

## BVMed Annual Report 2017/18

The Medical  
Technology Companies :  
[www.bvmed.de](http://www.bvmed.de)





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.

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**Publisher** BVMed—Bundesverband Medizintechnologie e.V.  
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Berlin, March 2018



Dr. Meinrad Lugan  
Chairman of the Board of BVMed

## Foreword

# Medical-technological Progress Must Reach Patients Faster

Dear Members,

people in Germany are living longer and longer. Researchers and developers in the medical technology industry work every day to ensure that people live longer lives and do so in better health.

Medical-technological progress helps society to master the challenges posed by demographic change. Medical-technological procedures play an important role in the fight against widespread diseases such as cancer, cardiovascular diseases, arthrosis, diabetes, or obesity.

In effect, medical-technological progress is the result of a large number of ongoing improvements of the procedures used and the devices applied, as well as a positive approach to new inventions. Only in this way will it be possible to offer patients the medical-technological progress they need on a timely basis.

The present developments such as increasing bureaucracy through the new Medical Device Regulation, the impending excessive demands on the Notified Bodies, or the long period of government formation in Germany make timely access to modern procedures, devices, and examination methods increasingly difficult for patients.

What is the current situation of the medtech industry in Germany?

The assessment of new methods using medical devices according to article 137 h of the Social Security Code V, which was introduced during the last legislative period, has turned into an obstacle that will slow down progress. The trial regulations based on article 137 c and e of the Social Security Code V have not proved useful in practice, either. The procedures will likely take between 8 and 10 years, which will benefit neither the patients nor the institutions making applications.

In Germany, we need an improved culture of progress that focuses more on the needs of patients and enables faster assessment procedures with a specific medtech methodology.

Also with regard to the current discussion about the improvement of care, medical technology can provide support. Many medical-technological procedures are able to relieve physicians and nursing staff from part of their burdens. Medtech procedures create the basis for shorter surgery times, shorter stays in hospital, and faster recovery times at the same time they contribute to better quality of life as well as more ambulatory examination and treatment methods.

What is important to us is that treatment methods that have previously been used in hospitals and are transferred to the ambulatory sector must receive an EBM number immediately so that they can be prescribed to patients and reimbursed.

With regard to the provision of medical technical aids, BVMed is working towards greater transparency and the effective control of the quality of the supply of medical technical aids by the health insurance funds.

A greater focus on a culture of progress in patient care in Germany with the help of new technical solutions, a favorable climate for medical-technological progress, and the faster transfer of research results can really improve healthcare.

In 2018, all partners in the healthcare market – especially physicians, researchers, businesses, and health insurance funds – should be committed to better cooperation and towards shaping health together.

Yours,

Dr. Meinrad Lugan  
Chairman of the Board of BVMed



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

## Market and Member Development

### Member development

For the time being (March 2018) 224 industrial and trading companies are members of BVMed. In 2017, six companies joined BVMed. In early 2018, another four joined as well, while six companies left BVMed. There were also four instances of mergers or acquisitions in 2017. Despite noticeable consolidation processes and increasing pressure on margins, BVMed's number of members is still remaining stable. A complete list of members can be found on pages 22 and 23 and at [www.bvmed.de/mitglieder](http://www.bvmed.de/mitglieder).

### Market development

The expected worldwide sales growth of the medical technology industry is at around 6 percent, according to the 2017 fall survey conducted by BVMed. This means that internationally operating medtech companies are growing significantly faster abroad than in Germany (up 2.8 percent). Despite continued price pressure, companies are investing more in their German production sites.

The most important results of the BVMed fall survey 2017 are:

1. The international sales of the medical-technological companies are still growing by almost 6 percent on average. With a sales growth rate of 2.8 percent, the development of the domestic market has declined significantly compared to the previous year. Within Germany, the companies' profits have declined due to sinking prices and higher costs.
2. The largest obstacles to the future development of the medical-technology industry, the companies say, are the increased requirements and the rising costs through the new EU Medical Device Regulation (MDR) as well as bottlenecks at the certifying Notified Bodies. As a result of the implementation of the MDR, two thirds of the companies fear that devices will be withdrawn from the market or not launched at all for economic reasons, which will negatively affect patient care.
3. What is especially relevant for the medtech companies with regard to healthcare politics is the acceleration of the medtech assessment procedures (49 percent), the active industry participation in G-BA processes, as well as greater international acceptance of studies.

4. The increasingly difficult framework has caused the medtech job engine to falter in Germany. Only 44 percent of the companies will create additional jobs this year (in the previous year: 66 percent), 17 percent will even have to cut jobs.
5. Only 39 percent of the medtech companies say that they are currently affected by digitization. The significant changes they expect concern electronic procurement processes, medical apps, and electronic invoicing.

### Key industry data

The medtech industry is an important factor for the economy and the labor market.

- > **Jobs:** The medical technology industry consists of around 1,250 businesses (considered are those with more than 20 employees in each business) that employ around 133,000 people in Germany. In addition, there are another 11,300 small businesses with almost 81,000 people. The medtech industry thus employs over 210,000 people in Germany.
- > **Medium-sized companies:** 93 per cent of all medical technology businesses have fewer than 250 employees. This shows that the medtech industry in Germany is predominantly still an SME industry.
- > **Revenue and export:** The total revenue of the manufacturing medical technology companies (considered are those with more than 20 employees) in Germany was at over 28 billion euros in 2016, according to the official economic statistics. The export rate was at around 65 percent.
- > **Growth market:** The exceptionally innovative medtech industry will continue to be a growth market due to the demographic development, medical-technological progress, and the dynamics of the emerging and developing markets. Experts estimate that the yearly growth rate will be between four and five percent.

In order to preserve the innovative capacity of the medtech industry, we must adapt our remuneration and assessment systems to the dynamics of our technologies so that patients will in future be able to benefit from medical progress without any delay.





BVMed discussing with Jens Spahn



State Secretary and patient commissioner  
Ingrid Fischbach at BVMed's Summer Reception



BVMed health policy talk with Maria Klein-Schmeink,  
Member of Parliament for the Green Party

## Healthcare Politics

### Focus on the provision of medical technical aids

By mid-2017, recent legislative proposals by the 18th legislative session in Berlin were almost completed. With regard to healthcare politics, this included the Heil- und Hilfsmittelversorgungsgesetz, HHVG, a law regulating the provision of therapeutic services and medical technical aids, which will have far-reaching effects on medical technical aids suppliers.

While the law improves the framework of supplies with medical technical aids for patients, it has also created problems regarding its implementation, which will necessitate a further HHVG law in the new legislative period. The additional law will affect tenders for medical technical aids with a high level of service that at present are still used by the health insurance funds. These tenders are against the declared will of the government. Also, the new so-called open-house contracts created by the health insurance funds violate the HHVG law.

BVMed continues to be in intensive dialog with the government's patient commissioner, the Ministry of Health, and the expert politicians who enabled the HHVG, as one of a few laws, to be developed and pushed on the initiative of parliament itself.

### Preparation of implant register

The implant register law was not implemented by the grand coalition during the last session as planned, which, however, is not due to a lack of will, but to the complexity of the legislation. Despite the federal elections, the experts in the Ministry of Health and the DIMDI continued their planning without interruption. All the involved groups – such as physicians, health insurance funds, and manufacturers – as well as the experiences with the existing registers were taken into account. The manufacturers advocate a mandatory implant register, as a learning system. The register ought to start with only a few product groups, such as joint replacements, cardiac pacemakers, and aortic valves.

### European politics: MDR

The European Medical Device Regulation, MDR, came into force in May 2017. It will become binding from 2020. The MDR poses significant challenges for the medtech industry in Germany, in particular for small and medium-

sized enterprises, SME. This is due to additional requirements for the manufacturers, for instance during clinical investigations. The transitional provisions of the MDR are extremely tight. A large number of implementing acts and delegated acts have not been passed so far. As yet, no Notified Bodies have been set up on the basis of the new law. The designation process is currently underway. Afterwards, a backlog in the recertification process is expected.

With the working-group for the implementation of the MDR, Nationaler Arbeitskreis zur Implementierung der MDR (NAKI), a committee has been set up in Germany that will voice the challenges created for German companies in Brussels. BVMed will continue its dialog with the European decision-makers in order to achieve a feasible implementation.

### Requirements of the medtech industry during the new legislative period

In politics, the past year in Germany was dominated by the federal elections and the difficult negotiations for the formation of a government. At rounds of talks, events, dialogs with decision-makers, and during the coalition negotiations, BVMed emphasized the needs of the medical technology industry during the new legislative period. These include greater transparency and the active involvement in the self-governing structure and the relevant committees, adequate remuneration of high-quality care with medical technologies in hospitals, the improved ambulatory provision of advanced medical devices, or the actual remuneration of effective hygiene measures for the prevention of infections.

Further requirements of the industry for the next years are the continuation of the government's high-tech strategy and the medical technology strategy process as well as the support of SMEs in research projects and clinical studies.

In order to achieve a better culture of progress in patient care with medical technologies, a greater attention to the medtech industry by research and economics politicians is particularly important.



Medical technologies are essential in terms of health and improve people's quality of life: Doctor-patient talk about hip joint replacement, remote adjustment of a cochlear hearing implant, drainage system in outpatient care, hand prosthesis

## Medtech Benefit Assessment and Trial Regulation

### BVMed advocates individual assessment method for medical technologies

The benefit assessment of advanced medical technologies is appropriate and important. We need suitable methods that take better account of the specific characteristics of medical technologies. The government should place greater emphasis on the significance of registers and healthcare research in the assessment of medical devices (in terms of "real world evidence").

After the legal requirements for benefit assessments have recently been tightened, the new instruments will need to prove their validity. The manufacturers need planning certainty. Therefore, there will be no further tightening of benefit assessments during the next legislative period.

### Assessment procedures for medtech methods

In 2017, the G-BA committee made the initial decisions on the new assessment procedure for new examination and treatment methods, NUB, for high-class medical devices according to article 137 h of the Social Security Code V. There are three conditions for the application of the new assessment procedure:

1. The hospital making the application is the first one to apply to the German Institute for Hospital Reimbursement, Institut für das Entgeltsystem im Krankenhaus (InEK), for additional remuneration.
2. Regarding its utilization, the method must essentially be based on a high-class medical device and a new theoretical-scientific concept.
3. The method must be characterized by its especially invasive nature.

Before making the application, the hospital must consult with the manufacturer of the medical device and coordinate the NUB application and the data to be submitted. The G-BA will decide about the benefit, potential or harm of the method on the basis of the data provided and the subsequent statement procedure.

The G-BA assessment found in only two of eight procedures a potential treatment alternative. The other procedures were assessed according to article 137 c of the Social Security Code V and, if necessary, excluded from the services provided by the Statutory Health Insurance, SHI.

### Definition of "potential" interpreted too restrictively

The initial G-BA decisions on the assessment of methods according to article 137 h of the Social Security Code V confirm that the new concept of "potential" contained in the law is interpreted too restrictively. In this way the innovation-friendly principle of "permission subject to prohibition" is in fact eroded in hospitals.

In the first year, the opportunity to receive advice on the new assessment procedures was used reluctantly. With regard to the method assessment for medical devices the obligation to involve the manufacturers in the application and assessment procedure must be ensured.

The companies must be able to calculate the costs of the benefit assessment in advance.

### Trial regulation

For the manufacturers of medical devices, the trial regulation according to article 137 e of the Social Security Code V, introduced in 2012, increasingly proves to be an obstacle for the implementation of new examination and treatment methods that are primarily based on the use of a medical device.

The G-BA examines the benefit and potential of a method based on the currently available knowledge. If the G-BA committee finds that the benefit of a method has not been proved sufficiently, but there is potential for a successful treatment alternative, it can arrange for the method to be tested during a trial. The resulting research costs of the study must usually be borne fully by the manufacturer.

In fact, only few decisions have been made since the introduction of the trial regulation. The application and assessment procedure is very difficult and time-consuming. The funding regulation has been found to be impracticable.

### Procedures must be accelerated

The Federal Ministry of Health has asked the G-BA to examine how the procedural steps can be amended in order to identify further opportunities for improvement. This concerns especially the duration of the procedure, cost sharing by the manufacturers, and methodological requirements for conducting studies.



Intensive care unit (including cover picture): The intensive care unit of a hospital provides state-of-the-art technology for the treatment of severely ill patients

## Hospitals and DRGs

### Reduction of material costs

The reduction of material costs calculated in case fees that started in 2017 will be continued in 2018. In the DRG catalog, the material costs of all case fees are reduced by around 7 percent without any differentiation. The staff and infrastructure cost components are raised by around 1.9 percent. The base rate leverage for these costs – in relation to the federal base rate for 2018 – is 16 percent above the reference value and 18.2 percent above the correction value after the reduction of the material costs. The German Hospital Federation, Deutsche Krankenhausgesellschaft, estimates that within the DRG system there is a restructuring potential of over one billion euros.

The consequences with regard to medical devices are already noticeable. In hospital procurement, the price of goods is more important than any other considerations. The price pressure is passed on to the industry. The shift in the cost evaluation particularly affects specialized high-performance centers and complex treatment procedures.

Innovative, high-quality hospital care needs medical devices that are adequately remunerated. Regulatory interferences in the DRG system must be reversed. The medtech companies require the German Institute for Hospital Reimbursement, InEK, to carry out a transparent, plausible, and verifiable cost calculation. In the political debate, staff costs, especially in nursing care, are regarded as a positive aspect while high material costs are considered as a negative factor. However, this view misjudges the fact that medical devices create the basis for shorter surgery times, shorter stays in hospital, and quicker recovery times at the same time as contributing to better quality of life.

### Reduction of remuneration for economically motivated increases of case numbers

The hospital reform ought to benefit the patients. It is supposed to support the specialization of hospitals and the quality of care. Precisely the opposite is true. In particular, specialized expert hospitals for orthopedics and trauma surgery are severely affected by this recent DRG reduction.

The DRG hospital case fee catalog 2018 provides for a number of cuts. Hospitals receive, for instance, up to 7 percent less remuneration for a simple hip total endoprosthesis. The proportional reduction of the relative weights, however, concerns all costs. Therefore, the reduction of the valuation ratio for the DRG catalog 2018 will be applied to the DRG catalog 2018 with a proportional rate of 60 percent. This means a reduction of 7 percent. From the point of view of the hospitals, this restructuring can only be compensated by shorter stays in hospital, cheaper implants, or lower material costs, which will mean poorer patient care. The political decision-makers must change course if they do not want to thwart the desired quality-oriented remuneration.

### Quantity control through fixed-cost degression and quality-oriented remuneration

The fixed-cost degression deduction is a measure used by the hospitals to avoid positive economies of scale in the provision of additional services. The fixed-cost degression deduction, which has had to be applied since 2017, amounts to between at least 35 percent and 50 percent for a period of three years. It replaces the discount for additional services. Ambulatory hospital services, medical devices, additional remunerations, already reduced case fees (DRGs), as well as DRGs with a share of material costs of more than two thirds are exempt from the fixed-cost degression deduction. An in-depth analysis of the DRGs that are actually affected is advisable. The current design of the fixed-cost degression deduction carries a risk of inducing undesirable effects when services with high labor costs are offset by unjustified reductions in material costs.

An appropriate excess quantity regulation must also take into account the rising life expectancy and the demographic development. The instrument of quality contracts must be extended. In general, with regard to hospital services, existing approaches to reimbursement based on differences of quality must become more important and be consistently focused on outcome quality. The federal government should create incentives for the federal states if they fulfill their investment obligations in the hospital sectors to an above-average degree.





Care with medical technical aids and surgical dressings: Wound care, incontinence care, artificial nourishment, and ostomy care

## Medical Technical Aids and Wound Dressings

### Implementation of the HHVG law with regard to medical technical aids

In April 2017, the Heil- und Hilfsmittelversorgungsgesetz, HHVG, the law regulating the provision of therapeutic services and medical technical aids, came into force. Even after this date, tenders and types of contracts that according to BVMed and the political decision-makers are not permitted were issued for certain service fields. Despite the increased number of tenders, framework agreements are still the first contract option for most cost-bearers. Since the HHVG came into force, all the groups involved have been concerned with the implementation of the law. The focus of BVMed continues to be on assuring and strengthening the quality of the supply of medical technical aids.

### Tenders

The initial experiences show that the new regulations for the use of tenders have not been implemented or only applied insufficiently by the cost-bearers yet. For care areas that require a high level of service, such as ostomy, draining incontinence help, and decubitus care, the health insurance funds issue tenders contrary to the HHVG law. Contrary to the law, quality criteria are not included in the weighting for the award of tenders, either. In order to safeguard the quality of care, especially with regard to tenders for medical technical aids, BVMed advocates the consistent implementation of the new regulations of the HHVG law.

### Monitoring of contracts

The Federal Association of the Statutory Health Insurance Funds, GKV-Spitzenverband, has developed the framework recommendations according to article 127, section 5b of the Social Security Code V in due time. From the point of view of BVMed, these are inadequate, though, to assess the actual quality of care and thus correct any quality deficits. The same applies to the depth of regulation in the HHVG with regard to this aspect. BVMed sees need for action here and advocates obligatory requirements for contract control that are identical in all federal states. In this way, it will be possible to record the results on a comparable basis and to establish competition for quality between the health insurance funds.

### Register of medical technical aids

BVMed has presented its suggestions regarding the necessary details for the design of the code of procedure to the Federal Association of the Statutory Health Insurance Funds early on. In order to ensure objective and quality-oriented updates, binding definitions and transparency are required for the procedures and decision-making processes. This applies e. g. with regard to new types of medical technical aids that might be connected to a new method.

### Framework recommendations

During the rounds of negotiation with the cost-bearers, BVMed acted as one of the driving forces and the coordinator of the associations of medical technical aids providers in order to achieve far-reaching regulations for less bureaucracy. It has only been possible to reach agreement on a few points. Therefore, in 2018, an arbitrator will decide on the contentious points to be regulated. BVMed will play an active role during the arbitration proceedings, too.

### Implementation of the HHVG law with regard to wound dressings

The HHVG law provides a legal definition of what constitutes a wound dressing that encompasses all “conventional” dressings. The G-BA committee implemented the law in a regulation that differentiates “conventional” dressings and other products for the treatment of wounds, with the draft regulation being presented in November 2017. BVMed has developed an expert statement on this matter.

If the basic criteria for the differentiation and the elements of the procedure are not amended in the regulation, BVMed considers this a clear contradiction of the law’s intention. Many wound dressings that have been accepted and established for decades, such as antimicrobial dressings or gels, would then – after the end of a one-year transitional period – not be remunerated by the Statutory Health Insurance without an additional assessment procedure by the G-BA. Therefore, BVMed continues to advocate the modern and phase-specific treatment of wounds and thus the correct implementation of the intention of the law.





Homecare companies care for patients with medical technical aids, enteral nutrition, and surgical dressings – at home and in nursing homes.

## Homecare

The present continuing skills shortage and the aging population effectuate that caring for people in their own homes is becoming more and more important. To this end, homecare companies offer a solution. Homecare means that patients receive medical technical aids, wound dressings, or medical nutrition together with any relevant service by specialist providers at home or in nursing and retirement homes.

### Services are an essential part of homecare

Through the Heil- und Hilfsmittelversorgungsgesetz, HHVG, the law regulating the provision of therapeutic services and medical technical aids, the importance of services as an inseparable part of the supply of medical technical aids and homecare has been officially recognized for the first time. It has expanded the entitlement of patients to use the service that is part of the medical technical aid. Whether a type of care can be issued to tender will now depend, among other things, on the level of service required for the care provision. Tenders in areas of care that require a high level of service are inappropriate because they may jeopardize the quality of care.

### Competition for quality, not for price

Despite the law regulating the provision of therapeutic services and medical technical aids, HHVG, price reductions for a wide range of medical technical aids continued in 2017. The HHVG law intended to strengthen the quality of the provision of medical technical aids and homecare. The act is also meant to counteract the price competition dominating the market. Still, all too often it is the price and not the quality criteria, which are the focus of negotiations. Tenders continue to be an important instrument, even though, generally, they are inappropriate, and therefore inadmissible, in the homecare areas of care.

A survey conducted by the BVMed “Quality of Life” initiative ([www.faktor-lebensqualitaet.de](http://www.faktor-lebensqualitaet.de)) among patients in the sensitive areas of ostomy and draining incontinence care confirms that tenders pose a threat to the quality of care. The initiative with its active press and public relations work supports a ban on tenders in these areas of care.

### Awareness of homecare

In order to improve awareness of homecare and the importance of homecare companies within the care process, BVMed organized the 4th Homecare Management Congress. More than 160 representatives of the providers of homecare and medical technical aids as well as the cost-bearers and physicians discussed the requirements for the implementation of the HHVG law. In addition, BVMed conducts trainings for health insurance fund employees in order to improve their awareness of the specific quality requirements in homecare therapies.

### “Open house” procedure

Some cost-bearers interpreted a court decision by the Dusseldorf Higher Regional Court to mean that with regard to medical technical aids, apart from tenders, only so-called “open-house” procedures are permissible. Due to the special legislative regulations in article 127, section 2 of the Social Security Code V, which expressly provide for the option of contract negotiations, the German Federal Social Insurance Authority, the Federal Ministry of Health, and the Research Services of the German Parliament declared this inadmissible in summer 2017. A number of health insurance funds carried out open-house procedures nevertheless. A legal clarification of this matter will have to take place in the Social Courts.

### Discharge management

After the patient entitlement to hospital discharge management has been strengthened by law, the German Hospital Federation, the National Association of Statutory Health Insurance Physicians, and the Federal Association of the Statutory Health Insurance Funds have settled the details in a framework agreement. Nevertheless, with regard to the practical application, the relevant institutions, especially the hospitals, are still uncertain how the requirements are to be implemented correctly and how ambulatory care with medical technical aids after hospital treatments should be organized. BVMed has therefore published an FAQ catalog in order to provide advice to the hospitals about the key issues regarding the supply of medical technical aids during hospital discharge management ([www.bvmed.de/faq-entlassmanagement](http://www.bvmed.de/faq-entlassmanagement)).



Education, research, manufacturing, and quality assurance in medtech companies focus on one goal: helping patients.

## Medical Devices Law

New EU Medical Device Regulation has come into effect. After long and difficult wrangling of the three EU institutions involved, Commission, Parliament, and Council, the new EU Regulation 2017/745 on Medical Devices – Medical Device Regulation, MDR – came into force on May 25, 2017. The initial proposal had been announced on September 26, 2012. The three-year countdown until the application date of the MDR on May 26, 2020, is now running.

The MDR is a basic legal act and on 175 pages of the EU Official Journal it lists 101 recitals, 123 articles, and 17 annexes. The new legal text is, therefore, significantly longer than the former EU directives 90/385/EEC and 93/42/EEC.

Many details concerning the application of the MDR, for instance with regard to the functioning of the extended European database “Eudamed” including UDI codes, are to be regulated by the enactment of at least 8 and at most 43 further (delegated and implementing) acts, including Common Specifications.

Certain issues, however, will remain unregulated, among them the inadequate only three-year long transitional period for the renewed certification on the basis of the new law until the deadline May 26, 2020. It seems impossible that this tight time schedule can be met given the short period of 18 months for the designation procedure of the Notified Bodies under the new law, which only started in November 2017, and the rush of a large number of manufacturers to a limited number of Notified Bodies which can be expected to occur all at once in spring 2019. Even the continuation of the old certificates for a limited period of time will hardly be able to compensate for the expected bottleneck. BVMed demands the suitable and appropriate handling of the transition and sell-off periods by the competent authorities. Any overregulation caused by a too narrow interpretation of the new provisions should be avoided especially during the initial phase.

### Federal Ministry of Health: NAKI recommendations

In early 2017, the Federal Ministry of Health set up the working group for the implementation of the MDR and IVDR, NAKI, in order to develop suggestions for the implementation of the MDR requirements in cooperation

with German industry representatives and public officials. The proposals are to be presented to the EU Commission. The NAKI group will continue its work in 2018 for an indefinite period. The initial results of the NAKI sub-groups have been published by the Federal Ministry of Health on its website [www.bundesgesundheitsministerium.de/naki](http://www.bundesgesundheitsministerium.de/naki).

### EU Commission and CAMD: FAQs

So far, the EU Commission has shied away from amending the MDR in order to improve the shortcomings that have been identified. Instead, “interpretative guidelines” are to be used as a support in the hope that these will be generally accepted and not be challenged in court by competitors.

Therefore, the EU Commission has begun – with the help of an EU working group consisting of representatives of the relevant authorities in the member states, called “Competent Authorities for Medical Devices”, CAMD – to draw up catalogs of questions and answers to assist with the interpretation of the MDR requirements. The first catalog of this type relates to the interpretation of the transitional provisions and mostly follows the recommendations made by NAKI or the Federal Ministry of Health. Further interpretation guides will follow for the issues of labeling, vigilance, clinical investigations, and classification.

### National law

In 2017, the Medical Devices Law (Medizinproduktegesetz, MPG), the Medical Devices Operator Ordinance (Medizinprodukte-Betreiberverordnung, MPBetreibV), and the Medical Devices Safety Plan Regulation (Medizinprodukte-Sicherheitsplanverordnung, MPSV) were amended. The Medical Devices Operator Ordinance was amended extensively, which has in fact resulted in a revision of the law. At present, it is still uncertain which national acts will continue to apply after the implementation date of the MDR.

It is expected that the Medical Devices Law will continue to exist in an abbreviated version and contain references to the MDR.



Safety devices to avoid needle stick injuries

## Patient, Occupational and Environmental Safety

**Protection of patients: hygiene and medical devices**

During their first meeting in May 2017 in Berlin, the health ministers of the group of 20 leading industrialized countries and emerging economies (G20) stated that infectious diseases can have severe impacts in a globally connected world. They stressed that global cooperation was urgently required in order to being able to fight effectively against the spread of infectious diseases and the resistance to antibiotics. Germany plays a leading role in the fight against infections. The prevention of nosocomial infections works at a high level thanks to the existence of institutions such as the Commission for Hospital Hygiene and Infection Prevention (Kommission für Krankenhaushygiene und Infektionsprävention, KRINKO) and the German strategy against antibiotics resistance (Deutsche Antibiotika-Resistenzstrategie, DART 2020).

For 2017, it can already be seen that the number of notifiable MRSA infections has decreased. Therefore, BVMed advocates an approach that, apart from the still relevant issue of multi-resistant pathogens, focuses on the significant industry potential by asking: "Where can medical technology contribute to the prevention of hospital infections?"

The most important instrument for raising awareness of this matter is the website "Infektionen vermeiden. Bewusst handeln" ("Avoiding infections – acting sensibly") at [www.krankenhausinfektionen.info](http://www.krankenhausinfektionen.info) that offers comprehensive information and relevant graphics for teachers and students. Another important platform of the hygiene initiative is the Hygiene Forum of BVMed, which takes place every year and is in strong demand.

### Reprocessing of medical devices

A practical contribution towards preventing specific cases of hospital infections is the correct handling of single-use medical devices. The new EU Medical Device Regulation, MDR, contains a number of requirements aimed at ensuring patient safety during the reprocessing of single-use devices. However, it is up to the EU member states to allow exceptions with regard to the reprocessing by medical institutions. In these cases, the requirements of the relevant "Common Specifications" must be fulfilled. In its comment, BVMed demanded that medical devices whose reprocessing cannot be reliably ensured must generally be exempt from reprocessing.

### Employee and nursing staff protection: work-related accidents with potentially infectious materials

Risk of infection and hygiene also play an important role in health and safety at work when medical devices are handled. The Technical Rule for Biological Agents TRBA 250 protects medical staff such as physicians and nurses by making the use of safety devices mandatory if there is a risk of injury from sharp medical devices. In hospitals, the rule is generally being applied satisfactorily. In physicians' surgeries, care homes, or at home, no consistent remuneration for safety devices is ensured by the health insurance funds so that their use is often dispensed with. BVMed aims to ensure that the protection of the users does not depend on their place of work, and it advocates for a uniform remuneration of the devices. Not only medical staff but also employees of medical technology companies, e.g. field staff, are at risk of work-related accidents with a risk of infection. Therefore, BVMed will in future provide an information package on accidents with potentially infectious materials as part of its health and safety information.

### Environmental protection in the medtech industry

Apart from the increasingly complex ban and restrictions of substances as well as reporting requirements contained in the chemicals Regulation REACH and the RoHS Directive for medical devices there will in future be the requirements of the EU Medical Device Regulation, MDR, too. There will be labeling and information requirements that still need interpretation for the following medical devices: 1. those that touch the human body; 2. that are used for the transport or storage of substances which are introduced into the human body or extracted out of it; 3. and that contain carcinogenic, mutagenic, or toxic substances (CMR substances) of the category 1A or 1B; 4. or hormonally active substances (endocrine disruptors). Former exceptions regarding the use of substances in medical devices, which were based on the benefit-risk assessment during the production of a medical device stipulated in the Medical Devices Law, will gradually be replaced by the regulations in the three-part package REACH, RoHS, and MDR.





BVMed's yearly press conference on the situation of the medtech industry and the results of the BVMed fall survey

## Communications and Media Projects

### “Translating technology into life”

The stories of patients, users, or developers have great communicative power for the medical technology companies, the experts taking part in the 2017 Medtech Communication Conference stressed. BVMed hosted the conference for the thirteenth time already. “People like you and me” who others can identify with enjoy a particularly high level of trust. Moreover, the technical experts of the companies enjoy considerable credibility. The most authentic messages are patient stories. They can educate, build trust and identification, but also create the impulse to ask questions. It is the person who has to be at the center of the story, the product only plays the supporting role. This is also the concept behind the “Body Pride” campaign of BVMed with its motto “every human being is unique.” The companies need to “translate technology into life,” as one of the experts said during the conference.

### “Measuring by the human standard”

Providing information about the importance and value of medical technologies is an important task of BVMed: 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” (“Measuring by the Human Standard. Medical Technology”; [www.massstab-mensch.de](http://www.massstab-mensch.de)), which was started in 2010. With its sophisticated aesthetics, large posters, and unusual magazines the campaign is breaking new ground in the medtech industry.

### Patients showing “Body Pride”

The industry campaign has been running for three years with a series of themes called “Körperstolz” (“Body Pride”; [www.bvmed.de/koerperstolz](http://www.bvmed.de/koerperstolz)). They portray patients with chronic diseases who live their lives to the fullest. The campaign currently focuses on nine advertising motifs – ostomy, incontinence, artificial nourishment, diabetes, tracheotomy / laryngectomy, dialysis, lymphedema after breast cancer, heart diseases, and shoulder joint replacement –, as well as in-depth interviews with patients and video clips. In 2018, the care areas of heart valve diseases and joint arthrosis will be added. 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.”

### 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](http://www.aktion-meditech.de)) – always working closely together with physicians and patient groups. BVMed's website ([www.bvmed.de](http://www.bvmed.de)) also offers clearly structured information about medical-technological solutions for various diseases, as well as patient information films.

### Media activities

BVMed is continuously addressing and working with the media. Thus, BVMed was able to assure that over 3,800 articles mentioned the association in various print and online publications in 2017, reaching over 150 million readers. The weekly BVMed newsletter with more than 8,000 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, guest articles, and industry reports in German and English.

### Social media and medical technology

Social networks have become an important element of the communication activities of the medical technology industry. BVMed makes use of the opportunities that social networks offer, e.g. via its own Twitter channel ([www.twitter.com/bvmed](https://twitter.com/bvmed)) with more than 2,300 followers as well as several Facebook pages displaying technological and career topics. In addition, BVMed provides short news items via a WhatsApp news service ([www.bvmed.de/whatsapp](http://www.bvmed.de/whatsapp)).





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

## 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 of BVMed and the management team in this particular field.

A complete list of BVMed's groups can be found at [www.bvmed.de/arbeitsgremien](http://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 an initiative consisting of BVMed member companies and hospital purchasing groups, and 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, and electronic invoicing. Other focal topics of AKE are the UDI (Unique Device Identification), logistics in the healthcare system, and cyber security.

#### Working group “Environment, Health and Safety” (AKEHS)

AKEHS is concerned with the issues of environmental protection, health, and safety at work, which are often connected to each other. The project group “Occupational health and safety for employees of medical-technology

companies” (AGAG) deals with the requirements and practical ways of protecting the employees working in distribution, service, and application support and who are thus exposed to a higher risk of infection. After presenting a comprehensive information package about how to handle medical devices returns, the project group presented recommendations on accidents with potentially infectious materials, including an emergency information sheet, in the reporting year. The project group “Product properties, design” is concerned with the comprehensive and continuously growing legal provisions, proposed bans, and restrictions concerning the use of substances. It is working towards a more appropriate assessment of medical and environmental goals. The focus of the project group on recycling management is the Packaging Act.

#### 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. This includes legal matters, e.g. with regard to the rules for submitting tenders. Together with the relevant purchasing organizations, it discusses market requirements and process optimization during the buying process. Another focus is on the logistic processes between the suppliers, service providers, and hospitals. In addition, AK KHM closely cooperates with AKE, e.g. on the development and design of the recommendation on Sales Reports, the electronic transfer of sales data.

#### Working group “Legal Affairs” (AKR)

The members of AKR – in-house legal advisers – and the external lawyers of the associated “Network Medical Devices Law” answer questions concerning legal matters from the BVMed working committees. To this end, AKR has formed 16 sub-working and project groups. AKR mostly deals with medical devices law, compliance, product liability, and data protection on a national and European level. A major issue was the new EU General Data Protection Regulation, which will apply from May 25, 2018. AKR also cooperates with the Legal Affairs Committee, LAC, of the European medical technology



Eye surgery: Modern procedures for defective vision and cataract



Cataract surgery

trade association MedTech Europe, and the medical devices law research center at the University of Augsburg. AKR provides member companies with legal assistance via events, journal articles, and guidelines, most recently about data protection with regard to medical devices. The members and the network of AKR also update the BVMed loose-leaf commentary on the Medical Devices Law “WiKo – Medizinprodukterecht,” which will be published in the second quarter of 2018 in two volumes in its 18th edition. From 2018, it will also contain comments regarding the EU Medical Device Regulation MDR. The commentary is accompanied by a blog ([www.wiko-mpg.de](http://www.wiko-mpg.de)), which is updated regularly. The blog is an online law database, which is currently listing nearly 500 court decisions about medical devices. Two years ago, the blog was complemented by an electronic newsletter ([www.gesr.de/wiko-newsletter.htm](http://www.gesr.de/wiko-newsletter.htm)), which provides comments on the latest court decisions listed in the blog.

### **Working group “Regulatory and Public Affairs” (AKRP)**

AKRP answers questions concerning regulatory matters from the BVMed working committees. To this end, AKRP has formed eleven sub-working and project groups. In 2017, AKRP put the focus on interpreting the EU Medical Device Regulation, MDR. To this end, it closely cooperated with the working-group for the implementation of the MDR and IVDR, Nationaler Arbeitskreis zur Implementierung der MDR und IVDR (NAKI), of the Federal Ministry of Health and sent representatives to the seven sub-groups of NAKI. Further, AKRP closely cooperated with the Regulatory Affairs Committee of MedTech Europe, whilst an AKRP member is chairing the committee. On its own and within the national Medical Devices Law Working Group of the Associations of the MedTech Industry (AG MPG), AKRP develops regulatory statements and information flyers and hosts regular events on the MDR. In addition, AKRP together with AKR edits the BVMed information sequence “Medizinprodukterecht” (Medical Devices Law), which by now consists of twelve guidelines on different regulatory and legal matters.

### **Healthcare Compliance Committee (HCCC)**

The key issue of HCCC continued to be the Anti-bribery in Healthcare Act passed in 2016 with its new articles 299 a and b of the Criminal Code. The Healthcare Compliance Committee handles inquiries from companies about the interpretation and implementation of the law. Many events and training courses ensure that companies, medical facilities, and physicians are able to continue to work together on a legally secure basis as well as to develop medical devices and organize further training courses on their own.

The Medical Device Code (“Kodex Medizinprodukte”) was supplemented by the following addendum on January 1, 2018: “Financial support of individual healthcare professionals [HCPs] of the participation in training or educational events or medical conferences (direct sponsorship), which has not been prohibited in Germany yet, is being discussed as follows: To what extent may or shall the direct sponsorship of science and healthcare professionals, healthcare providers, and any other experts / specialists be continued by manufacturers and distributors in the future?”

The primary goal for all professionals attached to the healthcare business is to avoid being suspected of corruption. In order to minimize the risk with direct medtech conference sponsoring of HCPs entirely, companies have to cease any such support of passive participation in conferences organized by third parties.

### **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” ([www.initiativegrauerstar.de](http://www.initiativegrauerstar.de)), FBA explains the additional benefits of innovative intraocular lenses.

#### **Sectoral interest group “Blood” (FB Blut)**

The members of FB Blut are the global suppliers of medical devices for transfusion. The sectoral interest group was newly constituted during the reporting year with the aim of handling important issues regarding blood donations.



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



Endoprosthetics: Doctor-patient talk about hip and knee joint replacements

The group's major concerns are the safety of blood donations and the reliable supply of blood products as well as the relevant German and European frameworks. In future, FB Blut will also contribute its expertise to the blood working group of the Federal Ministry of Health.

### **Sectoral interest group “Diabetes” (FBD)**

With its active press and public relations work FBD aims to ensure that innovative diabetes technologies and therapies are available to all those who need them on a timely basis. One of the main concerns of FBD was the update of the register of medical technical aids.

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

FB DRG accompanies the further development of the hospital financing system, focusing especially 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 and draws up statements on legislative processes. In addition, the sectoral interest group devises informational events and develops the guideline on the implementation of the Hospital Structure Law. It is in dialog with the hospital federations, the health insurance funds, and the hospital market associations.

### **Sectoral interest group “Endoprosthetics – Implants” (FBEI)**

The most important issue that FBEI deals with is the value of the provision of hip and knee replacements. Joint replacements are among the most successful types of surgery, and FBEI aims to highlight this fact through more public relations work. In order to achieve this aim it plans to work more closely with physicians and medical societies in future. The Endoprostheses Register Germany, EPRD, is a good example of this kind of cooperation in terms of an arthroplasty registry. It was jointly developed by the medical societies, the health insurance funds, and the manufacturers. At the end of 2017, more than 751 hospitals had registered for participation in the EPRD. In total, the register has recorded more than 730,000 operations over a period of around five years, 292,000 of those in 2017. Meanwhile, in some areas, the first reliable evaluations have been presented. The EPRD is considered

a “blueprint” for a mandatory official implant register, which is to be attached to the German Institute of Medical Documentation and Information, DIMDI. A law to this effect has been planned for the next legislative period. The EPRD has committed itself to support DIMDI with planning and establishing the official register. The register data that have been collected so far will later be transferred to the official register. The modalities and data protection issues still need to be resolved.

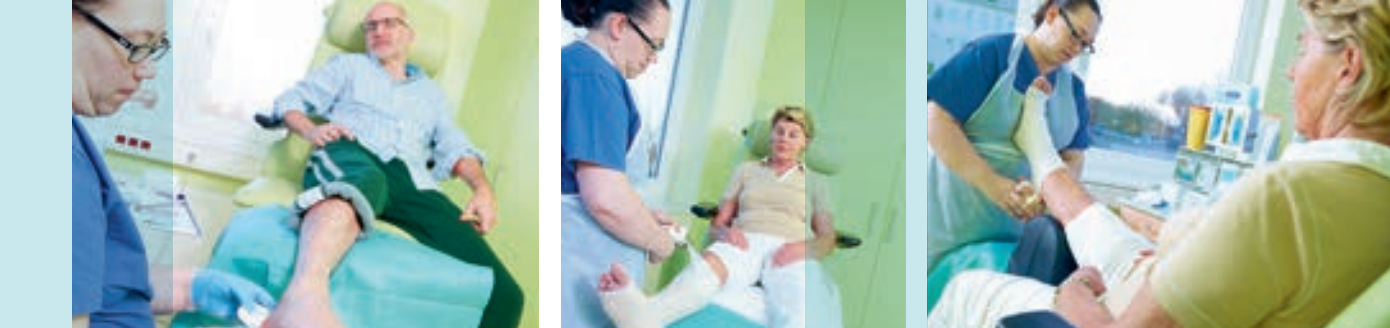
### **Sectoral interest group “First-Aid Material” (FBEH)**

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 adjustment of first-aid materials according to the latest findings of modern emergency and disaster medicine. Within FBEH, the working group “Communication” (AGK) provides information about the importance and benefits of first-aid kits in cars and motorcycles and about the duties of the users through its continuous press work.

### **Sectoral interest group “Homecare” (FBHC)**

FBHC accompanied the legislative process and the implementation of the law regulating the provision of therapeutic services and medical technical aids, HHVG. The key issue is the applicability of tenders in the medical technical devices sector. Other important matters were open-house procedures with regard to medical technical aids, new regulations regarding hospital discharge management, as well as the Medical Devices Operator Ordinance. One of the key goals of FBHC is stressing and strengthening the importance and role of homecare in ambulatory care. Therefore, FBHC played a prominent role in organizing the fourth Homecare Management Congress as well as the BVMed trade fair participations at REHAB, MEDCARE, and REHACARE. The activities of FBHC are accompanied by its active public relations work and the website [www.perspektive-homecare.de](http://www.perspektive-homecare.de).





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.

### **Sectoral interest group “Cardiac Medical Devices” (FBKMP)**

FBKMP is concerned with medical technologies that are used in cardiovascular treatments and examinations. Working groups and projects within the sectoral interest group exist for active implants (cardiac pacemakers, ICD-CRT systems, telecardiology), interventional technologies (stents), as well as interventions through heart surgery, such as prosthetic heart valve technologies, cardio-pulmonary systems, or artificial heart technologies. The key issues are the inclusion of devices into service catalogs (EBM and DRG) as well as quality assurance tools. An exhibitors' advisory council is in dialog with the medical societies and professional associations in terms of congress and further training activities.

### **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 the contact point for the public, authorities, and other institutions for issues concerning the use of condoms.

### **Sectoral interest group “Artificial Nourishment” (FBKE)**

FBKE developed quality criteria for the supply of medical technical aids for the application of enteral and tube feed nutrition and presented these during the discussions about the update of product group 03 of the register of medical technical aids. FBKE also developed quality criteria for the supply of the relevant sip and tube feed as well as special products. 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 training event for health insurance fund employees in 2017. During its activities, FBKE is in close contact with the “Diätverband,” the association of the manufacturers of food for special dietary use.

### **Sectoral interest group “Benefits Law for Care Providers” (FBLL)**

FBLL supports BVMed in drawing up statements and analyzing legislative processes and court decisions with regard to social and procurement law. In 2017, the focus was on aspects of the implementation of the law regulating the provision of therapeutic services and medical technical aids, HHVG, such as the code of procedure for the register of medical technical aids, and contract controlling. In addition, FBLL was concerned with the applicability of tenders with regard to medical technical aids. According to the opinion of FBLL, open-house procedures are inadmissible. The sectoral interest group developed an interpretation guide for a court decision by the Dusseldorf Higher Regional Court, which was often wrongly interpreted. FBLL also compiled an FAQ catalog for medical technical aids in order to address the uncertainties of those involved with implementing the new regulation for hospital discharge management.

### **Sectoral interest group “Market Access” (FB MA)**

FB MA combines the activities for the timely market launch of innovative medical devices and their representation in the service catalogs. This involves adequate reimbursement levels and overcoming access barriers to remuneration and reimbursement. Other focal topics of FB MA are methodological approaches to benefit assessment and healthcare research. In order to inform the manufacturers about the benefit assessment procedures, FB MA prepares guidelines, develops seminars, and holds talks with the partners and institutions in the healthcare system.

### **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.

### **Sectoral interest group “Modern Wound Care” (FBMW)**

The focus of FBMW in 2017 was on the legal definition of what constitutes a wound dressing in article 31, section 1a of the Social Security Code V, based on the law regulat-





E-Health: Blood sugar monitoring and doctor consultation via iPhone app

ing the provision of therapeutic services and medical technical aids, HHVG. The activities of the sectoral interest group aim to ensure the phase-specific treatment of chronic wounds. To this end, FBMW prepared statements on the draft law as well as on the implementation concept for the differentiation guideline by the G-BA committee. In addition, FBMW continued its public relations work ([www.info-wundversorgung.de](http://www.info-wundversorgung.de)). 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. The best practice guidelines project group will publish its results on the issue of local antimicrobial treatment of wounds in 2018 and present them at the upcoming Wound Congresses.

#### **Sectoral interest group “Needlestick Prevention” (FBNSP)**

FBNSP is the interest group of the manufacturers of safety devices for the prevention of sharps injuries. According to the Technical Rule for Biological Agents TRBA 250 “Biological Agents in Healthcare and Welfare Facilities” safety devices must be used if there is a risk of infection. In ambulatory care, especially when patients are cared for at home or in care homes, there are still deficits in remuneration by the health insurance funds. The sectoral interest group advocates a uniformly high protection level for all those who are at risk of sharps injuries, skilled professionals as well as private caregivers.

#### **Sectoral interest group “Nosocomial Infections” (FBNI)**

FBNI continuously provides healthcare professionals with information about how to avoid hospital infections. The website [www.krankenhausinfektionen.info](http://www.krankenhausinfektionen.info) (“Infektionen vermeiden – bewusst handeln”; “Avoiding infections – acting sensibly”) contains clearly comprehensible graphics about the major ways of infections and their respective prevention. Most recently, a film explaining hospital infections and graphics about the development of multi-resistant pathogens were added. The Hygiene Forum of BVMed, which takes place every year, presents up-to-date and practical contributions by renowned experts. There is strong demand for attendance especially among nursing staff and hygiene specialist staff.

#### **Sectoral interest group “Peripheral Vascular Medicine” (FBPG)**

FBPG is concerned with medical technologies used in the peripheral circulatory system, e.g. PTA technologies, drug-coated stents, stent grafts, and inter-cranial systems for stroke therapy. In connection with these technologies, FBPG prepared patient information materials such as explanatory films and websites. With the professional medical bodies, FBPG discusses further training programs as well as the appropriate representation of medical devices in the relevant service catalogs.

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

FB Rehatechnik aims to create the necessary framework for facility-assured supply of rehabilitation technology. 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 in their homes. FB Rehatechnik developed quality requirements for the provision of rehabilitation technology and presented these during the update process of the register of medical technical aids. In addition, the sectoral interest group is in close contact with other relevant associations.

#### **Sectoral interest group “Absorbing Incontinence Care – Manufacturers” (FBI-H)**

FBI-H plays a significant role in taking a critical look at the care and contract situation for absorbing incontinence products. The key issue in 2017 was the law regulating the provision of therapeutic services and medical technical aids, HHVG, which aims to improve the quality of supply and service, especially in those areas affected by tenders. In addition, FBI-H prepared a joint position paper with the nursing associations advocating a differentiation of diagnosis-related flat rates for ambulatory and hospital care ([www.bvmed.de/positionspapier-pflegeverbaende](http://www.bvmed.de/positionspapier-pflegeverbaende)).



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 “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. In the context of health service research, the sectoral interest group accompanies the register project dealing with hernia and biological implants, Herniamed. In addition, FB STRI discusses new types of care with the service providers.

### **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, as well as the development of instruments for health service research. In cooperation with the German Spine Society (Deutsche Gesellschaft für Wirbelsäulenchirurgie, DWG), FBSC is involved in the development and design of the German spine register. Together with the professional societies, 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. Specific topics are dealt with in the sub-working groups “Ethylene Oxide Sterilization” (AGEO) and “Radiosterilization” (AGS).

### **Sectoral interest group “Ostomy / Incontinence Care” (FBSI)**

The aim of FBSI is the quality-assurance in ostomy and draining incontinence help care. Against the background of the current tenders for this area of care, the “Quality of Life” initiative, which consists of members of FBSI, actively work on the further implementation of quality aspects and choice in these sensitive areas of care. At the meeting of the European Council of Enterostomal Therapy (ECET), medical and nursing experts, members of the professional associations and self-help organizations, who had been invited by the initiative, discussed the present challenges and requirements of quality-assured ostomy and incontinence care. In order to create aware-

ness among cost-bearers for the manifold requirements of adequate ostomy and draining incontinence care, FBSI hosted a training event for employees of health insurance funds in 2017.

### **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 will compile 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.

### **Sectoral interest group “Tracheotomy / Laryngectomy” (FBTL)**

FBTL aims to ensure and improve the quality of care for tracheotomy / laryngectomy patients. In order for them to receive good follow-up care, service contracts with the cost-bearers are required. The sectoral interest group has devised a training program as a contribution to the advanced and further training of the employees of health insurance funds and the Medical Review Board of the Statutory Health Insurance Funds. In addition, FBTL supported the survey among physicians that was conducted by the German Society of Otorhinolaryngology, Head and Neck Surgery with the aim of measuring the quality of care. Apart from that, a project group within FBTL has updated the BVMed brochure “Empfehlung für die Versorgung von tracheotomierten Patienten” (“Recommendations for the care for patients who have undergone a tracheostomy”; [www.bvmed.de/empfehlung-tracheotomieversorgung](http://www.bvmed.de/empfehlung-tracheotomieversorgung)).

### **Sectoral interest group “Shortened Supply Channel” (FBVV)**

The public relations work of FBVV particularly informs the healthcare benefactors and physicians on the supply of hearing aids via the shortened supply channel directly at the ENT surgery. Through the quality initiative “Shortened Supply Channel” (“Verkürzter Versorgungsweg”, QVV) the members have defined mandatory requirements and quality features for the supply of hearing aids.



From care with medical technical aids to the OR: Medical devices increase quality of life and save lives.

These include a quality management manual and a compliance codex. FBVV published an information card to advise patients and contractual partners about this shortened and quality-assured alternative to the traditional supply channel for hearing aids ([www.bvmed.de/qvv](http://www.bvmed.de/qvv)).

## PROJECT GROUPS

### Decubitus Forum (DF)

DF is in regular dialog with the associations of care providers. The forum has prepared a joint position paper as well as new survey questionnaires for resting and seating aids. The questionnaires have been presented to the Federal Association of the Statutory Health Insurance Funds as a basis for discussion for the coordination in the course of the framework recommendations according to article 127, section 6 of the Social Security Code. Other focus areas of DF are public relations ([www.dekubitus-forum.de](http://www.dekubitus-forum.de)), as well as the revision of product group 11 (medical technical aids for the prevention of decubitus) of the register of medical technical aids. DF aims to create a suitable framework for patient-oriented care with anti-decubitus medical technical aids.

### Project group “Neurostimulation” (PG Neuro)

The project group brings together the manufacturers of mostly implantable medical technologies that are applied to treat Parkinson’s disease, epilepsy, migraine, cluster headaches, or chronic pain. Its activities are mainly focused on the promotion of the appropriate representation of these technologies in the reimbursement systems, as well as on patient information.

### Project group “Intermittent Self-Catheterization” (PG ISK)

The project group aims to guarantee quality of care in the field of intermittent self-catheterization, ISC. In 2017, it conducted a survey among ISC patients in order to proclaim their care needs. The survey results constitute the basis for the continuing activities of PG ISK’s “Quality of Life” initiative. Given the tenders in ostomy and draining incontinence help care, further supporters joined the initiative in 2017. PG ISK works closely with

the German-language Paraplegia Association (Deutschsprachige Medizinische Gesellschaft für Paraplegie, DMGP).

### Project group

#### “Medical Care and Remuneration” (PG MVV)

PG MVV issues the newsletter “MedTech ambulant” ([www.bvmed.de/medtech-ambulant](http://www.bvmed.de/medtech-ambulant)) in order to inform practice-based healthcare professionals about specific issues and relevant topics regarding medical devices. In 2017, the group produced newsletters on the following topics: delegation of physicians’ services, capsule endoscopy, e-health for services provided by Statutory Health Insurance physicians, as well as the definition of wound dressings in the law regulating the provision of therapeutic services and medical technical aids, HHVG. In addition, PG MVV updated its brochure on the framework for outpatient surgery within the Statutory Health Insurance system ([www.bvmed.de/aop-broschuere](http://www.bvmed.de/aop-broschuere)).

### Project group “Re-Use” (PG Re-Use)

PG Re-Use is the group that serves as a contact point with regard to the reprocessing and reuse of medical devices. At present, the key issue is the Common Specification for the Reprocessing of Single-use Medical Devices. It regulates the requirements of the EU Medical Device Regulation, MDR, concerning the reprocessing of single-use devices by medical institutions or their service providers. The specification takes effect if a member state decides that, in contrast to the MDR regulations, medical institutions will not be treated as the manufacturers of the reprocessed devices. Another issue the project group dealt with was the pending requirement that reusable class I devices are to be assessed by a Notified Body. This includes their respective operating instructions. The matter also results from the MDR.





The 2017 heroes of our “Körperstolz” campaign (“Body Pride”; [www.bvmed.de/koerperstolz](http://www.bvmed.de/koerperstolz)): Christine, Willibald, and Nic

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Our “Body Pride” heroes in a Berlin underground station and on a bridge crossing the Rhine river in Cologne

## 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 consumer goods sector. The scope of BVMed’s members comprises the entire sector of medical dressings, medical technical aids such as ostomy and incontinence products or bandages, plastic disposable items such as syringes, catheters and cannulae, as well as the implants sector of intraocular lenses, hip, knee, shoulder and spinal implants, heart valves and defibrillators, and even artificial hearts. Homecare services, applications of nanomedicine and biotechnology procedures, such as tissue engineering (tissue replacement), are further fields of activity of its members.

As a trade association, BVMed promotes and represents the combined interests of the medical technology industry and trade companies. In various sectoral interest groups, focus groups, and working 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 services of BVMed can be subdivided into four sectors:

### 1. Organisation

BVMed carries out the joint formation of opinion in more than 50 committees covering specific subjects. Further information can be found in this report starting on page 13. An up-to-date list of the BVMed working committees can be found at [www.bvmed.de/arbeitsgremien](http://www.bvmed.de/arbeitsgremien).

### 2. Consultancy

The experts of BVMed are ready to offer accurate advice to members on such diverse topics as the Medical Devices Law, reimbursement for medical devices in hospital and ambulatory care, the Law on Advertising in the Healthcare System, standardization projects, or ordinances.

### 3. Information

BVMed offers a wide range of information through its internal as well as external communications, e. g.:

#### INTERNAL COMMUNICATIONS

General circulars to all members, specific circulars for the individual expert committees, weekly newsletters, weekly infographics, monthly report in English, extranet for member companies, BVMed special events.

#### EXTERNAL COMMUNICATIONS

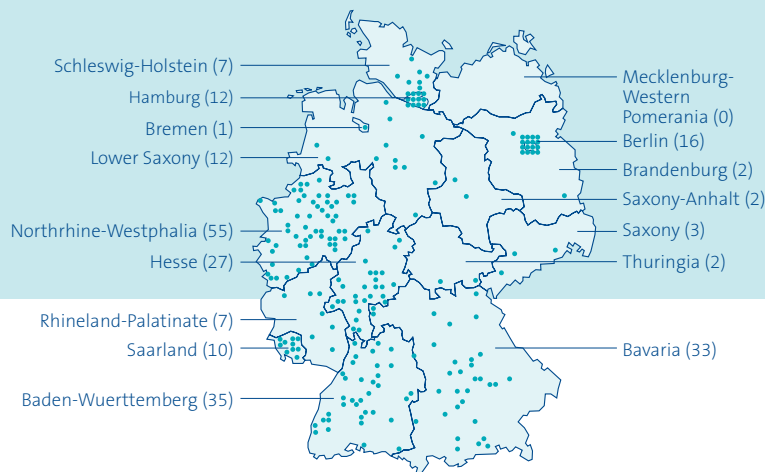
Website at [www.bvmed.de](http://www.bvmed.de), brochures, information cards, BVMed special events, MedInform conferences, training seminars (medical device consultants, SHI training, workshops on bidding / tendering law and CRM topics), press releases and conferences, press seminars, TV and radio service with film material, background discussions with the media and social media channels (Youtube, Facebook, Twitter).

### 4. Representation

BVMed represents the interests of the medical technology sector. Important aspects of this work include political marketing and one-on-one interviews, the maintenance and support of networks, parliamentary discussion evenings, background discussions, participation in parliamentary hearings, as well as representation in committees, advisory councils, commissions, etc.

#### 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](http://www.bvmed.de/satzung). Applications for membership must be submitted in a letter to the managing director of BVMed. Please contact us. We look forward to helping you!



Interactive map of Germany  
showing the locations of our member companies  
at [www.bvmed.de](http://www.bvmed.de)



As of March 2018: 224 members — current list available at [www.bvmed.de](http://www.bvmed.de)

## BVMed Member Companies

1stQ Deutschland GmbH  
3M Deutschland GmbH

aap Implantate AG  
Abbott GmbH & Co. KG,  
Abbott Diabetes Care (ADC)  
Abbott Medical GmbH  
(vormals St. Jude Medical GmbH)  
Abbott Vascular Deutschland GmbH  
Abena GmbH  
Abiomed Europe GmbH  
Acandis GmbH & Co. KG  
Aesculap AG  
aktivmed GmbH  
ALCON PHARMA GMBH  
alloPlus GmbH  
AMPLITUDE GmbH  
Andreas Fahl Medizintechnik-Vertrieb GmbH  
AngioDynamics Inc. Germany  
Ansell GmbH  
ArjoHuntleigh GmbH  
ASSamed GmbH  
ATMOS MedizinTechnik GmbH & Co. KG  
Attends GmbH  
auric Hörsysteme GmbH & Co. KG  
Autonomic Technologies Europe GmbH

B. Braun Melsungen AG  
Bausch & Lomb GmbH  
Baxter Deutschland GmbH  
Becton Dickinson GmbH (BD)  
Berlin Heart GmbH  
BGS Beta-Gamma-Service GmbH & Co. KG  
biolitec biomedical technology GmbH  
Biomet Deutschland GmbH  
Bioness Europe B.V.  
BIOTRONIK SE & Co. KG  
BONESUPPORT GmbH  
Boston Scientific Medizintechnik GmbH  
Bracco Imaging Deutschland GmbH  
BSN medical GmbH  
BTG International Germany GmbH

C. R. Bard GmbH  
Cardinal Health Germany 507 GmbH  
CARDIONOVUM GmbH  
CareFusion Germany 318 GmbH

Carl Zeiss Meditec Vertriebsgesellschaft mbH,  
Vertrieb Ophthamo-Chirurgie  
CeramTec GmbH  
Chemische Fabrik Kreussler & Co. GmbH  
CINOGY GmbH  
Coloplast GmbH  
Coltène / Whaledent GmbH + Co. KG  
ConvaTec (Germany) GmbH  
COOK Deutschland GmbH  
CORIN GSA GmbH  
Corizon GmbH  
CPR GmbH  
curasan AG  
curea medical GmbH

Declimed GmbH – Tochtergesellschaft der  
Desitin Arzneimittel GmbH  
DEWE + Co. Verbandstoff-Fabrik Dr. Wüsthoff & Co.  
DIAMED Medizintechnik GmbH  
DIASHOP GmbH  
Dr. Ausbüttel & Co. GmbH

Eckert & Ziegler BEBIG GmbH  
Edwards Lifesciences Services GmbH  
ElringKlinger Kunststofftechnik GmbH  
Essity Germany GmbH  
(vormals SCA Hygiene Products)  
Eurocor GmbH  
ewimed Medizintechnik Egon Wiest

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

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

HAEMONETICS GmbH  
HANS HEPP GmbH & Co. KG  
Helm Medical GmbH  
Henry Schein Medical GmbH  
Heraeus Medical 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  
Inspire Medical Systems, Inc.  
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  
KCI Medizinprodukte GmbH / An Acclity Company  
Kettenbach GmbH & Co. KG  
Kramer MT GmbH & Co. KG  
KRAUTH Invest GmbH & Co. KG  
KREWI Medical Produkte GmbH  
KUBIVENT GmbH

LDR Medical  
LEINA-WERKE GmbH  
Licher MT GmbH  
LivaNova Deutschland GmbH  
Livica GmbH  
Lohmann & Rauscher International GmbH & Co. KG  
Ludwig Bertram GmbH

MagForce AG  
Mammotome Devicor Medical Germany GmbH  
Maquet Cardiopulmonary GmbH  
Mathys Orthopädie GmbH  
medac Gesellschaft für klinische Spezialpräparate  
mbH  
medi GmbH & Co. KG



Diverse medtech professions: The industry employs over 210,000 people, ranging from development engineers, designers to production workers.

Medi-Globe Technologies GmbH  
medimex GmbH  
Mediq Deutschland GmbH  
Medisize Deutschland GmbH  
Medizintechnik & Sanitätshaus Harald Kröger GmbH  
Medtronic GmbH  
megro GmbH & Co. KG  
Merete GmbH  
MicroPort Scientific GmbH  
Miltenyi Biotec GmbH  
Mohage – Mommsen Handelsgesellschaft mbH  
Molecular Health GmbH  
Mölnlycke Health Care GmbH

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

Ontex Healthcare Deutschland GmbH  
OPED GmbH  
OptiMed Medizinische Instrumente GmbH  
Oriplast Kraymer GmbH  
OSD Medical GmbH  
Otsuka Pharma GmbH  
Otto Bock HealthCare GmbH

P.J. Dahlhausen & Co. GmbH  
Pajunk Medical Produkte GmbH  
PALL GmbH Medical  
Paradigm Spine GmbH  
Param GmbH  
PAUL HARTMANN AG  
PETER BREHM GmbH  
pfm medical ag  
PHADIMED Pharma-Medica Vertriebs-GmbH  
Pharm-Allergan GmbH  
PharmaCept GmbH  
Philips Volcano International  
PMT Präzision-Medizin-Technik GmbH  
POLYTECH Health & Aesthetics GmbH

Polytech-Domilens GmbH  
Primed Halberstadt Medizintechnik GmbH  
PubliCare GmbH  
Pulmonx GmbH  
PULSION Medical Systems SE

R. Cegla GmbH & Co. KG  
Raguse Gesellschaft für medizinische Produkte mbH  
RAUMEDIC AG  
Rayner Surgical GmbH  
recusana GmbH  
rehaVital Gesundheitsservice GmbH  
Retina Implant AG  
Ritex GmbH  
RSR Reha-Service-Ring GmbH

S & V Technologies GmbH  
SANDER Chemisch-Pharmazeutische Fabrik GmbH  
sangro medical service GmbH  
SANIMED GmbH  
Sanitätshaus Aktuell AG  
Sanitop GmbH  
Santen GmbH  
Schülke & Mayr GmbH  
Sengewald Klinikprodukte GmbH  
SERAG-WIESSNER GmbH & Co. KG  
servoprax GmbH  
sfm medical devices GmbH  
SI-BONE Deutschland GmbH  
SIGNUS Medizintechnik GmbH  
Sirtex Medical Europe GmbH  
SMB Sanitätshaus Müller Betten GmbH & Co. KG  
Smith & Nephew GmbH  
Smiths Medical Deutschland GmbH  
Sonovum AG  
Spectranetics Deutschland GmbH  
speziMED GmbH  
Spring Medical Wilhelm Spring GmbH & Co. KG  
Stryker GmbH & Co. KG  
Sunrise Medical GmbH & Co. KG  
Symbios Deutschland GmbH  
Synergy Health Allershausen GmbH  
System SAS France / System DE-Verbindungsbüro

Teleflex Medical GmbH  
Terumo Deutschland GmbH  
The ROHO Group – ROHO International, Inc.  
Thomashilfen für Körperbehinderte GmbH & Co. Medico KG  
TK pharma trade Handelsgesellschaft mbH  
TRACOE medical GmbH  
TRiCares GmbH  
Tutogen Medical GmbH

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

### Bildnachweis

The pictures either originate from BVMed's own photoshoots (photographer: Kurt Paulus) or were taken from the BVMed image pool ([www.bvmed.de/bilder](http://www.bvmed.de/bilder)). We would like to thank the BVMed member companies that provided photographs for the BVMed image pool. Cover photo: Catheter laboratory using the latest medical technology, source: BVMed, photographer: Kurt Paulus



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