex data analysis and user-centred design, which are necessary to design transformative technologies and require the education of technology experts. However, employees must gain “future skills” on a wide scale as well to be able to hold their own on the job market of the future. This includes digital key qualifications such as agile working and digital learning as well as other overarching key qualifications such as creativity and capacity for adaptation.

This also implies that entirely new job profiles will emerge over the coming five to ten years that will bundle these competences. Vocational schools and universities (of applied science) are already today facing this challenge and will have to further reinforce their efforts to develop suitable new training and education programmes. By creating suitable framework conditions, politics can very effectively support digitalisation. Nevertheless, broader social changes are also necessary. The importance of professional further education is set to increase significantly. Companies must offer their employees with suitable opportunities and actively demand the willingness to commit to “lifelong learning”. We are of the firm conviction that companies which prioritise instilling in their employees the competences specified above, while making use of their own digital experts, will have a considerable competitive edge in the future!
A strong domestic market as a driver of global success – how Germany can defend its edge in medical technology

Roland Berger, founded in 1967, is one of the only globally leading management consultancies with German origins and European roots. The company is successfully active on all important global markets, with around 2,400 employees in 35 countries. The Competence Center Pharma & Healthcare advises customers from the pharmaceutical industry, medical technology, as well as health insurers and healthcare providers in the fields of digital transformation, regulative changes, reorganisation, and growth strategies.

Interview with Dr Thilo Kaltenbach, Senior Partner at Roland Berger and author of the study jointly published with SPECTARIS on “Health 4.0 – why Germany must become the leading market for the digital healthcare economy and medical technology, and steps to take now.” (available online – in German – at https://www.rolandberger.com/de/Publications/Digitalisierung-der-Gesundheitswirtschaft-in-Deutschland.html)

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Mr Kaltenbach, in your study you are looking at the current state of digitalisation in German healthcare, and how this impacts medical technology. The sector was for a long time considered a model German industry. Does this still ring true?

This is certainly still the ambition, and rightfully so. German medical technology is in high demand across the globe, with 64% of medical products produced in the country exported. Taken as a whole, the German producers still take second place in the global ranking, with revenues of 32 billion euros and a share of around 10%; behind the US but ahead of Japan. I use the world “still”, because we are currently experiencing a worrying development: The strength of German medical technology is attributable to the strong domestic market. And this market is facing pressure, with Germany lagging behind when it comes to digitalisation. Currently, we can rightfully claim to be ahead of the pack, but we must now take action to ensure that it stays that way in the future. Only if Germany manages to develop into the leading market for digital healthcare can the country defend its leadership position.

Why is the digital transformation more successful in other countries?

Countries such as the Netherlands, Denmark, Sweden, as well as Austria and Estonia, above all have one thing in common: The political determination to act emerged at an early stage, setting the course for digitalisation – for example in Austria, with the introduction of the Electronic Patient File (ELGA) following the opt-out principle: Insured persons participate in the plan unless they actively object to it. Of course, this gives them a significant advantage in experience with digital methods. In Germany, political actors delegated responsibility for the issue to stakeholders of the healthcare system for a long time – in line with the principle of self-administration. However, this actually slows down innovation, because the slowest player sets the pace.

What opportunities does digitalisation bring for German medical technology producers?

Let me illustrate this using the three most significant threats in the event that Germany continues to make such hesitant progress in digitalisation, as pointed out by the medical companies...
surveyed by us: displacement by new competitors, more difficult foreign market access, loss of market shares. Digital innovations are indispensable to even retain market competitiveness of company products, otherwise producers will lose customers to competitors from countries such as the USA and China. On the other hand, digitalisation also offers the opportunity to provide new services in addition to conventional product sales, reinforcing the company’s position on the market and boosting revenues. This is joined by further effects, for example in development and production, because producers directly monitor their devices during use through digital methods and can immediately integrate user feedback into further development.

**What can companies do to tap into this potential?**

For our study, we not only collected the current impressions on digitalisation and the medical industry, but also developed recommendations for actions for politics and companies. There is one crucial issue for medical technology producers. They should first and foremost recognise the importance of digitalisation and set their priorities properly – a lot of companies still haven’t managed to do so. Above all, this entails developing a clearly defined strategy for handling the issue. Key questions are, to name some examples, how and where digital technologies can be used in the company’s business, which competences are required for this, and how staff can be suitably qualified. After working out the strategy, companies should then invest massively in digitalisation projects in a targeted manner – for new products as well as services. Ideally, this would amount to between three and 5% of revenue – currently, this usually falls short of 2%. Politics is, however, partially to blame for this reluctance as well; officials still have their work cut out for them.

**For example?**

Politics must take control and create regulatory requirements to establish a framework in which companies can pursue their own path towards digitalisation. Our recommendation therefore comprises, in addition to the development of a national e-Health strategy with electronic patient files, a comprehensive infrastructure programme to connect inpatient and outpatient care. Besides this, we need legal standards, such as technical baseline requirements and data protection regulations. Moreover, the approval of new digital products and services must be expedited and health insurers must introduce reimbursement processes. With all these measures, focus should always be placed on patient benefits.

**Are the current legislative proposals sufficient?**

Numerous measures have been initiated over the past months, which is a positive development; nevertheless, the laws often remain too superficial and once again leave too much to self-administration. Instead, they should describe in greater detail which measures should lead to attainment of the aspired objectives. This also includes clear specifications, e.g. obligations for physicians and pharmacists to participate in the electronic patient file.

**What is your vision for the German healthcare economy in 2030?**

Even with less-than-optimal conditions in place for the rapid digitalisation of German healthcare, I remain optimistic. Germany is currently a leading market in medical technology and can still assume a leadership role in 2030. As previously mentioned, the legislative proposals are already a step in the right direction. Another important factor is that more and more stakeholders – from physicians to hospital operators and health insurers to patients – are demonstrating openness towards digitalisation. This is partially the result of a generational change, but also attributable to the fact that digital technologies are increasingly playing a role in many parts of everyday life, which in turn gives rise to greater acceptance in healthcare as well. For this reason, an increasing number of companies and start-ups are working on relevant projects. Germany might be late to the game, but we haven’t missed our opportunity, and I expect the industry to retain or even consolidate its competitive edge on the market in the coming ten years.

*The interview was conducted by Mike Bähren, Head of Business Administration and Market Research at SPECTARIS e. V.*
Medical Technology in the German Industry Association SPECTARIS

SPECTARIS is the German Industry Association for optics, photonics, and analysis and medical technology with headquarters in Berlin. The association represents 400 German high-tech companies, primarily small and medium-sized enterprises. Overall revenue of the optics, photonics, medical technology, as well as analysis, bio-, and laboratory devices industries amounted to almost 72 billion euros in 2018, employing around 316,000 individuals.

The Medical Technology segment of the German Industry Association SPECTARIS unites companies in medical technology, an industry characterised by strong exports and SMEs. The objective is to improve national and international competitiveness as well as the innovative strength of member companies through a targeted service offer, above all in the fields of regulatory affairs, foreign trade, and export promotion. The association is particularly valued as a powerful representative of interests because it bundles well-founded and reliable information, building on the expertise of its member companies, and brings it into political discussion as an industry stance.

The members of the Medical Technology segment of the German Industry Association SPECTARIS are German medical technology companies – primarily SMEs. The member companies research and develop products and methods for medical and nursing care for the benefit of patients. In the field of respiratory home therapy, the Industry Association also has service providers – so-called homecare providers – among its members, in addition to producers.

The companies active in medical technology operate on the future-oriented and growing healthcare market with their innovative products, which are in high demand across the globe. The industry is renowned for a range of global market leaders in demanding niche markets and characterised by small and medium-sized enterprises. They invest great effort in the development of products and methods for medical and nursing care, for the benefit of patients.

With the three pillars of SPECTARIS – representing interests, networks, service offers – at its foundation, the Industry Association brings together stakeholders in the medical technology industry by actively connecting its members through various event formats and by forming alliances at the national, European, and international level. The Medical Technology segment of the German Industry Association SPECTARIS maintains close ties to politics, at the national level as well as at the European level through the European umbrella association Medtech Europe. Moreover, the Medical Technology segment of the German Industry Association SPECTARIS is a partner of the national Federal Ministries, particularly of the Federal Ministry of Health, which is very relevant to the medical technology industry, but also to the Federal Ministry of Economics and not least the Federal Ministry of Research. There are partnerships and close ties to the associated industry and specialist associations as well as to the numerous health institutions (G-BA, IQWiG, ZLG, GKV-5V, BfArM, etc.). The Medical Technology segment of the German Industry Association SPECTARIS offers its members a platform and forum to form opinions and competently represents their interests in politics and society, towards customers and further partners along the value-added chain.

Marcus Kuhlmann
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SPECTARIS – Management

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goldenstede@spectaris.de

Dr. Markus Safaricz
Head of Research & Innovation

Phone +49 30 414021-39
safaricz@spectaris.de
### Board Medical Technology

<table>
<thead>
<tr>
<th>Position</th>
<th>Name</th>
<th>Company/Role</th>
</tr>
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<tbody>
<tr>
<td>Chairman</td>
<td>Dr Martin Leonhard</td>
<td>Department Head Technology Management, Karl Storz SE &amp; Co. KG</td>
</tr>
<tr>
<td>Deputy Chairman</td>
<td>Michael Koller</td>
<td>Managing Partner and President, Münchener Medizin Mechanik GmbH</td>
</tr>
<tr>
<td>Deputy Chairman</td>
<td>Thorsten Weide</td>
<td>Senior Consultant, Drägerwerk AG &amp; Co. KGaA</td>
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**Further members of the Board**

<table>
<thead>
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<th>Name</th>
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<tr>
<td>Dr Steffen Gebauer</td>
<td>Managing Director, MELAG Medizintechnik oHG</td>
</tr>
<tr>
<td>Hubertus Lasthaus</td>
<td>Regulatory Affairs &amp; Risk Management, VitalAire GmbH</td>
</tr>
<tr>
<td>Louise Meiners</td>
<td>Managing Director, b o n Optic Vertriebsgesellschaft mbH</td>
</tr>
<tr>
<td>Michael Scherf</td>
<td>Head of Sales &amp; Marketing, GETEMED Medizin- und Informationstechnik AG</td>
</tr>
<tr>
<td>Ludolf Schmitz</td>
<td>Managing Director, SCHMITZ u. Söhne GmbH &amp; Co. KG</td>
</tr>
<tr>
<td>André Schulte</td>
<td>Managing Director, WEINMANN Emergency Medical Technology GmbH + Co. KG</td>
</tr>
<tr>
<td>Hans-Peter Welsch</td>
<td>Managing Director AESCULAP AKademie AG</td>
</tr>
<tr>
<td>Ralf Wiedemann</td>
<td>Managing Director, Joh. Stieglmeyer GmbH &amp; Co. KG</td>
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**Co-opted Members**

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<tr>
<td>Alexander Schmitt</td>
<td>Division Manager, Ofa Bamberg GmbH</td>
</tr>
<tr>
<td>Christian Grapow</td>
<td>Managing Director Abbott Deutschland GmbH &amp; Co. KG</td>
</tr>
</tbody>
</table>

> From left to right: Mr Welsch, Mr Weide, Mr Dr Leonhard, Mr Dr Gebauer, Ms Meiners, Mr Schulte, Mr Lasthaus, Mr Kuhlmann, Mr Wiedemann
SPECTARIS is the German Industry Association for optics, photonics, and analysis and medical technology. The majority of its 400 member companies are German small and medium-sized producers, operating in their segments as “hidden champions” on the global markets.

To ensure that the key technologies underpinning their success can continue to be developed and produced in Germany, the Industry Association SPECTARIS is investing efforts to ensure framework conditions conducive to growth and innovation. The association provides information on market developments, offers consulting services with regulatory and foreign trade issues, connects companies to partners in business or politics, and puts the most important industry topics on the public agenda.
Abbott GmbH & Co. KG


Aesculap AG

Aesculap ist verlässlicher Partner für Behandlungskonzepte in Chirurgie, Orthopädie und interventioneller Gefäßmedizin. Das Unternehmen strebt nach Innovationen, die medizinischen Fortschritt bringen. Seit 1976 gehört Aesculap zur B. Braun-Gruppe und ist damit Teil eines familiengeführten Konzerns mit rund 64.000 Mitarbeitern in 64 Ländern.

air-be-c Medizintechnik GmbH

Die air-be-c Medizintechnik GmbH ist ein bundesweit tätiger Hilfsmittelversorger für die Heimtherapie. Als Anbieter aller mobilen Sauerstoffkonzentratoren besitzt das mittelständische Unternehmen ein Alleinstellungsmerkmal. Beratung vor Ort und Kundendienst rund um die Uhr zählen ebenso zum Service wie Testmieten, Privatverkäufe und Kassenversorgungen.

Alcon Pharma GmbH


ALS Automated Lab Solutions GmbH

ALS Automated Lab Solutions ist Spezialist für innovative, maßgeschneiderte Automatisierungslosungen. Durch Automatisierung + Standardisierung vormals manueller Verfahren sorgen die Lösungen von ALS für mehr Effizienz in verschiedensten Bereichen der Forschung und ebnen den Weg für neue Methoden + Möglichkeiten der Wissenschaft von Morgen.

Alu Rehab ApS


ASANUS Medizintechnik GmbH


ATMOS MedizinTechnik GmbH & Co. KG

aXcent medical GmbH


Bauer und Häselbarth-Chirurg GmbH

B. Braun Avitum


Metallwarenfabrik Walter H. Becker GmbH


Belimed GmbH

Belimed ist ein weltweit führender Anbieter von innovativen Systemlösungen für Reinigung, Desinfektion und Sterilisation Medizin Sektor. Das Unternehmen beschäftigt rund 1.200 Mitarbeitende in zehn Ländern und ist mit einem Netz eigener Vertriebsgesellschaften und autorisierter Geschäftspartner in mehr als 80 Ländern vertreten.

Metallwarenfabrik Walter H. Becker GmbH

Belimed GmbH

B. Braun Avitum


Metallwarenfabrik Walter H. Becker GmbH


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Condor® MedTec GmbH

DeVilbiss Healthcare GmbH

DMB Apparatebau GmbH

DOCERAM Medical Ceramics GmbH
DOCERAM Medical Ceramics GmbH befasst sich seit über 20 Jahren mit der Entwicklung und Herstellung von Zirkonoxid-Komponenten für die Dentaltechnik. Mit der Marke Nacera® erhält der Zahntechniker ein Zirkonoxid, das eine hohe Biegefestigkeit und das Maximum an Ästhetik vereint. Fräszentren und Dentallabore weltweit sind überzeugt. Hochwertige Nacera® Prozessoptimierungs-Produkte und Zubehör zum Finalisieren vollmonolithischer Restaurationen komplettieren das Produktportfolio.

Dornier MedTech GmbH

Dr. Hönle Medizintechnik GmbH
Das bayrische Unternehmen Dr. Hönle Medizintechnik GmbH ist seit über 40 Jahren spezialisiert auf die Entwicklung, Produktion, den weltweiten Vertrieb und Service von qualitativ hochwertigen UV-Bestrahlungsgeräten sowie der Leitungswasser-Iontophorese zur Behandlung von Hauterkrankungen und Hyperhidrose. Besonderes Augenmerk gilt der sicheren und einfachen Bedienung der Medizinprodukte.

Dr. Mach GmbH + Co. KG
Dr. Mach steht im Bereich der medizinischen Untersuchungs- und Operationsleuchten für höchste Qualität und modernste Technik. Unsere Fertigungstiefe beträgt 85 Prozent und reicht von Metallbearbeitung über Herstellung von Elektronikbauteilen bis hin zur Endmontage. Unseren Kunden bieten wir ein Höchstmaß an Flexibilität und eine gleichbleibend hohe Produktqualität.

Drägerwerk AG & Co. KGaA

Eppendorf AG
ERKA. Kallmeyer Medizintechnik GmbH & Co. KG
ERKA ist ein traditionsreiches Familienunternehmen, das seit über 130 Jahren mit besonderer Leidenschaft Geräte zur Blutdruckmessung von höchster Präzision und Qualität entwickelt. Unser Anspruch bei ERKA ist es, Medizinern die exaktesten und effizientesten Geräte in die Hand zu geben, die sie zur Ausübung ihrer professionellen Tätigkeit benötigen. MADE IN GERMANY
www.erca.org

Ernst Krauskopf – Fabrik für chirurgische und zahnärztliche Instrumente

Eschenbach Optik GmbH
Eschenbach Optik zählt weltweit zu den führenden Herstellern optischer Erzeugnisse. Das Produktportfolio reicht von Brillenfassungen und Sonnenbrillen über Ferngläser bis zu vergrößern, Sehhilfen. Insbesondere mit letzteren galt das Unternehmen als Garant für Innovation und hochwertige Markenqualität „Made in Germany“.
www.eschenbach-optik.de

EsCo Orthopädie-Service GmbH

Esslilor GmbH
www essilor.de

Ferdinand Menrad GmbH & Co. KG
In vierter Generation im Familienbesitz ist MENRAD seit 120 Jahren im Fassungsgeschäft aktiv. Die Fassungen und Sonnenbrillen aus dem Markenportfolio werden in eigenen Werken produziert und in über 100 Ländern verkauft. MENRAD ist eines der führenden Unternehmen dieser Branche.
www.menrad.de

FISBA AG
www.fisba.de

Fisher & Paykel Healthcare GmbH
www.fpbhc.de

FLO Medizintechnik GmbH

FMB Care GmbH
www.fmb-care.de

Fraunhofer-Institut für Lasertechnik ILT
www.ilt.fraunhofer.de

Fritz Stephan GmbH – Medizintechnik
www.stephan-gmbh.com

Galifa Contactlinsen AG
Das Schweizer Unternehmen Galifa ist spezialisiert auf die Entwicklung und Produktion von individuell gefertigten Präzisionskontaktlinsen nach Maß. Als Partner von Augenoptikern bietet das Schweizer Hightechunternehmen eine vielseitige Auswahl innovativer Kontaktlinsen für natürliches und gesundes Sehen, die nur im Fachhandel vertrieben werden.
www.galifa.ch
Gebrüder Martin GmbH & Co. KG

GETEMED Medizin- und Informationstechnik AG

GIMMI GmbH

Greiner GmbH

GTI medicare GmbH

HÄLSA Pharma GmbH

Handicare Group AB
Die Handicare Gruppe produziert und liefert verschiedene Hilfsmittel zur Verbesserung der Mobilität im und um das Haus. Diese Produkte werden für Menschen mit einer Funktionsbeeinträchtigung und Senioren entwickelt, aber auch für Betreuer wie Familienmitglieder, Pfleger und Therapeuten. Handicare legt den Fokus in Deutschland auf Treppenlifte.

Hans Müller HMP Medizintechnik GmbH

Hecht Contactlinsen GmbH

Heidelberg Engineering GmbH

HEINE Optotechnik GmbH & Co. KG
Als ein weltweit führender Hersteller von Primärdiagnostik-Instrumenten ist HEINE Optotechnik seit mehr als 70 Jahren ein zu 100 Prozent inhabergeführtes Familienunternehmen. HEINE entwickelt und fertigt Instrumente in den Produktionseinrichtungen in Deutschland, wo Erfahrung und Handwerkskunst mit modernsten Fertigungstechnologien vereint werden.

Andreas Hettich GmbH & Co. KG
Hermann Bock GmbH

HEYER Medical AG

Hillrom GmbH
Hillrom ist ein weltweit führendes Medizintechnikunternehmen, das sich auf die ständige Weiterentwicklung der vernetzten Gesundheitsversorgung konzentriert. Unsere Innovationen ermöglichen eine frühere Diagnose und Behandlung, optimieren die chirurgische Effizienz und beschleunigen die Genesung der Patienten. Gleichzeitig vereinfachen unsere vernetzten intelligenten Betten, Patientenlifter, Technologien zur Patientenbewertung und -überwachung die klinische Kommunikation.

Hittech Group BV

Hoffrichter Medizintechnik GmbH

HP Medizintechnik GmbH

Hu-Friedy Mfg.Co., LLC.

Industrieverband Schneid- und Haushaltswaren e.V.

Infors GmbH Deutschland

Infoteam Software AG

Insulet Germany GmbH
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<tr>
<td>INTERSPIRO GmbH</td>
<td>Interco GmbH</td>
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<td>Karl Leibinger Medizintechnik GmbH &amp; Co. KG</td>
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<td>KEK GmbH</td>
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<tr>
<td>KaWe – KIRCHNER &amp; WILHELM GmbH + Co. KG</td>
<td>KaWe – KIRCHNER &amp; WILHELM GmbH + Co. KG ist seit 1890 in der deutschen Medizintechnik etabliert. Unsere kleindiagnostischen Produkte wie Otoskope, Laryngoskope und Stethoskope zeichnen sich durch hochwertige Qualität und besondere Zuverlässigkeit aus. Weltweit werden unsere Produkte in über 100 Ländern über den medizinischen Fachhandel angeboten.</td>
</tr>
<tr>
<td>KLS Martin Group</td>
<td>Die KLS Martin Group ist eine international agierende Unternehmensgruppe für innovative Medizintechnik. Seit 1923 widmet sich die Gruppe der Chirurgie und ist heute in über 140 Ländern aktiv. Mit dem Anspruch „Surgical Innovation is our Passion“ entwickelt und vertreibt die Unternehmensgruppe eine Vielzahl von hochwertigen medizintechnischen Produkten.</td>
</tr>
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</table>
Koberg & Tente GmbH + Co. KG

Kröber Medizintechnik GmbH

Labotect Labor-Technik Göttingen GmbH

Landesinnung Chirurgiemechanik

LAP GmbH Laser Applikationen

F. & M. Lautenschläger GmbH & Co. KG

Leica Microsystems CMS GmbH

LEJ || Systempartner der Photonik

Linde Gas Therapeutics GmbH / Linde Healthcare
Linde Healthcare Deutschland ist ein führender Anbieter für die Arzneimittelversorgung mit Gasen und den dazugehörigen Medizinprodukten. Wir versorgen Patienten zu Hause sowie in spezialisierten Beatmungspflege-Centern und vereinen die Bereiche Homecare und Hospital Care der Linde Gas Therapeutics GmbH sowie das Beatmungspflegekonzept der Linde Remeo Deutschland GmbH.

Löwenstein Medical GmbH & Co. KG
Löwenstein Medical mit Sitz in Bad Ems agiert als weltweit tätiger Hersteller und Produzent hochwertiger Geräte und Medizinprodukte in Anästhesie, Intensivbeatmung und Neonatologie und Diagnostik sowie in ausgewählten Ländern als Vertriebspartner international führender Hersteller und Leistungserbringer in der außerklinischen respiratorischen Therapie.

Löwenstein Medical Innovation GmbH & Co. KG
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<thead>
<tr>
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<tr>
<td>Löwenstein Medical Technology GmbH + Co. KG</td>
<td><a href="http://www.loewensteinmedical.com">www.loewensteinmedical.com</a></td>
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<tr>
<td>Luneau Technology Deutschland GmbH</td>
<td><a href="http://www.luneautech.de">www.luneautech.de</a></td>
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<td>MAICO Diagnostics GmbH</td>
<td><a href="http://www.maico-diagnostics.de/">www.maico-diagnostics.de/</a></td>
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<td><a href="http://www.medicare-cpap.de">www.medicare-cpap.de</a></td>
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<td>Medicon eG Chirurgiemechaniker-Genossenschaft</td>
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<td>MEYER-HAAKE GmbH OBERMÖRLEN Medical Innovations</td>
<td><a href="http://www.meyer-haake.com">www.meyer-haake.com</a></td>
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<tr>
<td>Miele &amp; Cie. KG</td>
<td><a href="http://www.miele.de">www.miele.de</a></td>
</tr>
</tbody>
</table>

Löwenstein Medical Technology GmbH mit Sitz in Hamburg und weiteren Standorten in Deutschland ist Hersteller von Therapie- und Diagnosesystemen zur Behandlung respiratorischer Störungen. Schwerpunkte im Produktportfolio des international ausgerichteten Unternehmens sind die außerklinische Beatmung, die Schlafatmetherapie sowie telemedizinische Anwendungen.

Löwenstein Medical Technology + Co. KG
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Luneau Technology Deutschland GmbH
Luneau Technology Deutschland GmbH ist ein international ausgerichtetes Unternehmen, das innovative Geräte für die Medizinherstellung und -verwaltung entwickelt und vertreibt. Das Produktspektrum umfasst Lösungen für die Sterilisierung, Desinfektion und Sterilgutverwaltung.

MAICO Diagnostics GmbH

Matachana Germany GmbH

MEDICARE Medizinische Geräte GmbH
MEDICARE Medizinische Geräte GmbH ist ein international tätiges Unternehmen, das innovative Geräte für die Medizinherstellung und -verwaltung entwickelt und vertreibt. Das Produktspektrum umfasst Lösungen für die Sterilisierung, Desinfektion und Sterilgutverwaltung.

Medicon eG Chirurgiemechaniker-Genossenschaft
Seit 1941 bündelt die Medicon eG die Stärken von Herstellerbetrieben innerhalb der Genossenschaft und bietet ein Komplettprogramm von chirurgischen Instrumenten und Implantaten. Die Produkte unserer Kernbereiche SURGICAL, CMF und NEURO+SPINE genießen weltweit einen exzellenten Ruf hinsichtlich ihrer Verlässlichkeit, Qualität und Verfügbarkeit.

MELAG Medizintechnik oHG
MELAG Medizintechnik oHG ist ein international tätiges Unternehmen, das innovative Geräte für die Medizinherstellung und -verwaltung entwickelt und vertreibt. Das Produktspektrum umfasst Lösungen für die Sterilisierung, Desinfektion und Sterilgutverwaltung.

Memmert GmbH + CO. KG
In der dritten Generation entwickelt und produziert Memmert an zwei Standorten in Deutschland Temperiergeräte. Die Produktpalette umfasst Wärme-/Trockenschränke, Vakuumumschranken, Sterilisatoren und Sterilisationsgeräte. Memmert bietet Lösungen für die medizinische, pharmazeutische und wissenschaftliche Industrie.

Die Messer Gruppe

MEYER-HAAKE GmbH OBERMÖRLEN Medical Innovations

Miele & Cie. KG
Eine starke strategische Aufstellung: Miele und Steelco. Während Miele auf innovative Lösungen für die Instrumenten- und Laborglasbefälldung in Arztpraxen und Laboren fokussiert, bietet das Tochterunternehmen Steelco kundenspezifische High-Class-Systemlösungen für den Hospital-, Pharma- und Life-Science-Bereich.
Mikrop AG

MMM Group

MÖLLER-WEDEL GmbH & Co.KG

MPV MEDICAL GmbH

Mühle Müller Pflegebetten | M2 handels- und vertriebs GmbH

NDI Europe GmbH
NDI ist ein weltweit führender Hersteller von 3-D-Messtechnik für den Einsatz in Industrie, Forschung und Medizintechnik. NDI Navigations-Systeme ermöglichen es dem Chirurgen, Instrumente in den Körper des Patienten in Bezug auf medizinische Bilder (z. B. CT, MRT, etc.) zu navigieren, und machen dadurch minimalinvasive Eingriffe möglich.

nova:med GmbH & Co. KG

nova motum Services & Consulting GmbH

OBERON GmbH Fiber Technologies
OBERON Fiber Technologies entwickelt und produziert ausschließlich in Deutschland sterile medizinische Lasersonden für operative Anwendungen in der endovaskulären Chirurgie, Urologie, Orthopädie, Proktologie, Ophthalmologie, Gastroenterologie, Gynäkologie, Dentalmedizin und HNO. OBERON Fiber Technologies ist zertifizierter Medizinproduktehersteller nach ISO 13485 und verfügt über die notwendigen Zulassungen in der EU/EWR (CE) sowie in den USA (FDA), Australien (TGA), Brasilien (ANVISA) und Israel (AMAR).

OCULUS Optikgeräte GmbH
Ofa Bamberg GmbH

www.ofa.de

OLYMPUS SURGICAL TECHNOLOGIES EUROPE | Olympus Winter & Ibe GmbH
Olympus Surgical Technologies Europe ist als Hightech-Spezialist das Entwicklungs- und Produktionszentrum für Endoskopie, bipolare Hochfrequenz-Chirurgie, Systemintegration und Aufbereitung. Mit 1.700 Mitarbeitern steht das Unternehmen für Spitzenleistungen in Diagnostik und Therapie und bietet die gesamte Bandbreite modernster endoskopischer Anwendungen vom Produkt bis zur Systemlösung.

www.olympus-ost.de.eu

Ottobock SE & Co. KGaA
Für Menschen mit eingeschränkter Mobilität entwickelt Ottobock medizintechnische Produkte und Versorgungskonzepte in den Bereichen Prothetik, Orthetik, Human Mobility und MedicalCare. Tochtergesellschaften in über 50 Ländern bieten Qualität „Made in Germany“ weltweit an und beschäftigen mehr als 7.000 Menschen. Ottobock ist seit der Gründung 1919 ein familiengeführtes Unternehmen.

www.ottobock.de

Otto Rüttgers GmbH + Co. KG

Ovesco Endoscopy AG
Die Ovesco Endoscopy AG ist ein innovatives und internationales Medizintechnikunternehmen mit den Standorten in Deutschland und den USA, welches in der flexiblen und der endoluminalen Chirurgie tätig ist. Wir entwickeln, produzieren und vertreiben Produkte für die Behandlung von gastrointestinalen Erkrankungen. Markenzeichen sind endoskopische Clip-Systeme wie z. B. der OTSC® – Over-the-scope-Clip.

www.ovesco.com

PARI GmbH Spezialisten für effektive Inhalation

www.pari.com

PENTAX Europe GmbH

www.pentaxmedical.com

phenox GmbH

www.phenox.net

Philips GmbH Respironics

www.respironics.com/de

Radimed GmbH
Die Radimed GmbH entwickelt und vertreibt Produkte zur Schmerztherapie an der Wirbelsäule mit dem Fokus auf Methoden zwischen konventioneller Therapie und operativen Eingriffen. Die Spezialisierung der Radimed GmbH auf Methoden und nicht nur auf reine Produkte macht sie zu Ihrem kompetenten Zulieferer für minimalinvasive Eingriffe an der Wirbelsäule.

www.radimed.de

RAYLYTIC GmbH
ResMed Deutschland GmbH


ReWalk Robotics GmbH

Richard Wolf GmbH
Richard Wolf GmbH ist ein mittelständisches Medizintechnikunternehmen, das ein breites Spektrum an Produkten und Lösungen für die Endoskopie und extrakorporale Stoßwellenbehandlung anbietet. Integrierte OP-Systeme runden das Produkt-Portfolio ab. Das Unternehmen beschäftigt weltweit rund 1.500 Mitarbeiter und ist mit 15 Niederlassungen sowie 130 Auslandsvertretungen weltweit präsent.

ROWIAK GmbH

Rudolf Riester GmbH
Rudolf Riester hilft Dienstleistern in der Gesundheitsvorsorge und Krankenversorgung mit innovativen und diagnostischen Instrumenten das Leben ihrer Patienten zu verbessern. Wir reagieren auf die Bedürfnisse unserer Kunden mit Flexibilität, jedoch auch mit Innovationskraft, fortschrittlichen Fertigungsmethoden und dem qualifizierten Vertrieb eines Global Players.

Rupp + Hubrach Optik GmbH

SAPIO Life – Spezialist in der respiratorischen Heimtherapie

Sartorius AG

www.resmed.com
www.resmed-healthcare.de
www.rewalk.com/de
www.rowiak.de
www.rudolf-riester.de
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