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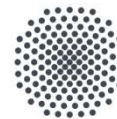
Market Study Medical Technology 2020

In cooperation with

BVMed
Gesundheit gestalten.



Working Group
Medical Technology



Universität Stuttgart
Institute of Medical Device Technology

Medical technology is a global growth market characterized by a fast pace of innovation. Small and medium-sized German companies have traditionally been able to secure competitive advantages by virtue of their strong innovative capacity. Currently, the industry, especially in Germany and Europe, is faced with a process of far-reaching changes because of increasing competitive and cost pressures, stricter regulatory requirements, and the new challenges posed by digitization. For some companies, the coronavirus pandemic has further aggravated this situation. Business models that have been successful so far, as well as the trade in medical devices, are coming under greater pressure, and companies are forced to question their present strategy, the resilience of their business model, and the future viability of their product portfolio. In addition, the succession scenarios in many small and medium-sized companies remain unclear.

These developments will significantly accelerate the concentration in the medical technology sector and influence the M&A market. Given the still positive climate for investment, taking an opportunity-oriented look from a buyer as well as a seller perspective will pay off.

We conducted a detailed analysis of the market and the actions required that will enable us to provide customized solutions for your business so that we can support you throughout the transformation process.



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BVMed is an industry association that represents more than 220 industry and trade companies. Among the members of the association are 20 of the largest medical device manufacturers worldwide in the consumer goods sector.



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The Study at a Glance

Contents: Overview of the current development of the medical technology market in Germany, Europe, the US, and Asia from a legal, technical, and transaction-oriented point of view.

Focus: Products that can be attributed to medical technology. Due to the heavy restrictions for in-vitro diagnostics (IVD), this particular field is not considered here. Apart from focusing on traditional medical technology products, this study covers the entire medical technology ecosystem.

Major trends and key messages of the study:

- An aging world population, the development of healthcare systems, and the continuous growth in the emerging markets are the main drivers of the steadily rising demand for medical technology products.
- Internationally, the regulatory requirements for the approval and distribution of medical devices can differ significantly. Therefore, a strategic reorientation of existing product portfolios has become necessary.
- Most important technological trends: digitization, the use of artificial intelligence, significant developments in sensor technology, individualized medical technology, and additive manufacturing.
- Medical technology hubs have arisen worldwide. Sometimes, M&A transactions focus on different segments of medical technology depending on their region, while the trend towards consolidation in medical technology continues.
- The trade in medical devices is under significant pressure with manufacturers increasingly trying to regain their trade margins.

The annex to the study: Expert interviews with medical technology companies about the current situation of medical technology provide an outlook for 2021.

Current Challenges

Digitization: Medtech companies will have to organize their business models digitally if they want to be successful in the long term. This means that specific requirements regarding data privacy and data security must be observed.

Regulatory requirements: Substantially increased regulatory requirements directly affect the technological development, the pace of innovation, and the business models of the companies in different markets, and thus effectively have a major influence on the profitability and the value of the company.

Special challenges in Asia: Regulatory complexity and the skills shortage, inadequate infrastructure, and intense competition hamper market access.

Our Recommendations

Small and medium-sized companies must review their business model in order to prepare themselves for increasing price pressure, continuing digitization and competition. Often, the development of new technologies and business models can only be realized with the help of new equity investors or through mergers.

Startups may rely on the help of venture capital firms in order to secure initial investments. The number of investors in this field in Germany is still relatively low. Increasingly, however, venture capital funds from abroad are showing interest in the German market. The number of startups in the areas of software, wearables, and diagnostics supported by big data is rising.

Companies from outside the industry are increasingly entering the medical technology market, especially from the automotive and IT sector. Also in this case, strategic alliances and mergers can increase the competitiveness of well-established medtech companies.

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A.

The Market for Medical Technology

“Currently, we are seeing strong competition for interesting medtech opportunities as well as a matching environment of high valuations.”

Ken Eichmann, Principal GHO Capital Partners LLP

“The medical technology industry is stable, highly innovative, and altogether less volatile and less dependent on economic trends than other sectors.”

Prof. Dr. Christian Koziol, University of Tübingen

“The medical technology market is growing in a sustainable way. The areas that are of particular interest are minimally invasive surgery, digital health, and robotics.”

Uwe Steinbacher, Managing Partner of SHS Gesellschaft für Beteiligungsmanagement mbH

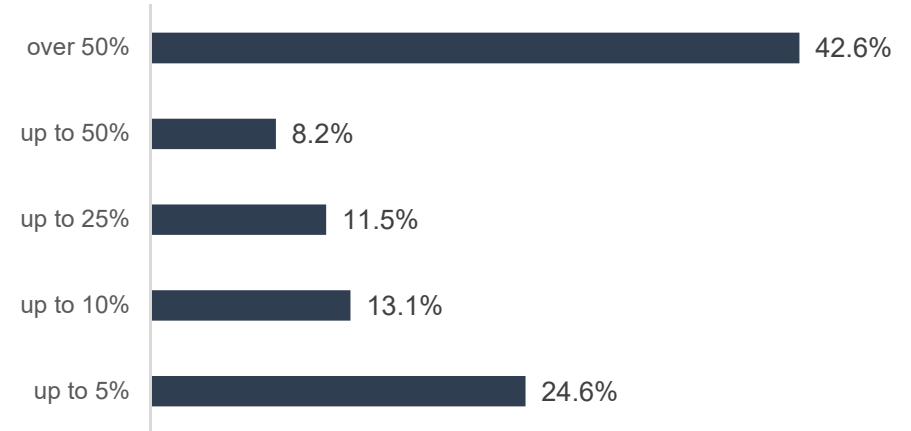
Global Trends and Market Overview in Figures



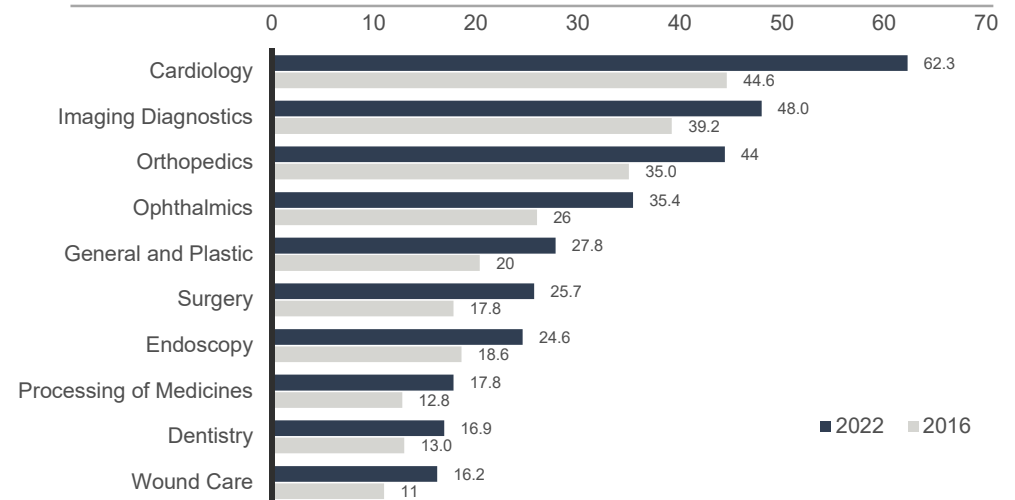
Market Overview

- The ten leading medtech companies worldwide generate a share of 37 percent of the industry’s overall sales.
- Worldwide, around 95 percent of all medtech businesses are small and medium-sized companies (SME), with the majority having fewer than 50 employees.
- The global market for medical technology will achieve a volume of 490 billion euros in 2020.
- The market is international in nature and German SME have to compete, both domestically and internationally, with large conglomerates.
- The export rate of German medical technology companies is at around 65 percent.
- Companies from outside the industry are entering the market and are able to position themselves in the market through their technological know-how as well as their expertise with regard to development, materials, and manufacturing.
- Consumer influence, digital innovations, and new market participants are all affecting the medical technology market as never before.
- Technological leaders and startups are increasingly developing smart medical devices and service-oriented solutions.
- The development cycle of medical devices is very short – a third of the devices developed and sold are younger than three years.
- The strongest medical technology segments by 2022 will be cardiology, imaging diagnostics, and orthopedics with all movement areas and elements of surgery. In total, these account for around 50 percent of the market. Especially the area of robotics has seen a disproportionate increase within orthopedics and surgery.

Medical Technology Share of the Companies Surveyed

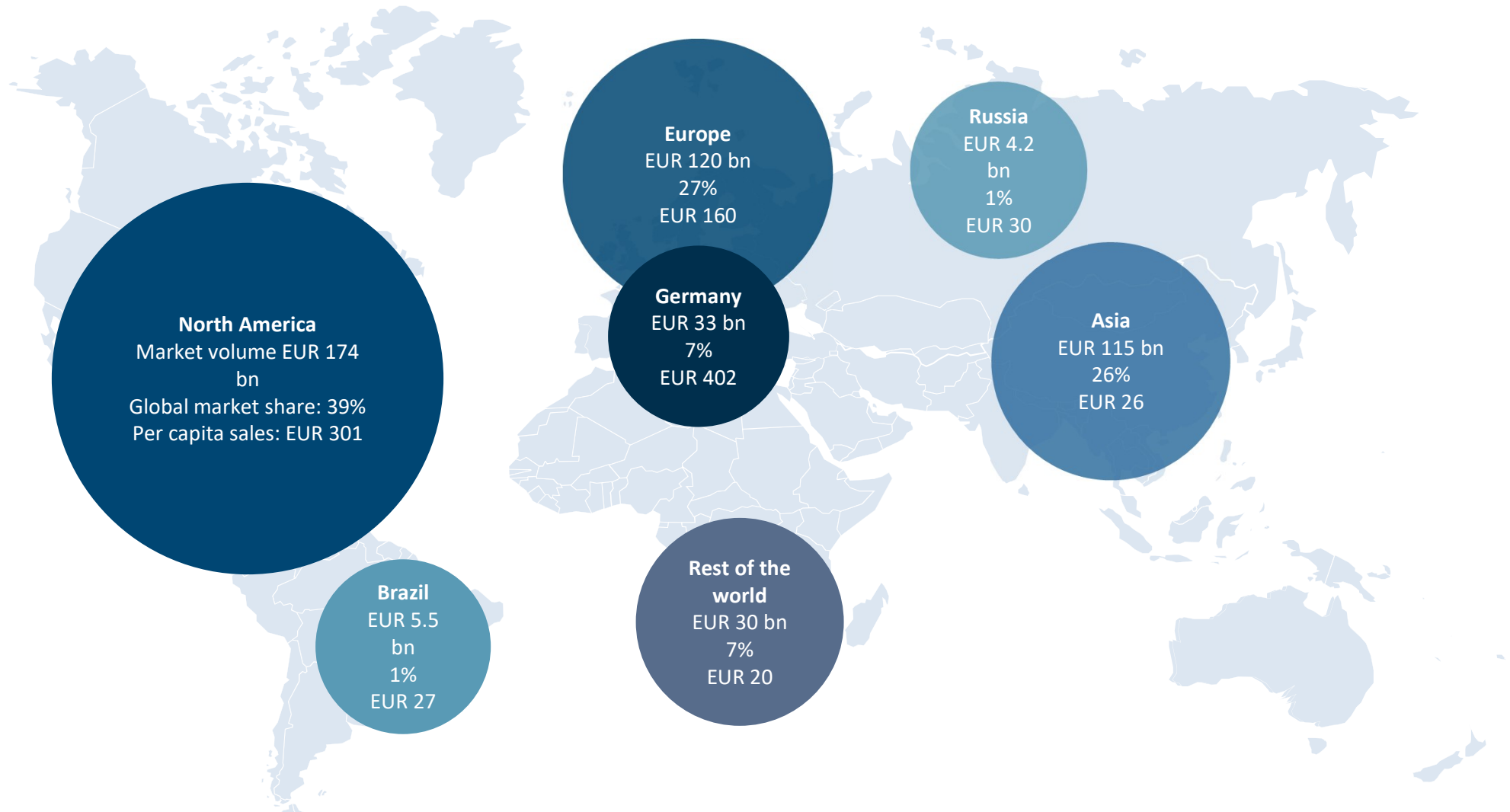


Worldwide Sales of Devices by Segments Until 2022, in Billion Dollars



Regional Market Overview 2019 in Figures (1/2)

North America is the Leading Market for Medical Technology, Before Europe and Asia



Regional Market Overview 2019 in Figures (2/2)

Europe

- Europe with its 27,000 medtech companies, almost half of which are based in Germany, is characterized by a large number of small and medium-sized businesses.
- In Europe, around 650,000 people work for medical technology businesses, around 210,000 in Germany alone.
- Only two of the highest-turnover companies worldwide, Siemens Healthineers and Fresenius Medical Care, are based in Germany. Philipps in the Netherlands and Novartis as well as Roche in Switzerland are another three top 10 companies worldwide.
- The majority of European companies are based in Germany, followed by Britain, Ireland, Italy, Switzerland, Spain, and France.

Asia

- Asia is the third largest market for medical technology after North America and Europe and is expected to overtake the EU in 2020.
- One of the reasons for the rapid growth of the Asian market is the growing middle class as well as the increasing average age in China (and in other Asian countries). By 2025, the middle class is expected to grow to about 600 million people.
- A number of Asian countries, such as Singapore and China, are very open to innovations and are providing immense support for technical developments. The funding program Startup SG, for instance, provides 40 million dollars for small medtech startups and the further development of innovative ideas. In the course of the so-called RIE2020 Plan, 19 billion dollars will be invested in research and innovations.

North America

- North America is still the largest market for medical technology.
- Seven of the ten medical technology businesses with the highest turnover are US companies.
- In addition, there are around 6,500 small and medium-sized medtech businesses in North America.
- Around 80 percent of the companies have fewer than 50 employees while the total number of employees is about 520,000.
- The most important hubs for medical technology companies in the US are in California, Minnesota, and Massachusetts. Other important federal states are Florida, Indiana, Pennsylvania, Texas, New York, New Jersey, and Illinois.

Rest of the World

- Asia, Latin America, and the Middle East provide the largest growth potential for medical products.
- Especially the medtech market in the Middle East is growing significantly, which can also be seen from the fact that the largest medtech trade fair, the Arab Health, is held in Dubai.
- Emerging markets such as Mexico, Malaysia, and Brazil forecast double-digit growth rates.
- Brazil is one of the largest growth markets worldwide. In recent years, its imports of medical technology products have been growing by around 26 percent annually.
- These import ratios can be explained, among other reasons, by the free trade agreement Mercosur which was concluded in 2019 and will continue to facilitate the export of medtech devices to South America.

Overview of Trends: Market, Technology, and M&A



Market Trends

Aging of the world's population

- According to the US Department of Health, the percentage of the population over the age of 60 years in the industrialized countries will rise from 23 percent to 32 percent by 2050.
- This development will happen more dynamically in the emerging markets due to the overall higher population growth and the improvements in healthcare infrastructure.
- In 2020, the demand for medical devices has been rising most strongly in China with 1.5 percent, followed by Europe with 1.25 percent, and the US with 1 percent.

Growth of the emerging markets

- In emerging countries, customer confidence in medical devices from industrialized countries is very high. Therefore, an increase of activities in emerging markets can be expected.
- Especially in Asia, high investments in healthcare infrastructure are taking place. In connection with the dynamic growth of the middle class and the accompanying rising demand for high-quality healthcare among the public this will result in dynamic increases in the numbers of elective operations.
- India's medtech market is estimated to be at 7.8 billion dollars in 2020. The country's expenditure on medical devices is at 4 dollars per person, the lowest worldwide (the global average is 66.3 dollars per person). By 2022 the volume is expected to be 9.6 billion dollars. This indicates a significant potential for growth over the next ten years.
- The emerging markets will exert a lasting influence on the development of the medical technology industry over the coming 50 years: Against the background of stagnating domestic demand, it is therefore important to have an early presence in the growth markets.

Technology and M&A Trends

Artificial intelligence and big data

- Artificial intelligence and big data are becoming increasingly a part of medicine and medical technology. In imaging diagnostics e.g., artificial intelligence and big data are already used extensively to accelerate analyses and support decisions.

Sensor technology

- Sensor technology is playing an increasingly important role in medical technology in order to make medical devices more efficient and safer as well as easier to operate. In addition, wearables are fitted with ever more intelligent and versatile sensors.

Patient-specific medical technology

- Increasingly, individual therapies and medical devices are being developed on the basis of patient-specific data.

E-health

- E-health supports the provision of medical care in a digital way. It is increasingly used in patient care in Germany and is already well established in other countries such as the US and Switzerland.

Robotics and networked operating room

- Apart from the increasing integration of robotic systems into operating rooms, the range of available technical assistance systems is expanding too. Medtech providers are no longer only product suppliers but are turning into system providers with open interface concepts that enable networked and advanced surgery environments.

Consolidation in the healthcare system

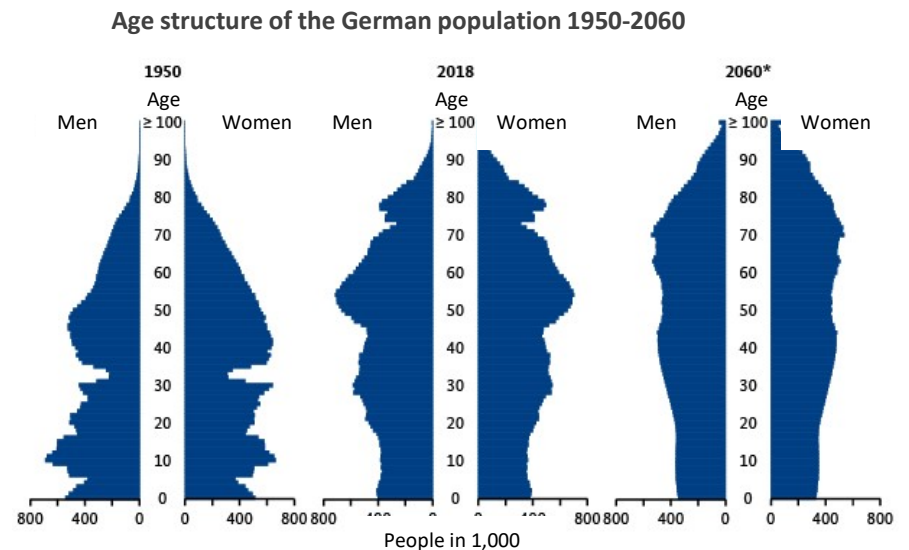
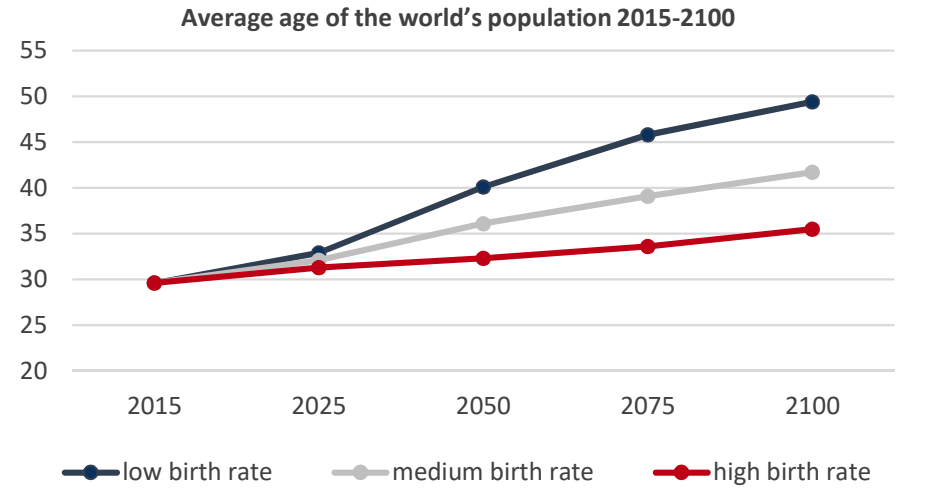
- M&A transactions in the medtech field are taking place with the aim of gaining greater competitiveness, and involve neighboring areas, e.g. AI.
- The consolidation pressure, from cooperation contracts to takeovers, is intensifying, with small and medium-sized transactions dominating.

Market Trend 1: Aging of the World's Population



Detailed Analysis: Aging of the World's Population

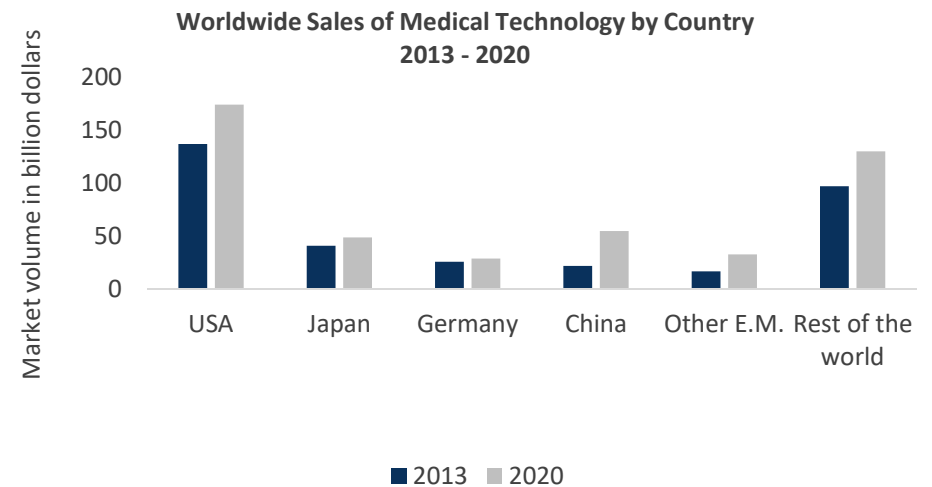
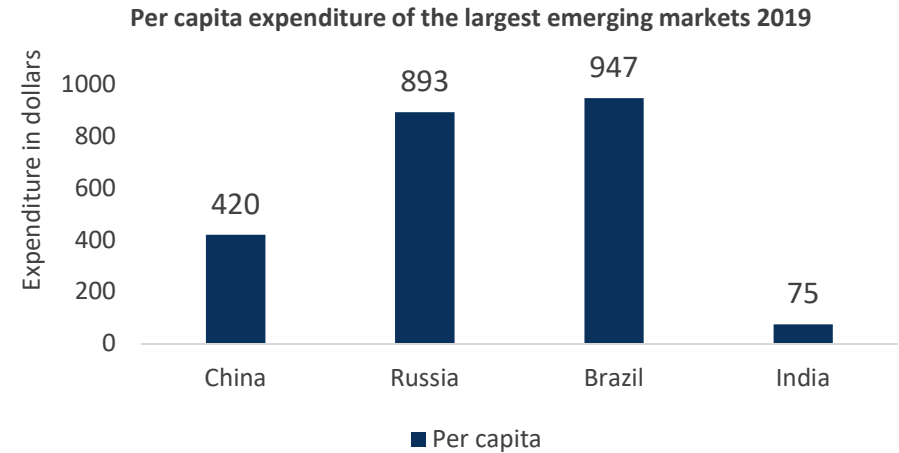
- In 2010, an estimated number of 524 million people were 65 years old or older, i.e. 8 percent of the world's population.
- It is estimated that this number will triple by 2050 and rise to around 1.5 billion people. This would correspond to 16 percent of the world's population.
- The declining birth rate and the rise in life expectancy are the major factors responsible for this phenomenon.
- Based on a low, medium, or high birth rate, the average age of the world's population will be
 - between 32 and 40 years by 2050
 - between 36 and 49 years by 2100
- Against this background of a higher age profile especially in industrialized countries, the vast and fastest growing majority of people is living in medium-developed countries.
- A declining number of young people must support a rising number of older people. This is the case especially in the APAC countries. In China, for instance, 2.4 young people will have to support 7.9 old people in 2050.
- The increasing demand for medical technology over the long term and the corresponding growth in sales are due to the age profile of the world's population and the rise in life expectancy.
- In addition, state support is provided for services in the healthcare field.
- Therefore, the age profile of the world's population determines the buyer profile in the medtech sector.
- Global turnover for medical devices is estimated at approx. 484 bn dollars in 2020. By 2025, it is expected to be at 615 bn dollars, which means an average yearly growth of 5.4 percent.



Market Trend 2: Growth of the Emerging Markets

Detailed Analysis: Growth of the Emerging Markets

- It is estimated that manufacturers of medical devices from industrialized countries will try to further expand their market share in the major emerging markets such as China, India, and Brazil.
- At the same time, emerging markets are the main drivers within the market for medical technology and will exert a lasting influence on this market over the coming 50 years.
- Over half of the world's population lives in the Asiatic region with a rising healthcare demand and need for care.
- Although medical devices made by Western manufacturers enjoy a high amount of trust, this trend will change with manufacturers from emerging markets fast becoming more important in all areas of technology.
- The rising income level and the significant investments in healthcare infrastructure seen in the Asiatic region will further increase the market potential for medtech devices.
- Successful companies will meet the individual medical requirements of different regions in Asia in order to secure their market position, and in some cases a leading position.
- Apart from Asia and India, it is especially Brazil that offers a market with a very high growth potential. Already, the US export rate to Brazil is around 30 percent of the total volume of medical products.



Overview of growth factors in Asia

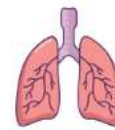


Technological Trend 1: Artificial Intelligence and Big Data

Detailed Analysis: Artificial Intelligence and Big Data

- Artificial intelligence (AI) and big data will have a significant influence on the labor market and the way physicians work.
- On the basis of data from wearables and catalogs of questions it will be possible to develop detailed analyses, compare diagnoses with a large number of comparable cases in real time, and to derive the relevant measures. In this way, unnecessary medical appointments can be avoided.
- Companies in the traditional medical sector and manufacturers of smart devices (watches, mobile technology, and sensor technology) will cooperate more and more closely.
- In the diagnostic field, the use of learning computer systems is on the increase. According to a study commissioned by the US Department of Health, AI-based systems are already ahead of humans in certain areas of analysis, e.g. in the diagnosis of breast cancer on the basis of MRT scans. If humans and machines work together, the potential error rate is only at 0.5 percent.
- Hospital information systems already record economic and clinical data. The requirements for the use of artificial intelligence are thus mostly fulfilled by hospitals.
- Economic data can be used to develop models that show not only how medical care can be improved but also cost savings in hospitals.
- Structural barriers, especially with regard to technology, training, and funding, hamper Germany's progress in the field of digitization. Hospitals must make data machine-readable and transferable. Physicians and nurses need more IT know-how. These measures require significant investments in equipment, know-how, IT, and software.

Examples for Diagnostic Use



Detection of lung cancer from CT scans



Classification of skin lesions on the basis of images of the skin

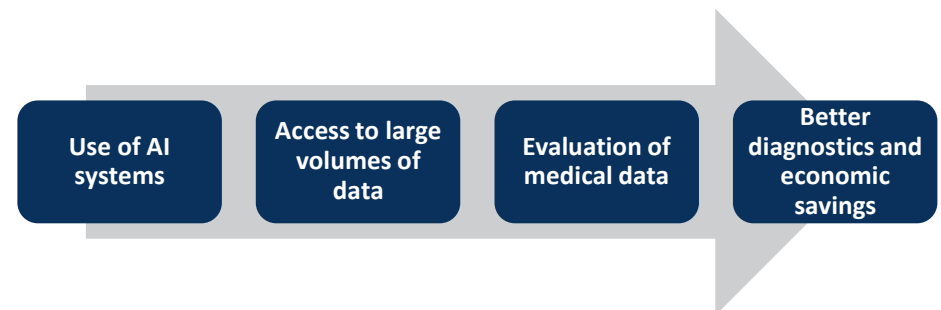


Assessment of cardiac health on the basis of electrocardiograms



Identification of retinopathy from eye images

Process sequence of AI systems

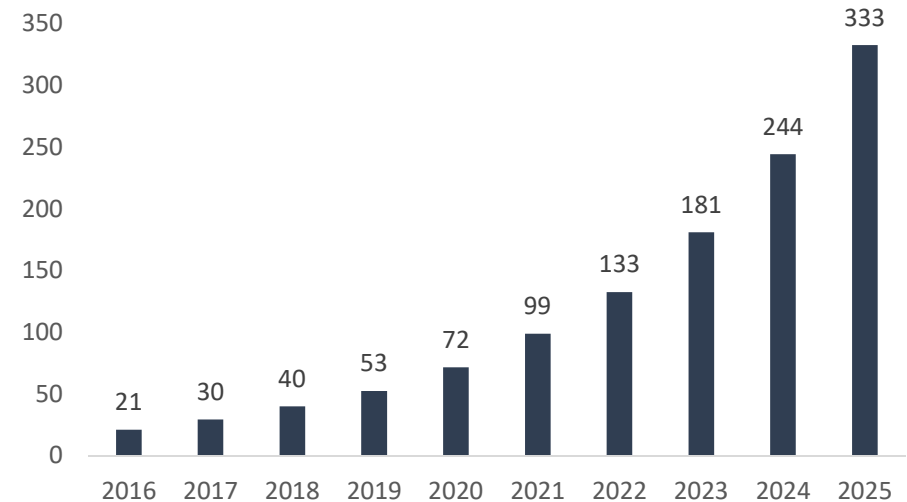


Technological Trend 2: Sensor Technology

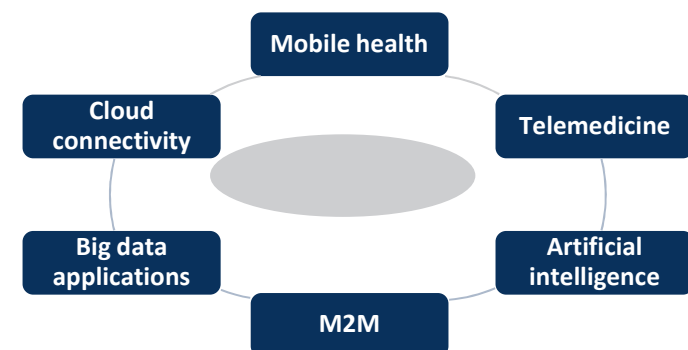
Detailed Analysis: Sensor Technology

- “Smart” active implants of the future will not only operate bioelectric functions in the body – a principle well-known in modern pacemakers that measure wide-ranging patterns and regulate the heart muscle function – but also evaluate further physical and biochemical parameters.
- These include highly miniaturized brain-pressure sensors or sensors in general that react to the biochemical environment, or highly specialized biomarker detectors e.g. for monitoring inflammation during healing processes.
- The safety and stability of these medical devices used inside bodily fluids places the highest demands on their development and materials.
- Another area of sensor technology is mobile health (mHealth). Medical procedures as well as processes of private and public healthcare offered via mobile devices are called mHealth.
- According to a study by Deloitte and Bitkom, already 42 percent of all smartphone owners in Germany use a health, nutrition, or sports app whose functionality is based on modern sensor technology.
- Apart from apps and technical gadgets, it is possible to connect scales for weight control, blood glucose meters, and blood pressure meters in order to simplify medical examinations and monitoring.
- When the pursuit of health and fitness is combined with mHealth, this will lead to the integration of technical gadgets and apps into daily use.
- Especially with regard to chronic diseases such as rheumatism and allergies, patients’ everyday lives will be made easier by mHealth.
- The trend towards self-tracking and health apps is moving into the direction of better networks and dialog functions. In some instances, the app is able to communicate with the physician and thus an unnecessary appointment can be avoided.
- Due to the coronavirus, apps are taking on a whole new meaning with regard to analysis.

Forecast of the total global mHealth market between 2016 and 2025 in million euros



Further trends and areas with strong influence of sensor technology



Technological Trend 3: Patient-specific Medical Technology



Detailed Analysis: Patient-specific Medical Technology

- Modern medicine increasingly focuses on the individual patient and gathers comprehensive data on the person, their vital data, and the resulting medical condition.
- On the basis of these data more and more individual therapies and medical devices are being developed. The progress in individual medicine promises patients perfectly adapted treatments.
- An already significant area where individualized medical technology is used is model casting in dentistry. For a number of years, many dental laboratories have been using the CAD/CAM process for milling inlays, crowns, and bridges out of a ceramic block. Sometimes, crowns, secondary parts, bridges, and even model castings are milled out of massive metal blocks.
- Meanwhile, some companies have managed to map the entire process chain of their titanium implant production on an integrated basis, starting with the acquisition of images (CT), through data conversion and 3D modeling, via manufacturing and qualification to post-processing and cleaning.
- One of the sub-categories of individualized medical technology is 3D printing.
 - 3D printing offers several advantages and a wide range of applications. It can, for instance, be used to print stencils that facilitate the work of the surgeon during operations on the spine.
 - Another milestone of medical technology is 3D printing of human organs. For example, a 3D printer has been brought on the market that can reproduce the haptics, the sensitivity, and the biomechanical properties of the human body.
 - In future, 3D printing of human organs (so-called bioprinting) will make it possible to print organs for transplantation (ears, kidney, liver, heart, and cornea).

Examples of Innovative Companies



Materialise NV with its headquarters in Leuven, Belgium, is one of the largest and most established independent companies in the area of 3D printing / additive manufacturing

Device	Description of device
Hips from 3D printers	Using a medical 3D printer and with the support of Materialise, orthopedists from the HELIOS hospital in Hildesheim produced an individually adapted implant, tailored to the individual hip.



vhf manufacture AG is a world-leading manufacturer of CNC milling machines, milling tools as well as the accompanying CAM software for dentistry, manufacturing, advertising technology, and many other industries.

Vhf Dental	Grinding machines for dental laboratories and same day dentistry as well as dry and wet processing, blocks, and circular blanks
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Technological Trend 4: E-health

Detailed Analysis: E-health

E-health is a general term used for different concepts of medical care whose common feature is the basic approach that medical services in the healthcare areas of diagnostics, therapy, and rehabilitation as well as medical consultations for decision-finding are provided remotely (or at different times). To this end, information and communications technology is used.

- Most of the medtech applications collect a wide range of data which is shared in a secure way, evaluated, and used for analyzing and optimizing the treatment method.
- E-health has two major advantages:
 - It creates an electronic patient file for each patient. It provides physicians with information on comorbidities and enables them to directly view findings and laboratory reports.
 - Healthcare providers in different areas of the healthcare system are connected, and thus double or multiple examinations are avoided and treatments can be organized more efficiently.
- A pioneer in the research and development of e-health or telemedicine is the Centre for Cardiovascular Telemedicine at Charité Berlin.
- In Switzerland there are already health insurance packages that offer telemedicine initial treatment via app or telephone.
- Many physicians and insurance funds in Switzerland already require telemedicine initial treatment to take place before other treatments begin.
- Since the beginning of the corona crisis, telemedicine has been pushed forward. German providers such as Teleclinic, Fernarzt, and Kry have seen triple-digit growth rates since January 2020.

Examples of Companies



MedGate from Switzerland operates Medgate Tele Clinic, the largest telemedical center in Europe.

MedGate app

After entering the symptoms into the app, the patient receives a recommendation whether an appointment at a physician's practice or treatment via the MedGate physicians is the better option.



Teleclinic offers remote treatments through accredited physicians via telephone and video chat. The service is provided 24 hours a day, 365 days a year.

Teleclinic and COVID-19

- Since the beginning of the corona crisis, Teleclinic has increased the number of treatments by 250 percent, and the length of the consultations to 1,000 hours.
- More than 35 percent of telemedical treatments concerned COVID-19.
- If there is a justified suspicion, the patient is sent a smear test to use at home



KRY is a healthcare business that operates across Europe. The KRY app provides medical diagnoses and consultations via video chat.

KRY app and COVID-19

Due to the corona crisis the number of physicians has doubled to 2,000 and the number of appointments has risen by 350 percent.

Technological Trend 5: Robotics and Networked Operating Room



Detailed Analysis: Robotics and Networked Operating Room

- Robot-assisted surgery allows minimally invasive procedures with a high level of precision. The da Vinci Xi surgical system is the most advanced medical and technical development in minimally invasive surgical technology and represents a new era.
- It consists of a console that is controlled by the surgeon and translates their movements into those of the surgical instruments.
- The instruments are inserted into the body through small skin incisions (keyhole technique). Via the console, the hand and finger movements of the physician are transferred directly to the surgical instruments.
- With the help of a 3D image of the operating field that is magnified tenfold and an up to fivefold translation of the hand movements this allows millimeter precision during surgery. The finest tissue structures can be detected, thus enabling gentle and precise procedures.
- The system is no “robot” that operates on its own without being controlled but a high-precision instrument controlled only by the surgeon. There is no need, however, for the surgeon to be on site.
- Apart from the integration of robots into the surgical procedure, linking of different technical devices that are essential for surgery is becoming more and more important.
- Medtech providers are no longer only product suppliers but are developing into system providers. Creating interfaces to third party suppliers is increasingly relevant in order to enable networked and advanced operating rooms.
- Intelligent software solutions that are able to integrate the surgeon’s know-how into the functionality of the robot as well as a high-performance IT infrastructure are the requirements for the ongoing development of this technology. The manufacturers depend on appropriate partners or have to integrate their own expertise via acquisitions.

Overview Surgery Robots



Advantages for the patient	Advantages for the surgeon
<ul style="list-style-type: none"> ▪ No external incisional wounds ▪ Little loss of blood ▪ Fast wound healing 	<ul style="list-style-type: none"> ▪ Relaxed body posture during surgery ▪ Spatial organ representation with enlarged image ▪ Sterile movement of the instruments

Use Case: Intuitive



Intuitive is the manufacturer of the da Vinci surgical systems. Worldwide, over 5 million da Vinci procedures have been performed, and 44,000 surgeons trained.

Da Vinci systems

The da Vinci robotic surgery systems facilitate minimally invasive surgery. Each da Vinci system can be configured as desired and adapted to the scheduled operation.

M&A Market Overview

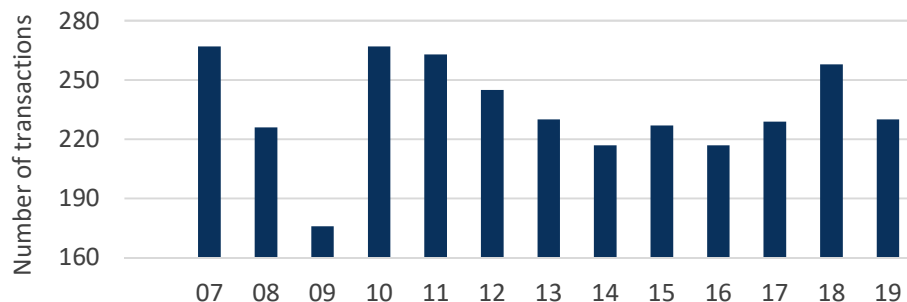
Consolidation in the Healthcare System

- The M&A market has changed significantly in recent years. Only a few years ago, the majority of transactions concerned specific medical topics. Today, however, this has changed and many transactions are now conducted across thematic areas or initiated by companies from outside the industry.
- In the DACH region (Germany, Austria, and Switzerland), M&A are predominantly small and mid-cap transactions.
- These smaller transactions dominated the M&A market within the medical technology industry in 2019.
- The reasons for acquisitions are similar to those in other industries:
 - Acquisition of methodological and technical know-how
 - Acquisition of software or hardware expertise
 - Acquisition of resources and capacities
 - Entry into new markets
 - Access to new customer groups
 - Strategic expansion of the range of products

M&A Drivers

- The ongoing consolidation trend is characterized by the following driving forces:
- Highly fragmented market characterized by small and medium-sized companies, especially in Germany
 - Market power of large, well-established groups
 - Power of new market players with a strong capital position (Google etc.)
 - Demand for shorter development cycles
 - Great variety with many product groups
 - External succession as a solution for succession-related problems
 - Integration process in order to improve the development of new innovation areas and master new technologies
 - Market demand, especially by hospitals, for integrated solutions with highly flexible and secure interface concepts
 - Costs and effort to comply with regulatory requirements no longer feasible for smaller market participants
 - From the point of view of large groups, acquisitions are interesting especially with regard to expanding their product range
 - On the seller side it is not only strategists that are considered, but, as in the US, increasingly financial investors too.

M&A Transactions in Medical Technology 2007-2019



Conclusion

- The new MDR, increasing competition, and innovative technologies create complex challenges
- Significant consolidation pressure with different cooperation models
- M&A transactions within the medical technology industry are characterized by a continuously high number of small and medium-sized transactions
- Financial investors are able to support young enterprises as well as established companies with equity and international expertise and to accelerate developments

COVID-19 and Trends in Medical Technology

Artificial Intelligence and Big Data

- OLFC-4, a so-called supercomputer, was built by IBM to simulate highly-complex situations, such as the spread of cancer through the human body.
- The production costs for this kind of supercomputer are in the three-digit million range.
- In these times of the coronavirus, OLFC-4, also known as Summit, is being used to select 77 product candidates from 8,000 molecules that might be used as a vaccine against the coronavirus.
- With its computing power, Summit can perform 200 quadrillion calculations.

Robotics and Sensor Technology

- The German tech company G2K installs smart thermal cameras in hospitals and at airports in order to keep patients infected with the coronavirus away from crowds of people.
- Patients are scanned by a thermal camera based on AI, built by tech company G2K, that tests them for a possible infection with the coronavirus.
- The technology consists of a thermal camera made by Chinese companies Hikvision, Dahua, or the German company Mobotix.
- The thermal camera is equipped with sensor technology that is able to measure a person's body temperature at their forehead. The artificial intelligence (AI) developed by G2K and integrated into the camera will send signals in case of elevated temperature, enabling staff to react.

E-health

- The Minister of Health in North Rhine-Westphalia, Karl-Josef Laumann (CDU), is planning a large-scale expansion of the Virtual Hospital project.
- Throughout Germany, hospitals are connecting their data.
- With the help of tele-intensive care, specialists from maximum medical care hospitals can take their expertise to smaller hospitals without being present on site.
- At the same time, maximum care providers are protected from a large rush of patients by establishing stable and secure video connections and the transfer of vital data in real time.
- During the corona crisis there has been significant backing for telemedicine applications and these are promoted unbureaucratically through legal regulations.

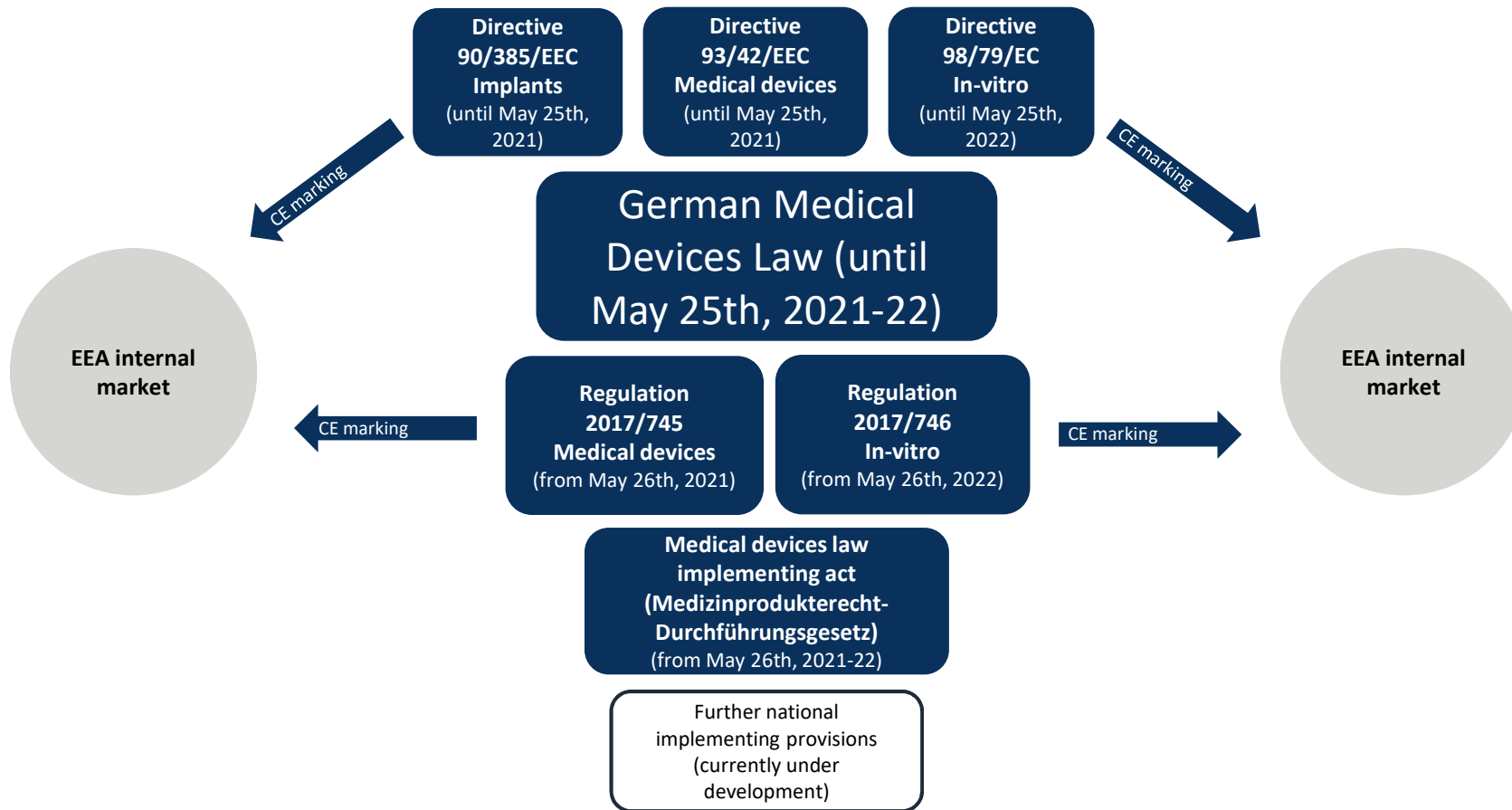
3D Printing

- The dental clinic of the University Hospital Freiburg, in collaboration with Charité Berlin and the University of Stuttgart, produces protective clothing for the corona crisis via 3D printers.
- Visor brackets and other technical aids are printed from the biopolymer polylactic acid which is sterilizable and biodegradable. So far, the digital printing process has been used, among other applications, for manufacturing dental prostheses.
- Due to the high demand for protective clothing, cooperation projects with other clinics and institutions throughout Germany are to be developed.
- In this way, the production can be extended to plastic parts for ventilators and masks.

Regulations for Placing Medical Devices on the Market

The New European Medical Device Regulation (MDR) and the In Vitro Diagnostics Regulation (IVDR)

- When the new European Medical Device Regulation (MDR) and the In Vitro Diagnostics Regulation (IVDR) came into force in May 2017 this created an EU-wide legal framework for placing medical devices on the market.



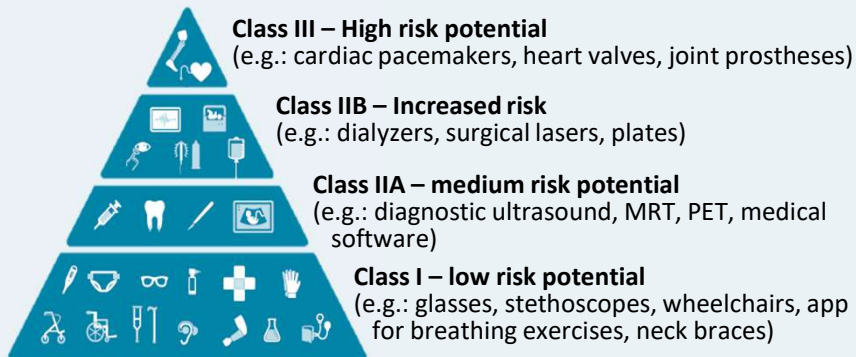
Approval of Medical Devices

New Regulations for Market Access

New EU Medical Device Regulation (MDR)

- Mandatory from May 26th, 2021 (the planned application date in May 2020 has been postponed by one year due to the corona crisis. The repealing of the directives on medical devices and implants has also been postponed by one year to May 2021, with the Medical Devices Law continuing to apply accordingly).
- All medical devices that are now marketable must be recertified.
- Special attention must be paid to the transitional provisions regarding the validity of the conformity assessment certificates that have been issued (possibly until May 26th, 2024) and regarding sell-offs (by May 26th, 2025).

Rules for the classification of medical devices



Further important amendments of the MDR

- Requirement of a Unique Device Identification (UDI) number for each device for identification and traceability.
- Extension of the EUDAMED database to ensure transparency and improved cooperation during monitoring.

Particular Barriers and Challenges for Manufacturers

- Stricter requirements for the compilation of clinical data and the post-market follow-up of devices (Post Market Surveillance Plans, Post Market Clinical Follow-Up Reports, Periodic Safety Update Reports, vigilance system).
- New scrutiny procedure (consultation of expert panels) for class III implants and active class IIb devices.
- Requirement to appoint a qualified person (PRRC) who is responsible for compliance with the regulatory requirements of the MDR.

Particular Barriers and Challenges for Manufacturers

- The postponement of the regulation must be used for the timely (re)certification of the Notified Bodies as well as the introduction of the implementing acts in good time so that the companies will continue to have planning certainty.
- The experiences gained during the corona crisis should lead to a critical review of administrative barriers.
- The EUDAMED database is expected to be fully functional from May 2022 only. Until its availability, devices will be listed in DIMDI. What is necessary in time for the application date are the appointment of a responsible person on the basis of article 15 of the MDR, the establishment of QM systems, risk management procedures, clinical evaluation procedures as well as procedures for post-market surveillance and post-market clinical follow-up.
- Perspective: Further requirements in addition to the MDR are planned in the form of an EU-wide benefit assessment for risk classes IIb and III (Health Technology Assessment).

Distribution of Medical Devices

Distribution Strategies

Reimbursability of medical devices

- Especially in the German market this is a requirement for market success.
- With regard to regular ambulatory care this depends on a positive recommendation by the G-BA committee (reservation of permission, article 135, section 5 of the Social Security Code V).
- In hospital care, new examination and treatment methods may be used at the expense of the health insurance funds without any delay. However, the G-BA may exclude them if such a request is made (permission subject to prohibition, article 137c of the Social Security Code V).
 - With regard to both sectors, manufacturers should consider the requirements for proof of benefit, necessity, and efficiency.
- Innovations in the hospital sector are included in the DRG system through coding and changes to classification. In order to prevent innovation gaps, it is possible to conclude agreements with temporary remunerations, unless the innovations have already been considered for the case fees (Hospital Remuneration Law). Other funding opportunities are e.g. pilot projects according to article 63 et seq. of the Social Security Code V as well as integrated care on the basis of article 140a et seq. of the Social Security Code V.
- Digital healthcare applications (class I, IIa) can be included in regular care via the digital care law “Digitale-Versorgung-Gesetz”, articles 33a, 139e of the Social Security Code V, new complex procedure of the Federal Institute for Drugs and Medical Devices.

Professional dealer organizations

- Advantageous for devices that improve the handling of an existing device or require new work processes. Thus it can be ensured that medical device consultants act on the basis of high expertise and that the manufacturer will benefit from the well-developed networks of the dealer organization.
- Please note: When cooperating with dealers, the manufacturer must offer in-depth product trainings for the distributor’s members of staff.

Legal Requirements for Distribution

Responsible person and medical device consultant

- According to article 15 of the MDR, manufacturers or their representatives must appoint a responsible person who has to ensure compliance with the regulatory requirements throughout the lifecycle of the device. Provided that dealers or importers offer a device under their own name or trademark they must appoint a responsible person as well.
- If distribution is organized by the manufacturer themselves, article 83 of the draft medical devices law implementing act in Germany provides for the appointment of a trained medical device consultant.

Inspection and information duties for dealers and importers

- If dealers or importers believe, or have reason to believe, that a device does not meet the requirements of the MDR, they may not make the device available on the market (articles 13 II, 14 II MDR); information duties to manufacturer or the manufacturer’s representative and the importer. If there is reason to believe that the device poses a serious risk (cf. article 2, section 66 MDR) or that the device is a counterfeit product, the competent authority in the relevant country must be informed.

Promotional gifts and grants

- According to the ban on gifts in article 7 of the Law on Advertising in the Healthcare System, the use of non-cash benefits by the distributor is only permitted within very narrow limits. This must be taken into account especially when addressing patients directly through pharmacies or drugstores.
- Marketing claims are part of the technical documentation and linked to the intended use.

Approval of Medical Devices ASEAN - South-East Asian Nations

ASEAN Market Access

- The ASEAN Medical Device Directive (AMDD) was ratified in 2015 and has provided a common regulatory framework for the approval of medical devices in ASEAN member states.
- So far, Singapore, Malaysia, and Indonesia have fully implemented AMDD while Thailand, the Philippines, and Cambodia have done so partially. Myanmar and Laos are still going through the legislative process for adapting their laws to AMDD.
- Approval by the competent authority in the individual country required: in Singapore e.g. through the Health Science-Authority (HSA).
- The legal basis is the relevant national law: in Singapore e.g. the Health Products Act and the Health Products (Medical Device Regulations).
- AMDD categorizes medical devices into four risk classes:
 - Class A (low risk)
 - Class B (low to moderate risk)
 - Class C (moderate to high risk)
 - Class D (high risk)
- **The general registration requirements according to AMDD are as follows:**
 - Submission of the application via the so-called Common Submission Dossier Template (CSDT), a dedicated online format for the submission of the required documents and applications by the applicant.
 - Proof of compliance with the quality standards according to annex 1 of AMDD (“Essential Principles of Safety and Performance”), typically through proof of an internationally recognized QM system standard such as ISO13485.
 - Compliance with the requirements of the Post Marketing Alert System (PMAS) according to annex 5 of AMDD.
 - If approval has already been granted in one ASEAN member state: making a declaration of conformity.

Detailed Approval Process Based on the Example of Singapore

Application for product registration

- Risk analysis and assessment of the medical device.
- Class A devices are exempted from registration.
- With regard to class B, C, and D devices, there are different assessment paths with different levels of intensity depending on whether a recognized foreign regulatory authority or a notified body has already approved the device (certain class C and D devices, however, are excluded).
- For devices from the EU, the CE marking satisfies the requirements for a simplified procedure.
- The applicant must be a company registered in Singapore.
- The application must be submitted through the Medical Device Information Communication System (MEDICS); the application documentation is dependent on the risk class and the fact whether approval has already been granted in another country (see above).
- The application fees range between SGD 1,500 and 17,500.
- The approval process takes between 4 and 10 months.

Conclusion

The processes are basically comparable, especially with regard to quality management and the high density of controls for devices with greater risks.

A.1

Medical Technology in Germany

“Due to its high rate of innovation and its exceptionally well trained staff, the German medical technology industry is well prepared for international competition. This also evident from the industry’s high export rate.”

Dr. Meinrad Lugan, Chairman of B. Braun Melsungen AG, Chairman of the Board of The German Medical Technology Association, BVMed

“Medtech made in Germany is still a brand that carries weight. When it comes to telemedicine applications, the German market is lagging behind.”

Dr. Gert Frank, CEO Geratherm Medical AG

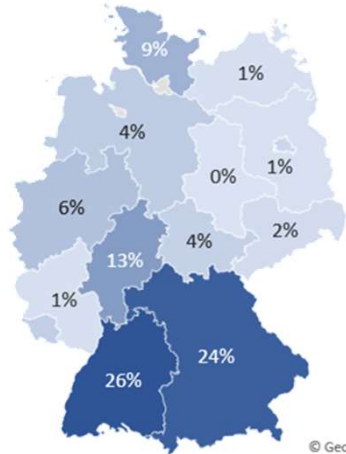
“The great advantage of the German medtech market is its high number of highly-qualified companies with a strong international market position.”

Ken Eichmann, Principal GHO Capital Partners LLP

Structure and Specifics in Germany

Medtech Corporate Landscape

- With around 26 percent, Baden-Wuerttemberg has the highest density of medtech companies in Germany.
- The second largest agglomeration area for medtech companies is Bavaria with 24 percent.
- Baden-Wuerttemberg and Bavaria together account for 51 percent of the total German sales.



New Frameworks

- **Companies from outside the industry:** Automotive suppliers and software companies in particular are using their technical expertise to enter the medtech market.
- **Data privacy and cybersecurity:** Health data are especially sensitive data and are therefore protected by a number of special legal regulations that the suppliers of digital devices must comply with.
- A recent example is the General Data Protection Regulation that has been directly applicable in all member states of the EU since May 2018. Networked medical devices are potential targets for cybercriminals. However, these developments still provide opportunities for specialized niche providers and software businesses.
- **Increasing regulation:** With the EU Medical Device Regulation coming into effect on May 26th, 2021 (postponed by one year due to the corona crisis) the regulatory requirements will increase further.

Export Structure

- Germany exports almost one sixth of its medical devices to the US and Asia each. America and Asia, therefore, are the most significant export partners of the German medtech industry.
- Within the global regions, the export of medical devices and medical technology from Germany is distributed as follows:
 - Europe 51.7%
 - Asia 25.4%
 - North America 18.5%
 - South America, Africa only 4.4%

Market Access Barriers

- New market participants must fulfill special structures and strict requirements for certification and approval. With regard to fixed assets the dual hospital funding system applies as well.
- The remuneration amount is determined by the contractual rules for remuneration.
- Within the context of the provision of medical supplies, medical devices may only be prescribed if the G-BA has explicitly included them in annex V of the prescription guideline.
- Significantly more staff needed and higher costs for the manufacturers due to the large number of regulations, often external consultation needed to aid navigation through regulations and to ensure reimbursement of devices.
- Personal contacts within the medtech community are very important, built through investing much time and money into developing a network.
- Companies from outside the industry often underestimate the specifics of national and international standards and regulations. Automotive companies, for instance, have to prove the existence of a specific quality management system for medical technology. In some cases, software companies must classify their products as medical devices, requiring conformity assessment and CE marking.

Companies from Outside the Industry and the Influence of Digitization



Companies from Outside the Industry Entering the Market

Target company	Target company description	Purchaser	Purchaser industry
Bavaria Medizin Technologie GmbH	Company that develops and manufactures intravascular and non-vascular devices	Lubrizol Deutschland GmbH	Chemicals and materials
FRANK Plastik AG	Company that supplies plastic parts and devices for medical and industrial purposes	Röchling SE & Co. KG	Automotive industry, manufacturing
Josef Ganter Feinmechanik GmbH	Supplier of dental torque wrenches for implant systems	KLINGEL GmbH	Industrial products and services

New Potentials Through Digitization

- Digitization supports the early detection of diseases, leads to shorter stays in hospitals, and, via telemedicine, apps or care robots, helps patients to stay mobile for longer.
- Sensors and actuators gather data about the patient's weight, blood pressure, temperature, activity, or ECG, and transfer the data in digitized form via the internet, often directly to the relevant person. Today, these technologies are already in use in the form of wearables and smartwatches.
- Mobile health applications, networked devices, data recording as well as analysis and artificial intelligence are playing an increasingly important role.
- For the companies, digitization is most important in research and development, distribution as well as manufacturing.

Advantages and Actions in Connection with Digitization

Advantages of digitization

According to the medtech companies the advantages of increasing digitization are basically stricter requirements regarding data privacy, an increase in productivity, as well as better monitoring. The companies believe that an increase in productivity will result especially from greater efficiency during purchasing and/or sales as well as improvements in intralogistics (networked internal processes).

Actions in connection with digitization

A survey found that the majority of companies are meeting the challenges and the opportunities arising from digitization through internal solutions as well as by purchasing external consultancy services. 40 percent of the companies surveyed forecast a rise in sales by 5 percent through the successful implementation of digitization.

Business Models in the German Market

Current Challenges

- The market for medtech devices is international in nature and German SME have to compete, both domestically and internationally, with large groups.
- German SME often follow a long-term business strategy which they combine with a high level of flexibility. Their focus is mostly on high-margin niche segments.
 - **Differentiated premium segment:** Premium products that differ from competing offers in the market and cover a niche segment.
 - **Value segment:** Tailored solutions for customers with at the same time lower prices compared to the premium segment.

“Digital devices need a homogeneous market, straightforward and secure data collection, as well as good infrastructure.”

Dr. Meinrad Lugan, Chairman of B. Braun Melsungen AG

Influence of the International Market

- Internationalization is a significant factor in order to secure a company’s market position.
- Position in the US market, the largest worldwide, also necessary in order to remain competitive over the long term.
- Increasing demand from emerging markets, especially from the United Arab Emirates, Brazil, and India.
- Development of low-cost variants in line with market requirements in order to approach different markets in the best possible way.
- Targeted acquisitions can facilitate the development of new markets as the purchaser gains capacities, customers, and the know-how of the market region.

Market Positions of Medical Technology Companies

- **Digitization:** Companies will have to organize their business models digitally if they want to be successful in the long term. In doing so, they must observe the high standards of data privacy that apply when sensitive personal health data are used.
- **Cost pressure:** The continuing privatization of hospitals, the aggregation of demand through purchasing groups, the pressure from Asian suppliers, and the increasing requirements for benefit assessments as a condition for remuneration in the ambulatory sector are increasingly reducing gross profit margins.
- **Technology:** Regulatory requirements lead to greater complexity, more demands, and control. The approval regulations differ worldwide and directly affect the technological development, the pace of innovation, market access, and therefore the company value and the implementation of the companies in different markets.

Trends in the German market:

- Due to strict regulations, German companies invest, on average, around 9 percent of their sales in regulatory requirements and another 16 percent in research and development.
- Given the high investments in regulation, medtech companies are increasingly specializing in certain business divisions and selling irrelevant divisions.
- German medtech startups suffer most from the huge capital needs for regulatory requirements which means that businesses are quickly sold and new ones started instead.

M&A Transactions

Medtech Transactions in Germany: Predominantly Small and Medium-Sized Transactions

Date	Description	Segment	Target company	Sales 2018 target company (in million euros)	Purchaser
Mar 2020	Masimo, the global market leader for non-invasive patient monitoring systems, purchases 100 percent of the shares of the innovative manufacturer of high flow devices for COPD patients, TNI medical, whose investor syndicate was led by SHS Gesellschaft für Beteiligungsmanagement.	Respiratory / COPD	TNI medical AG	undiscl.	Masimo Inc.
Feb 2020	The Tübingen-based medical technology and life science investor SHS Gesellschaft für Beteiligungsmanagement mbH invests in the endoscope specialist Blazejewski MEDI-TECH GmbH from Baden. The medium-sized medical technology company believes that SHS's minority interest will provide it with industry know-how, and intends to develop its internationalization in a strategic way.	Endoscopy / imaging	Blazejewski MEDI-TECH GmbH	undiscl.	SHS Gesellschaft für Beteiligungsmanagement mbH
Nov 2019	Armira Partners GmbH & Co. KG, acquires SCHEU-DENTAL GmbH, a company based in Germany that supplies products and services in the area of orthodontics. Armira bought SCHEU-DENTAL for strategic reasons.	Medical technology, dentistry, orthodontics	SCHEU-DENTAL GmbH	20	Armira Partners GmbH & Co. KG
Jul 2019	By purchasing BMT, Lubrizol expands its expertise in the production of intravascular and non-vascular devices and establishes itself as an end-to-end partner for the global medical device and pharmaceutical industry. The acquisition of BMT expands Lubrizol's product design, development, and manufacturing capabilities and provides access to company-owned catheter and balloon technologies.	Medical technology intravascular and non-vascular devices	Bavaria Medizin Technologie GmbH	11	Lubrizol Deutschland GmbH
Jul 2019	IK Investment Partners Limited, the private equity firm based in Britain, acquires LAP GmbH Laser Applikationen, a developer of laser-based projection and measuring systems for medical and industrial applications. The takeover will allow LAP to continue its development and to tap into new markets.	Medical technology measuring systems	LAP GmbH Laser Applikationen	56	IK Investment Partners Limited
Jun 2019	Steadfast Capital GmbH, a German private equity firm, acquired W. Söhne GmbH, a manufacturer of wound care products and devices for first aid and emergency medicine.	Medical technology first aid, emergency medicine	W. Söhne GmbH	11	Steadfast Capital GmbH
Feb 2019	Triton Partners, the private equity firm based in Britain, and Tempus Capital GmbH, a private equity firm based in Germany, agreed, together with the company's management team, to acquire Deutsche Radiologie Holding GmbH, a consolidation platform for radiology and radiotherapy operations.	Health IT, radiology	Deutsche Radiologie Holding GmbH	undiscl.	Triton Partners, Tempus Capital GmbH

Conclusion on the German Market

Competition

- Companies from outside the industry, from the automotive, software, and sensor segment, are intensifying the competition.
- The continuing privatization of hospitals, the aggregation of demand through purchasing groups, and the pressure from Asian suppliers, are increasingly reducing gross profit margins.
- In order to maintain or expand their market position, companies can adopt the following solution strategies:
 - Process and cost optimization along the supply chain
 - Review of the long-term protection of the company with regard to the increase in legal and regulatory requirements
 - **Preparation of an M&A strategy and development of new markets**
 - **Targeted acquisitions of missing technologies or know-how (buy & build)**

Distribution

- It is important to stress the customer benefit if a medical device is to assert its position in the market.
- Successful differentiation strategies are based on customer orientation without compromise:
 - Improving medical results through technological advantages
 - Expanding the indication area
 - Lowering treatment costs
- Apart from professional dealer organizations it is also possible to drive forward the distribution of products via new examination and treatment methods.

Regulatory Measures

- The regulatory pressure with regard to product approvals is increasing because of the new EU Medical Device Regulation.
- 86 percent of the companies surveyed said that the regulation is a challenge for their company or has a great impact on the business.
- Research & development, product monitoring, and manufacturing are the areas where the companies surveyed feel most affected by the regulations.
- According to the companies, the regulatory requirements mainly lead to more complex processes, higher costs, and the need for additional staff.
- Companies from outside the industry are advised to acquire a market participant in order to gain know-how and existing regulatory requirements.

Internationalization

- Current forecasts show that Asia will be the second largest medtech market in 2020, after the US. Half of the companies surveyed expect Asia to be the strongest growth market over the next five years.
- Entering the Asian market is often difficult for German companies because of language barriers, the geographical distance, and cultural differences.
- 70 percent of the companies surveyed expect more international market players to enter the market. More than 80 percent expect a greater market share for Chinese companies.
- Despite the market barriers for the European market many German companies expect challenges to arise from Asian devices and services entering the market.
- The major challenges are price pressure and quality management.

A.2

Medical Technology in Europe

“Medical technology businesses with a vision will be strengthened by the crisis: The framework will become friendlier because the euro zone countries now want a strong domestic healthcare economy. Small and medium-sized businesses with an equity base are now able to actively develop their position through innovations and acquisitions.”

Hubertus Leonhardt, Managing Partner of SHS Gesellschaft für Beteiligungsmanagement mbH

“The constantly rising regulatory requirements are increasing the complexity of value creation. This leads to higher costs and in the long term to a thinning of products offered and to fewer companies.”

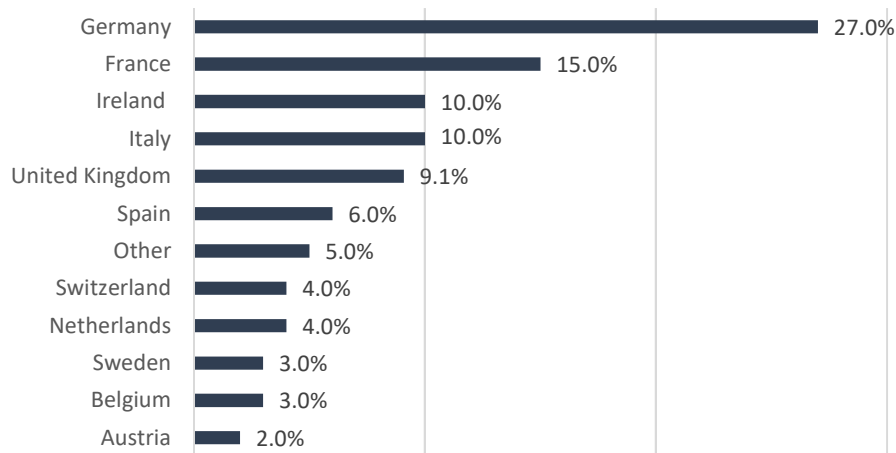
Dr. Gert Frank, CEO Geratherm Medical AG

“The political decision-makers should focus on ensuring that patients have fast access to safe innovations and on creating the legal basis for a true wave of digitization.”

Dr. Meinrad Lugan, Chairman of B. Braun Melsungen AG, Chairman of the Board of The German Medical Technology Association, BVMed

Structure and Specifics in Europe

Share of the Medtech Market in Europe: Selected Countries in 2019



Driver of Innovation: Medical Technology

- Medical technology heads the list of technological fields with 13,795 worldwide patent applications submitted to the European Patent Office in 2018.
- Within Europe, Germany comes first with 1,336 patent applications. The Netherlands takes second place with 841 patent applications, ahead of Switzerland (753), France (545), and Britain (417).
- The other member states of the European Patent Organisation account for 1,440 patent applications.
- Ireland is considered to be the major rising country of the European medical technology industry.
- The Johnson & Johnson group made the largest number of patent applications (700) in medical technology.
- Among the German companies, Fresenius Medical Care ranked 9th worldwide (130).

Key Technologies

Machine-to-machine communication (M2M):

- Internet of things or machine-to-machine communication via smartwatches, wearables, and mobile devices, will become increasingly important for the medtech companies.
- Polar or Garmin, e.g., that up to now have not been perceived as medical technology companies, are now occupying key positions in patient interaction by building intelligent partnerships with medical software companies.

E-health:

- Telemedicine and remote diagnostics are increasingly important and help to minimize the number of medical appointments and to avoid double appointments.
- Companies like MedGate or ADA that are already active in the market provide remote diagnostics and are seeing a huge growth in the European market.

Conclusion

- Germany: By far the medical technology market in Europe with the strongest sales, followed by France and Ireland
- Most patent applications in Europe by German companies
- Technological product innovations in medical technology ensure market share and expansion
- Important centers for medical technology in Europe are Tuttlingen in Germany and Galway in Ireland.
- The Irish medical technology market is the fastest growing in Europe. Already, nine out of ten of the largest medical technology companies are based in Ireland.
- Ireland's medical technology sector employs over 38,000 people and is thus the largest market in Europe.

Medical Technology – Important Centers in Europe



Number of Medtech Companies in the Individual Centers



Overview Medtech Centers in Europe

City	Major companies	Focus/ influence
Basel, Switzerland 1,400 companies	<ul style="list-style-type: none"> J&J Medical Roche Diagnostics Straumann 	Medtech/ pharma
Tuttlingen, Germany 450 companies	<ul style="list-style-type: none"> Karl Storz SE & Co. KG Aesculap KLS Martin 	Medtech devices
Galway, Ireland 300 companies	<ul style="list-style-type: none"> Boston Scientific Ash Technologies 	Medtech software
Eindhoven, Netherlands 150 companies	<ul style="list-style-type: none"> Philips Usono 	Medtech devices
Alsace, France 150 companies	<ul style="list-style-type: none"> Clinerion Movisens 	Medtech software/ research
Copenhagen, Denmark 140 companies	<ul style="list-style-type: none"> Coloplast Invacare 	Digital health/ medtech devices
Barcelona, Spain 94 companies	<ul style="list-style-type: none"> Dornier Grifols 	Medtech/ pharma

M&A Transactions

Medtech Transactions in Europe: Small and Medium-Sized Transactions in Different Segments

Date	Description	Segment	Target company	Sales 2018 target company (in million euros)	Purchaser
Dec 2019	The acquisition is part of Healthcare 21's strategy for the expansion of its product portfolio in order to become a leading European supplier of medical equipment.	Medical technology, radiology	Xograph Healthcare Limited	10	Healthcare 21 Group
Dec 2019	Advanced Medical Solutions Group Plc (AMS), a manufacturer of medical equipment, acquired Biomatlante SA, a developer and manufacturer of synthetic bone transplant technologies that is based in France. The takeover happened for strategic reasons.	Medical technology, synthetic materials	Biomatlante SA	4	Advanced Medical Solutions Group Plc
Oct 2019	The takeover is a useful geographic addition and part of Unilab's plans for growth in Spain.	Health IT, imaging diagnostics	Centros Medicos De Diagnostico Integral SL	undiscl.	Unilabs Diagnosticos, S.L
Oct 2019	Cardiolex Medical AB acquires AMEDTEC Medizintechnik Aue GmbH, an ECG system supplier. The takeover will allow Cardiolex to expand in northern and central Europe and to complement its product portfolio.	Medical technology, ECG	AMEDTEC Medizintechnik Aue GmbH	5	Cardiolex Medical AB
Aug 2019	The acquisition of Optotek Medical d.o.o. will increase the competitiveness of the ophthalmic lasers that Quantel Medical SAS already provides and accelerate the development of new products.	Medical technology, medical laser solutions	Optotek Medical d.o.o.	8	Quantel Medical SAS
Jul 2019	Lagarrigue S.A.S acquired Regnier Orthopedie, the France-based manufacturer of custom-made prostheses, orthoses, and corsets. The takeover will strengthen Lagarrigue's network in northern France.	Medical technology, prostheses	Regnier Orthopedie	4	Lagarrigue S.A.S
Jul 2019	Surgical Science Sweden AB, a developer of virtual reality simulators for laparoscopic and endoscopic trainings, acquired SenseGraphics AB. The acquisition will strengthen the business of Surgical Science Sweden and complement it through technical capabilities in the development of advanced simulation products.	Health IT, simulator	SenseGraphics AB	30	Surgical Science Sweden AB
Jun 2019	Ginefiv SL, a provider of infertility treatment and other services, acquires Instituto De Estudios Citogeneticos SL, a provider of genetic analyses and related medical services based in Spain. The takeover happened for strategic reasons.	Medical technology, genetic analyses	Instituto De Estudios Citogeneticos SL	undiscl.	Ginefiv SL

A.3

Medical Technology in Asia

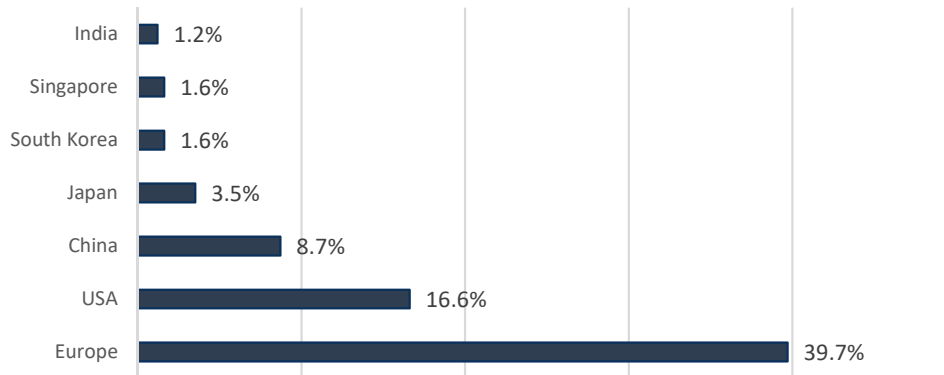
“We aim to support hospitals, surgery centers, and clinics in South-East Asia in fulfilling their vision of increasing their performance, and to contribute to the further improvement of standards in the medical sector. For Richard Wolf as a globally operating medical technology company, South-East Asia is a key market.”

Jürgen Steinbeck, Co-CEO Richard Wolf

Market Overview – Export Opportunities for German Companies



Exports of the German Medtech Industry



- Exports of German companies to China on the rise: After the US, Germany is the second largest importer in the field of medical technology (2018: 1.97 bn euros).
- The five-year plan “Made in China 2025” aims to strengthen medical technology devices especially in the high-end segment where products made in Germany are in great demand.
- Market growth in South Korea has potential for foreign companies: 2/3 of the demand is covered by imports (2017: 549 million dollars from Germany).
- In 2016, Taiwan imported medical-technological goods worth 1.6 bn dollars, 11 percent of which from Germany.
- German companies are not yet realizing the full potential that the Asian markets offer, and the majority of exports are made to Europe and the US.

Growth Drivers of the Asian Markets

- **Population:** over 50 percent of the world’s population live in APAC countries.
- **Growth in prosperity:** The percentage of the middle class of the overall population is expected to rise from 24 percent in 2010 to up to 65 percent in 2030.
- **Demographic development:** Aging population, population growth, and urbanization will increase the demand for better quality healthcare.
- **Morbidity:** Almost 2/3 of all chronic respiratory diseases occur in the APAC countries.
- **Development:** Medical devices still not widely in use in the ASEAN countries, much room for growth and market expansion.
- **Heterogeneity of the ASEAN market:** Different market strategies possible, much room for product segmentation.
- **Large volume of state funding/investments:** Aims to improve the medical infrastructure; governments in South-East Asia are creating an attractive environment for foreign companies in order to attract successful companies and thus to react to the current social and economic burdens; China, for instance, has tripled its government spending on healthcare since 2010.
- **Lack of domestic competition** in the ASEAN market: In total, ASEAN is a net importer of medical devices; Vietnam e.g. currently imports 90 percent of all medical devices used in the country.
- **Two macro trends for regional developments:** Digitization of healthcare systems and increasing emancipation of patients who become consumers of healthcare services.

MedTech in Asia - Regional Breakdown

Medtech Hubs in Asia

- **Japan** is the fastest-growing medical technology market in the Asia-Pacific region and home to the top medtech players.
- Japan has a long history of high-tech innovations as well as strong engineering capabilities and advanced manufacturing. Its relatively old population makes it a hub for innovative Senior Care Solutions.
- **India** (Bengaluru), China (Beijing), and Singapore, apart from Japan, are turning into high-tech medical technology innovation centers; one of the most important priorities in Beijing right now is genome analysis.
- **Taiwan** is a manufacturing center for electronics. This also influences medical technology: Due to Taiwan's long history as a global manufacturing hub for electronic devices, including medical devices such as blood glucose meters, the country possesses the suitable infrastructure to enable and host medical innovations such as the development of prototypes and the manufacturing of increasingly advanced equipment.
- Currently, **China** mostly manufactures and exports simple technologies, but in the long run it aims to expand its development and production of more sophisticated technologies.
- Due to its billions in funding, China is considered a strong location for AI also with regard to the medtech market.
- Because of the continuing tensions between the US and China as well as the rising labor costs, manufacturing and investments are increasingly being moved to **Malaysia** and **Vietnam**.
- Especially **Thailand's** long-term aim is to establish itself as a center of medical tourism; the infrastructure is to be developed accordingly and the standard of medical care to be improved.
- **South Korea** is an important location for the medical technology industry; the German Dräger group e.g. has been present in the country since 1990.

Startups in Asia – Singapore as an Attractive Center

- Approximately 80 percent of the healthcare startups are concentrated in the following Asian countries: India (32%), China (22%), Singapore (11%), Japan (8%).
- 60 percent of all microarrays used worldwide and a third of all thermal cyclers and mass spectrometers are manufactured in Singapore.
- Singapore is home to over 220 medtech startups and SMEs.
- Singapore is a hub for research and development with over 60 multinational medtech companies.
- 50 regional headquarters of world-leading medtech companies are based in Singapore.
- The key drivers are: the increasing use of everyday devices by medtech companies (smartphone, smartwatch) to gather medical data, the inter-professional collaboration with physicians and care staff in order to adapt the devices to the requirements of physicians and patients, as well as a robust startup ecosystem and cooperation.
- Singapore: In 2018, investments of approx. 6.3 billion dollars were made in the healthcare systems of the Asia-Pacific region; Singapore is the location with the highest investments of over 105 million dollars.

Conclusion on the Asian Market



Investment Climate in the Medtech Field in Asia

- The medical technology market in the Asia-Pacific region is expected to grow by 133 billion dollars in 2020.
- More and more investors invest in early-stage startups in Asia; this includes especially foreign companies that aim to gain market access in order to expand to Asia.
- The Irish company Health Beacon expanded in 2019 through investments in Asia. The medical technology company Edwards Lifesciences invested the equivalent of approx. 23 million dollars in Malaysia to improve the competitiveness of one of the regional medtech key businesses.
- In order to facilitate market entry, well-established investors and businesses, often from the electronics and electrical engineering sector, invest in medical technology companies.
- German companies are also increasingly investing in Asian markets: The listed German company Evonik Industries AG invested millions in a Chinese 3D printing startup in Shanghai via Evonik Venture Capital in order to gain access to implants for neurosurgery and spine surgery in China.

Conclusion

- In the foreseeable future Asia will become the most important growth engine of the global medical technology market.
- The high investment volume, in particular also with regard to startups, will turn countries such as Singapore into major regions of the medical technology industry.
- The results of our online survey are consistent with our assumption that Asia is a strong growth market. 45.76 percent of those taking part view Asia as the fastest-growing region of the next five years, and 46 percent of those surveyed expect a rise in market share which they believe will increase the risk for market participants from other regions.
- The aging of the population will increase rapidly, especially in Asia, and lead to a huge demand for healthcare services.
- Technical progress and the accompanying infrastructure differ widely throughout Asia, and accordingly market potential for medical technology exists across the entire spectrum of development, from simple and cost-efficient devices to complex systems such as MRI or surgery robotics worth millions.

M&A Transactions

Transactions Involving German Companies

Date	Description	Segment	Target company	Sales target company (in million dollars)	Purchaser
Dec 2019	Chinese HumanOptics Holding AG, investor in the production of artificial lenses and eye implants, acquires the majority of HumanOptics AG, Erlangen, a manufacturer of artificial lenses and eye implants.	Medical devices	HumanOptics AG	12 (FY 2019)	HumanOptics Holding AG
Aug 2019	Beijing Aeonmed Co. Ltd, Beijing, manufacturer of equipment for surgery and intensive-care units and provider of systems solutions, acquires HEYER Medical AG, Bad Ems, a developer and manufacturer of medical devices.	Medical technology	HEYER Medical AG	undiscl.	Beijing Aeonmed Co., Ltd.
Jun 2019	Tentamus Group GmbH from Berlin, that operates laboratories, acquires a majority share in the Indian company Megsan Labs Pvt Ltd, a provider of analytical testing services.	Medical technology	Megsan Labs Pvt Ltd	undiscl.	Tentamus Group GmbH
Jul 2018	Bavarian company Optoflux GmbH, active in the design and manufacturing of optical devices and precision optics, acquires HPOI Corporation from the Philippines, a manufacturer of high-precision optical synthetics.	Medical devices	HPOI Corporation	undiscl.	Optoflux GmbH
Jan 2018	The Taiwanese subsidiary of German company Carl Zeiss AG, a manufacturer of optical systems, industrial tests, and medical devices, acquires the Taiwanese business Achelis Taiwan Co Ltd, a manufacturer of optical instruments and lenses.	Medical devices	Achelis Taiwan Co Ltd	undiscl.	Carl Zeiss Co., Ltd.
Ongoing (since Nov 2019)	Biofourmis Pte. Ltd. in Singapore that offers a personalized evaluation machine for physiological data, announces that it will acquire Biovotion AG, a developer of clinically tested wearables for health monitoring.	Medical technology, health IT	Biovotion AG	undiscl.	Biofourmis Pte. Ltd.
Nov 2019	Canon Medical Systems Corporation in Japan, operating in the development, manufacturing, distribution, and maintenance of medical equipment, buys Skope Magnetic Resonance Technologies AG, Zurich, a developer of magnetic field monitoring systems.	Medical technology, health IT	Skope Magnetic Resonance Technologies AG	undiscl.	Canon Medical Systems Corporation
Oct 2018	HOYA Medical Singapore Pte. Ltd., a developer of products for optimizing the application and safety in eye surgery, acquires the US business Medical Instrument Development, a developer of medical devices and instruments.	Medical technology	Medical Instruments Development Laboratories Inc.	undiscl.	HOYA Medical Singapore Pte. Ltd.

A.4

Medical Technology in the US

“As the world’s largest consumer market, the United States offers huge opportunities for manufacturing companies and medical technology suppliers. In the US, especially the market potential of innovative technologies, also from the supplier sector, is particularly high.”

Diethelm Carius, VDMA - Working Group Medical Technology

“Even though strong technology exists in Germany, this is often not applied because the health insurance funds do not cover the costs. The situation is different in the US. Here, the patients pay privately.”

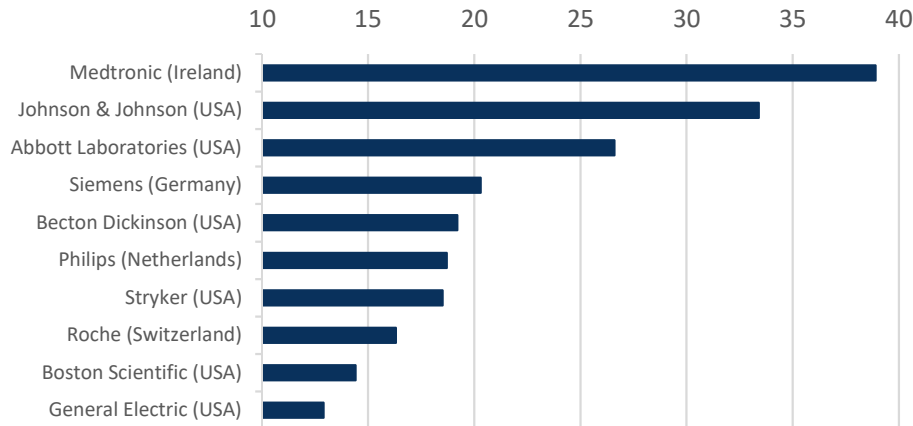
Dr. Gert Frank, CEO Geratherm Medical AG

“Due to the change in regulatory requirements, innovative medtech businesses will increasingly have their products approved in the US first.”

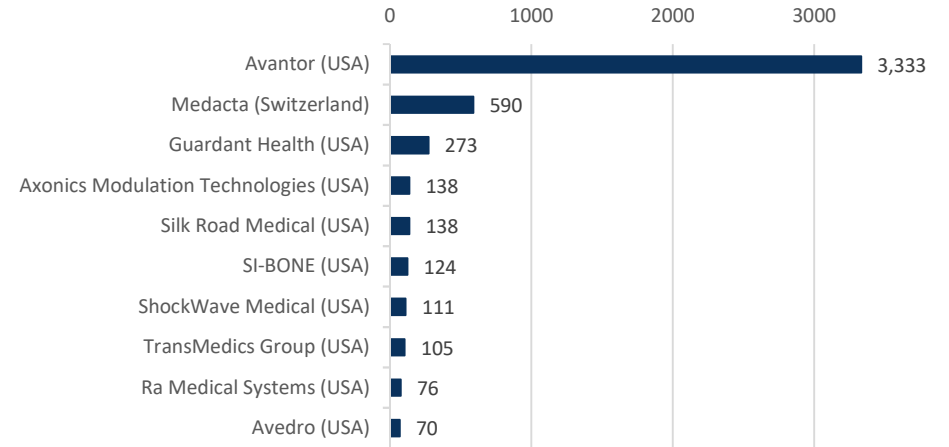
Dr. Andre Zimmermann, Partner of SHS Gesellschaft für Beteiligungsmanagement mbH

Structure and Specifics

Most Profitable Medtech Businesses in 2024, in Billion Dollars



IPOs: Predominantly Medtech Companies from the US



Medical Technology in the US

- The American medtech sector is very much characterized by military and space technology.
- For decades, the United States has had the best equipped military power worldwide, with the second largest number of staff, that funds innovations for medical care.
- Telemedicine, for instance, is largely based on military and space technology from the 1960s when NASA equipped its astronauts during their lunar mission with medical devices for telemetry and heart monitoring.
- In 2019, North America had the largest share of the global market for medical technology with 39.2 percent.
- Average growth of 4.9 percent forecast: the market is expected to grow from 164 bn dollars in 2018 to 208 bn dollars in 2023.

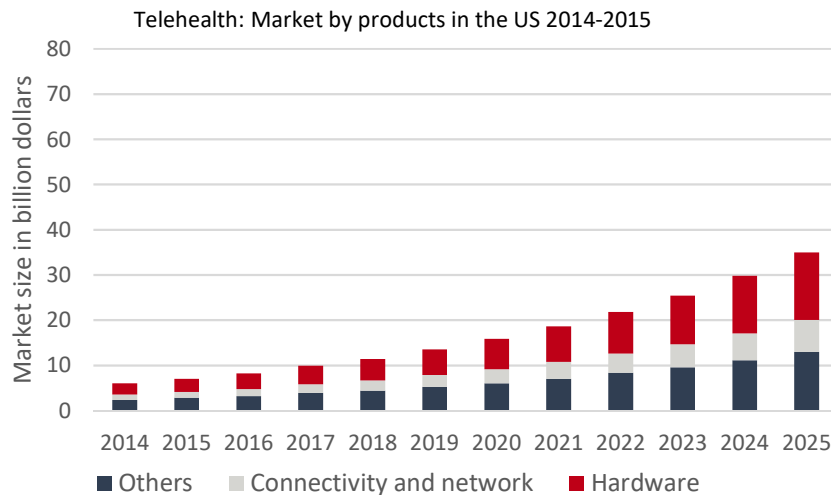
Conclusion

- The highest number of world-leading companies will likely continue to be based in the US; this goes beyond the estimates of our survey participants who expect the US to take second place of the fastest-growing regions during the next five years, after China.
- This is made possible by technologically leading companies in the field of medical technology that have been working on their market position for decades.
- A large number of technological innovations are based on the aerospace technology of the American military.
- In addition, American companies are successful in acquiring technologies and know-how they lack in the US, Europe, and Israel.

Key Technologies

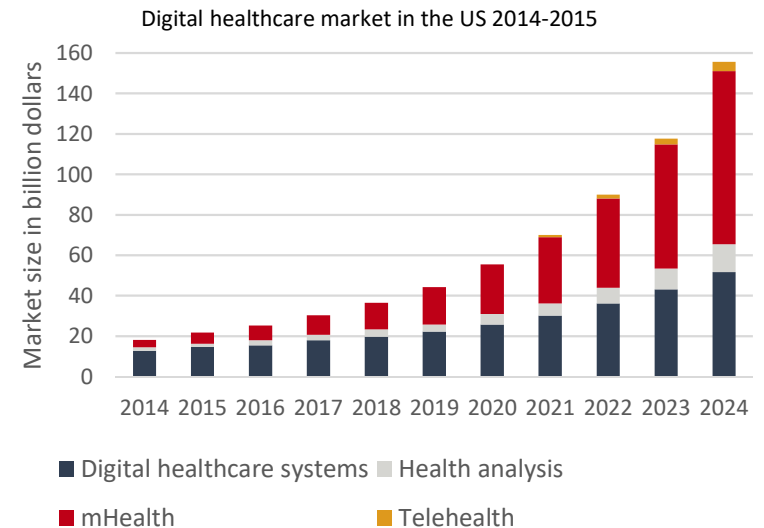
Telehealth

- Telehealth will continue to become more important during the coming years.
- This development is based mainly on the advantages it provides for overcoming distance-related barriers to care and for establishing highly efficient care processes that involve all the contributing sectors by introducing useful applications.



mHealth

- Since 2013, sales from the mHealth market have been continuously rising.
- Worldwide, the mHealth market is expected to grow to 316.8 billion dollars by 2027.
- The forecast shows that especially mHealth in the US will become increasingly important.



Artificial Intelligence

- High level of investments: the healthcare system is currently the most significant industry for deals in artificial intelligence in the US.
- For 2022, revenues of 6.16 billion dollars in connection with AI are expected for the global medical technology market.

Wearables

- The number of adult users (18 years and older) of wearables in the US is expected to rise to 67 million by 2022.

M&A Transactions

Medtech Transactions in the US

Date	Description	Segment	Target company	Sales 2018 target company (in million dollars)	Purchaser
Dec 2019	US company Danaher Corp., Washington, D.C., a technology company and manufacturer of electronic testing systems, acquires the biopharma division of General Electric for 21.4 billion dollars.	Biopharma	General Electric Corp. biopharma division	3,000	Danaher Corp.
Oct 2019	US company 3M Corp., Saint Paul, acquired Acelyt, also a US company and a provider of wound care devices and solutions.	Medical technology	Acelyt, Inc.	1,500	3M Corp.
Aug 2019	US corporation Boston Scientific Corp., Marlborough, acquires BTG, a company that specializes in the development and distribution of devices for minimally invasive surgery.	Medical technology	BTG plc.	620	Boston Scientific Corp.
Apr 2019	US company Johnson & Johnson, New Brunswick, acquires Auris Health, a company specializing in surgical robots, for 3.4 billion dollars.	Medical technology	Auris Health, Inc.	undiscl.	Johnson & Johnson (Ethicon, Inc.)
Mar 2019	US manufacturer of scientific instruments Thermo Fisher Scientific Inc., Waltham, acquires Brammer Bio, a leading provider of viral vectors for cell and gene therapy.	Medical technology	Brammer Bio, LLC.	undiscl.	Thermo Fisher Scientific Inc.
Feb 2019	Colfax Corp., Annapolis, acquires medical technology and medical technical aids supplier DJO for 3.15 billion dollars.	Medical technology	DJO Global, Inc.	undiscl.	Colfax Corp.
Nov 2018	The medical technology group Stryker Corp., Kalamazoo, acquires the US company K2M, specialized in technologies for the treatment of spine damage.	Medical technology	K2M Group Holdings, Inc.	undiscl.	Stryker Corp.
Nov 2018	The US supplier of cloud-based medical devices and software solutions, ResMed Corp., San Diego, acquires MatrixCare, a provider of software solutions used in care, for 750 million dollars.	Health IT	MatrixCare, Inc.	122 (est.)	ResMed Corp.

B.

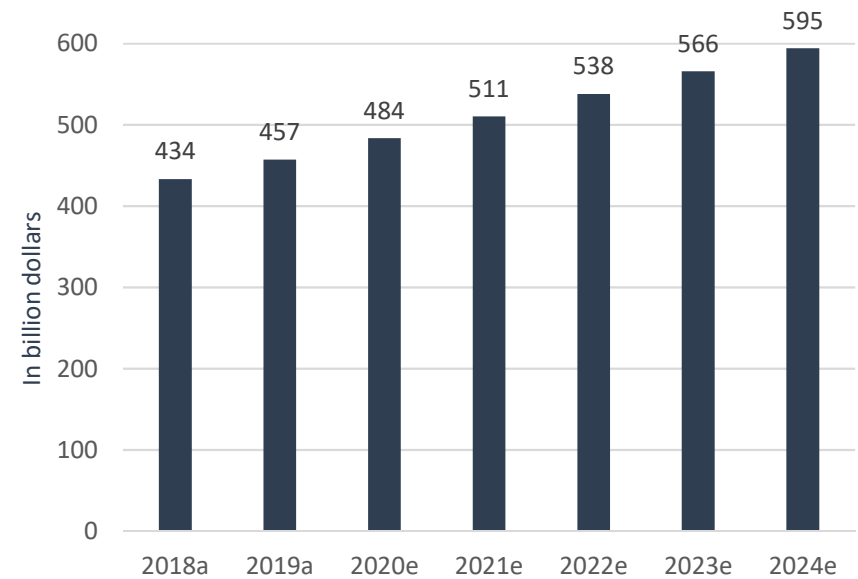
Summary and Outlook

Outlook 2021

Outlook

- Rising life expectancy of the world's population and increasing healthcare demands with the accompanying need for care will lead to greater demand for medtech products.
- The market volume worldwide will rise strongly over the coming years due to the growing middle class in the Asian region, and thus push Europe from its second place of the leading medtech markets.
- Medical technology manufacturers will have to position themselves in the emerging markets and especially the Asian market at an early stage in order to be able to take a leading role, or any role at all.
- The manufacturers will have to organize their business models digitally if they want to be successful in the long term. As is the case in many other industries, German companies cannot rest on their typical technical capabilities but must make huge investments in software and methodologies such as AI and big data.
- Most important future technological trends: artificial intelligence and big data, sensor technology, e-health, patient-specific medical technology, robotics and networked operating rooms
- The continuing privatization of hospitals, the aggregation of demand through purchasing groups, the pressure from Asian suppliers, and the increasing requirements for benefit assessments as a condition for remuneration in the ambulatory sector are increasingly reducing gross profit margins.
- Companies from outside the industry are entering the market as competitors of traditional medtech companies.
- Automotive suppliers with their highly specialized manufacturing capabilities and international presence are expanding their industry focus and entering the medtech market.
- The pressure on established medical technology companies is rising all around, pushing companies to take action.

Development Forecast for the Global Medtech Industry



“During the coming years we can expect exponential growth in the use of robotics in medicine, with growth rates of 20 percent per year. The question we should ask is why the leaders in this field always have to be US companies. European companies and hospitals have this potential too, they must cooperate more closely, however. One of the problems in Germany is the restrictive position adopted by the statutory health insurance funds when it comes to funding innovative methods. With regard to this issue we need political support.”

Professor Thomas Schildhauer, Medical Director of the Occupational Health and Safety University Hospital Bochum

Summary and Recommendations

Small and Medium-Sized Companies

- Medical technology market facing huge changes, medium-sized companies must realign their business models.
- In addition, there are current challenges that must be dealt with: digitization, cost pressure, and intensity of competition.
- Medtech market is an SME industry with, at the same time, market power of large groups
- Result: consolidation dynamics because smaller manufacturers are not competitive
- In addition, integration process: mergers of small and medium-sized companies, leading to stronger market positions and mastery of new technologies



Small and medium-sized companies must protect their business models and adapt them to the new trends and challenges.

SMEs are not only challenged by regulations but at the same time by rapid technical change, digitization, and international competition.

Mergers, alliances, cooperation, and acquisitions are safeguarding measures that should be reviewed and implemented at an early stage.

Startups

- Legal preconditions and initial funding problems are major challenges.
- Regulations regarding the approval process and the distribution of medical devices are becoming increasingly strict: the new EU Medical Device Regulation will come into effect on May 26th, 2021.
- Distribution of products varies depending on the region: not an easy process. For instance, huge differences in the approval process for the European and the American market. This, together with the continuing consolidation dynamics, hampers competitiveness.



Early-stage financing, available from numerous public funding schemes of the EU, the German federal and regional governments, and using venture capital firms to support growth financing.

As is necessary for medium-sized companies, the cooperation and mergers with established companies must be sought at an early stage.

“It is very difficult for one company in Tuttlingen or Berlin alone to conquer the Chinese market.”

Companies from Outside the Industry

- Increasing attempts by companies, e.g. from the automotive sector, to enter the market for medical technology
- Reason: highly complex technologies that medical technology increasingly relies on
- In addition, acquisitions by companies from outside the industry: acceleration of the approval process for new medical technology products or to acquire know-how in this sector
- Trend can be observed from the M&A transactions conducted in 2019: continuously high number of small and medium-sized transactions in the DACH region



Companies from outside the industry should analyze opportunities and risks associated with the realignment and consider the specific regulatory requirements of the healthcare sector at an early stage in order to be able to develop a suitable strategy for the diversification of their product range, and to facilitate their market entry, approvals, and distribution with the help of targeted acquisitions.

C.

Annex

Interview with Dr. Meinrad Lugan (Chairman of the Board of The German Medical Technology Association, BVMed) (1/2)



Asia is a growth market for medical technology, and new suppliers from the Asian region are entering the global market. Which are the strategic steps that must be taken to enable German suppliers to keep up with the competition and to enter the Asian growth market?

The market for medical technology is growing fast in China, but also in the emerging countries in South-East Asia. German medtech companies are benefiting from the huge demand and even today they are among the major importers for some of these countries. We are very successful already. After all, the export rate of the German medtech industry is at 65 percent! But German companies are not yet realizing the full potential that the Asian growth markets offer. The export rate to Asia is only at around 18 percent.

Do you expect that German suppliers will expand their capacities in the Asian region during the coming years? If so, which are the main locations?

Yes, German companies will have to put a much stronger focus on these new markets. However, there are a number of barriers to be overcome to gain market access because the approvals can be difficult. Apart from sophisticated business strategies, companies need to develop good cooperation strategies with distributors in the countries themselves.

The postponement of the application of the Medical Device Regulation by one year also provides the opportunity to correct undesired effects. What possibilities does BVMed believe exist to achieve this?

Regardless of the corona crisis: The new regulatory system was not and still is not ready. The problems with regard to the implementation of the MDR would have remained even without COVID-19: we have a shortage of Notified Bodies able to certify devices on the basis of the MDR. Only 12 of the present 55 Notified Bodies have been notified for the MDR. We have capacity problems with regard to the recertification of existing devices by the effective date in May 2020. We do not have enough trained members of staff for these regulatory questions, and there is also a lack of experienced staff at the EU Commission. Implementing acts and the important guidelines are missing. Specifications for the Eudamed database – which meanwhile has been postponed – are missing. The result: The medtech industry is prepared. The system is not.

The emergence of the coronavirus has created another problem for the medtech industry. The coronavirus pandemic directly affects the preparations for the application date of the MDR. Already, Notified Bodies are closing or their activities are restricted. Companies and manufacturing sites are also affected by sickness among their employees. Companies are losing their suppliers. All this is happening at a time when the industry is expected to increase its production capacities in order to meet the rising demand because of the coronavirus.

The German government has announced that it will source necessary medical devices, especially protective equipment, even without a CE marking if this is necessary in this time of crisis. If this is possible, it must also be possible to keep devices that carry an old CE certificate in the market for longer. The postponement of the MDR offers the opportunity to address its shortcomings and to organize the system in such a way that the companies will be able to actually implement the MDR.

The corona pandemic illustrates the strong dependence of the German healthcare system on global supply chains. Do you expect that the political decision-makers will learn lessons from this crisis and adopt measures that will effectively strengthen Germany as a research and manufacturing location?

Yes, we expect this to happen. And the government has already given clear signals to this effect. I believe that we need a public dialog about Germany as a medtech location and its infrastructure that is considered to be systemically relevant. In the course of this “medtech dialog” we must develop measures that will safeguard and strengthen Germany as a manufacturing and research location for medical devices.

BVMed believes that this “medtech location offensive” is necessary and should include the following aspects:

- Joint development of a catalog of measures during a “medtech dialog” by the medical technology industry, the relevant government departments, and the German parliament
- Evaluation of regulatory and social security law frameworks and development of a bureaucracy offensive in order to accelerate evaluation processes
- Customized support and reduction of the burdens for the medtech industry with its medium-sized companies through targeted funding programs for the implementation of the MDR
- Funding programs to support the generation of clinical studies or for clinical studies for established products
- Package of measures to combat the skills shortage especially in rural areas
- Qualification initiative for digitization and development of new occupational profiles for the medtech sector

Interview with Dr. Meinrad Lugan (Chairman of the Board of The German Medical Technology Association, BVMed) (2/2)



Until now the healthcare sector has not been regarded as a significant part of the critical infrastructure. What must be done to be better prepared for crisis situations?

What we need now is a structured dialog about the systemically relevant infrastructure that will ensure patient care.

The issue of supply shortages of medical products must be dealt with in a strategic way. In my opinion this includes the following aspects:

- Analyzing and evaluating global supply chains
- Identifying and evaluating dependencies
- Definition of products that should be stored in order to ensure patient care in Germany even in times of crisis
- Sufficient reserves of medical devices for pandemics in healthcare institutions (medtech reserve)
- Production and research for medical devices in Germany must be strengthened.

Do you expect that the pandemic will lead to greater consolidation pressure in the industry and thus to a takeover wave with regard to medtech companies?

Pressure on the medtech industry, which is predominantly characterized by small and medium-sized companies, will no doubt increase. One contributing factor is the EU Medical Device Regulation. Another one is the corona pandemic and its economic consequences. We can expect further concentration processes unless Germany provides better support for small and medium-sized businesses with an SME offensive and a campaign to truly reduce bureaucracy. This is a task not only for the Ministry of Health but also the Ministry of Economics.

During the crisis, entirely new players are entering the market. They provide valuable support during the crisis. Do you expect that some of them will permanently establish themselves in the healthcare sector?

No, I don't think so. Businesses from other industries than medical technology can provide temporary support during the corona crisis. They can help by supplying components or by expanding the capacities of the medical technology industry.

But I do not expect them to stay in the market for the long-term because the requirements regarding the safety, efficiency, and quality of medical technologies are highly complex and strict.

Digitization is increasingly important for medical technology. There are several legislative proposals to support digitization, e.g. the digital care law Digitale Versorgungsgesetz (DVG) that regulates the reimbursability of class I and II medical devices. Are these processes sufficient?

Federal Minister of Health Jens Spahn has generated great momentum in this respect. The pace of the Federal Ministry of Health is positive. Generally, the digital care law provides some good ideas for a fast introduction of digital solutions into medical care. BVMed supports the fact that the Ministry has chosen a low-threshold and therefore patient-centered approach. Also the regulations for the prescription and funding of digital health applications, and the transparency via a central register of digital healthcare applications that are to be remunerated, are positive aspects.

We believe that restricting the applications to class I and IIb devices is insufficient. We call for the inclusion of digital medical devices of classes IIb and III in the procedure of the Federal Institute for Drugs and Medical Devices. We understand the purpose of testing the fast track procedure with class I and IIa devices as a first step. But we need a reliable time frame for the inclusion of higher class digital medical devices in the register of the Federal Institute for Drugs and Medical Devices as soon as possible. This is the right way forward with regard to the development of a wide range of future innovations in the German healthcare market. In addition, we call for the inclusion of so-called combination devices, i.e. software or apps that process the data provided by another medical device, such as cardiac pacemakers, to be used by the physician or the patient, and therefore increase treatment compliance. So far, the law does not include combination devices. These digital solutions used in connection with a traditional medical device, however, possess great potential to improve medical care.

Blazejewski MEDI-TECH GmbH Plans Growth with the Help of Investor SHS



Interview with the Owner Reinhold Blazejewski, and with Manfred Ulmer-Weber

Blazejewski MEDI-TECH GmbH is based in Sexau in the region of Baden and is one of the leading manufacturers of flexible 2D endoscopes. 3D endoscopes will soon be approved. Now, the company has decided to work together with the growth investor SHS. An interview with Reinhold Blazejewski and Manfred Ulmer-Weber of SHS.

Clairfield: Mr. Blazejewski, your medical technology company is among the leading manufacturers of flexible 2D endoscopes. Your 3D endoscopes will soon be granted their first approval. Why have you decided to work together with a growth investor like SHS?

Reinhold Blazejewski: As an engineer my main task has always been the development of new devices. Three years ago, then, the first contact with SHS in Tübingen came about. I think that if you cooperate with an investor such as SHS you are able to push the strategic development of a company with much more force compared to when you are on your own. Especially international growth is a very capital-intensive matter. As SHS has been on this road with several partners already I also hope to be able to benefit from their valuable know-how regarding internationalization.

Clairfield: What did your choice of partner depend on?

Reinhold Blazejewski: For me it was important to find a partner that has sector expertise. I hope that the cooperation with SHS will strengthen our product development and marketing as well as provide support for the regulatory challenge ahead.

Clairfield: What does the start of an investment process actually look like, Mr. Ulmer-Weber? You have been assisting this project from the start.

Manfred Ulmer-Weber: As an investment company in the medical technology and life science sector, SHS meets many companies faced with fundamental challenges: developing new products until they achieve market readiness, the continuously increasing regulatory barriers, especially through the EU Medical Device Regulation, and international expansion. We are pleased when successful, innovative medium-sized companies such as Mr. Blazejewski's contact us because they want to work with us. After seeing that the "chemistry" is right, we developed a concept that provides for a minority investment by SHS.

Clairfield: What do you expect with regard to SHS, Mr. Blazejewski?

Blazejewski: With the help of SHS we want to continue our growth and expand as well as strengthen our sales. We will continue to develop devices, such as the, at present, smallest 3D endoscope worldwide, and to launch these on the market together with our partners.

Clairfield: Is medical technology still an interesting field for SHS, despite the decreasing growth dynamic?

Manfred Ulmer-Weber: Even though the growth dynamic has decreased slightly, the industry will continue to grow. We have been in the market for almost 30 years and we believe that we are a qualified partner for medium-sized companies, e.g. for financing growth as in the case of Blazejewski, but also in cases of planned successions.

Prof. Dr. Christian Koziol: “Innovation Needs Equity”



The Importance of Medical Technology will Increase

Christian Koziol is a professor and holds the Chair of Finance at the University of Tübingen. Together with the Tübingen-based industry investor SHS he has developed the *SHS Medical Technology Index*. The index measures the growth potential, innovative capacity, and economic performance of the German medical technology industry in relation to the overall economy. We spoke with Professor Dr. Koziol about the momentum of the medtech sector and the importance of equity capital for medical technology companies.

Clairfield: Professor Koziol, the *SHS Medical Technology Index* has shown that momentum has slowed since 2016. Now, there is the additional effect of the corona crisis. Do we have to be concerned about the medical technology industry?

Professor Koziol: No, I don't think so right now. The slowdown in economic growth can largely be attributed to the stricter regulatory requirements that have been in effect throughout the EU since 2017. The medical technology industry is stable, highly innovative, and altogether less volatile and less dependent on economic trends than other sectors. Moreover, the corona crisis shows the importance of the, world-leading, vital medical technology industry for the high-tech location Germany. I believe that medical technology will become more important, and not only because of the lack of respirators.

Clairfield: What is the distinguishing feature of medical technology in Germany?

Professor Koziol: Worldwide, we are envied the innovative capacity of our highly qualified engineers working in the German medical technology industry. In addition, the industry cooperates closely with universities and research institutions, and the regional clustering in various parts of Germany proves to be highly stimulating.

As an example, I would like to point to the Medical Mountains region Tuttlingen. Our frameworks are basically very good.

Clairfield: Which are the challenges faced by medical technology?

Professor Koziol: First of all, we should be careful not to burden the industry and its innovation activities with regulatory barriers and bureaucracy. Also, we notice that especially the small and medium-sized companies in medical technology need a sound equity ratio in order to ensure their innovative capacity and to drive the necessary internationalization.

Clairfield: What is the role of equity capital and funding?

Professor Koziol: Innovation and growth need equity. In 2017 we conducted a market analysis together with SHS that showed that medical technology companies prosper especially if they have high equity ratios. In contrast to DAX companies they want to keep their independence from risk-averse debt capital providers. Especially innovative and high-growth companies regard equity providers with industry experience as good partners, not least because this leads to better investment and growth decisions, as is well known from corporate finance textbooks.

Clairfield: Thank you very much for the interview.

Hubertus Leonhardt About Good Investments



Investments are About Developing the Portfolio Company

Hubertus Leonhardt is a Managing Partner of SHS Gesellschaft für Beteiligungsmanagement mbH based in Tübingen. For the past 27 years, the company has been investing in medical technology and life science companies in the German-speaking countries. Its portfolio companies have been or are, for instance: *EIT* (spine implants from 3D printing), *Blazejewski MEDI-TECH GmbH* (endoscopes), *puracon* (validation, packaging, and logistics for medical devices). The industry investor's focus is on growth financing, shareholder changes, and successions. At present, SHS provides investments from the SHS V fund that has capital commitments of over 130 million euros.

Clairfield: Looking at the *SHS Medical Technology Index* it can be seen that momentum has somewhat slowed. Is the medical technology sector still attractive for investment companies?

Hubertus Leonhardt: We have been active in medical technology for 27 years, this is the industry that we know well. We still consider this to be a dynamic, extremely innovative industry that is facing some difficulties at the moment.

Clairfield: What kind of difficulties are these?

Hubertus Leonhardt: The EU Medical Device Regulation is a regulatory barrier that our companies have to face. To do so, they need expertise and capital. In addition, they have to deal with the costly development of new devices and their introduction into high-threshold markets such as the US. This can be a huge challenge sometimes.

Clairfield: You have just launched your fifth fund, with over 130 million euros one of the largest industry funds in Europe. What kind of companies are particularly interesting as investment companies for SHS?

Hubertus Leonhardt: As an industry investor we are looking for medium-sized medical technology businesses with market ready products that have a unique selling proposition. Companies that are on a clear growth course and are systematically entering new markets and need to strengthen their equity basis to do so.

Clairfield: How do you approach investment projects?

Hubertus Leonhardt: We have been active in medical technology for almost thirty years and have successfully implemented a large number of investment projects with medium-sized companies. It is always important to really understand the company and its projects. Only then are we able to develop tailored financing and investment solutions in cooperation with the business owner. SHS is no passive investor looking for a quick profit. We want to take an active part in developing our portfolio companies. To this end we have built a strong knowledge network. Apart from that we are basically flexible with regard to the amount we invest. Minority investments may be just as interesting as majority interests or co-investment projects. This is also the case with regard to successions that we have also implemented successfully.

Clairfield: Thank you very much for the interview.

Interview with Renée Marie (Bogdanovic) Hoff (Investment Manager Duke Street)

Which medtech targets are you interested in? What kind of investment strategy do you pursue in the medtech sector?

Duke Street is always interested in supporting good management teams and their visions and ambitious plans, even in times of great economic and social uncertainty. We have split our search for deals into different sub-sectors. We define our investment propositions in terms of market attractiveness, market dynamic, the availability of potential targets, and Duke Street's "value-add potential", e.g. manufacturers of medical-technological devices for ophthalmology or medtech CMOs.

Please tell us about your medtech investment in Medi-Globe in 2016. Which parts of the process were particularly challenging?

The core part of our investment strategy regarding Medi-Globe Group is the introduction and guarantee of operational excellence as well as the optimal integration of business units that historically have not yet been able to benefit from synergies. In addition, we have significantly increased investments in research and development, which can be regarded as the most important leverage factor for value creation in an innovative company such as Medi-Globe Group. We regard this incremental and continuous change of surgical devices that are critical success factors as a strong industry driver.

Have these investments developed as expected and if not, what was the reason?

Medi-Globe Group has been growing as planned, despite the additional investments needed due to the announcement of the new EU Medical Device Regulation (MDR). Its stable growth is based on the strong underlying market which has been strengthened in particular by the switch from reusable devices to single-use devices as well as by the focus on the prevention of infections. These properties are part of the main reasons for our investment decision.

In your experience, what kinds of market segment have proved to be unsuitable for private equity investments? Which segments are the ideal targets? And what are the reasons for this?

In the medical devices sector, private equity firms should question "commodity" products that, especially in Germany, are subject to the increasingly strong

purchasing power of group purchasing organizations (GPOs).

Private equity investors contribute a significant added value by making available the capital required for innovations (e.g. for the development of wireless health monitoring systems) and by providing the M&A expertise for the further consolidation of the market, especially because 99 percent of the companies in Germany are SMEs.

In what way do new regulations (e.g. the new EU Medical Device Regulation (MDR)) affect your investment focus? In what way do you think will they affect your portfolio companies?

The new EU Medical Device Regulation (MDR) will influence the industry because it requires greater transparency and demands additional resources for compliance. These changes will cause problems especially for smaller businesses because they may not possess the required capital (human or financial) to comply with the regulations. However, this provides opportunities for strong medium-sized players to increase their market share.

In your view, what makes a successful team in the medtech industry special?

A successful team shows great versatility: the ability to understand the complexity of a business model in the medtech industry and to manage it successfully. This includes an excellent understanding of the healthcare system and the manufacturer of the devices.

How would you describe the current situation regarding the medtech M&A market in one sentence?

Medical technology is an attractive field for investments especially given the current market volatility because medtech shows great resilience in all economic cycles, has a consistent growth profile, and a huge potential for market consolidation.

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