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CLAIRFIELD INTERNATIONAL

# Market Survey Medical Technology 2018

The market for medical technology is a global growth market with a high speed of innovation. Up to now, German medium sized companies have been able to secure competitive advantages due to their strong innovative drive. Due to sharply increased competition and cost pressures, stricter regulatory requirements and the new challenges posed by digitalization, the industry is currently undergoing profound changes, especially in Germany and Europe. This has led to a significant increase in consolidation in the industry and will continue to influence the M&A market.

It is therefore now more necessary than ever to review business models to ensure they are competitive and viable in the future and to develop individual solutions that also enable medium sized companies to defend their competitive position in the global market.

This was an opportunity for us to carry out a detailed analysis of the market and assess the needs for action so that we can support your company in the transformation process with tailor-made solutions.

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# Management Summary

## The study at a glance

- Content: Overview of the current developments in the medical technology market in Germany, Europe and the USA from a legal, technical and transaction-oriented perspective
- Focus: Products that can be assigned to medical technology. Due to the strong restrictions for in vitro diagnostics, this sub-area has not been included in this study
- The main trends and statements of the study are:
  - Ageing of the world's population and growth in the emerging markets are the main reasons for the sustained increase in demand for medical technology products
  - In some cases, the regulatory requirements for the approval and sale of medical technology products differ considerably when compared internationally
  - Most important technology trends in the course of digitalization: Use of artificial intelligence and smart medical technology solutions
  - Depending on the region, M&A transactions focus on different segments of medical technology, although the trend in consolidation in medical technology continues. By doing so, the MedTech companies usually want to save costs, gain access to distribution networks or purchase innovative technology
- Interviews with experts from MedTech entrepreneurs on the current situation in medical technology provide an outlook for 2020

## Current challenges

**Digitalization:** MedTech companies need to digitalize their business models in order to succeed in the long term. Thus, specific data protection and data security requirements must be observed

**Cost pressure:** Ongoing privatization of the hospitals, the bundling of demand in purchasing groups and the gradual "arming" of DRGs for reimbursement in the hospital sector, as well as increasing requirements for refundability in the outpatient sector, are increasingly reducing the gross margins for companies

**Regulatory requirements:** Strongly tightened regulatory requirements have a direct impact on technological development, the speed of innovation and the business models of companies in different markets and can thus ultimately have a significant influence on profitability and corporate value

## Our recommendations

**Startups** can rely on help from venture capital companies to secure their first investments. The number of investors in this area is still manageable in Germany. The first new companies have already been established in the software, wearables and diagnostics sectors using Big Data

**Medium sized companies** must review their business models in order to be prepared for continuing price decline and increasing digitalization. The development of new technologies and business models can often only be realized through new investors or mergers

**Companies from outside the industry** are increasingly entering the medical technology market, especially from the automotive and IT sectors. New approval procedures (EU law) and the associated requirements in distribution and monitoring must be observed here

Sources: MedTech Europe, German Federal Medical Technology Association (BVMed), Angermann M&A International GmbH, Statista,

# Contents

# A.

# The Medical Technology Market

"There is currently strong competition for interesting MedTech investment opportunities and a correspondingly high valuation environment."
**Ken Eichmann, Principal GHO**

"On the supplier side (doctors, hospitals, but also MedTech companies) a change in thinking must take place, as the "classic patient" is changing into a paying customer."
**Till Gumz, MedforceOne GmbH**

"The medical technology market is a rapidly growing market. Especially interesting areas are currently home care, digitalization, minimally invasive surgery and e-health."
**Cornelius Maas, SHS Capital**

# Medical technology at a glance

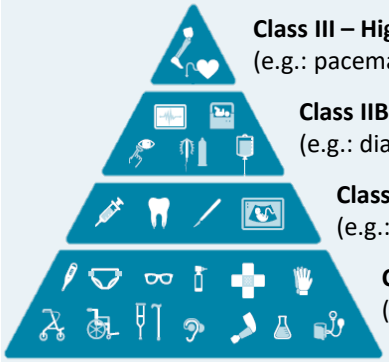
## Definition of medical devices under Section 3 German Medical Devices Act ("*Medizinproduktegesetz - MPG*")

*"Medical devices are all instruments, apparatus, software, substances or preparations made from substances or other articles, used alone or in combination, including the software intended by the manufacturer to be used specifically for diagnostic or therapeutic purposes and necessary for the medical device's proper application, intended by the manufacturer to be used for human beings, by virtue of their functions, for the purpose of*

- *diagnosis, prevention, monitoring, treatment or alleviation of disease,*
- *diagnosis, monitoring, treatment, alleviation or compensation of injuries or handicaps,*
- *investigation, replacement or modification of the anatomy or of a physiological process […]"*

## Risk classification of medical devices under Section 3 et seq. German Medical Devices Act

Medical devices are classified according to their risk potential for human health:



**Class III – High risk potential**
(e.g.: pacemakers, heart valves, prostheses)

**Class IIB – Increased risk**
(e.g.: dialyzers, surgical lasers, plates)

**Class IIA – Medium risk potential**
(e.g.: diagnostic ultrasound, MRI, PET)

**Class I – Low risk potential**
(e.g.: glasses, stethoscopes, wheelchairs)

## Areas of application of medical devices

Medical devices are used in the following areas of application:

- Hospital technology (operating robots, emergency stop buttons)
- Medical devices (pacemakers, dental implants)
- Imaging diagnostics (sonography, X-rays)
- Tissue engineering (artificial organs)
- Medical informatics (simulation of surgical procedures)

Medical informatics has a special position in all areas of application. In this digital age, computer science influences almost all the areas of application in medical technology

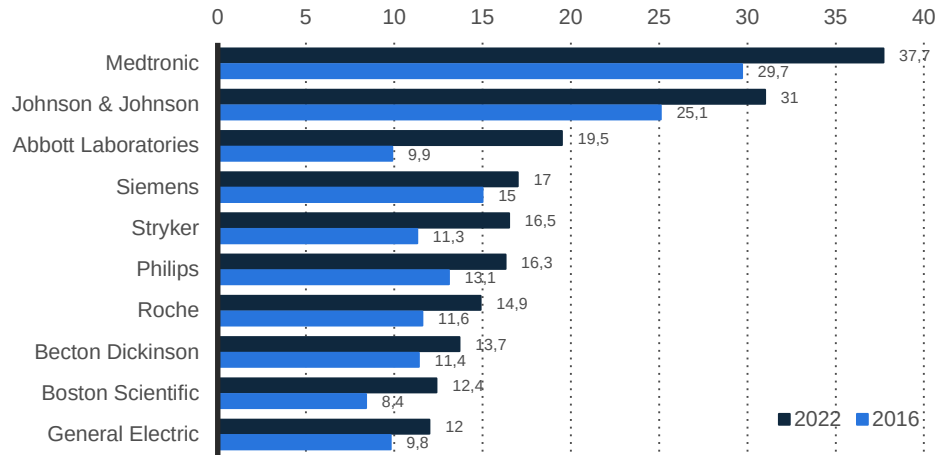
Sources: MedTech Europe, Picture from German Federal Medical Technology Association (BVMed)

# Overview global trends and market in figures

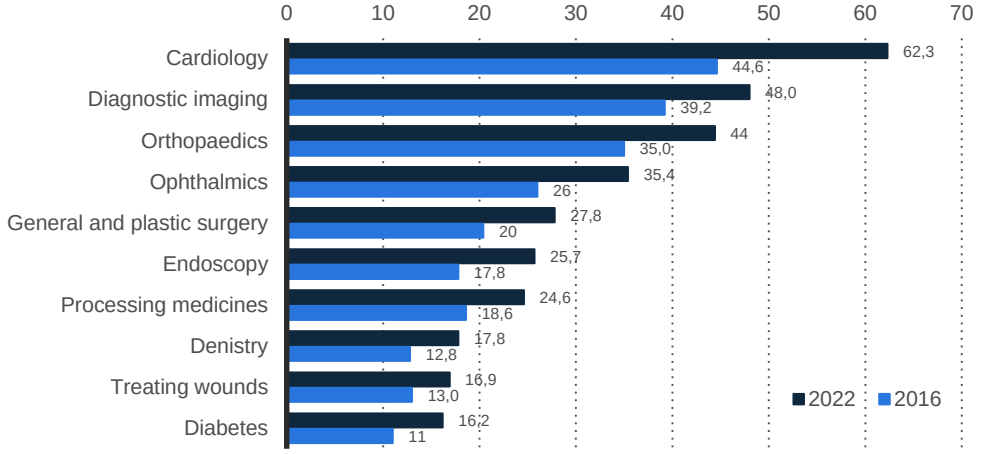
## Overview market

- Lesser dominance, very large market leaders
- Ten of the world's leading companies generate 37% of the industry's total revenue
- About 95% of all MedTech companies are small and medium sized enterprises (SMEs); the majority of SMEs employ less than 50 people
- Internationally defined market in which German SMEs have to compete with large conglomerates at home and abroad
- The companies with the highest revenue come predominantly from the USA: Johnson & Johnson, Medtronic and General Electric Healthcare generate the highest revenue worldwide
- With Fresenius Medical Care and Siemens Healthineers, Germany is also represented amongst the world's leading companies
- Medical technology is characterized above all by a consistently high level of research and development expenditure
- Companies from other industries are entering the market and contributing their technological know-how, as well as development and production competence in medical technology
- More consumer influence, digital innovations and new market entrants are having an unprecedented impact on the medical technology market. Therefore, MedTech companies face the challenge of adapting their business models to these changes
- Technology leaders and startups are increasingly developing smart medical devices and service-oriented solutions
- Highest revenue segments in medical technology by 2022: Orthopaedics, imaging diagnostics and cardiology

## Highest revenue medical technology companies 2016 in $bn



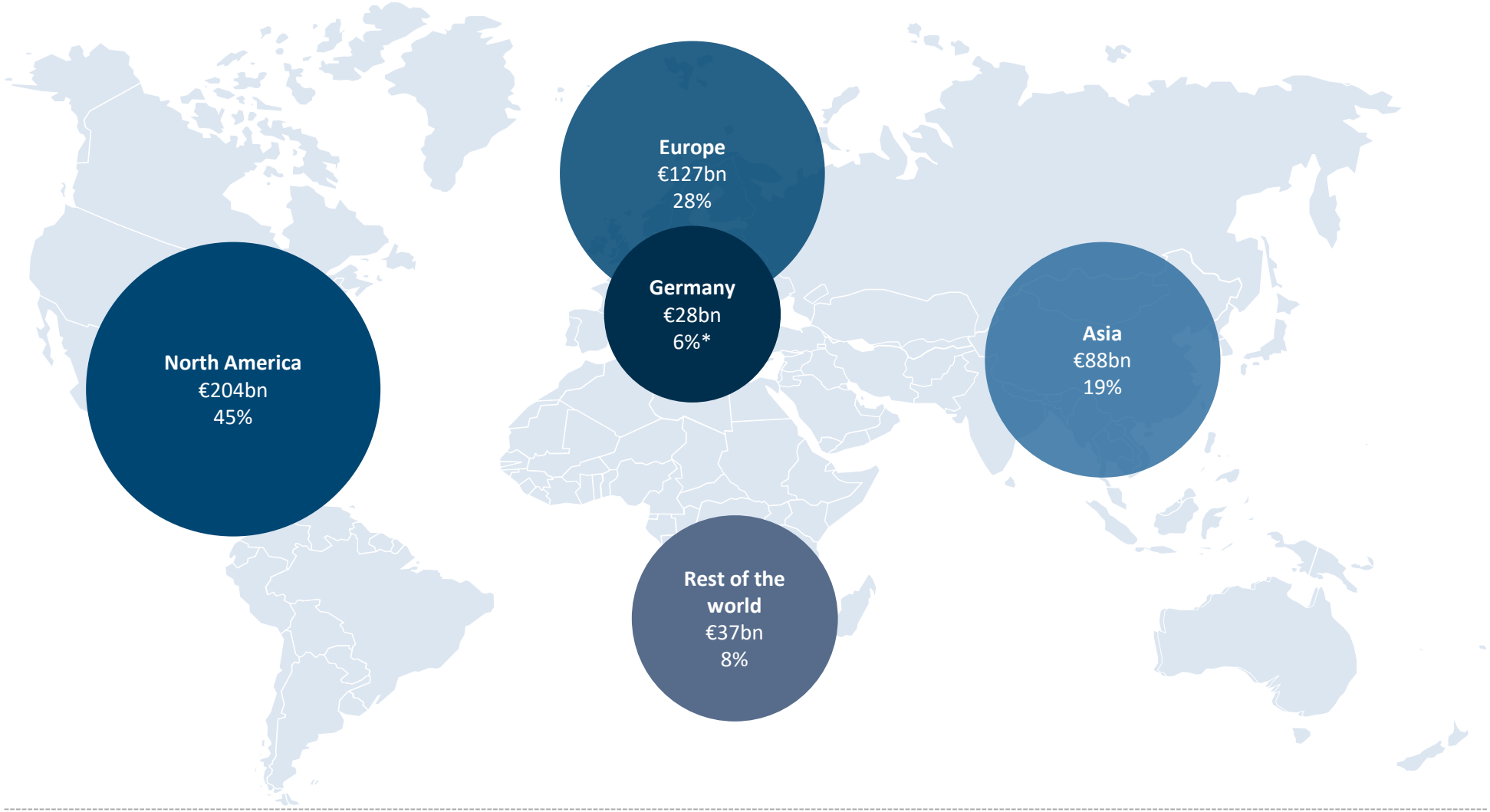

## Worldwide equipment sales by segment by 2022 in $bn




Source: MedTech Europe, German Federal Medical Technology Association (BVMed), , Statista

# Overview regional market in figures (1/2)

## North America is the leading market for medical technology, followed by Europe and Asia




Sources: German Federal Medical Technology Association (BVMed), *Share of the German market volume in the European MedTech market in 2016

# Overview regional market in figures (2/2)

## Europe

- With approx. 25,000 MedTech companies, half of them in Germany, Europe is defined by a large number of SMEs
- In Europe approx. 650,000 people work for medical technology companies, approx. 210,000 of which are in Germany
- Siemens Healthineers and Fresenius Medical Care are just two of the world's highest revenue companies in Germany. Philipps in the Netherlands and Novartis in Switzerland are two more companies under the top 10 worldwide
- The majority of the European companies are based in Germany, followed by the UK, Italy, Switzerland, Spain and France
- Average expenditure per head for medical technology in Europe amounts to approx. EUR 195 per annum

## North America

- North America is the largest market for medical technology
- Six of the ten medical technology companies with the highest revenue come from the USA
- In addition, there are approx. 6,500 small and medium sized MedTech companies in North America
- Approx. 80% of the companies employ less than 50 employees, a total of approx. 520,000 employees
- The majority of medical technology companies are located in California, Florida, New York and Pennsylvania
- Average expenditure per head for medical technology in North America amounts to approx. EUR 380 per annum

## Asia

- Asia is the third largest market for medical technology after North America and Europe
- One of the main reasons for the rapid growth of the Asian market is the growing middle class in China
- By 2025, the absolute number of the middle class population is expected to rise to approx. 600 million
- Similarly, the increasing average age of the Chinese population is creating an increasing demand for medical products
- Estimated growth in demand for medical products in China is expected to reach 15% by 2020
- Within the next few years, the Asian region is expected to replace Europe in second place amongst the largest markets for medical technology

## Rest of the world

- Latin America and the Middle East have the greatest growth potential for medical products
- Double-digit growth rates are forecast in emerging markets such as Mexico, Malaysia and Brazil
- It is expected that MedTech companies will expand their activities to these high-growth countries

Sources: German Federal Medical Technology Association (BVMed), McKinsey&Company, medtecheurope.org

# Overview: Trends in the market, technology and M&A

## Market trends

**Ageing of the world's population**

- According to the US Department of Health, the proportion of the world's population over 60 years of age in industrialized countries will rise from 23% to 32% by 2050
- Against the background that industrialized countries in particular have a high age profile, the overwhelming and fastest-growing majority live in developing countries
- By 2020, it is expected that the demand for medical products will increase the most in China with 1.5%, followed by Europe with 1.25% and the USA with 1%

**Growth of emerging markets**

- Manufacturers of medical products from industrialized countries are expected to increase their activities in emerging markets such as China, India and Brazil
- The emerging markets will have a lasting impact on the development of the medical technology industry over the next 50 years: With stagnating domestic demand, it is crucial to develop a strong presence in growth markets at an early stage
- Customer confidence in Western product brands is very high, but the trend is inevitably shifting towards product brands from emerging markets

## Trends in technology and M&A

**Artificial intelligence**

- Artificial intelligence and Big Data are increasingly finding their way into medicine and medical technology. Artificial intelligence and Big Data are already widely used in imaging diagnostics to speed up analyses and support decisions
- With the Big Data software developed in Germany, such as ADA, the health situation of a patient can be ascertained. A variety of questions are used to identify symptoms and compare them with similar cases
- Well-known companies from the industry, such as Medtronic or Philips, are already cooperating with companies from the AI sector to develop innovative solutions for the healthcare market

**Smart medical technology**

- In the digital age, more and more "smart products" and "wearables" that are connected to the Internet and pass on additional functions and data to the consumer are entering the market
- According to estimates, the global market volume of "smart" health products amounts to approx. US$ 285bn
- However, a connection to the Internet also poses the risk of hackers who can gain access to confidential information or affect the vital functions of a device

**Consolidation in healthcare**

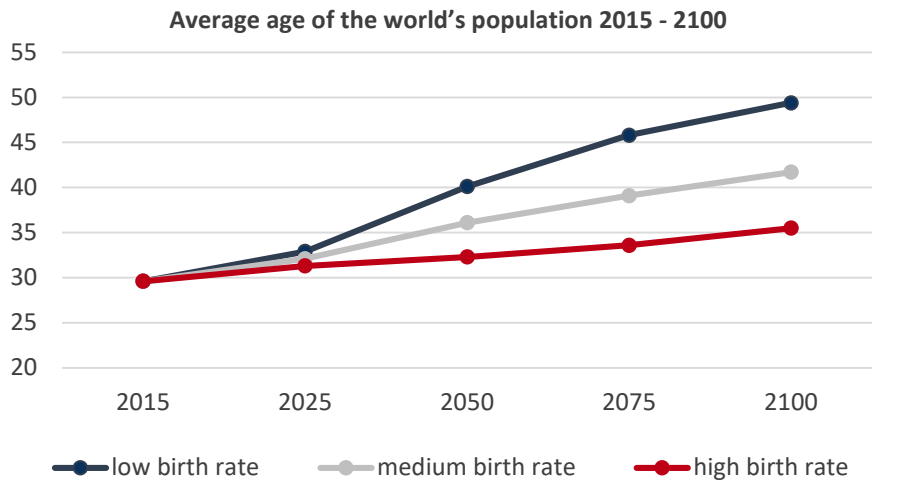
- M&A transactions in the MedTech sector are increasingly taking place in related areas such as AI and wearables
- A consolidation trend in medical technology (from the cooperation agreement to the takeover) is still apparent
- M&A transactions within the medical technology sector continue to be characterized by a high number of small and medium sized transactions

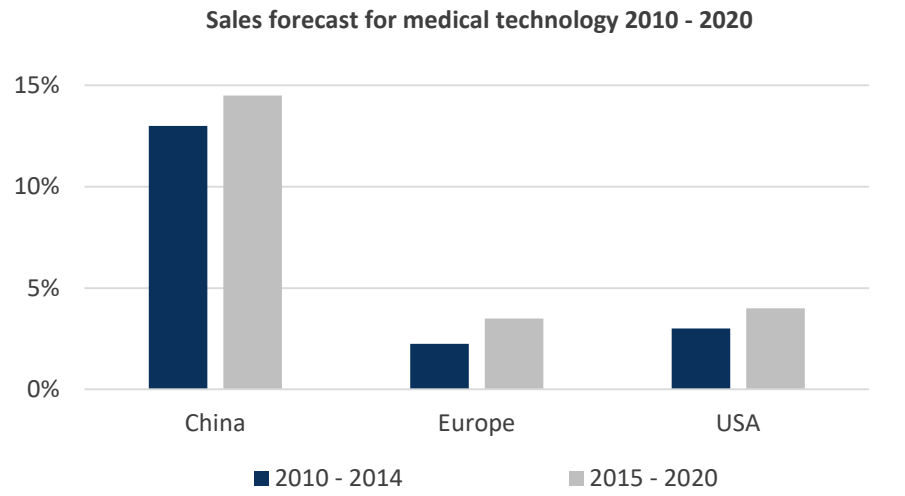
Sources: Galway City and County Economic and Industrial Baseline Study, PwC Healthcare Group, Global Industry Analysts

# Market trend 1: Ageing of the world's population

## Detailed analysis: Ageing of the world's population

- In 2010, an estimated 524 million people were aged 65 or older, representing 8% of the world's population
- According to estimates, this number will triple by 2050 and rise to around 1.5 billion. This would represent 16% of the world's population
- The fall in birth rates and longer life expectancy are largely responsible for this phenomenon
- Depending on whether a low, medium or high birth rate, the average age of the world population is
  - between 32 and 40 years by 2050
  - between 36 and 49 years by 2100
- Given the fact that industrialized countries in particular have a high age profile, the overwhelming and fastest-growing majority live in developing countries
- The long-term increase in demand for medical technology and the associated increase in sales are due to the age profile of the world's population and increasing life expectancy
- In addition, services in the healthcare sector are state-sponsored
- Consequently, the age profile of the world population determines the buyer profile in the MedTech sector
- The demand for medical products will rise most in China with 1.5% by 2020, followed by Europe with 1.25% and the USA with 1%



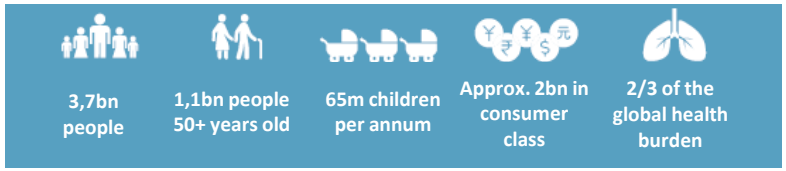

Sources: Statista, World Health Organization (WHO)

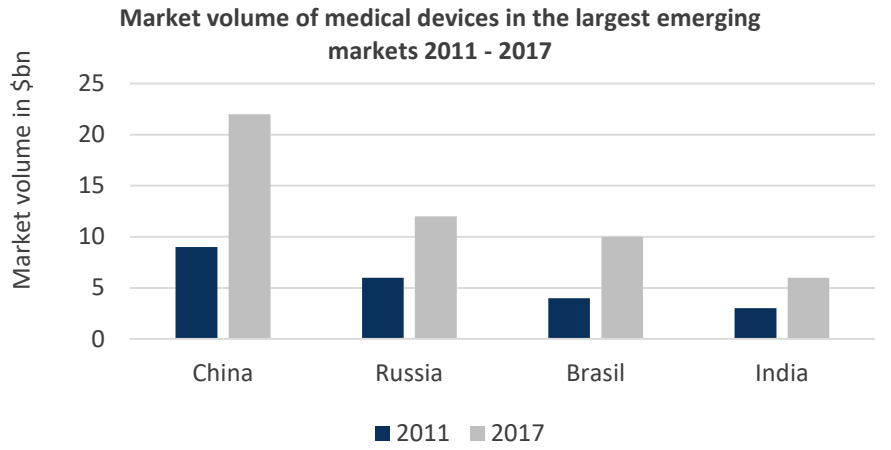
# Market trend 2: Growth in the emerging markets

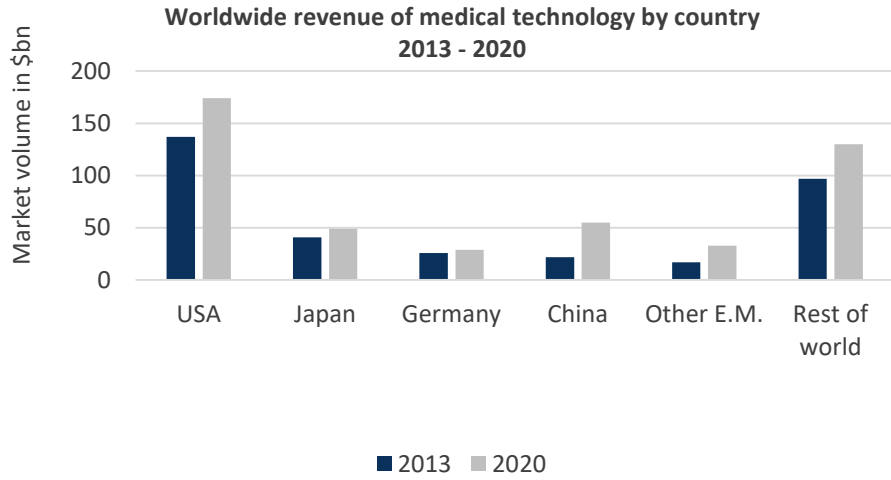
## Detailed analysis: Growth in the emerging markets

- According to estimates, manufacturers of medical products from industrialized countries are expected to try to further expand their market share in the most important emerging markets such as China, India and Brazil
- Emerging markets are also the driving force within the medical technology market and will have a lasting impact on it over the next 50 years
- More than half of the world's population lives in the Asian region, which is being confronted with an increased rate of illness
- Even though consumers continue to have a high level of confidence in medical products from Western manufacturers, the trend will change in such a way that manufacturers from the emerging markets will gain in importance
- In addition, an increase in the level of income is expected in the Asian region. This will have an impact on purchasing power in connection with MedTech products
- Successful companies will respond to the individual medical needs of the different regions of Asia and thereby secure a leading position in the upcoming second-largest market for MedTech products
- In addition to Asia, Brazil is a market with very high growth potential. The export rate of the USA to Brazil already amounts to approx. 30% of the total volume of medical products

**Overview of Asian growth factors**



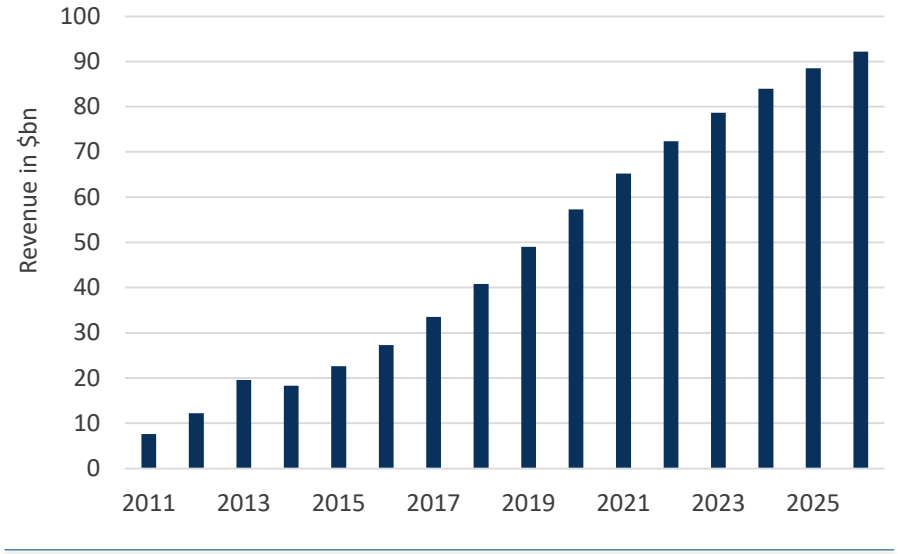

Sources: Statista, Marketrealist, picture from McKinsey&Company

# Technology trend 1: Artificial intelligence

## Detailed analysis: Artificial intelligence

- "Artificial Intelligence" (AI) and Big Data will have a significant impact on the job market and the way doctors work
- Using the data gained from wearables and questionnaires, very detailed analyses can be created, compared with a large number of comparison cases in real time and corresponding measures can be determined. This means that a large proportion of visits to the doctor can be avoided
- Companies from the classic medical sector and manufacturers of smart products (watches, mobile communications and sensor technology) will work together ever more closely
- Since the majority of hospital information systems collect economic and clinical data, the requirements for the use of artificial intelligence are met, especially by clinics
- In addition, the economic data can be used to develop models which, in addition to optimizing medical care, also show how to save costs in clinics
- A study commissioned by the US government on the use of learning computer systems in the diagnosis of breast cancer using MRI scans showed in 2016 that whilst the error rate of the best physicians was 3.5%, the most capable AI systems reached 7.5%
- If man and machine work together, the potential error rate is only 0.5%
- However, there are also structural obstacles to Germany's progress in the field of digitalization
  - Technology
  - Training
  - Financing
- Hospitals must make the data produced legible and transferable for machines, while doctors and nursing staff need more IT know-how, which is ultimately based on financing

**Worldwide revenue in the area of Big Data by 2026**




**Process sequences of IA systems**

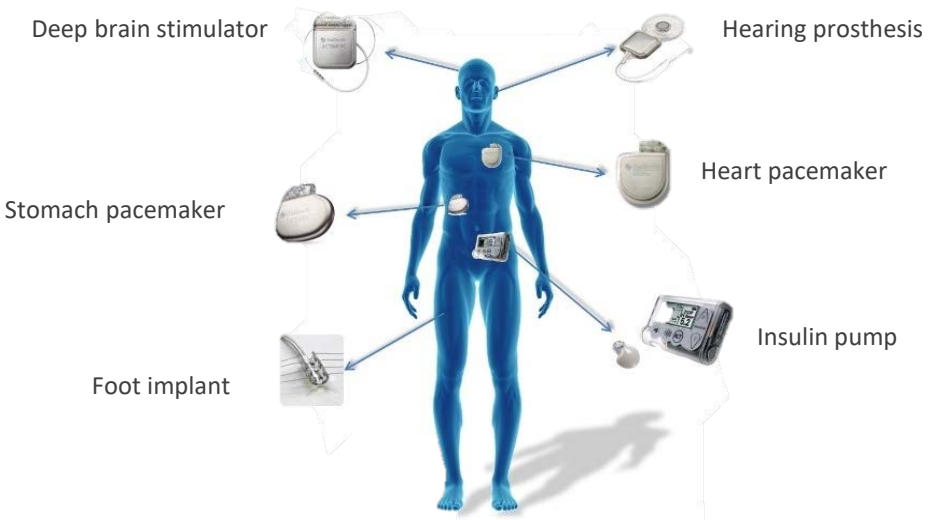

Sources: German Federal Medical Technology Association (BVMed), Handelsblatt, Statista

# Technology trend 2: Smart medical technology

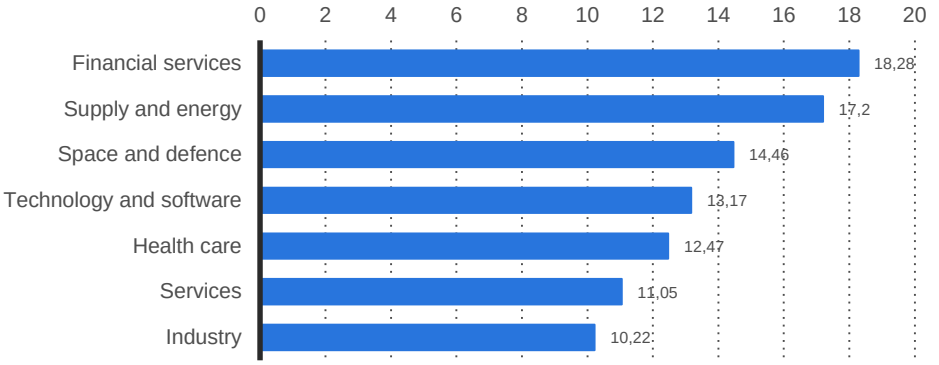
## Detailed analysis: Smart medical technology

- Smart medical technology offers a wide range of benefits: Comprehensive 24/7/365 monitoring and care, personalized therapy, improved prevention, longer average life expectancy, targeted research to combat cancer, lower treatment costs, etc.
- In order to be able to use digital ecosystems, mass data analysis and emerging value-added services, medical technology must network on the Internet of Things with the help of cloud services
- Fitness apps and wristbands are still predominantly lifestyle products today, but they also show that the majority of consumers have long since arrived in the age of e-health. The task now is to validate the real-time data obtained and prove their clinical significance in such a way that they can be used in prevention and therapy. This already shows that patients are much further advanced than doctors are in general
- From a company's perspective, it is important to take advantage of the opportunities offered by the digital revolution and to offer the patients of the future simple, more user-friendly solutions.
- The market volume of health products connected to the Internet is estimated at approximately US$ 285bn
- The dark side to smart medical technology:
  - Medical systems which are connected online, such as anaesthesia devices, pacemakers and magnetic resonance tomography, can be attacked via the Internet
  - Security breaches of medical products are very critical for data protection reasons alone
  - When it comes to the cyber security of networked medical technology solutions, manufacturers must ensure that users are effectively protected against unwanted access by third parties

**Overview of wireless implantable medical devices**




**Estimated costs of cybercrime incidents in companies by industry worldwide in 2017 (in US $m)**




Sources: German Federal Medical Technology Association (BVMed), Aerztezeitung.de, smarte-medizintechnik.de, Statista, picture from KQED

# M&A trend: Consolidation in healthcare

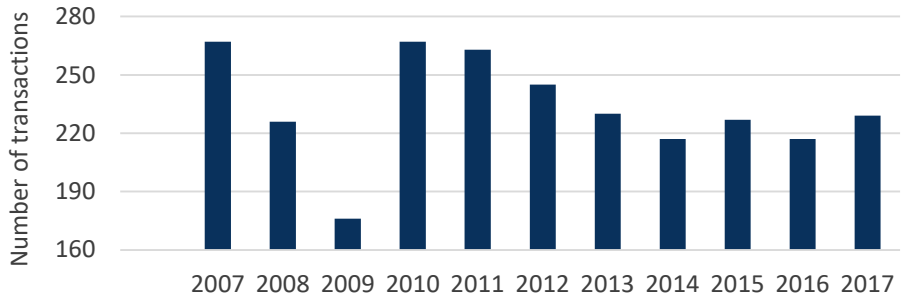
## Consolidation in healthcare

- M&A transactions in the MedTech sector are being increasingly defined by blurred borders compared with previously clearly distinguishable neighbouring industries; medical technology is becoming increasingly more difficult to separate from pharmaceuticals, biotechnology, digital health or medical services
- M&A transactions in the Germany, Austria and Switzerland regions continue to be defined by a high number of small and medium sized transactions
- These smaller M&A transactions had a significant impact on the total number of transactions in the industry in 2017
- On the one hand, companies are trying to gain dominance in the respective area by means of M&A transactions, but often this is with the wrong products or with companies with which this is not possible
- Other companies are trying to further optimize their portfolio by closing gaps or expanding their geographic reach

## M&A driving forces

- Continued consolidation trend in an originally fragmented market
- Short development cycles lead to many product groups and a market defined by medium sized companies, at the same time the large corporations have the market power
- Dynamic consolidation, as smaller manufacturers are not competitive
- Integration movement for better development of new fields of innovation and mastering of new technologies
- Demand from the market, especially hospitals, to be able to purchase all products from the same manufacturer
- Costs and time spent on compliance with regulatory requirements no longer tolerable for smaller market participants
- From the perspective of large corporations, acquisitions are particularly interesting in terms of expanding their product range
- On the buyer side, not only strategists, but also, as already in the USA, private equity firms are becoming increasingly more interested

## M&A transactions in medical technology 2007 - 2017



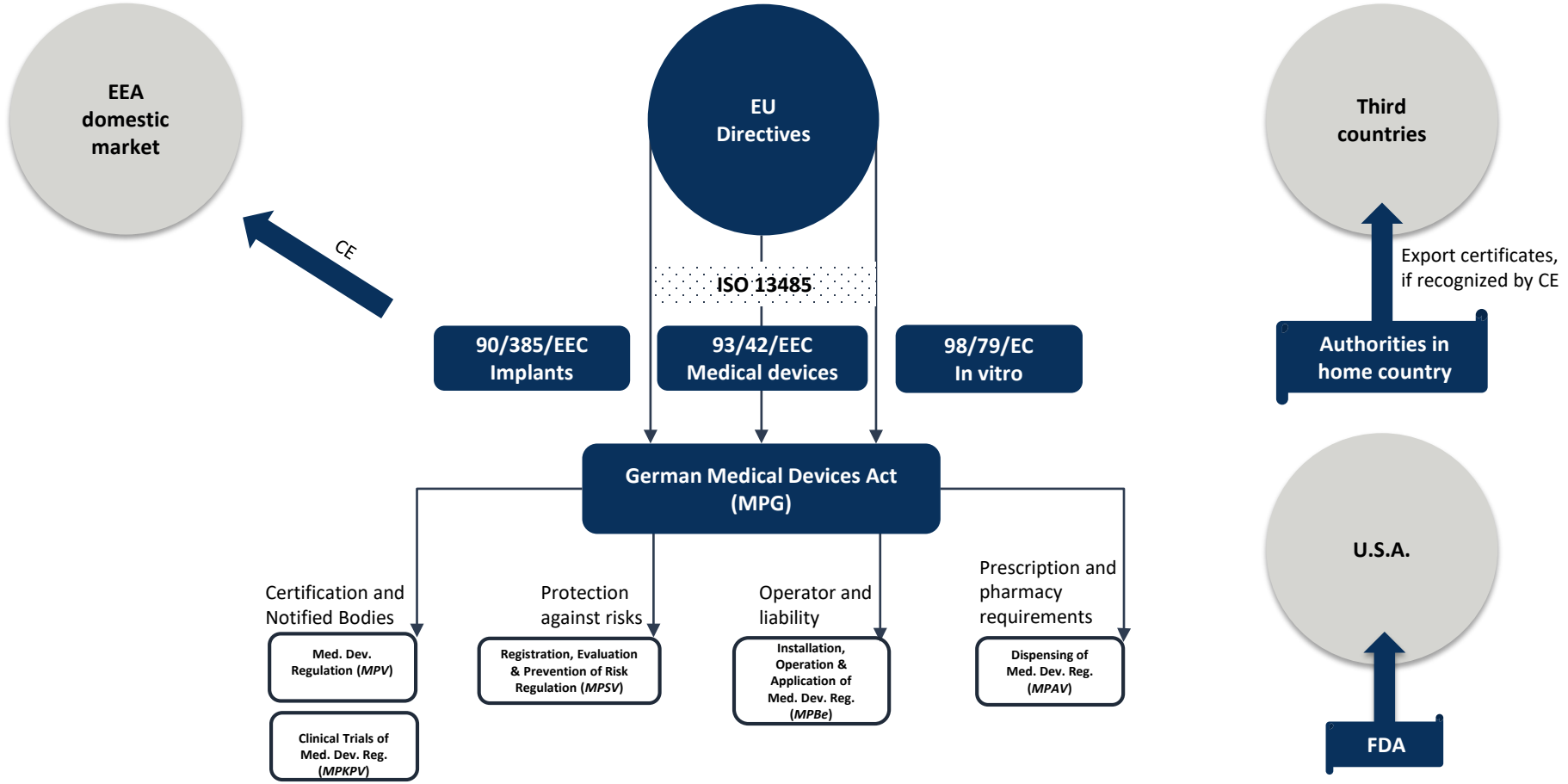

## Conclusion

- ➢ New regulations, increasing competition and innovative technologies lead to complex challenges in this sector
- The consolidation trend in medical technology (from the cooperation agreement to the takeover) is still apparent
- ➢ M&A transactions within the medical technology sector continue to be defined by a high number of small and medium sized transactions
- ➢ Private Equity/Venture Capital companies can help startups to overcome the initial financing problems more quickly

Sources: German Federal Medical Technology Association (BVMed), Statista

# Regulating the placing of medical devices on the market

## Decentralised approval procedure for the marketing of medical devices in Europe




**With the EU Medical Devices Regulation (MDR) coming into force in May 2017, a uniform EU legal framework for the marketing of medical devices was created**

Sources: Beck-Online, tec4U

# Approval of medical devices

## Market access regulations

When entering the market, special structures, regulations and registration procedures must be observed. Companies from outside the industry often underestimate the special features of national and international standards and regulations. For example, automotive companies must demonstrate a special quality management system for medical technology

**CE Certification**

- Access to the German and European domestic market requires CE certification
- To this end, in accordance with the European risk classification, the manufacturer must carry out its own controls of its products
- Normally, the manufacturer selects a so-called Notified Body, i.e. a private body accredited for the risk class, which carries out a clinical trial in accordance with Sec. 20 German Medical Devices Act (*MPG*) and a conformity assessment in accordance with Sec. 3 Medical Devices Regulation (*MPV*)

**Other requirements**

- Obligation of the importer to notify the competent authority when placing products on the German market pursuant to Sec. 5 (1) German Medical Devices Act (*MPG*)
- Equipping the product with German user information

**Other EU countries**

- If third countries recognize this control procedure, the person responsible may apply for an export or free trade certificate to be issued by the competent national authority in its member state of residence
- Approval procedure in the USA organized centrally and by the state. To gain access to the U.S. market, an independent certification process must be conducted with the FDA (Food and Drug Administration)

**Health Technology Assessment (HTA)**

New requirements will result from the EU uniform benefit assessment for medical devices of risk classes II B and III. The EU Commission presented a draft regulation in January 2018

## New EU Medical Devices Regulation (*MPV*)

When the EU Medical Devices Regulation (*MPV*) came into force on 25 May 2017, the legal framework for the placing of medical devices on the EU domestic market was harmonized. At the same time, however, the processes became more complex. For the duration of a three-year transitional period, manufacturers currently can choose between certification under the new law or the old law. Existing certificates remain valid until they expire, although the interpretation of the transitional regulations is still being discussed. Manufacturers should check whether they should extend the existing certificates before the transitional period expires, in order to ensure they are valid until 2024. In any event, all manufacturers are advised to draw up transitional plans now and to seek dialogue with the Notified Bodies, as recertification involves a considerable amount of effort

**Overview of the most important changes**

- New classification rules require adapting the conformity assessment procedure for products, e.g. for automatic defibrillators
- The EUDAMED database has been significantly enlarged to create transparency and improve cooperation in monitoring
- For identification and traceability purposes, a uniform unique device identification number (UDI) is required for each product
- Specific rules for "stand alone software", significantly higher requirements for the creation of clinical data and additional reporting obligations, such as Post Market Surveillance Plans, Post Market Clinical Follow-Up Reports and Periodic Safety Update Reports
- A new scrutiny procedure provides for consultation with expert panels for Class III implants and Class IIb active products, which could significantly extend the conformity assessment procedures
- As all “Notified Bodies” have to be recertified, bottleneck periods are conceivable, which will further complicate the necessary adjustments within the tight transition period for manufacturers

“Increasingly complex approval processes are noticeably slowing down the speed at the expense of German suppliers.”
**Dr. Meinrad Lugan, Board, B. Braun Melsungen AG**

Sources: German Federal Medical Technology Association (BVMed), Medizintechnologie.com

# Distribution of medical devices

## Legal restrictions on distribution

**Corporate gifts and benefits**

Due to the ban set out in Sec. 7 German Pharmaceutical Adverting Act (*HWG*), the distributor is very limited with regard to when it may extend non-cash benefits. This is particularly important when addressing patients directly, e.g. in pharmacies or drugstores

**Safety officer and medical device consultant**

- In accordance with Sec. 30 (3) German Medical Devices Act (*MPG*), the company must appoint a safety officer to coordinate product safety measures
- If distribution is organized by the manufacturer itself, paragraphs 2 to 4 of Sec. 31 of the German Medical Devices Act (*MPG*) also stipulate the use of a trained medical product consultant

**Trend**

Patient associations, self-help groups and the German Statutory Pension Insurance Scheme (*Deutsche Rentenversicherung*) are gaining influence regarding reimbursement issues and also regards the introduction of the reimbursement, so that distribution strategies should consider approaching these groups at an early stage

## Distribution strategies

**Professional dealer organisations**

- Advantageous for products that improve the handling of another product or require new work processes. This ensures that medical product consultants proceed with great expertise and the manufacturer can benefit from a good network within the dealer organization
- Please note: In cooperation agreements with dealers, the manufacturer must offer sales staff solid product training courses

**Refundability of medical devices (new cost structures)**

- Often a prerequisite for market success, especially in the German market
- In standard outpatient care, dependent on a positive recommendation from the joint Federal Committee [Subject to authorization, Sec. 135 German Federal Social Code Book Five (*SGB V*)]
- In inpatient care, new examination and treatment methods may be used immediately at the expense of health insurance companies. However, a joint Federal Committee can only exclude them by application [Authorization with prohibition reservation, Sec. 135c German Federal Social Code Book Five (*SGB V*)]
  - ➢ Manufacturers should consider necessity and economic viability regarding the requirements for proof of use in both sectors
- Innovations in the stationary sector are incorporated into the DRG system via coding and classification changes. In order to avoid innovation gaps, fixed-term reimbursements can be agreed, as long as they are not yet covered by flat rates per case (German Hospital Fees Act - *KHEntgG*). Further financing options include model projects under Sec. 63 et seq German Federal Social Code Book Five (SGB V) and the integrated supply under Sec. 140 a et seq German Federal Social Code Book Five (SGB V)

**International dealer network**

- Possible further introduction in Austria, Switzerland, Benelux. Eastern Europe and the Middle East are recommended as the next stage of the expansion
- Expansion into the American market is a challenge for many manufacturers due to the FDA approval process

Sources: German Federal Medical Technology Association (BVMed), Medizintechnologie.com

# Comparison: Approval of medical devices in Europe and the USA (1/2)

## EU market access

Requirements of the Medical Devices Directive + CE labelling

**CE label = "safety-related passport"**

- Introduced in 1995 to promote the free movement of goods ("*Communauté Européenne", "Comunidad Europea", "Comunidade Europeia, "Comunità Europea*")
- Applies to all medical technology devices marketed within the EU
- Affixing the CE label and signing the declaration of conformity confirms compliance with all relevant requirements of the directive

- Responsibility lies with the manufacturer => involvement of Notified Bodies
- The exact requirements depend upon which of the four risk classes set out in Annex IX of Directive 93/42/EEC the product is to be classified:
  - Class I low risk during use
  - Class II medium risk during use
  - Class II b increased risk during use
  - Class III/active implants high risk during use

- The general requirements are:
  - Establishment and maintenance of a quality management system (QM system) according to the EU wide harmonized standard DIN EN ISO 13485:2012, audited and certified by Notified Bodies, not required for Class I products
  - Proof of compliance with normative and legal requirements (risk analysis and risk assessment)

- Recertification audits and reissue of the certificate of conformity every 5 years at the latest

## U.S. market access

- U.S. Food and Drug Administration (FDA) approval required
- Classification of risk regulated by the Medical Devices Regulation Act 1976
- Class I low risk: In addition to registration with the FDA, no additional approval required
- Class II moderate risk: Registration with FDA and
  - if a comparable product already exists on the US market, application must be made under 510 (k) (Premarket Notification)
  - New types of products fall under Class III, for low-risk products a De Novo Classification can be applied for
- Class III high risk: Registration with the FDA and premarket approval PMA procedure and application for the Investigational Device Exemption to carry out the necessary studies (only 1% of products)

**Registration with the FDA: Establishment Registration 21 CFR Part 807**

- Electronic registration
- Registration of the permanent establishment
- Naming the products to be marketed
- Possible naming of the premarket submission number
- Naming a local US Agent
- Registration fee: US$ 3,382 (2017)

Sources: Medizintechnologie.de, German Federal Medical Technology Association (BVMed), FDA, Tüv-Süd

# Comparison: Approval of medical devices in Europe and the USA (2/2)

## EU process in detail

**Risk analysis and risk assessment**

- Minimization, analysis and evaluation of remaining product risks
- Ensuring biological compatibility, reduction or prevention of infection risks
- Guaranteeing mechanical, electrical and electromagnetic product safety
- Testing and instructions for combining with third-party products
- Checking the product-related safety and operating instructions for completeness and comprehensibility
- Adhering to declared product characteristics and specifications
- Guaranteeing measurement accuracy
- Monitoring of manufacturers and medical devices in the product life cycle

**Conformity assessment procedure by Notified Body**

- Application to the Notified Body
- Sending technical and clinical documentation to the Notified Body
- Evaluating the technical documentation by the various specialists of the Notified Body; evaluating the clinical documentation by independent, experienced specialist doctors of the Notified Body
- Clarifying requests, if necessary adapting documents or performing additional tests
- Completing the technical and clinical conformity assessment
- Issuing the certificate of conformity for a maximum of 5 years
- On the basis of this certificate of conformity and the certificates for the quality management system, the manufacturer prepares the declaration of conformity
- The declaration of conformity is the prerequisite for affixing the CE label and thus for the placing of the medical device on the market in the European Economic Area and, if applicable, in EU third countries (via mutual recognition agreements of the EU)

## US process in detail

**Application under 510 (k) (Premarket Notification)**

- Application to FDA under 510 (k) (Premarket Notification) for a "Clearance Letter“
- The FDA checks the equivalence of the product with a product already legally marketed in the USA with regard to safety and efficiency
- Applications to the FDA can be submitted by the manufacturer directly or through the Accredited Persons Program (not permitted for all products) through accredited organizations, the processing time is then reduced from 90 to 30 days.
- Application procedure fees range from $2,500 - $5,000
- An inspection of the quality management according to 21 CFR Part 820 and compliance with FDA requirements is carried out.
- The inspection lasts for 4 days and relates to management, development, corrective and preventive measures as well as production and process control.
- Conducted by FDA or in the Accredited Persons Program by a third party (Accredited Person)

**Conclusion**

- Due to the decentralization of the CE certification procedure, companies prefer the European market for the first registration
- Procedures are generally comparable, especially with regard to quality management and increasing the control density with increased risks
- Overall, however, the requirements in the European procedure are more clearly defined and more predictable, whereas in the USA the authorities have more discretionary powers

Sources: German Federal Medical Technology Association (BVMed), Goingpublic.de

# A.1

# Medical Technology in Germany

"The German medical technology industry is well equipped for international competition due to its high rate of innovation and above-average well-trained workforce. This is still clearly demonstrated by the high export ratio."
**Dr. Meinrad Lugan, Board, B. Braun Melsungen AG**

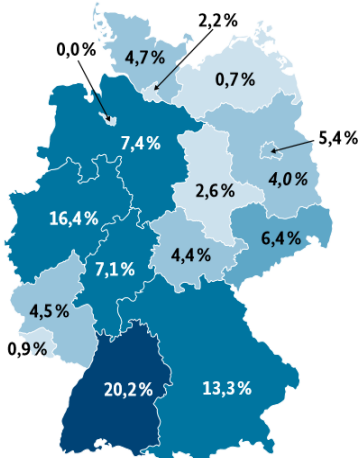
"'MedTech made in Germany' is still a brand which carries weight. In the field of telemedical applications, the German market is lagging behind."
**Dr. Gert Frank, CEO, Geratherm Medical AG**

"The big plus in the German MedTech market is the large number of high-quality companies which have a strong international market position."
**Ken Eichmann, Principal, GHO**

# Structure and special features in Germany

## MedTech business landscape

- With approx. 20%, Baden-Württemberg has the highest density of MedTech companies in Germany
- The second-largest conurbation for MedTech companies is North Rhine-Westphalia with 16%.
- 13% of all MedTech companies have their headquarters in Bavaria, with these companies accounting for the largest share of total revenue




## New framework conditions

- **Companies from outside the industry:** Automotive suppliers and software companies, in particular, are using their technological know-how and are forcing their way onto the MedTech market
- **Data protection and cyber security:** Health data is particularly sensitive data and is therefore protected by a series of special legal regulations, which must be fully observed by the provider of digital products. A current topic is the General Data Protection Regulation, which will directly apply in all EU member states from May 2018. Networked medical devices are potential targets for cyber criminals. However, these developments also open up opportunities for specialized niche providers and software companies
- **Increasing regulation:** With the EU Medical Devices Regulation, which came into force on 25 May 2017, regulation continues to increase

## Export structure

- Germany exports just under one-sixth of its medical products to the USA. America is, therefore, the most important export partner within the German MedTech industry
- Within the different regions of the world, the export of medical devices and medical technology from Germany is distributed as follows:
  - Europe 50.9%
  - Asia 26.2%
  - North America 18.6%
  - South America, Africa and Oceania only 4.4%

## Market entry barriers

- New market participants must meet special structures and stringent requirements for certification and approval. In the case of capital goods, dual hospital financing also has an impact
- The amount refunded is determined by the contractual reimbursement rules
- Within the framework of the pharmaceutical supply, medical devices can only be prescribed if a joint Federal Committee has explicitly included them in Annex V of the pharmaceutical guidelines
- Considerable personnel and cost expenditure for the manufacturers due to the variety of regulations, often navigational assistance from external consultants is necessary to guarantee the refundability of its products
- Personal contacts in the MedTech community are very important - created by investing a lot of time and money into building up a network
- Companies from outside the industry often underestimate the characteristics of national and international standards and regulations. E.g., automotive companies must demonstrate a special quality management system for medical technology. Some software companies must classify their products as medical devices, which requires a conformity assessment and the CE label

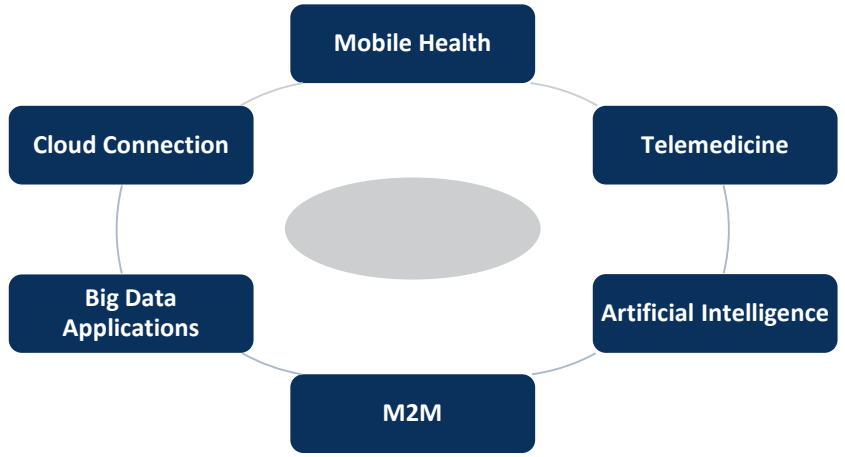
Souces: Geman Federal Ministry for Economic Affairs and Energy, Aerztezeitung.de, TÜV

# Market leaders, key technology and potential

## Market leaders in Germany 2017

| Rank | Company | No. of employees | Revenue ($bn) |
|---|---|---|---|
| 1 | Fresenius Medical Care | 90,690 | 16.74 |
| 2 | Siemens Healthineers | 45,000 | 12.93 |
| 3 | Roche Diagnostics | 88,509 | 9.99 |
| 4 | B. Braun | 54,017 | 6.13 |
| 5 | Paul Hartmann | 10,389 | 1.94 |
| 6 | Drägerwerke | 13,500 | 1.58 |
| 7 | Karl Storz | 7,100 | 1.28 |
| 8 | Carl Zeiss Meditec | 2,190 | 1.21 |
| 9 | Otto Bock Healthcare | 6,522 | 0.77 |

## Overview of current trends




## New potential through digitalization

- Digitalization helps recognize diseases early on, reduces the duration of hospitalization and through telemedicine, apps or care robots can help people to stay mobile for longer
- E.g., in the future, sensors and actuators will record data on weight, blood pressure, temperature, activity or ECG from a patient and in a digitized form transmit such data to an intranet or the Internet. Nowadays these technologies, in the form of wearables and smart watches, are already frequently used, but mostly only for personal use
- Mobile health applications, the Internet of Things, wearables, smart implants and textiles are therefore playing an increasingly important role

## Key technology

**Machine to Machine Communication (M2M)**

Half of the companies that took part in a German Federal Medical Technology Association (*BVMed*) survey in 2015 saw the potential for the production of medical technology for hospitals based on M2M communication. Examples were networking devices independently from manufacturers in the operating room or on the wards

**Big Data**

Genome data, MRI images and blood count levels - data from the medical sector is not only very heterogeneous, but above all extremely comprehensive. It is therefore particularly important that they can not only be collected, but also analysed and processed in a qualified manner

Using Big Data and artificial intelligence, individual cases can be compared with extensive data and analyses can be created

Sources: German Federal Medical Technology Association (BVMed), Statista

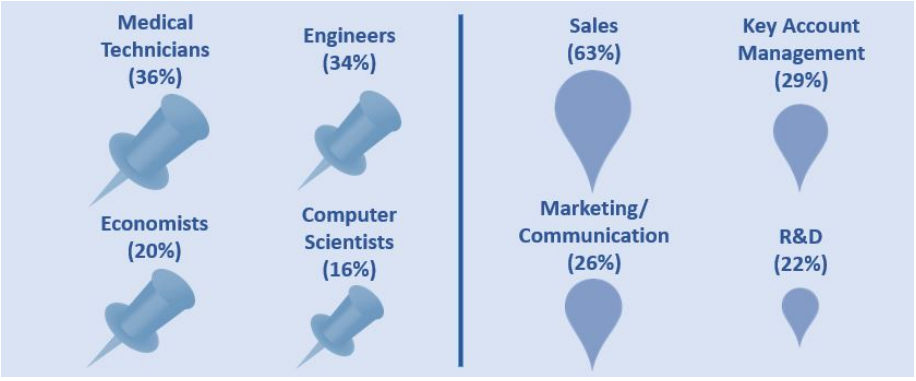
# Business models in the German market

## Current challenges

- The market for MedTech products is an international market in which German medium sized companies have to compete with large corporations at home and abroad
- German SMEs often pursue a long-term corporate strategy combined with a high degree of flexibility. The focus is mainly on high-margin niche segments:
  - **Differentiated premium segment:** Premium products that differ from competing products on the market and cover a niche area
  - **Value segment:** Tailor-made solutions for customers at a lower price compared to the premium segment

"Digital products need a homogeneous market, simple and secure data collection and a good infrastructure."
**Dr. Meinrad Lugan, Board, B. Braun Melsungen AG**

## What MedTech companies are looking for and where




## What here MedTech companies are looking and where

- **Digitalization:** Companies need to digitalize their business models in order to be successful in the long term. In doing so, however, the strict data protection requirements applicable to the deployment and use of personal, sensitive health data must be observed
- **Cost pressure:** Ongoing privatization of the hospitals, the bundling of demand in purchasing groups, the gradual "arming" of DRGs and the increasing requirements for benefit assessment as a prerequisite for reimbursement in the outpatient sector, are increasingly reducing the gross margins for companies
- **Technology:**
  - Regulatory requirements lead to more complexity, demands and control
  - Different regulations in connection with the approval and distribution of MedTech products in Europe, Asia and the USA must be observed
  - Requirements have a direct impact on technological development, speed of innovation, market access and thus also on company value and the implementation of companies in different markets
- **Necessity for further internationalization:**
  - Internationalization as a decisive factor for securing one's own market position
  - It is important to position oneself early on in the rapidly growing emerging markets
  - The countries with the highest growth potential are China, Russia, Brazil and India
  - Positioning in the - world's largest - US market also necessary to remain competitive in the long term

Sources: Angermann M&A International GmbH , McKinsey&Company, German Federal Medical Technology Association (BVMed)

# M&A transactions

## MedTech transactions in Germany: Mainly small to medium sized transactions

| Date | Description | Segment | Target company | Revenue 2016 target company (€m) | Purchaser |
|---|---|---|---|---|---|
| Dec 2017 | Siemens Healthineers acquired Fast Track Diagnostics (FTD), Luxembourg, a manufacturer of tests for molecular laboratory diagnostics | Laboratory diagnostics | Fast Track Diagnostics (FTD) | Undisclosed | Siemens Healthineers |
| Dec 2017 | B.Braun Melsungen AG, Melsungen, Germany acquired the disposable syringes division from Henke-Sass Wolf GmbH, Tuttlingen, Germany | Medical technology | Henke-Sass Wolf GmbH (Business Segment disposable syringes) | Undisclosed | B.Braun Melsungen AG |
| Dec 2017 | The German subsidiary Zimmer Medizin Systeme, Neu-Ulm, of the US medical technology group Zimmer took over Medset Medizintechnik GmbH, Hamburg, as well as the rights to the distribution and construction of the Axion treatment tables series of the South German manufacturer Movepoint | Medical technology | Medset Medizintechnik GmbH | Undisclosed | Zimmer Medizin Systeme, Neu-Ulm, Germany |
| Oct 2017 | Johnson & Johnson Medical GmbH announced the acquisition of the software company Surgical Process Institute (SPI). SPI is one of the global pioneers in the digitalization and structuring of medical processes in hospitals | Health IT | Surgical Process Institute (SPI) | Undisclosed | Johnson&Johnson Medical GmbH, Norderstedt, Germany |
| Jul 2017 | Siemens Healthineers acquired Epocal Inc. of the United States, a manufacturer of blood gas diagnostic systems. The acquisition is conditional upon Abbott Inc. being allowed to finally acquire Alere Inc, Epocal's parent company | Medical technology | Epocal Inc. | 7 | Siemens Healthineers |
| Jul 2017 | The investment company of the Helmig family, Aton GmbH, sold its portfolio company W.O.M. World of Medicine, Berlin, to the US-American Novanta Inc. | Medical technology | W.O.M World of Medicine, Berlin | 71 | Novanta Inc. |
| Apr 2017 | Fresenius Kabi AG, a pharmaceuticals specialist, acquired Akorn, Inc., a generics specialist pharmaceutical group | Pharmaceuticals | Akorn, Inc. | 901 | Fresenius Kabi AG |
| Apr 2017 | Hamilton Thorne, Inc. medical technology manufacturer, acquired Gynemed GmbH & Co. KG, a specialist in reproductive medicine | Reproductive medicine | Gynemed Gmbh & Co. KG | 3.5* | Hamilton Thorne, Inc. |

Sources: German Federal Medical Technology Association (BVMed), MergerMarket, * = estimate based on revenue per head multiples

# Conclusion on the market in Germany

## Competition

- Companies from outside the industry from the automotive, software and sensor segments are increasing competition
- The ongoing privatization of hospitals, the bundling of demand in purchasing groups and the gradual "arming" of DRGs for reimbursement are increasingly reducing gross margins
- In order to maintain or expand one's own market position, the following solution strategies are recommended:
  - Process and cost optimization along the value-added chain
  - Reviewing long term corporate security under the aspect of increasing legal and regulatory requirements
  - **Devising an M&A strategy and developing new markets**
  - **Targeted acquisition of missing technologies or know-how (buy & build)**

## Distribution

- Customer benefits must be accentuated so that a MedTech product can hold its own on the market
- Successful differentiation strategies are derived from uncompromising customer orientation:
  - Improving medical results through technological advantages
  - Extending the range of areas
  - Reducing the treatment costs
- In addition to professional dealer organizations, the distribution of products can be driven forward by new examination and treatment methods

## Market entry

- Regulatory pressure with regard to product approval is increasing due to the new EU Medical Devices Regulation
- Establishing personal contacts in the MedTech community and with the decision-makers of OEMs is crucial for success
- The marketability of new products is strongly linked to refundability
- For companies from outside the industry, the acquisition of a market participant is recommended in order to gain know-how about the MedTech industry

"Access to finance is made more difficult by increasing regulation, as the time at which profits are made is postponed."
**Dr. Gert Frank, CEO, Geratherm Medical AG**

## Internationalization

- Rising demand from the emerging markets
- Developing low-cost variants in line with market requirements in order to address different markets in the best possible way
- After the German, Austria and Switzerland regions, the BENELUX countries are the first candidates for international product launches
- Eastern Europe, the Gulf States and the Middle East are generally a logical step in expansion
- Expansion into the American MedTech market should only take place after the manufacturer has gained experience
- Targeted acquisitions facilitate the development of new markets by gaining capacity, customers and know-how in the market region

# A.2

# Medical Technology in Europe

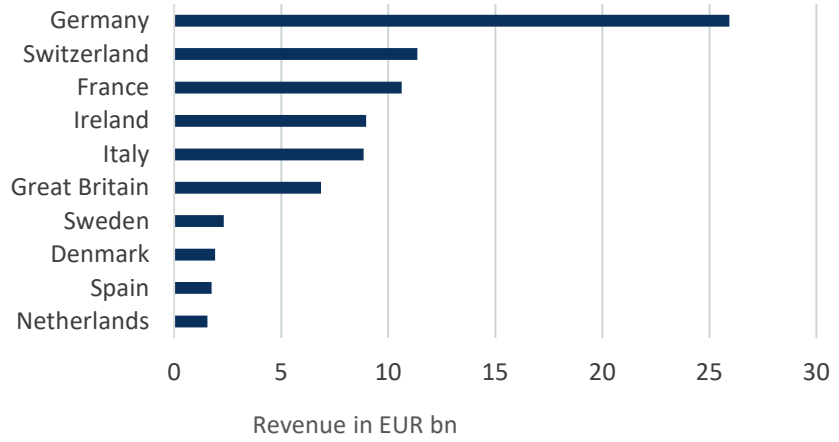
"Stricter regulatory requirements require a smarter and more structured market approach. More resources and higher investments are needed. SMEs are finding it difficult."
**Till Gumz, MedforceOne GmbH**

"The ever-increasing regulatory requirements increase the complexity of added value. This leads to higher costs and in the long run to a thinning out of the range of products and companies on offer."
**Dr. Gert Frank, CEO, Geratherm Medical AG**

"Politicians should focus on allowing patients quick access to safe innovations and creating the legal conditions for a real wave of digitalization."
**Dr. Meinrad Lugan, Board, B. Braun Melsungen AG**

# Structure and special features in Europe

## MedTech revenue in leading European countries 2017




## Fast growing MedTech companies from Europe

| Company | Revenue 2009 ($m) | Revenue 2016 ($m) | Growth (%) |
|---|---|---|---|
| Elekta (SE) | 1,020 | 1,399 | 137% |
| Essilor International S.A. (FR) | 4,684 | 7,511 | 160% |
| Halma plc (UK) | 652 | 1145 | 176% |
| Merck KGaA: EMD Millipore (DE) | 883 | 5,658 | 641% |
| Novartis AG: Alcon (CH) | 2,997 | 5,800 | 194% |
| Össur Corporate (IS) | 331 | 521 | 157% |
| Semperit AG: Sempermed (AT) | 389 | 426 | 110% |
| Wright Medical Group: Tornier (NL) | 202 | 690 | 342% |

## Innovative driving forces in medical technology

- Number of patent applications filed illustrates the innovative strength and dynamism of the MedTech industry
- Medical technology leads in the list of technology areas with 12,263 worldwide patent applications to the European Patent Office in 2016
- In Europe, Germany ranks 1st with 1,323 patent applications. The Netherlands ranks 2nd with 868 patent applications, followed by Switzerland (598), France (492) and Great Britain (339).
- The remaining Member States of the European Patent Organisation registered 1,403 patent applications
- The Dutch group Philips filed the most patents (761) in medical technology
- Fresenius Medical Care ranks 9th among German companies worldwide (125)

## Conclusion

- Germany: By far the strongest market for medical technology in Europe, followed by Switzerland and France
- Market position and Germany's innovative strength are essential in this respect
- Most patent applications in Europe are made by German companies
- Market shares can be secured or even expanded through technological product innovation in the field of medical technology
- For example, Elekta (Sweden) and Halma (UK) achieved an above-average growth rate between 2009 and 2014.
- Both companies use technologies from the areas of the Internet of Things and Big Data

Sources: German Federal Medical Technology Association (BVMed), Medizintechnologie.de, Statista

# Key technology

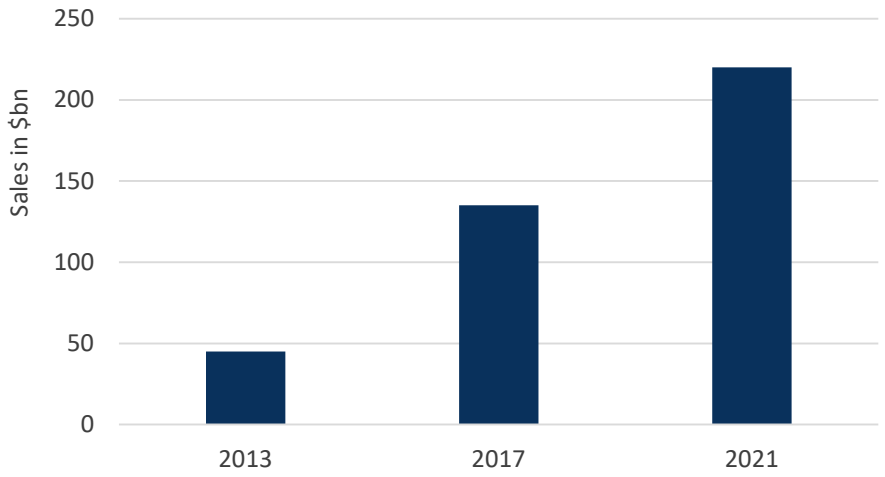
## Machine to machine communication (M2M)

- Internet of Things (IOT) and machine to machine communication (M2M) will also become increasingly important for MedTech companies with smart watches, wearables and mobile phones
- Companies such as Polar or Garmin, which were not previously perceived as medical technology companies, now, through intelligent partnerships with medical software companies, occupy a key position in patient interaction
- Smartwatches already monitor a patient's health status 24/7 and give warning signals in case of sleep disorders, exhaustion or heart rhythm disturbances
- Web-based communication solutions, such as learning assistance systems or communicating devices, have high potential
- Biggest hurdles for M2M applications: Unresolved question of approval as a medical device, lack of billability, data transfer

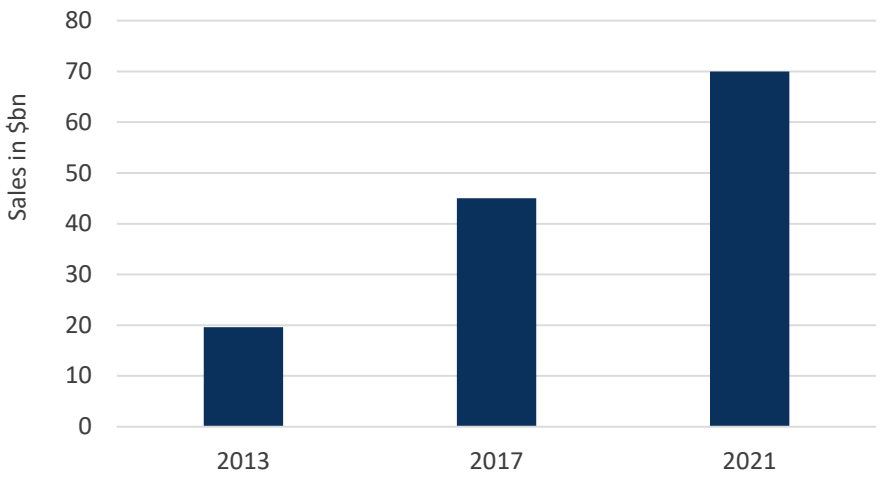
## Big Data

- Medicine is becoming digital, there are more and more possibilities to heal with data or to make it the basis for medical devices and therapies
- The largest data collectors Garmin, Polar, Apple, Facebook and Google, where Big Data is already a business model, no longer only collect customer data to create lifestyle products
- Google develops medical technologies to ensure it can help steer global healthcare
- A blood sugar measuring contact lens, developed in collaboration with Novartis, is almost ready to be launched on the market
- Google scientists are developing life-prolonging technologies with the biopharmaceutical company Abbvie
- In Germany, ADA is currently the leader when it comes to initial medical analyses based on Big Data

**Worldwide sales in the M2M sector by 2021**




**Worldwide sales in the Big Data Sector by 2021**




Sources: German Federal Medical Technology Association (BVMed), Medizintechnologie.de, Research2Guidance, Statista

# M&A transactions

## MedTech transactions in Europe: Small and medium sized transactions in various segments

| Date | Description | Segment | Target company | Revenue 2016 Target company (€m) | Purchaser |
|---|---|---|---|---|---|
| Dec 2017 | Royal Philips acquired Vital Health, a specialist in cloud-based health management solutions, expanding its population health management portfolio | Health IT | Vital Health | 7 | Royal Philips |
| Oct 2017 | Marle International SAS acquired the Swiss contract manufacturer SMB Medical SA as a specialist for the manufacture of orthopaedic components and products from the associated company Patrimonium AG | Medical technology | SMB Medical SA | Undisclosed | Marle International SAS |
| Jul 2017 | Philips announced the acquisition of the Munich based Tomtec Imaging Systems GmbH. Tomtec produces image analysis software and systems and has over 100 employees | Medical technology | Tomtec Imaging Systems GmbH | 15 | Royal Philips |
| Jul 2017 | Philips acquired US medical technology company Spectranetics Inc., a manufacturer of minimally invasive cardiovascular and medical laser devices | Medical technology | Spectranetics Inc. | 220 | Koninklijke Philips, Amsterdam (NL) |
| Jul 2017 | Philips acquired US company Electrical Geodesics Inc., Eugene (Oregon), a manufacturer of imaging systems for neurological applications, for a total of EUR 32.9m | Medical technology | Electrical Geodesics Inc. | 12 | Koninklijke Philips, Amsterdam (NL) |
| Apr 2017 | German laboratory equipment supplier Sartorius took over Swedish Umetrics (modelling of biopharmaceutical development processes) from the MKS Instruments Group | Health IT | Umetrics | 12* | Sartorius |
| Mar 2017 | Hologic GGO 4 Ltd, Manchester, UK, acquired all the shares in MMS Medicor Medical Supplies GmbH, Kerpen, and the group companies MMS Wien & MMS Cham, Switzerland | Medical technology | MMS Medicor Medical Supplies GmbH & MMS Wien & MMS Cham (CH) | Undisclosed | Hologic GGO 4 Ltd. (UK) |
| Feb 2017 | Serres Group Oy, specialist for surgical devices, acquired Innokas Medical Ltd, a manufacturer of various medical devices | Toll manufacturing medical devices | Innokas Medical Ltd. | 20 | Serres Group Oy |

Sources: MergerMarket, *Indicates revenue figures for the financial year 2017

# A.3

# Medical Technology in the USA

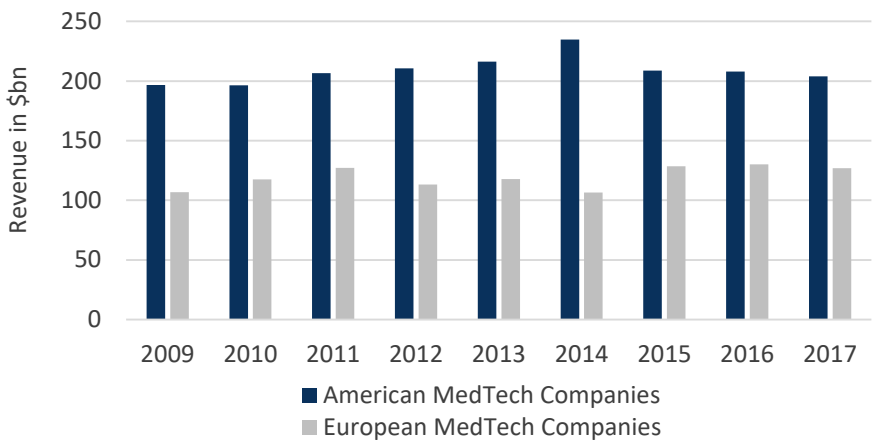
"The American market offers a similar quality, but differs from the German market in that there is less competition for interesting MedTech targets. There are more companies looking for external capital."
**Ken Eichmann, Principal, GHO**

"Despite the existing, strong technology, in Germany the application is often missing, as health insurance companies do not cover the costs. It is different in the U.S.: Here, the patient pays privately."
**Dr. Gert Frank, CEO, Geratherm Medical AG**

"Fault tolerance is higher in the US: Failure without condemnation."
**Cornelius Maas, SHS Capital**

# Structure and special features

## Total revenue medical technology: USA and Europe in comparison




## Fast-growing MedTech companies from the USA

| Company | Revenue 2008 ($m) | Revenue 2016 ($m) | Growth (%) |
|---|---|---|---|
| Align Technology | 312 | 1,079 | 346% |
| Cepheid | 171 | 470 | 275% |
| Corning: Life Sciences | 366 | 862 | 236% |
| Danaher: Life Sciences & Diagnostics | 3,142 | 9,379 | 299% |
| IDEX: Health & Science Technologies | 324 | 752 | 232% |
| Illumina | 666 | 1,861 | 279% |
| Intuitive Surgical | 1,052 | 2,116 | 201% |
| NuVasive | 370 | 762 | 206% |

## Medical technology in the USA is chiefly military

- American MedTech sector: Very strongly influenced by military and space technology
- For decades, the United States has had the world's best-equipped and second largest military power in terms of personnel, which supports innovations in the field of medical care
- For example, telemedicine in its modern form is largely based on military and space technology from the 1960s: NASA equipped its astronauts with medical telemetry and heart monitoring devices during its lunar mission
- Numerous MedTech innovations have also emerged from the wars in Iraq and Afghanistan: i.e., a new type of dressing material was developed from fibrin nets, which reduces blood loss by 50% - 85%

## Conclusion

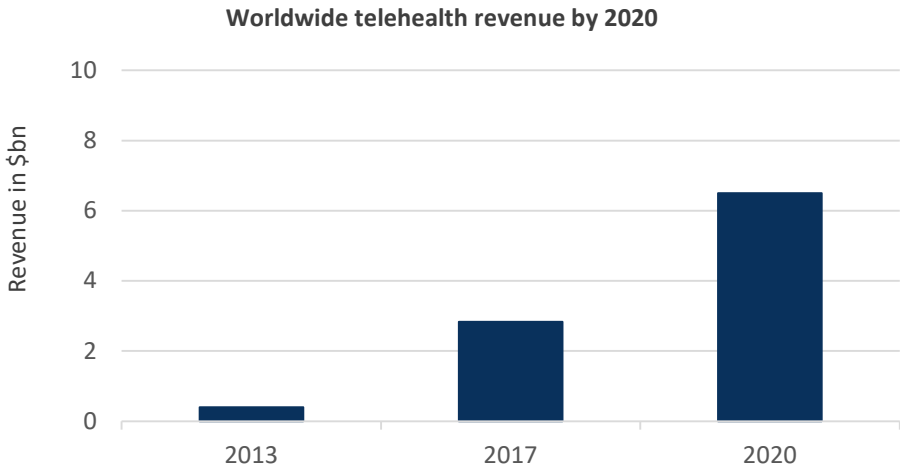
- Revenue for medical technology in the USA is much higher than in Europe
- Largest number of leading companies in the world comes from the USA: Very high total revenue despite relatively few companies
- This is made possible by technological leading companies in the field of medical technology that worked on their market position decades ago
- A large number of technological innovations are based on the aerospace technology of the American military
- Current key technology, such as telemedicine, has emerged from military research projects
- In addition, American companies are strong in acquiring missing technology and know-how in the USA, Europe and Israel

Sources: Statista, Americantelemed.com

# Key technology

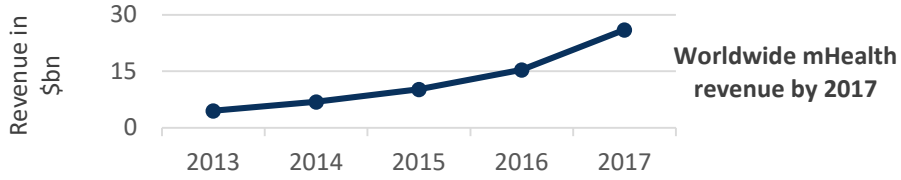
## Telemedicine

- Telemedicine: Exchanges medical information using electronic information and telecommunications technology to improve a patient's clinical health status
- Eliminates time and distance barriers and improves care in rural and medically underserved areas
- Services (e.g. remote treatment and monitoring of patients in real time), including using images, by phone or video conferencing, becoming increasingly more popular with hospitals, patients and insurers
- Important for telehealth development: Data security during transmission and security, adaptation of data protection guidelines
- On this basis, it is possible to establish highly efficient supply processes in coordination with all sectors involved by introducing useful applications



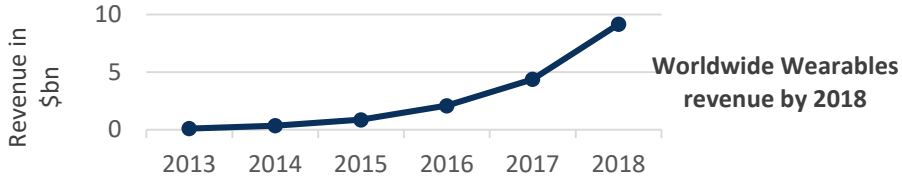

## mHealth

- mHealth (mobile Health) = Provision of health services using mobile communication devices
- The majority of healthcare providers contact patients via mobile devices
- Substantial growth of health apps by medical technology companies
- Revenue from the mHealth market has been rising steadily since 2013




## Wearables

- Wearables are portable computer systems worn close to the body, such as activity trackers or blood pressure devices
- They overcome transport-related or geographical restrictions and can help transform healthcare into an on-demand service
- They enable doctors or hospitals to monitor a wide range of data remotely and locally in order to initiate preventive medical measures and reduce the number of visits to the doctor




Sources: Statista, research2guidance.com, Americantelemed.com, mhealthshare.com, wearabledevices.com, MarketsandMarkets

# M&A transactions

## MedTech transactions in the USA: Predominantly small transactions, also increasing in the transfusion medicine segment

| Date | Description | Segment | Target company | Revenue 2016 target company (€m) | Purchaser |
|---|---|---|---|---|---|
| Dec 2017 | The US company Cirtec Medical LLC, Minneapolis, contract manufacturer for implantable and minimally invasive surgical instruments and products, took over Vascotube GmbH, Birkenfeld, Germany, a manufacturer of nitinol tubes | Medical technology | Vascotube GmbH | Undisclosed | Cirtec Medical LLC |
| Oct 2017 | The US company Cryo Life, Kennesaw, acquired Jotec AG, Hechingen, Germany, a specialist in vascular prostheses and stent systems, for EUR 225m | Medical technology | Jotec AG | 41 | Cryo Life |
| Aug 2017 | The US company Cantel Medical Corp. took over BHT Hygienetechnik Holding GmbH, Germany (reconditioning endoscopes and instruments) | Medical technology | BHT Hygienetechnik Holding GmbH | 6.8 | Cantel Medical Corp. |
| May 2017 | The US group Bruker Corp. of Billerica, MA, took over the Heidelberg based start-up Luxendo, a developer of light disk fluorescence microscopes | Medical technology | Luxendo | Undisclosed | Billerica |
| May 2017 | Apple Inc. acquired the Finnish startup Beddit, a specialist in sensor-controlled recording of sleep data via an app | Health IT | Beddit | Undisclosed | Apple Inc. |
| Apr 2017 | Boston Scientific Corp. of Marlborough, MA, USA, acquired Symetis SA, Ecublens, Switzerland, a manufacturer of equipment for endoscopy and interventional cardiology, for EUR 435m | Medical technology | Symetis SA | 33 | Boston Scientific Corp. |
| Apr 2017 | The US company Biotelemetry Inc. (ex-Cardio Net), Malvern, PA, acquired the Swiss Lifewatch AG, Zug, a specialist in telemedical systems for sleep and heart monitoring | Medical technology, Health IT | Lifewatch AG | 92 | Biotelemetry Inc. |
| Apr 2017 | Becton Dickinson & Co. (BD), a leading global manufacturer of disposable medical products and device systems, took over competitor C. R. Bard, a medical technology manufacturer specializing in the fields of urology, oncology and vascular diseases | Medical technology, medical devices | C.R. Bard | 3,518 | Becton Dickinson & Co. |

Sources: MergerMarket

# B.

# Analysis of Leading MedTech Companies

# Overview: Market leaders and startups in medical technology

## Market leaders and their strategies

FRESENIUS MEDICAL CARE

Germany

- As a dialysis specialist, Fresenius is increasingly interested in integrating patients into the entire value-added chain
- The Helios Hospital Group therefore acquired Spain's largest private hospital group Quirónsalud for $6,42bn
- Fresenius aims to increase global revenue to $28bn by 2020

B|BRAUN SHARING EXPERTISE

Germany

- B. Braun's business model is based on a broad product portfolio, which results in synergy effects for customers
- Through the acquisition of Aesculap, B. Braun gained new know-how in the field of nitinol and supplemented its product portfolio for interventional procedures
- A "Corporate Strategy 2020" is also being pursued: Global revenue are to rise to EUR 8bn

SIEMENS Healthineers

Germany

- The Healthineers Division of Siemens is the market leader in imaging diagnostics and laboratory diagnostics
- Focus on digitalization: Digital Ecosystem, eHealth Solutions and PEPconnect are novel solutions that support the digital transformation of healthcare providers
- Siemens plans an IPO of the Healthineers division by mid-2018 to realize additional growth potential

## Startups and their orientation

WHITE LION TECHNOLOGIES AG

Germany

- White Lion Technologies AG specializes in imaging, image processing, software and embedded systems
- The application portfolio includes 3D image reconstruction for medical applications and non-destructive testing (NDT), stereoscopic tracking systems for real-time navigation and high-end, zero-configuration embedded systems

Germany

- ADA is one of the fastest growing medical apps. It combines artificial intelligence with medical knowledge to help people to better assess the state of their health. ADA has stated that it has more than six years of research and development behind it and has a global network of medical experts working in the background

SURGICAL THEATER

USA

- ST's Surgical Rehearsal Platform (SRP) works with MRI images and CT scans to image 3D models of patients' brains
- As a result, surgeons can then remotely move medical utensils and test run upcoming operations first
- Well-known clinics, such as, Mount Sinai, Mayo Clinic or the university hospitals of NYU/UCLA are already using ST's technology

Sources: Statista, Fresenius Medical Care, B. Braun, Siemens Healthineers, WhiteLion Technologies AG, VivoSensMedical GmbH, Surgical Theater Ltd.

# C.

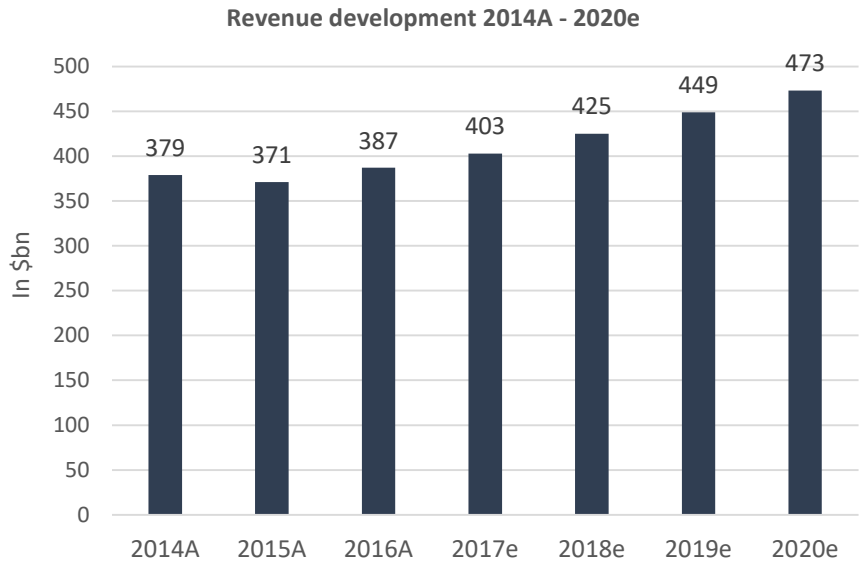
# Summary and Outlook

# Outlook 2020

## Outlook

- Increasing age profile of the world's population and increasing human life expectancy: Increase in a need for MedTech products
- Worldwide market volume will increase dramatically within the next few years due to the increasing middle classes in the Asian regions: In the future Europe will be relegated from second place in the most important MedTech markets
- Manufacturers in the MedTech sector must position themselves in the emerging markets early on in order to take up a leading position
- For long term success: Digital orientation of the manufacturers' business models
- Most important future technological trends: Machine to machine communication (M2M), Big Data, telemedicine, mHealth and wearables
- Ongoing privatization of hospitals, bundling the demand in purchasing groups and gradual "arming" of DRGs for reimbursement is putting increased price-related pressure on the branch
- Market participants from outside the industry are competition for the existing MedTech firms
- Especially companies from the automotive supply industry are contemplating reorienting their companies or diversifying their range of products
- Thus more digitized products on the MedTec market: These close existing gaps in the market and secure a large share in it

## Development forecast for the global MedTech industry




"An exponential growth in medicine is expected over the coming years through the use of robotics, with growth rates of 20% per annum. The question is, however, why is it only always American companies. European companies and hospitals also have the potential to lead in this field, they just need to work more closely together. The problem in Germany is amongst other things also the restrictive views of the statutory health insurers when financing innovative methods. We need support, especially from the politicians."

**Professor Thomas Schildhauer, Medical Director, Employers' Liability Insurance Association, University Hospital Bochum**

Sources: German Federal Ministry of Justice and Consumer Protection (BMJV), Gfk.com, Marketrealist, McKinsey&Company, World Health Organization (WHO), Statista

# Summary and recommendations

## Startups

- Legal prerequisites and initial financing issues: Big challenges
- Rules relating to the approval process and the distribution of medical devices are becoming increasingly tighter: On 25 May 2017, the new EU Medical Devices Regulation came into force
- Differences, depending on the region for distribution of products: Not an easy process, e.g. major differences in the approval process for the European and American markets. This, in conjunction with continued dynamic consolidation, is increasingly complicating competition

Startups have the opportunity in the early financing phases to use numerous public subsidiary programmes from the EU, the Federal State and the individual States of Germany and with regard to growth financing can get help from venture capital companies: Thus any initial financing problems can be resolved

## Medium sized enterprises

- The market for medical technology is about to change dramatically, medium sized companies need to adjust their business models accordingly
- In addition, they need to overcome current challenges: Digitalization, cost pressures and the intensity in competition
- The MedTech market defined by medium sized companies, at the same time the large corporations have the market power
- Result: Dynamic consolidation, as smaller manufacturers are not competitive
- Also, movement in integration: Consolidating medium sized companies which can improve market position and help master new technologies

Medium sized companies should focus on optimising their business models. In order to be able to act against an increase in price decline and increasing digitalization, synergy effects and new technologies must be realised by means of mergers or take overs

## Companies from outside the industry

- Increasingly frequent attempts to position oneself on the market for medical technology, e.g. from the automotive sector
- Reason: Highly complex technology which is increasingly needed for medical technology
- The number of takeovers by companies outside the industry are increasing: To accelerate the approval process for new medical technology products or to acquire know-how in this area
- Trend discernible when looking at the M&A transactions carried out in 2016: Continuing high number of small and medium sized transactions in the Germany, Austria and Switzerland regions

As a company from outside the industry, it is advisable to carry out an opportunity and risk analysis of the reorientation taking into consideration early on the specific regulatory requirements in the healthcare sector in order to develop a suitable strategy for diversifying the product range and to facilitate market entry, approval and distribution through targeted acquisitions

Sources: German Federal Medical Technology Association (BVMed), Clairfield Expert Group

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