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BVMed Annual Report
2019/20

The Medical
Technology Companies :
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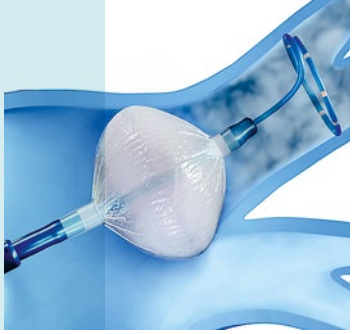
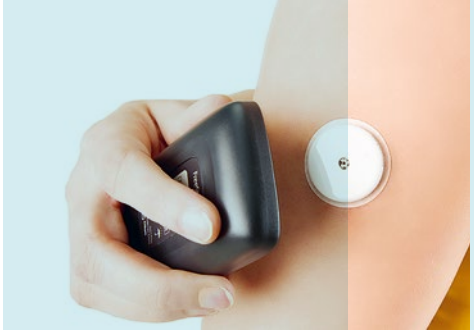
Modern medical technologies save lives and improve people's quality of life: 3D system for minimally invasive cardiac surgery



Cryoablation in atrial fibrillation



Continuous glucose monitoring for patients with diabetes

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IMPRINT

Publisher BVMed – Bundesverband Medizintechnologie e.V.
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Printed by Lettershop Berlin GmbH
Berlin, February 2020

Dr. Meinrad Lugan
Chairman of the Board of BVMed
(image: B. Braun Melsungen AG)

Dr. Marc-Pierre Möll
CEO of BVMed
(image: BVMed / Rene Staebler)

Foreword

MDR Year 2020: We need a strategy for the future of medtech made of one cast!

Dear Members,

2019 was an intense year for medical technology and politics that brought a large number of legislative processes.
Altogether, our mid-term review of the German federal government is positive. Many important steps were taken, for instance with regard to accelerated method assessments, the implant registry, the reform of the medical technical aids law, or the fast track procedures for digital health applications.

However, we still have outstanding issues and challenges on our to-do list that must now be tackled boldly.

- We need better support for small and medium-sized medtech companies. 93 percent of all medical technology businesses have fewer than 250 employees and thus count as small and medium-sized enterprises (SME).
- The new EU Medical Device Regulation MDR is a particular challenge for the medtech industry due to its greater requirements regarding the market access of medical devices. The MDR will already apply from May 26th, 2020. This can lead to bottlenecks in patient care.
- Other challenges the industry is facing are increasing administrative obstacles during the remuneration of medical devices, but also the digital transformation of the healthcare system and the development of digital healthcare services.

We suggest that the relevant politicians initiate a new "Medtech Dialog" involving the government departments of health, economics, and research.
We need to improve the integration of the regulatory measures that apply to the medtech industry with economic and research policies. Research, business, and health together. We call for a medtech strategy process made of one cast!

Issues that the Medtech Dialog should discuss are, for instance:

- greater focus on complete care processes,
- the reduction of regulatory bureaucracy for existing devices and orphan devices,
- the development of digital healthcare services, and
- the integration of artificial intelligence in order to support medical and nursing care.

For optimum patient care and progressive therapies, the regulatory and social law framework conditions need to be improved while unnecessary bureaucracy must be reduced.

This is what we want to achieve in cooperation with you. Let us continue to shape health together in 2020!

Dr. Meinrad Lugan
Chairman of the Board of BVMed

Dr. Marc-Pierre Möll
BVMed CEO



From care with medical technical aids to the OR: Medical devices improve quality of life and save lives
(images: Hollister Inc., B. Braun Melsungen AG, BIOTRONIK SE & Co. KG)

Medtech Market Development

The medtech industry – figures & facts

1. **The medtech industry is an important factor for the economy and the labor market.** The medtech industry employs over 200,000 people in Germany. In the past five years alone it created more than 12,000 new jobs. In addition, each medical technology job guarantees 0.75 jobs in other industries. The total revenue of the medtech industry in Germany was at 30.3 billion euros in 2018.The export rate was at over 65 percent.

2. **The German medtech industry is an SME industry.** 93 percent of all medical technology businesses have fewer than 250 employees. There are 13,000 small businesses alone that employ around 60,000 people. Only 90 medtech companies in Germany have more than 250 employees.

3. **The medtech industry is innovative and its product cycles are very short.** German medical technology manufacturers generate around one third of their revenues from devices that are less than 3 years old. On average, medtech companies invest around 9 percent of their revenue in research and development. This is why integrated innovation policy that is harmonized between the government departments of research, economics, and health is of great importance in order to preserve the innovative capacity of the medtech industry.

Market development

The medical technology industry will continue to be a growth market due to, among other factors, medical-technological progress and the demographic development with an increasingly older and multi-morbid population. This means that the demand for healthcare services will keep rising. The market research company Evaluate forecasts a yearly growth of 6 percent for the global medical technology market until 2024.

BVMed fall 2019 survey

The most important results of the fall 2019 survey conducted by BVMed, in which 102 member companies took part, are as follows:

1. Sentiment in the German medtech industry has clouded significantly according to the fall survey of BVMed in 2019. The expected domestic sales development of only 3.3 percent has declined significantly compared to the previous year (4.2 percent). A particularly alarming trend in this context is the development of profits because of sinking prices and higher costs. Only 12 percent of companies expect improved profits for this year. In addition, the innovation climate index surveyed by BVMed is at 4.2 points out of ten, the lowest result so far.
2. The main reason for the subdued mood is the EU Medical Device Regulation (MDR) which is responsible for a lack of resources at the Notified Bodies, longer assessment procedures, and price increases. Almost 90 percent of the medtech companies fear that devices will be withdrawn from the market or not launched at all for economic reasons, which would negatively affect patient care as well.
3. Export remains a stabilizing factor. With an expected sales growth of 5.8 percent, the worldwide growth of the medical technology companies is still significantly stronger than domestic growth.

Outlook

Enabling people to lead longer, healthier, more mobile, and pain-free lives: this is the everyday challenge for medical technology. In effect, medical-technological progress is the result of a large number of continuous improvements of the devices and procedures used. The medtech industry has very short development cycles. The companies, therefore, need innovation-friendly framework conditions so that medical progress can reach patients in a timely manner.

BVMed CEO Dr. Marc-Pierre Möll with German Health Minister Jens Spahn

BVMed Chairman Dr. Meinrad Lugan with former EU Commissioner Günther Oettinger

BVMed round of health talks "Gesprächskreis Gesundheit" with member of parliament Dietrich Monstadt
(images: BVMed)

Healthcare Politics

"20 laws in 20 months": This was the slogan used by Federal Minister of Health Jens Spahn when taking stock at the end of 2019. This unprecedentedly large number of laws naturally had significant implications for the medical technology companies.
BVMed has drawn attention to the specific characteristics and necessary framework conditions of the medical devices industry during a large number of talks and events with members of parliament, representatives of the government and the opposition, as well as governmental department officials and federal state representatives. With its well-founded proposals, BVMed was able to achieve significant improvements for patient care with medical devices.

Improvements for medical technical aids

The proposed amendments to the medical appointment service and care law "Terminservice- und Versorgungsgesetz (TSVG)" achieved a number of improvements for medical technical aids. After many years of debates, tenders for medical technical aids were abolished. Moreover, the law now makes it clear that so-called open-house contracts used by health insurance funds are unlawful. Further law improvements with regard to medical technical aids are addressed through proposed amendments to the draft law of the Medical Devices EU Amendment Act (Medizinprodukte-EU-Anpassungsgesetz, MPEUAnpG). This affects, for instance, the introduction of arbitration proceedings for the area of medical technical aids and provides the competent authorities with the ability to oblige health insurance funds to conduct genuine contract negotiations, and to stop unlawful contracts for medical technical aids.

EPRD and the implant registry

Another focus of healthcare politics during the past year was the law for the introduction of the German implant registry. In cooperation with physicians and health insurance funds, BVMed has established the voluntary German Arthroplasty Registry (EPRD) over the past ten years. The registry lists more than 1.3 million surgical procedures. Through the EPRD, BVMed has been able to successfully carry out significant preparatory work for the official implant registry which was passed into law in 2019 after several years of consultations.

The advantage of the official implant registry is its mandatory and complete registration of implant surgery. This concerns the actual devices that are implanted as well as the healthcare institutions carrying out the procedures. What matters from the perspective of the medtech industry is the timely presentation of a statutory ordinance on the implant registry, a reliable timetable for the introduction of the individual types of implants, and the quick clarification of the data protection requirements. This concerns in particular the transfer of the existing data from the arthroplasty and the aortic valve replacement registry. In order to ensure the quick and smooth star of the registry, the industry advocates entrusting the EPRD with the operative side of the official implant registry.

Accelerated assessment procedures at G-BA

The coalition agreement provides for the quicker introduction of medical innovations into regular care because the existing regulations for new examination and treatment methods with medical devices (Neue Untersuchungs- und Behandlungsmethoden mit Medizinprodukten, NUB) have not been working very well. To this end, the G-BA processes have been accelerated and made less bureaucratic and the benefit assessments shortened to two years through the medical appointment service and care law TSVG and the implant registry law. In future, hospitals will only be able to make NUB applications in consultation with the medtech industry. Also, companies will be able to make suggestions for their own clinical studies provided they bear the costs themselves. Apart from that, it has been clarified that in future the costs will have to be borne by the G-BA.

Still no medical technology strategy process

A critical aspect of the federal government's results is the fact that, as of early 2020, the continuation of the medical technology strategy process that had been envisaged by the coalition agreement has not started yet. BVMed is committed to a quick restart of the strategy process. To this end, close cooperation between the Federal Ministries – Ministry of Health, of Research, and of Economics – at a high political level is important in order to set a clear focus.

The production of medical devices meets the highest standards. All manufacturers require a special quality management system. The images show the production of IV administration sets (images: B. Braun Melsungen AG)

Regulatory Affairs / MDR

MDR prior to its application date

The new EU Medical Device Regulation (MDR) has been the dominant topic for the medtech industry in recent years. The MDR will apply from May 26th, 2020 after a three-year transitional period. The manufacturers are prepared, but the system is not:

- Only around 40 old and new Notified Bodies have applied for notification under the MDR, compared to 55 Notified Bodies working under the old framework most recently. Only nine of the bodies that have applied had been notified by the end of 2019. The EU Commission had always indicated that it expected 20 Notified Bodies to be available by the end of 2019. Because of the immense time pressure, BVMed has called upon the competent authorities to markedly accelerate the notification procedure, and to shorten the ensuing new certification procedure for existing devices while reducing its content.
- Several Notified Bodies, including one German body, have not been renotified on the basis of the MDR. As a consequence, many manufacturers whose old certificates have expired are now faced with not having any certification body to contact. BVMed has called on the authorities and members of parliament to issue permits or special approvals to ensure that the established devices of these manufacturers are still available for patient care. Otherwise, the very existence of these companies – mostly small and medium-sized businesses – and with them thousands of jobs are threatened.
- Of the 11 delegating acts envisaged by the MDR, not one has been adopted so far.
- Of the 32 implementing acts envisaged by the MDR, only three have been adopted, which is detrimental to the legally secure application of the MDR. As an alternative, the EU Commission has published a large number of guidelines, which, however, are not legally binding. Important guidelines are still missing.
- Under the MDR, newly harmonized European standards and Common Specifications are still completely missing.

As many had feared from the beginning, the new European medical devices database Eudamed was not able to start operating on schedule. Therefore, the EU Commission has postponed the start of Eudamed by two years to 2022. This means that none of the newly introduced notification and data recording functions that were meant to support transparency and market surveillance can be implemented at the EU level.

Second MDR corrigendum

Following the decisions of the European Commission and the European Council, the second MDR corrigendum was passed by the European Parliament as well at the end of 2019. The corrigendum grants former class I medical devices with a higher classification under MDR the same transitional period of four years that applies to other devices on the market. This is a positive step, but others must follow so that the MDR can be implemented. BVMed calls for a harmonized EU-wide emergency plan. Time is running out. Experts estimate that otherwise the existence or 10 to 15 percent of all European medtech companies is threatened and around 30 percent of all devices will have to be withdrawn from the market or cannot be recertified in time.

Exclusive service for BVMed members

In the BVMed office a new department has been concerned mainly with MDR-related questions but also further regulatory matters (environmental protection, health and safety at work, standardization, reprocessing etc.) since April 2019.
In the department there is a contact person for regulatory questions working full-time. As an exclusive service for members, the department regularly collects news and new publications by the European Commission, the Medical Device Coordination Group (MDCG), MedTech Europe, as well as German issues, and analyzes these and publishes them in an MDR newsletter. Also, it organizes specific training events. BVMed's own MDR portal at *www.bvmed.de/mdr* combines all the relevant information and documents about the new framework.

Safety devices to avoid needle stick injuries
(images: B. Braun Melsungen AG, Becton Dickinson GmbH, TERUMO Deutschland GmbH)

Medical Devices Law

National law: MPG becomes MPDG

The Federal Ministry of Health published the advisor's draft for the adjustment of the German medical devices law to the EU Regulation 2017/745 and the EU Regulation 2017/724, "Gesetz zur Anpassung des Medizinprodukterechts an die Verordnung (EU) 2017/745 und die Verordnung (EU) 2017/724", on August 29th, 2019, and the relevant cabinet's draft on November 6th, 2019. The German abbreviation is: MPEUAnpG.
Article 1 of the draft law contains the draft of a medical devices implementing law ("Medizinprodukte-Durchführungsgesetz, MPDG"). The MPDG will replace the former medical devices law "Medizinproduktegesetz (MPG)", which will be abolished on May 26th, 2020 after being in place for over 25 years, with the exception of in-vitro diagnostics, for which it will apply for another two years.
The draft MPDG contains legislation that will complement the provisions of the MDR for Germany, e.g. additional notification obligations for manufacturers, manufacturers of custom made devices, and in-house manufacturers of class III implants, stricter rules for (other) clinical investigations, vigilance (maintaining the German medical device consultant), and market surveillance by the authorities (shifting the responsibility for the notification of "serious risks" from the German states to the federal level). Contrary to expectations, the MPDG will contain 99 articles and thus be much more comprehensive than the MPG with its 44 articles.
The parliamentary hearing on the government's draft law took place on January 15th, 2020, with BVMed participating as one of the professional groups being heard. The publication of the MPDG in the German Federal Law Gazette is expected for early April before the law will most likely come into force on May 26th, 2020.

Legal regulations in Germany

Once the MPDG comes into force, the ordinances that implement the new law in Germany will change as well: With the exception of in-vitro diagnostics, the former ordinances implementing the Medical Devices Law will either be maintained, amended or abolished.

In addition, new ordinances will be introduced in Germany:

- Ban of placing potentially risky devices on the market and of putting them into operation;
- User Reporting Ordinance (Anwender-Meldeverordnung, MPAMV)
- UDI storage;
- Data processing in the DMIDS;
- Granting of special approvals.

Brexit

After much back and forth Britain decided to leave the European Union on January 31st, 2020, with a transitional period until December 31st, 2020. The "Withdrawal Agreement" between the EU and Britain was ratified on January 29th, 2020.
After the eleven-month transitional period, i.e. from January 1st, 2021, Britain as an EU third country will adopt the MDR requirements in largely identical form. The European Commission aims to ensure that no customs duties will be applied.

MRA EU-Switzerland

At present, it is unclear whether and how the Mutual Recognition Agreement between the EU and Switzerland can be continued after the application date of the MDR on May 26th, 2020. Due to a lack of political will on the part of the current Swiss government to negotiate the Mutual Recognition Agreement for the adoption of the MDR requirements under the terms of the EU that ensure the free movement of persons, it is likely that a mutual political compromise will be necessary in order to maintain the free movement of CE-marked medical devices after May 26th, 2020.
This means that no problems are expected with regard to EU exports to Switzerland but, from the MDR application date, Swiss manufacturers will need to have an authorized representative in the EU.

MRA EU-Turkey

The continuation of the existing Mutual Recognition Agreement between the EU and Turkey is also a matter of political debate. The reason behind this is that the EU objects to Turkey's violation of fundamental principles of the rule of law.

Catheter laboratory: Treating vascular occlusions with state-of-the-art medical technology.
A cardiologist inserts a guiding catheter via the groin to the narrowed section and expands it (images: BVMed / Kurt Paulus)

Hospitals and DRGs

The DRGs and "carexit"

Through the law for the reinforcement of care staff, Pflegepersonal-Stärkungsgesetz (PpSG), the exclusion of nursing staff costs from the DRG system will be put into effect for the first time in 2020. More than 15 billion euros will be removed from the case fees and introduced into the nursing care budget.

The funding of services will be split into

- service-based case fees of the new aG-DRG system, plus individual remuneration components such as additional remunerations; and
- cost-covering nursing care remuneration based on the individual hospital and days.

However, the calculation does not only exclude the nursing care for patients from the funding. Rather, an entirely new aG-DRG system was created that cannot be compared to the previous years anymore.

Needs-oriented patient care with high-quality medical devices in hospital must and can be ensured under the new requirements too. Advanced medical technologies lead to better outcome quality and improve patient care. The length of stays in hospital can often be cut and patients require less nursing care. The use of technologies that support patient care also means less work for the nursing staff, and these savings are taken into consideration when the nursing budget is calculated. This will compensate for staff resources that are often not available.

The start of the aG-DRG system means that the appropriate representation of medical technologies becomes an ongoing challenge requiring the correct expense-related calculation of technologies. The issue of inadequate investment cost financing remains unresolved, which will make it considerably more difficult to equip hospitals with digital applications and solutions as well as modern robot-assisted systems in particular.

Initial quality contracts with innovative medical technologies

In 2019/2020, the Statutory Health Insurance funds and the hospital bodies agreed quality contracts for hip and knee joint replacements for the first time. At present, there are four indications that allow funds and hospitals to conclude quality contracts. This means that hospital bodies and health insurance funds conclude temporary contracts that define quality goals and requirements for hospital treatment. The Institute for Quality Assurance and Transparency in the Healthcare System (Institut für Qualitätssicherung und Transparenz im Gesundheitswesen, IQTiG) is assessing the types of care and the related quality. Following this, a decision will be made whether the service can become part of regular care. BVMed supports these approaches that contribute to permanent improvements of medical care through innovative technologies, and calls for their extension to other areas of care.

Proposal to ensure hospital care with medical devices

The manufacturers that are members of BVMed have developed a proposal how to ensure patient safety during the medical devices supply process in hospitals. Patient safety is based on the condition of networked and cross-sector cooperation as well as the assumption of responsibility by all those involved in the German healthcare system. In order to assure the provision of high-quality, safe and future-oriented medical technologies and processes the following framework conditions must be created:

1. Regulatory requirements with realistic preconditions for their implementation;
2. Funding bases for care providers and manufacturers;
3. Standardized and digital procurement processes;
4. Effective use of existing resources through technical solutions for the reduction of the burdens on staff, and automation projects to involve the entire supply chain;
5. Networked cooperation of all those involved in the healthcare system.

Medical Review Boards reform law

BVMed is committed to the greater involvement of the medtech industry during the assessment of hospital services with medical devices carried out by the Medical Review Board of the Statutory Health Insurance Funds. In order to create an adequate basis of information, it is absolutely necessary that the Medical Review Board, the users of devices, and the manufacturers enter into a structured dialog. Apart from the necessary adjustment of processes, there must be more transparent procedures and a better qualification of the experts on the basis of the standard applied to specialist physicians.

Wound care: Around 2.7 million people in Germany suffer from complex wounds, and in approximately 900,000 patients, these take a chronic course. There are diverse types and locations of wounds as well as manifold products to treat them
(images: BVMed / Kurt Paulus)

Wound Dressings and Wound Care

New legal definition of wound dressings

The Heil- und Hilfsmittelversorgungsgesetz, HHVG, the law regulating the provision of therapeutic services and medical technical aids, provided a legal definition of what constitutes a wound dressing for the first time in 2017. This definition determines the kind of wound care products that those insured with the Statutory Health Insurance are legally entitled to.

At the end of 2018, the law ensuring greater safety in the provision of medical drugs, "Gesetz für mehr Sicherheit in der Arzneimittelversorgung (GSAV)", was presented. It constituted an unexpected turnaround with its new definition of what constitutes a wound dressing. Accordingly, the law distinguishes between the main effect and additional effects of the wound dressing. With regard to these, there may still be restrictions based on the mode of action and the place of action of certain properties. The additional effects may not be "pharmacological, immunological, or metabolic" and may not take place "in the human body". Thus the draft law contradicted the legislator's primary intention represented by the HHVG, i. e. an unambiguous regulation of wound dressing supplies with positive effects for patients suffering from wounds.

BVMed criticizes this legal regulation that came into effect in 2019, because it is to be feared that significant restrictions on the claims for benefits of patients in the area of wound care as well as far-reaching gaps in the provision of care are to be expected. It is true that the political legislative process has succeeded in extending the definition of wound dressings also to the additional property "metal-coated." The law intended to continue to provide wound products that have been tried and tested for many years as part of regular care. However, in its expert statements BVMed pointed out that in the interest of legal certainty and supply security further legal specifications are necessary.

G-BA differentiation guideline

Consequently, the G-BA committee is now tasked with adopting an amendment of the prescription guideline, which will differentiate "conventional wound dressings" from "other products for the treatment of wounds," and publishing this amendment by August 30th, 2020. During the relevant consultation process BVMed will continue to campaign to ensure the modern and phase-specific treatment of wounds and thus the correct implementation of the political intention behind the law. Up to 12 months after the publication of the differentiation guideline there will be no change with regard to the insured patients' claims against their health insurance funds when "wound dressings" are prescribed. The current reimbursement policy as well as the classification as "wound dressings" will remain the same. Devices that will in future be classified as "other products for the treatment of wounds" by the differentiation guideline must be approved through proof of benefit within 12 months of the publication of the differentiation guideline.

Caring for patients with chronic wounds

At the end of 2015, BVMed initiated the "Wound Dialog", an exclusive format which brings together politicians, physicians, nursing and care staff, as well as the health insurance funds in order to discuss the challenges of providing better care for patients with chronic wounds. The fifth Wound Dialog in December 2019 discussed the recommendations for the improvement of the structure of care for patients with chronic wounds in Germany, which were presented by the expert commission for the structural development of wound management in August 2019. The expert commission consisting of 13 specialists had been established after the 2017 BVMed Wound Dialog by the wound care initiative Deutscher Wundrat.

With these consensus recommendations, the cooperation partners from various professions and disciplines have developed cross-sectoral proposals for competences and structural approaches that can improve the future treatment of chronic wounds and wounds that do not heal easily as well as the necessary care processes. Participants and experts from politics, medicine, nursing, and patient care discussed the opportunities and limits of the recommendations and supported their swift implementation. Wound experts of all professions and disciplines are called upon to contribute their detailed proposals for the further development of the contents of the document. The concluding document presented by the expert commission can be accessed at *www.bvmed.de/expertenrat-wundmanagement*.



Homecare companies care for patients with medical technical aids, enteral nutrition, and surgical dressings – at home and in nursing homes (images: BVMed / Kurt Paulus)

Medical Technical Aids and Homecare

Quality: New regulations and ban on tenders

In 2017, the "Heil- und Hilfsmittelversorgungsgesetz (HHVG)", the law regulating the provision of therapeutic services and medical technical aids, introduced various regulations in order to ensure and strengthen the quality of the supply of medical technical aids and homecare. Following this, the medical appointment service and care law "Terminservice- und Versorgungsgesetz (TSVG)" brought further far-reaching amendments in 2019. Tenders were banned completely. Ongoing service contracts that were concluded on the basis of tenders lost their validity by the end of November 2019.
This was the legal consequence of the inadequate implementation of the HHVG that already contained the framework for the use of tenders. Accordingly, tenders were not to be held in individual areas of care that require high levels of service, and quality aspects had to play a greater role when contracts were awarded. Because some of the health insurance funds did not implement these regulations no essential quality improvements could be achieved.

BVMed activities

BVMed drew attention to these undesirable developments in the course of its political activities and advocated a quality-assured supply of medical technical aids and homecare as well as a competition for quality rather than a price competition. The focus was on ostomy care where the service component is especially relevant for individual patient care.
The "Quality of Life" initiative of BVMed ("Faktor Lebensqualität") (*www.faktor-lebensqualitaet.de*) accompanied these activities and provided information to the insured patients about their benefit claims , as well as about possible measures to assert claims in cases of inappropriate care or care shortages.

Quality control: additional payments and contract controlling

Even two years after the HHVG came into force, a number of the new regulations had not been completely implemented. In 2019, the Federal Association of the Statutory Health Insurance Funds, GKV-Spitzenverband, presented its first report on excess costs. BVMed, how-ever, criticized the incomplete data basis and the improvable methodology. A survey of the trend in additional payments can provide information about the quality developments in the supply of medical technical aids and show whether the principle of benefits in kind has been ensured. This, however, requires a sufficiently clear and transparent data basis.
BVMed also campaigns for more consistent regulations for contract controlling, which must be identical throughout Germany, mandatory, and transparent in order to establish a true quality competition among the health insurance funds.

Improving awareness of homecare

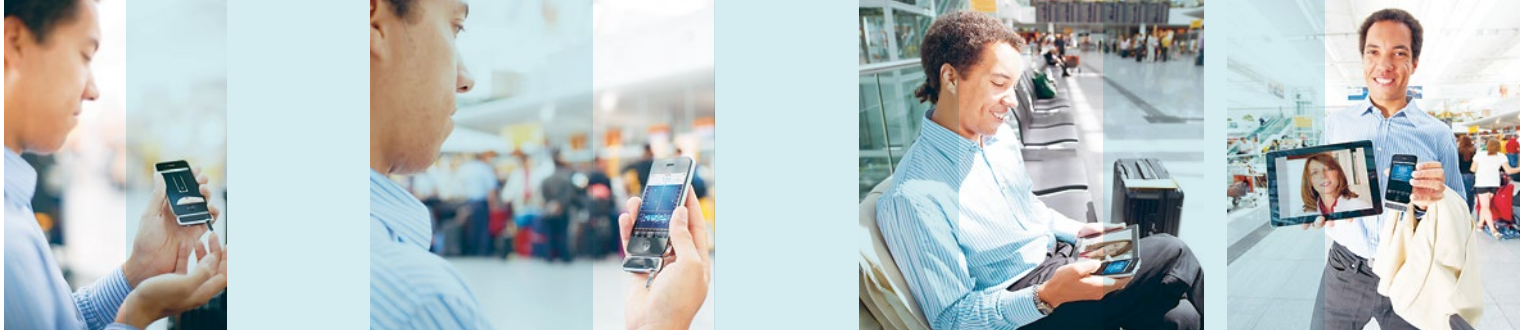
In order to improve awareness of homecare and its importance within the care process, BVMed again organized seminars and trainings for the employees of health insurance funds and the Medical Review Board of the health insurance funds in various areas of homecare therapy in 2019. Another element of its work was the 6th Homecare Management Congress at the end of 2019 to provide information about the current challenges in homecare to around 170 decision makers of the healthcare system.

Digitization and the integration of homecare

BVMed aims to ensure that the advantages brought by digitization are used for the provision of medical technical aids and homecare too. Digital prescriptions can only be implemented once the other care providers have been integrated into the telematics infrastructure.
To create the preconditions, BVMed developed the necessary arrangements and instruments such as the introduction of the organization ID on the basis of the relevant prequalification. BVMed closely coordinates its activities with other medical technical aids associations.

Simplification of administration

BVMed advocates the simplification and harmonization of the administrative procedures in the supply of medical technical aids. The negotiations of the framework recommendations on the administrative simplification (according to article 127, section 9 of the Social Security Code V) were concluded through arbitration proceedings in December 2019.



E-Health: Blood sugar monitoring and doctor consultation via iPhone app (images: BVMed / Kurt Paulus)

Digital Medical Devices

Digital care law

After its publication in June 2019, the digital care law "Digitale-Versorgung-Gesetz (DVG)" was passed by the German Federal Parliament on November 7th, 2019. With the help of the DVG, the Federal Ministry of Health intends to lower the threshold for the faster integration of digital solutions into regular care and thus to ensure high-quality and at the same time cost-effective medical and nursing-care today and in future. Through the relevant regulations in article 33a and 139e of the Social Security Code V, a fast track procedure for the introduction of digital health applications into medical care is to be established.

Digital health applications are medical devices

A digital health application that has passed the assessment by the Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM) and has been included in the catalog according to article 139e of the Social Security Code V is classified as a medical device with a low risk class (class I or IIa) according to the European Medical Device Regulation 2017/745 (MDR). In addition, a digital health application will be included in the catalog and thus can be prescribed during regular care if the manufacturer can demonstrate to the Statutory Health Insurance fund that the application is relevant for medical care due to its positive care effects.
Positive care effects can result either from medical benefits or from procedural and structural improvements during care that are relevant for patients. The details of the required evidence are to be clarified by an ordinance that the Federal Ministry of Health will pass during the first quarter of 2020.

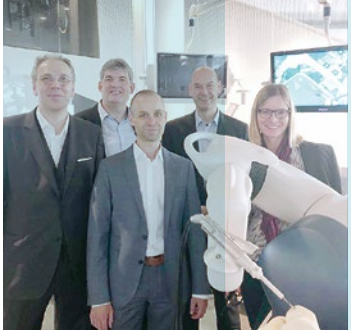
BVMed positions

In its statement and during the hearing of the law in the parliamentary health committee BVMed welcomed the approach. BVMed stressed, however, that these regulations cover only part of the digital solutions. Currently, there is still no solution for the fast introduction of standalone, digital medical devices with higher risk classes into regular care. At present, a positive benefit assessment carried out by the G-BA for a new, innovative class IIb or III medical device takes, on average, more than five years.
In addition, for today's healthcare market, digital solutions are not only developed as standalone software but also as accessories for existing medical devices. This applies to software and apps that process data for another medical device and thus provide information e. g. about the parameters of a cardiac pacemaker or an insulin pump to the physician or the patient. As combination products these solutions are classified as class III and are not covered by the health insurance benefit entitlement, even though their efficiency potentials for patient care can be huge. In 2020, the BVMed department Digital Medical Devices will be devoting more of its attention to this matter.

New BVMed department

Since June 1st, 2019, BVMed has been establishing its new department Digital Medical Devices. It aims to assist the BVMed members during these times of digital transformation and to identify issues and developments of interest to the industry in order to provide better support to the members. The focus will be on the market access of medical devices as well as eStandards and robotics in medical care. In 2020, the department will be expanded when more sectoral interest groups and working groups are added.






Images from the series of visits "BVMed visiting the manufacturing healthcare industry" – on-site with Ritex, Fresenius, Stryker, and Ottobock

SME and Business Development

The German healthcare industry contributes around 12 percent of the country's gross domestic product. This means: One in eight euros in Germany is generated through the healthcare industry. In addition, the healthcare industry employs over 7 million people in Germany. This makes it one of the largest and economically most important industries in Germany, even more so than the automotive industry or mechanical engineering.
The important pillars of medical technology are small and medium-sized companies. With around 90 percent of companies being small and medium-sized enterprises, the German medtech industry is a predominantly SME industry, may they be large family businesses, medium-sized traditional companies, or small start-ups. There are many global market leaders and "hidden champions" among these German companies.
Politicians have recognized how important small and medium-sized businesses are for the German economy and developed an SME strategy. Its key aspects are:

- less bureaucracy;
- reducing the shortage of skilled professionals;
- ensuring financing of small and medium-sized businesses;
- supporting innovations and digitization.

The government's SME strategy must explicitly include the healthcare industry in order to recognize the justified interests of medium-sized medtech companies and to ensure that the healthcare industry will continue to be a relevant factor for the employment market.

BVMed establishes its own SME department

In order to better represent the small and medium-sized medtech businesses' interests, BVMed established its new department "SME and Business Development" in November 2019. This BVMed department aims to adjust its political activities on the medtech SMEs and the particular concerns and challenges they face, as well as creating new services for these companies.
To this end, the SME forum of BVMed will develop a small and medium-sized medtech enterprise strategy. The first topics will be:

- **Support during the implementation of the EU Medical Device Regulation (MDR):** The increased requirements resulting from the MDR pose a significant challenge for small and medium-sized medtech companies. The risks can include bottlenecks in medical care as well as loss of livelihoods. In order to develop opportunities and recommendations for action we offer trainings and conferences on MDR.
- **Improving the tax framework / public funding:** Another focus of the department will be on services regarding public funding of the manufacturing healthcare industry in Germany in order to maintain the international competitiveness of medtech SMEs. To this end, the department is planning the exchange of information about the medtech funding landscape.
- **Regional support for medtech SMEs:** The BVMed SME department will be active especially in those federal states and regions where the small and medium-sized medtech enterprises are present. In these regions the department is going to raise awareness among politicians for the issues that affect medtech SMEs by providing information and organizing events.
- **Strengthening digitization and innovativeness, reducing bureaucracy:** In cooperation with the department for digital medical devices, the SME department keeps interested small and medium-sized medtech companies updated on new developments in the field of digital health. Moreover, the department supports SMEs during necessary digitization processes by providing information and networking opportunities.
- **Strengthening internationalization and globalization:** The BVMed department acts as an export initiative and addresses small and medium-sized companies that are based in Germany and aim to gain a foothold in new, international markets with their products and technologies. To this end, the department is developing close contacts for exchanging information with the Federal Ministry for Economic Affairs and Energy. The department is going to provide information about business delegation trips too.

New testimonials for the campaign "Every human being is unique" (Body Pride – *www.bvmed.de/koerperstolz*): Claudia, Torsten, Angela (images: BVMed / Darius Ramazani)

Communications and Media Projects

Patients showing "Body Pride"

Providing information about the importance and value of medical technologies is an important task of BVMed's communication activities: for the public, for healthcare, for the economy in general. A core element of BVMed's public relations activities is the information campaign "Der Mensch als Maßstab. Medizintechnologie," which translates as "Measuring by the Human Standard" (*www.massstab-mensch.de*). With its sophisticated aesthetics and large posters the campaign is breaking new ground in the medtech industry.

The Body Pride, "Körperstolz," series of themes (*www.bvmed.de/koerperstolz*) focuses on real patient stories, using the storytelling approach. The campaign aims to improve the public's understanding of the situations the patients face in their lives, and to show the importance of medical devices for a self-determined life.

The motto is: "Every human being is unique. We help some of them to live like everybody else."

It portrays patients with chronic diseases who live their lives to the fullest. The campaign focuses on patient stories and advertising motifs for different indications and areas of care: ostomy, incontinence, artificial nourishment, homecare, diabetes, tracheotomy / laryngectomy, dialysis, lymphedema after breast cancer, cardiac insufficiency, heart valve disease, hip and shoulder joint replacement, and dystonia. The large posters are complemented by in-depth interviews with patients and video clips.

"Joint replacements get you moving"

The storytelling approach also features in BVMed's campaign "Gelenkersatz bewegt" ("Joint replacements get you moving") which can be accessed at (*www.gelenkersatz-bewegt.de*). It features twelve patients who tell their stories in connection with hip, knee, or shoulder joint replacements. Joint replacements are among the most successful surgical interventions of medical history. Every year over 400,000 people in Germany receive an artificial hip or knee joint. With the help of modern and high-quality joint replacements they are able to again lead active and pain-free lives. Apart from the patient stories, the BVMed communications department has developed a patient checklist as well as useful tips.

Patient information

Medical-technological progress, an aging population, new information technologies: comprehensible and up-to-date patient information is becoming more and more important against this background. BVMed has accepted this challenge with "Aktion Meditech" (*www.aktion-meditech.de*) – always working closely together with physicians and patient groups.

BVMed's website (*www.bvmed.de*) also offers clearly structured information about medical-technological solutions for various diseases, as well as patient information films.

Media activities

In early 2020, BVMed carried out a detailed reach analysis entitled "BVMed in print and online media" for 2019. In this way, the Department Communications / Press is determining key figures that demonstrate the successful media work as part of the association's communications projects. In the print sector, the number of clippings mentioning BVMed could be increased to 687 articles. Our reach via print media was around 80 million readers. Online, the number of clippings mentioning BVMed was 1,704 articles.

The weekly BVMed newsletter with more than 9,000 subscribers remains an important feature of the medtech industry. The other areas of media work are our own photo galleries, "BVMed Bilderwelten," press conferences, the annual Media Seminar, as well as press releases, background services, editorials, and industry reports in German and English.

Website and social media

In 2019, our web portal *www.bvmed.de* registered 545,000 visits altogether with 1.05 million page views. This means a rise of 42 percent compared to the previous year. Social networks have become an important element of the communication activities of the medical technology industry too. BVMed makes use of the opportunities that social networks offer, e. g. via its own Twitter channel (*www.twitter.com/bvmed*) with more than 3,400 followers as well as several Facebook pages displaying technological and career topics. In the course of its social media strategy, BVMed addresses the entire range of topics that concern the medtech industry via expert channels on Twitter and LinkedIn.

Intensive care unit: The intensive care unit of a hospital provides state-of-the-art technology for the treatment of severely ill patients (images: BVMed / Kurt Paulus)

Reports from the BVMed Expert Committees

BVMed offers its members over 60 working groups, sectoral interest groups, and project groups, which function as a platform for constructive dialog and exchange, leading to a joint formation of opinions.

Working groups deal with issues of general concern to all members on a continuous basis, irrespective of their particular products.

Sectoral interest groups consist of members working in a specific market or product area, who wish for additional representation of their particular specialist interests.

Project groups are committees set up on a temporary basis. They deal with a specific subject and provide expert support to the board and the management team of BVMed in this particular field.

A complete list of BVMed's groups can be found at: *www.bvmed.de/arbeitsgremien*.

WORKING GROUPS

Working group "eStandards" (AKE)

AKE is the representation of BVMed's members in the "Forum eStandards". The forum is a joint initiative of BVMed member companies and hospital purchasing groups. It has established itself as a platform for the joint development and dissemination of recommendations for electronic communication in the exchange of business data. The basis are the papers published by the forum, which recommend a standardized approach to implementing product classification, master data exchange, electronic data interchange, sales reports, and electronic invoicing. Other current key issues are the implementation of the Eudamed requirements contained in the MDR as well as dealing with possible bottlenecks in the supply of devices.

Working group "Environment, Health and Safety" (AKEHS)

AKEHS is concerned with the issues of environmental protection, health, and safety at work. It assesses the relevant legislation and prepares statements on laws and legal initiatives.

Working group "Hospital Market" (AK KHM)

AK KHM is the contact point for industry-specific questions with regard to hospitals during the buying process. It provides a communication platform where joint projects and activities concerning the buying process of medical technologies in the hospital market can be developed. It is the contact point for the purchasing organizations in this market segment. A focus of its activities is supply security and ensuring the availability of medical devices in hospitals. To this end, the working group has developed detailed suggestions and a position paper on this matter. Together with the relevant purchasing organizations, the working group discusses market requirements and process optimization during the buying process. Another focus is on the logistic processes as well as the supply chain management between the suppliers, service providers, and hospitals.

Working group "Legal Affairs" (AKR)

The members of AKR – in-house legal advisors and associated external lawyers – answer questions concerning legal matters from BVMed's working committees. To this end, AKR has formed 16 sub-working and project groups. AKR provides member companies with legal assistance via position statements, publications, and information events. It updates the two-volume commentary on the Medical Devices Law, "WiKo – Medizinprodukterecht", as well as an online law database which lists around 500 court decisions about medical devices ("WiKo-Blog"). At the European level, AKR cooperates with MedTech Europe's Legal Affairs Committee (LAC). The current key issues are the legal duties of the economic operators according to the MDR, or questions of data privacy. In addition, AKR is concerned with the proposed new EU directive on the introduction of an EU class-action lawsuit. Against the background of the VW emissions scandal this directive will offer consumers – even those


Diabetes: Insulin pumps and continuous glucose monitoring for children with diabetes


Endoprosthetics: Doctor-patient talk about hip and knee joint replacements (images: BVMed / Kurt Paulus)

who have not suffered any losses – the opportunity to file a suit against a manufacturer in order to compel them to comply with legal regulations.

Working group "Regulatory Affairs" (AKRA)

AKRA (formerly: AKRP) answers questions concerning regulatory matters from the BVMed working committees. To this end, it has formed twelve sub-working and project groups. Together with the BVMed office, AKRA plans and organizes information and training events for the BVMed members with regard to the application of the MDR. As in the previous years, the focus was on the implementation of the MDR with its large number of regulatory sub-topics. AKRA has developed the BVMed statements on the MDR and the MPDG drafts, and together with AKR edits the BVMed information series "Medizinprodukterecht" (Medical Devices Law), which consists of twelve guidelines on different regulatory and legal matters. Most recently, AKRA updated the guideline on the self-certification of class I medical devices according to the MDR ("Die Selbstzertifizierung von Medizinprodukten der Klasse I nach der MDR"). Further, at the European level, AKRA cooperates closely with the Regulatory Affairs Committee of MedTech Europe, whilst an AKRA member is chairing the committee, as well as with the working group "MPG" (Medical Device Act) of the national medtech industry associations.

Healthcare Compliance Committee (HCCC)

BVMed hosted trainings and events not only for its members but also for representatives of the healthcare professions about the current developments in the field of healthcare compliance (*www.bvmed.de/compliance*). What matters most to all the partners in the healthcare market is avoiding any suspicion of corruption. They are aided by the four core principles: separation principle, transparency principle, documentation principle, and equivalence principle. During training seminars these are illustrated on the basis of specific case scenarios. The Healthcare Compliance Expert Forum, which took place for the first time, discussed the current developments in healthcare compliance, such as its implications for associated fields of law like employment law, electronic compliance tools, and not least the draft presented for the company sanctions law and the necessary steps of action. HCCC discussed the latter issue in great detail. The committee decided to take an active role in the legislative process and to provide the members of BVMed with a workable prevention tool once the law has come into existence. The third focus of BVMed's compliance work was on the revision of the Medical Device Codex ("Kodex Medizinprodukte") (*www.bvmed.de/kodex*).

SECTORAL INTEREST GROUPS

Sectoral interest group "Eye Surgery" (FBA)

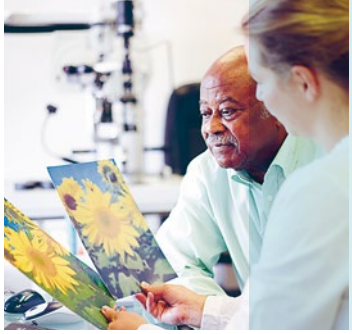
FBA represents the manufacturers and distributors of medical devices used in surgery on or in the eye, especially intraocular lenses, IOL. With its information campaign "Cataract Initiative", FBA explains the additional benefits of innovative intraocular lenses. The key element of the campaign is the website *www.initiative grauerstar.de*, which provides information for patients as well as a search function for surgery centers.

Sectoral interest group "Blood" (FB Blut)

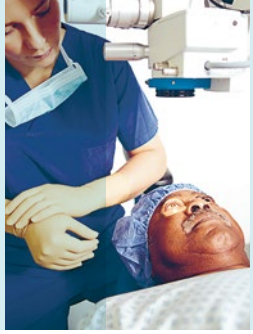
The members of FB Blut are the global suppliers of medical devices for transfusion. The group's concerns are the safety of blood donations and the reliable supply of blood products as well as the relevant German and European frameworks. As an active member, FB Blut contributes its expertise to the blood working group of the Federal Ministry of Health.

Decubitus Forum (DF)

DF campaigns for patient-oriented care with anti-decubitus medical technical aids. This must be based on the suitable framework and the update of product group 11 (medical technical aids for the prevention of decubitus) represented in the register of medical technical aids. To this end, DF is in continuous discussions with the Federal Association of the Statutory Health Insurance Funds, GKV-Spitzenverband. DF, moreover, regularly draws attention to improvements but also any continuing shortcomings regarding the provision of decubitus care (*www.dekubitus-forum.de*).



Eye surgery: Modern procedures for defective vision and cataract



Cataract surgery

Sectoral interest group “Diabetes” (FBD)

FBD aims to ensure that innovative diabetes technologies and therapies are available on a timely basis to all those who need them. The continuing digitization in healthcare also means further developments of the opportunities for the self-management of diabetes. Here, the newly established entitlement to digital medical devices created by the digital care law provides new opportunities. In addition, FBD is concerned with the further development as well as the quality assurance of diabetes therapy.

Sectoral interest group “Diagnosis Related Groups – Hospital Financing” (FB DRG)

FB DRG accompanies the further development of the hospital financing system, focusing on the appropriate representation of medical technologies. FB DRG coordinates the suggestions made for the further development of the DRG and OPS classifications within BVMed. It analyzes legislative initiatives such as the law for the reinforcement of nursing-care costs, Pflegekostenstärkungsgesetz, and the Medical Review Boards reform law, and prepares statements on the proposals. FB DRG also supports the companies through further training events as well as guidelines and other information materials. It is in dialog with the relevant hospital market stakeholders.

Sectoral interest group “Endoprosthetics – Implants” (FBEI)

FBEI considers the MDR to be a huge challenge for the provision of joint replacements. Some of the existing devices used in patient care will no longer be on the market once the MDR applies. Especially with regard to rare treatment devices the requirements made by the Notified Bodies, e. g. of clinical studies, are excessive and, given the small number of patients, cannot be met. For ethical reasons, clinical studies with existing devices that often have been on the market for decades are rejected by physicians and ethics committees. FBEI criticizes the lack of mandatory deadlines for the Notified Bodies, the absence of a regular administrative process with functioning legal protection, and the excessive costs through the MDR introduction. FBEI advocates an unbureaucratic approach for tried and tested arthroplasties that have shown no problems during care.

Sectoral interest group “First-Aid Material” (FBEH)

FBEH is the interest group of the manufacturers of first-aid materials and kits, which are used for cars, motorcycles, and businesses. The main goal of its members is the continuous update of first-aid materials according to the latest findings of modern emergency and disaster medicine. Through its press work, the working group “Communication” (AGK) of FBEH regularly provides information about the importance and benefits of first-aid kits in cars and motorcycles and about the duties of the users.

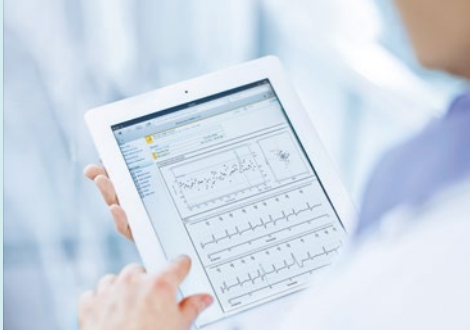
Sectoral interest group “Homecare” (FBHC)

FBHC analyzes the implementation of new legal regulations in the area of medical technical aids and their implications for homecare. Its focus was especially on the introduction of the ban on tenders, the confirmation of mandatory contract negotiations, and the publication of the report on excess costs. Other key issues were the execution of the update of the register of medical technical aids, and the introduction of qualification requirements for care staff. One of the key goals of FBHC is stressing and strengthening the importance and role of homecare in ambulatory care. To this end, it employs active communications and public relations work, which in 2019 also included the organization of the 6th Homecare Management Congress.

Sectoral interest group “Cardiac Medical Devices” (FBKMP)

FBKMP is concerned with medical technologies that are used in cardiovascular medicine. Within the sectoral interest group, the manufacturers are organized in the fields of active implants, interventional examination and treatment technologies, as well as interventions through heart surgery or artificial heart technologies. The key issues of the device-specific work are the inclusion of devices into service catalogs (AOP, EBM, and DRG) as well as quality indicators. An industry advisory council is in dialog with the medical societies regarding further training activities during medical congresses. Through framework agreements it contributes to the qualification of specialist physicians with regard to the application of technologies, e. g. expert courses on active implants.





Telemedicine system for remote supervision of patients with heart implants (images: BIOTRONIK SE & Co. KG)

FBKMP supports a so-called "Innovation Task Force" that is concerned with the establishment and representation of new technologies in patient care.

Sectoral interest group "Condoms" (FBK)

Through their active participation in various committees, the members of FBK work for a uniformly high safety and tolerability level of condoms. The sectoral interest group is in great demand as a contact point for the authorities and the media for issues concerning the use of condoms.

Sectoral interest group "Artificial Nourishment" (FBKE)

FBKE campaigns for the necessary, sufficient, and appropriate supply and reimbursement of medical enteral nutrition. FBKE believes that the quality-assured supply of medical nutrition also requires qualification specifications (prequalification), which the Federal Association of the Statutory Health Insurance Funds, GKV-Spitzenverband, has been tasked with defining since 2009. In 2019, the sectoral interest group advocated the speedy implementation of these requirements that now has been announced for 2020. FBKE was also very busy with the implementation of the update of product group 03 of the register of medical technical aids, as well as with the issue of malnutrition. In order to create an understanding for the specific requirements of the supply of products for enteral and parenteral nutrition, the sectoral interest group organized a seminar for health insurance fund employees in 2019.

Sectoral interest group "Benefits Law for Care Providers" (FBLL)

FBLL is concerned with current issues of the social security as well as procurement law and supports BVMed in drawing up statements and regulatory proposals as well as analyzing legislative processes and court decisions. In 2019, the activities of FBLL focused on the implementation of the laws HHVG and TSVG, the Medical Devices Operator Ordinance, and the MDR by the providers of medical technical aids.

Sectoral interest group "Market Access" (FB MA)

FB MA combines the activities for the timely market launch and remuneration of medical devices following their CE marking and their representation in the service catalogs. The focus of its work was on the adequate remuneration for medical technologies and overcoming market access barriers. In this respect, the methods of benefit assessment, healthcare research, and quality assurance are important contributory factors. In order to disseminate information about remuneration and the implementation of the benefit assessment procedures for the manufacturers, FB MA develops guidelines, organizes seminars, and is in dialog with the partners and institutions of the healthcare system. It represents the companies in the working group on benefit assessment, in which several associations cooperate.

Sectoral interest group "Mechanical Thrombosis Prophylaxis" (FBMT)

FBMT is concerned with all matters of physical thrombosis prophylaxis. Its focus is on public relations work and on regular dialogs with physicians and nursing staff about the current frameworks.

Sectoral interest group "Modern Wound Care" (FBMW)

The focus of FBMW was on the statutory clarification of the legal definition of what constitutes a wound dressing introduced in 2017 and the accompanying differentiation guideline for certain wound care products. FBMW has developed a statement on this matter which criticizes the proposed legal amendment with regard to the loss of the quality of patient care that is to be expected. FBMW aims to ensure phase-specific wound care during the treatment of chronic wounds. This includes the Wound Dialog, which takes place every year as a platform for discussion among all those involved in wound care and for the improvement of wound care in Germany. In addition, FBMW produced an edition of its newsletter "MedTech ambulant" to provide information to physicians about the most significant new updates.

Medical technical aids: Wound care, incontinence care, artificial nourishment, and ostomy care (images: BVMed / Kurt Paulus)

Sectoral interest group “Needlestick Prevention” (FBNSP)

FBNSP is the interest group of the manufacturers of safety devices for the prevention of sharps injuries. After the medical appointment service and care law TSVG passed in 2019 ensuring the patients’ entitlement to receive safety devices if care is delivered by a third person, FBNSP was actively involved in the further processes for the update of the medical technical aids guideline and the register of medical technical aids. To this end, it cooperates closely with the supply-specific BVMed sectoral interest groups for infusion and diabetes therapies.

Sectoral interest group “Nosocomial Infections” (FBNI)

FBNI has recognized that the prevention of nosocomial infections is the core challenge of the future, and it has established itself as a platform that, through its messages and positions, makes its own contribution to the prevention of infections in Germany. Nosocomial infections in patients and staff are infections that coincide with medical measures in hospitals, nursing institutions, or ambulatory physicians’ offices. The FBNI experts have developed a new communication concept for their campaign “Infektionen vermeiden – bewusst handeln” (“Avoiding infections – acting sensibly”, *www.krankenhausinfektionen.info*), and published two position papers on improving the prevention of infections as well as the effective prevention of antimicrobial resistance in patients. In addition, better remuneration of devices for the prevention of infections in ambulatory care as well as the restructuring of the topics discussed during the yearly Hygiene Forum of BVMed were part of the agenda of FBNI. The Hygiene Forum presents up-to-date and practical contributions by renowned experts. Moreover, it has established itself as a forum for the exchange of information among those who are interested in hygiene and working in hospitals, physicians’ practices, politics, and the self-governing bodies.

Sectoral interest group “Peripheral Vascular Medicine” (FBPG)

FBPG is concerned with medical technologies used in the peripheral circulatory system, e.g. PTA technologies, venous and arterial stents, stent grafts, and intercranial systems for stroke therapy as well as embolization technologies. With the medical societies, FBPG discusses the further development of professional training programs as well as the representation of these technologies in the classification and service catalogs.

Sectoral interest group “Rehabilitation Technology Supply for the Preservation of Mobility and Care” (FB Rehatechnik)

Medical technical aids for rehabilitation support patients' mobility and independence and facilitate nursing care. Thus, the supply of medical technical aids for rehabilitation significantly contributes to enabling patients to remain living in their homes. In order to improve the quality of care, the sectoral interest group discusses new concepts of care such as individual supplies based on the degree of disability.

Sectoral interest group “Robotics in Medical Care” (FBRO)

Since September 2019, the new BVMed sectoral interest group “Robotics in Medical Care" has been working to improve patient care through the establishment of robotics systems in regular medical care. One of the aims of FBRO is to initiate the appropriate financing of robotics systems through targeted funding programs. Moreover, the BVMed experts plan to provide better information about the advantages of robotics in medical care for professionals as well as patients with the aim of facilitating access to modern technologies for patients. The advantages of robotics systems include more precise and gentler surgical procedures for specific indications as well as improved care processes and a reduction of the burden of doctors and nurses.

Cardiology: Cardiac pacemaker, implantable defibrillators, and telecardiology monitoring of patients with pacemakers

Sectoral interest group "Absorbing Incontinence Care – Manufacturers" (FBI-H)

FBI-H analyzes and comments on the care and contract situation for absorbing incontinence products. Its focus is especially on the quality-assured and medically necessary supply of incontinence care as well as on adequate remuneration. Other issues are the ban on tenders for medical technical aids as well as the update of the register of medical technical aids. Already in 2019, FBI-H developed relevant technical approaches to these questions that were discussed with the patient organizations and the Federal Association of the Statutory Health Insurance Funds with a view to a timely update of the register.

Sectoral interest group "Soft Tissue Repair Implants – Soft Tissue" (FB STRI)

FB STRI represents the interests of the suppliers of implants for soft tissue reinforcement, especially for the therapy areas visceral surgery, gynecology, urology, and plastic surgery. It supports the register project dealing with hernia and biological implants, Herniamed. It discusses new types of care using these devices, which are presented to the sectoral interest group by the service providers involved.

Sectoral interest group "Supplies for consultations and physicians' practices and wound dressings" (FBSPV)

The focus of FBSPV is on the fundamental changes of the contract landscape. It advocates suitable framework conditions that will create legal certainty for all the stakeholders in the process. The information papers published by FBSPV explain how to deal with any recourse claims and provide advice on regulations for (re-)imports of medical devices.

Sectoral interest group "Spine Surgery" (FBSC)

FBSC supports the establishment and appropriate representation of medical technologies for the spine within the classification and remuneration catalogs. In cooperation with the German Spine Society, FBSC is involved in the development and design of the German spine register, for instance through the development of a product database. In addition, it coordinates further education programs.

Sectoral interest group "Sterile Materials Care" (FBSV)

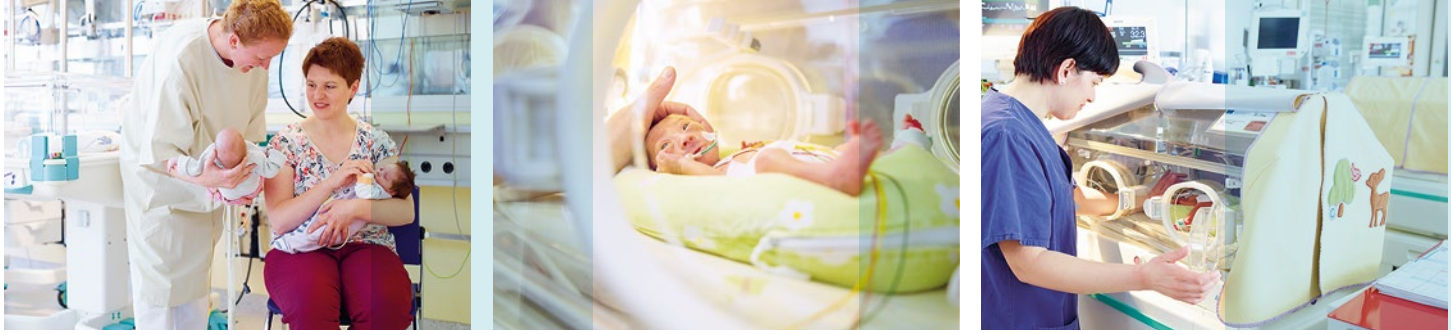
FBSV is concerned with the exchange on issues concerning the requirements of sterile products and devices that must be used in a low-germ environment. Currently, the sectoral interest group is involved in the evaluation process for the creation of the new apprenticeship training program in the field of medical devices reprocessing.

Sectoral interest group "Ostomy / Incontinence Care" (FBSI)

The political developments in recent years with regard to the quality assurance of the supply of medical technical aids – especially the ban on tenders – affected the existing service contracts to a significant degree. A particular political focus was on the supply of ostomy articles and the accompanying services. After a number of undesirable developments, FBSI with its "Quality of Life" initiative engaged in the debate about the quality requirements for ostomy care. With a view to effective quality assurance, FBSI advocates the introduction of quality requirements for care staff and supports the regulations introduced in 2019 through the prequalification recommendations. Now the focus must be on the appropriate implementation that also preserves existing structures. At the meeting of the European Council of Enterostomal Therapy (ECET), the participants discussed approaches to a common European solution. The discussions are to be continued.

Sectoral interest group "Therapeutic Apheresis" (FBTA)

The members of FBTA are companies that offer technologies for extracorporeal blood cleansing. The member companies support the German Lipidapheresis Register (Deutsches Lipidapherese-Register, DLAR), which compiles a systematic documentation of lipidapheresis procedures. The DLAR register aims to substantiate known positive results with the help of a wide range of data, thus securing established forms of therapy.



Caring for premature babies: Medical care for premature babies has constantly improved over the last 30 years thanks to the progress of medical technology.

Sectoral interest group "Tracheotomy / Laryngectomy" (FBTL)

The current key issues of FBTL are the comprehensive new legal and regulatory provisions as well as the implementation of the update of product groups 12 and 27, which occurred in 2018. FBTL aims to ensure and improve the quality of care for tracheotomy and laryngectomy patients. In order for them to receive good follow-up care, service contracts with the health insurance funds are needed. FBTL organized a seminar on this matter for employees of the health insurance funds and the Medical Review Board, thus contributing to their further training. In addition, FBTL provides information to the public in the form of brochures and information papers.

Sectoral interest group "Shortened Supply Channel" in the supply of hearing aids (FBVV)

FBVV is committed to the high-quality provision of hearing aids via the shortened supply channel. To this end, it has initiated the "Qualitätsinitiative Verkürzter Versorgungsweg" (Quality Initiative Abbreviated Supply Channel, *www.hörgeräte-qvv.de*). The shortened supply channel is a quality-assured alternative to the traditional supply channel for hearing aids. Surveys undertaken by QVV in 2019 found a markedly lower rate and amount of additional payments. FBVV publishes information cards on the shortened supply channel for patients and offers training seminars for the employees of the health insurance funds and the Medical Review Board.

PROJECT GROUPS

Project group "Neurostimulation" (AG Neuro)

AG Neuro brings together the manufacturers of mostly implantable medical technologies that are applied, e.g. within the treatment range of deep brain stimulation, to treat Parkinson's disease, epilepsy, migraine, cluster headaches, dystonia, or chronic pain. Its activities are mainly focused on the promotion of the appropriate representation of these technologies in the reimbursement systems.

Project group "Homecare Digital"

PG Homecare Digital deals with the implications of digital care processes for the supply of medical technical aids and homecare. The project group discusses possible solutions and tools in order to integrate other care providers into the telematics infrastructure and its applications in a timely manner. Another key issue is the impending introduction of the digital supply of medical technical aids. The focus here is on the technical requirements and the transmission paths.

Project group "Medical Care and Remuneration" (PG MVV)

PG MVV issues the newsletter "MedTech ambulant" (*www.bvmed.de/medtech-ambulant*) in order to keep practice-based care providers informed about current developments and specific issues regarding medical devices. Its key topics in 2019 were the supply of medical technical aids for laryngectomized patients, ambulatory intensive care, (re-)imports of medical devices, and the definition of what constitutes a wound dressing.

Project group PICC "Catheter Technology" (PG PICC)

Peripherally inserted central catheters (PICC) are used for a short or long period of time for central venous pressure monitoring, bloodsampling, drug and fluid administration, and for use with high-pressure injectors for the application of contrast media for CT scans.
PG PICC intends to make access to the devices easier for users and patients. To this end and to improve the coding and remuneration of PICC, the project group presented a change proposal for the German procedure classification OPS to the DIMDI. If more detailed distinctions can be made within coding, this will enable sound healthcare research and thus more valid studies.

The Board of BVMed 2018 to 2020
(image: BVMed)

With AdvaMed Chairman Kevin Lobo, CEO of Stryker, at the MedTech Conference 2019 in Boston

The speakers of the BVMed Media Seminar 2019 in Berlin
(images: Christian Kruppa)

BVMed – At Your Service

Board

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Head of Regulatory Affairs

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Head of Administration / Controlling

Sandra Gill
Assistant

RECEPTION
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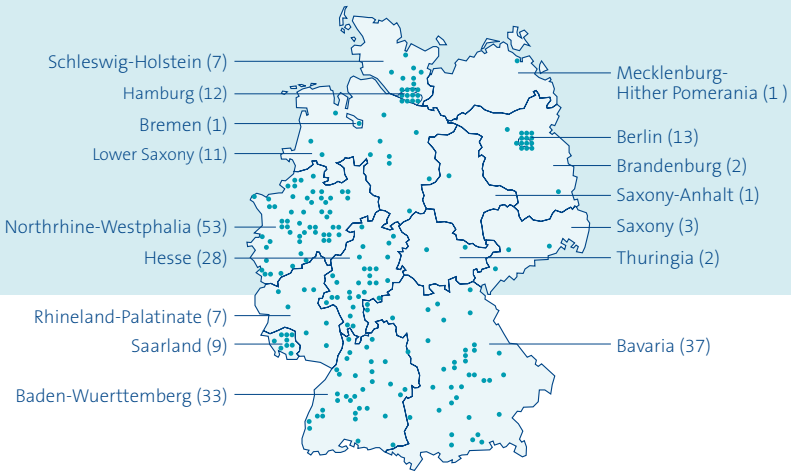
Office Assistant

Steffen Heidrich
Reception / Office Assistant



Map of Germany showing the number of member companies in the federal states

As of March 2020: 220 members – current list available at *www.bvmed.de*

BVMed Member Companies

1stQ Deutschland GmbH
3M Deutschland GmbH

aap Implantate AG
Abbott GmbH
Abbott Medical GmbH
Abena GmbH
Abiomed Europe GmbH
Acandis GmbH
Aesculap AG
aktivmed GmbH
ALCON PHARMA GMBH
Allergan GmbH
alloPlus GmbH
AMPLITUDE GmbH
Andreas Fahl Medizintechnik-Vertrieb GmbH
Ansell GmbH
Arjo Deutschland GmbH
ASSAmed GmbH
ATMOS MedizinTechnik GmbH & Co. KG
Attends GmbH
auric Hörsysteme GmbH & Co. KG

B. Braun Melsungen AG
Bausch & Lomb GmbH
Baxter Deutschland GmbH
Beiersdorf AG
BD Becton Dickinson GmbH
Berlin Heart GmbH
BGS Beta-Gamma-Service GmbH & Co. KG
biolitec biomedical technology GmbH
BIOTRONIK SE & Co. KG
BONESUPPORT GmbH
Boston Scientific Medizintechnik GmbH
Bracco Imaging Deutschland GmbH
Brainlab AG
BSN medical GmbH

C. R. Bard GmbH
Cardinal Health Germany 507 GmbH
Cardiobridge GmbH
CardioFocus Inc. German Office
CARDIONOVUM GmbH
Carl Zeiss Meditec Vertriebsgesellschaft mbH, Vertrieb Ophthalmo-Chirurgie
CeramTec GmbH
Cerus Europe B. V.
Chemische Fabrik Kreussler & Co. GmbH
CINOGY GmbH
Coloplast GmbH
Coltène / Whaledent GmbH + Co. KG
ConvaTec (Germany) GmbH
COOK Deutschland GmbH
CORIN GSA GmbH
curasan AG
curea medical GmbH

DEWE + Co. Verbandstoff-Fabrik Dr. Wüsthoff & Co.
DIAMED Medizintechnik GmbH
DIASHOP GmbH
Dr. Ausbüttel & Co. GmbH

Eckert & Ziegler BEBIG GmbH
Ecolab Deutschland GmbH
Edwards Lifesciences Services GmbH
ElringKlinger Kunststofftechnik GmbH
Essity Germany GmbH
ewimed GmbH

FEG Textiltechnik Forschungs- und Entwicklungsgesellschaft mbH
Fidia Pharma GmbH
FOR LIFE GmbH
Franz Kalff GmbH
Fresenius SE & Co. KGaA
Freudenberg Medical Europe GmbH
Fuhrmann GmbH
Fumedica Medizintechnik GmbH
Funke-Medical AG

Gambro Dialysatoren GmbH
GerroMed Pflege- und Medizintechnik GmbH
GHD GesundHeits GmbH Deutschland
Globus Medical Germany GmbH

HAEMONETICS GmbH
HANS HEPP GmbH & CO. KG
Heraeus Medical GmbH
HMT Medizintechnik GmbH
Hollister Incorporated Niederlassung Deutschland
Holthaus Medical GmbH & Co. KG
HOMANN-MEDICAL GmbH u. Co. KG
Hörkonzepte Vertriebs GmbH & Co. KG
HOYA Surgical Optics GmbH

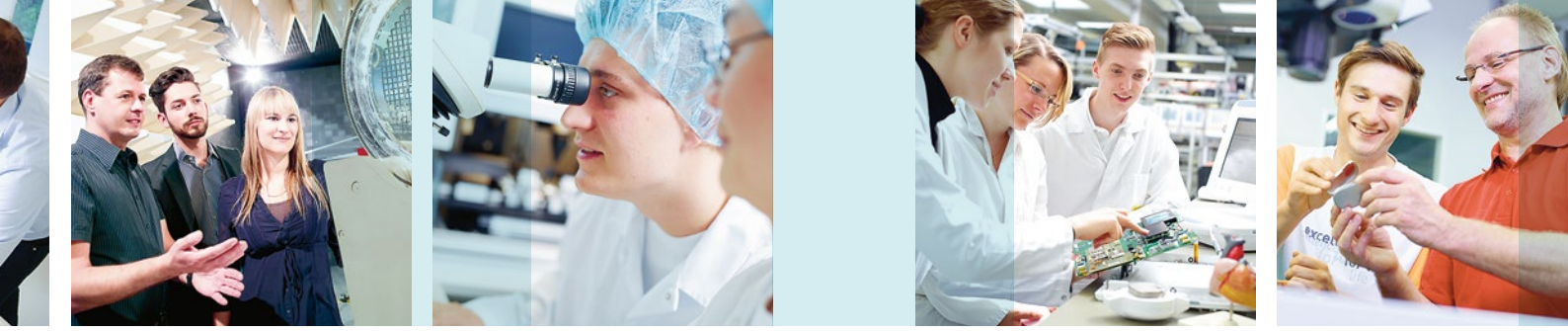
implantcast GmbH
Impulse Dynamics Germany GmbH
Integra GmbH
Intrinsic Therapeutics, Inc.
Intuitive Surgical Deutschland GmbH

JenaValve Technology GmbH
Johnson & Johnson MEDICAL GmbH
Johnson & Johnson Vision AMO Germany GmbH
Juka Pharma GmbH

Kaneka Pharma Europe N. V. German Branch
KARL OTTO BRAUN GmbH & Co. KG
Kaymogyn GmbH
KCI Medizinprodukte GmbH (An Acelity Company)
Kettenbach GmbH & Co. KG
Kramer MT GmbH & Co. KG
KRAUTH Invest GmbH & Co. KG
KREWI Medical Produkte GmbH
KUBIVENT GmbH

Leica Biosystems Deutschland GmbH
LEINA-WERKE GmbH
Licher MT GmbH
LightGuideOptics Germany GmbH
LivaNova Deutschland GmbH
Lohmann & Rauscher International GmbH & Co. KG
Ludwig Bertram GmbH

MagForce AG
Mainstay Medical GmbH
Mathys Orthopädie GmbH
medac Gesellschaft für klinische Spezialpräparate mbH
medi GmbH & Co. KG
Medi-Globe Technologies GmbH
medimex GmbH
Mediq Holding Deutschland GmbH
Medizintechnik & Sanitätshaus Harald Kröger GmbH
Medtronic GmbH
megro GmbH & Co. KG
Merete GmbH
MicroPort CRM GmbH
MicroPort Scientific GmbH
Miltenyi Biotec GmbH B. V. & Co. KG
Mohage – Mommsen Handelsgesellschaft mbH
Molecular Health GmbH
Mölnlycke Health Care GmbH



Diverse medtech professions: The industry employs over 210,000 people, ranging from development engineers and designers to production workers. (images: BVMed / Kurt Paulus)

NAWA Heilmittel GmbH
neoplas tools GmbH
Nestlé Health Science (Deutschland) GmbH
Nevro Germany GmbH
Nipro Diagnostics Germany GmbH
NOBAMED Paul Danz AG
noma-med GmbH
Novo Klinik-Service GmbH
Nutricia GmbH
NuVasive Germany GmbH

Okuvision GmbH
Oncare GmbH
Ontex Healthcare Deutschland GmbH
OPED GmbH
OptiMed Medizinische Instrumente GmbH
Oriplast Krayer GmbH
Otsuka Pharma GmbH
Ottobock SE & Co. KGaA

P. J. Dahlhausen & Co. GmbH
Pajunk Medical Produkte GmbH
PALL GmbH Medical
Paradigm Spine GmbH
Param GmbH
PAUL HARTMANN AG
Pedilay Care GmbH
PETER BREHM GmbH
pfm medical ag
PHADIMED Pharma-Medica Vertriebs-GmbH
Philips Volcano International
PMT Präzision-Medizin-Technik GmbH
POLYTECH Health & Aesthetics GmbH
Polytech-Domilens GmbH
PRECISIS AG
PubliCare GmbH
Pulmonx GmbH
PULSION Medical Systems SE

R. Cegla GmbH & Co. KG
RAUMEDIC AG
Raylytic GmbH
Rayner Surgical GmbH
recusana GmbH
rehaVital Gesundheitsservice GmbH
Ritex GmbH
RSR Reha-Service-Ring GmbH

S & V Technologies GmbH
Sanavita Pharmaceuticals GmbH
SANDER Chemisch-Pharmazeutische Fabrik GmbH
sangro medical service GmbH
SANIMED GmbH
Sanitätshaus Aktuell AG
Sanitop GmbH
Santen GmbH
Schülke & Mayr GmbH
SERAG-WIESSNER GmbH & Co. KG
servoprax GmbH
sfm medical devices GmbH
SIGNUS Medizintechnik GmbH
Sirtex Medical Europe GmbH
SMB Sanitätshaus Müller Betten GmbH & Co. KG
Smith & Nephew GmbH
Smiths Medical Deutschland GmbH
speziMED GmbH
Stryker GmbH & Co. KG
Sunrise Medical GmbH
SURGITENT GmbH
Symbios Deutschland GmbH
Syntellix AG
Systam SAS France / Systam DE-Verbindungsbüro

TapMed Medizintechnik Handels GmbH
Teleflex Medical GmbH
Teleon Surgical Vertriebs GmbH
Terumo Deutschland GmbH
The ROHO Group – ROHO International, Inc.
Thomas Hilfen für Körperbehinderte GmbH & Co. Medico KG
TK pharma trade Handelsgesellschaft mbH
TMH Medizinhandel GmbH & Co. KG
TRACOE medical GmbH
TRiCares GmbH
Tutogen Medical GmbH

ulrich GmbH & Co. KG
URGO GmbH
URSAPHARM Arzneimittel GmbH

Venner Medical (Deutschland) GmbH
VOSTRA GmbH
VYGON GmbH & Co. KG

W. L. Gore & Associates GmbH
W. Söhngen GmbH
Waldemar Link GmbH & Co. KG
Wellspect HealthCare (DENTSPLY IH GmbH)
WERO GmbH & Co. KG

Ypsomed GmbH

Zimmer Biomet Deutschland GmbH
ZOLL CMS GmbH

Picture credits
The pictures either originate from BVMed's own photoshoots (photographer: Kurt Paulus) or were taken from the BVMed image pool (*www.bvmed.de/bilder*). We would like to thank the BVMed member companies that provided photographs for the BVMed image pool. They are mentioned as the source in the individual image gallery.
Cover photo: Production of IV administration sets (image: B. Braun Melsungen AG)

BVMed – Our Services for You

The German Medical Technology Association, 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 durables and consumer goods sector.

- As a trade association, BVMed promotes and represents the combined interests of the medical technology industry and trade companies. In various working groups, sectoral interest groups, focus and project groups, the association offers its members a platform for a constructive dialog and exchange of views.
- BVMed represents the concerns of its member companies to policy makers and the public in general. Not only is this achieved by information and public relations work, but also by participation in the development of laws, guidelines, and standards.
- The experts of BVMed offer advice and training for the member companies with regard to all aspects of development, market access and the remuneration of medical devices, homecare services, or digital health applications.

BVMed is an active founding member of the European trade association for the medical technology industry MedTech Europe and works closely with the US association AdvaMed.

www.bvmed.de/bvmed-leistungen

How can your company join BVMed?

The terms and conditions for membership of BVMed are stated in article 3 of the BVMed statutes:
www.bvmed.de/satzung

Learn more:

HOW TO JOIN?
www.bvmed.de/mitglied-werden

HOW ARE THE MEMBERSHIP FEES CALCULATED?
www.bvmed.de/mitgliedsbeitrag

Please contact us.
We look forward to helping you!

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