Monthly news from the German Medical Technology Association: BVMed, Reinhardtstrasse 29b, D-10117 Berlin
Editor: Manfred Beeres, Phone: +49 (0) 30 - 24 62 55 - 20, E-Mail: beeres@bvmed.de, www.bvmed.de

BVMed Report № 12/19

December 2019 / January 2020
Circulation: 2.700

Government decides on MDR Amendment Act

Berlin. The Federal Cabinet passed the Federal Ministry of Health's draft law for a Medical Devices Amendment Law on November 6, 2019. In this way, the EU Medical Device Regulation (MDR) will be implemented and the former German Medical Devices Law replaced. German specifics such as the medical device consultant will remain unchanged. The law will also give greater competencies to the Federal Institute for Drugs and Medical Devices. In future, it will be the institute that decides on the required measures if complaints are received about medical devices that pose risks to health. The measures include banning devices on the German market, product recalls, and prohibitions of sale.

German Hospitals are lagging behind in digitization

Berlin. By international standards, Germany is lagging behind when it comes to digitization in hospitals. The main reasons for this are lack of funding, lack of IT specialists, and lack of confidence in the economic benefit of digitization. This is the result of a representative survey conducted by BDO and the German Hospital Institute. According to the experts, a public investment program is thus necessary.

Heart failure: Remote monitoring reduces mortality

Berlin. Patients with advanced heart failure can benefit from telemedical care. Compared to care without remote monitoring, fewer cardiovascular deaths occur in patients covered by remote monitoring with defined minimum requirements. This is what the Institute for Quality and Efficiency in Healthcare says in its "Rapid Report" conducted on behalf of the Federal Joint Committee (G-BA). In the past year already, scientists of the Berlin Charité University Hospital made similar findings.

Karl Broich head of the Institute for Medical Documentation

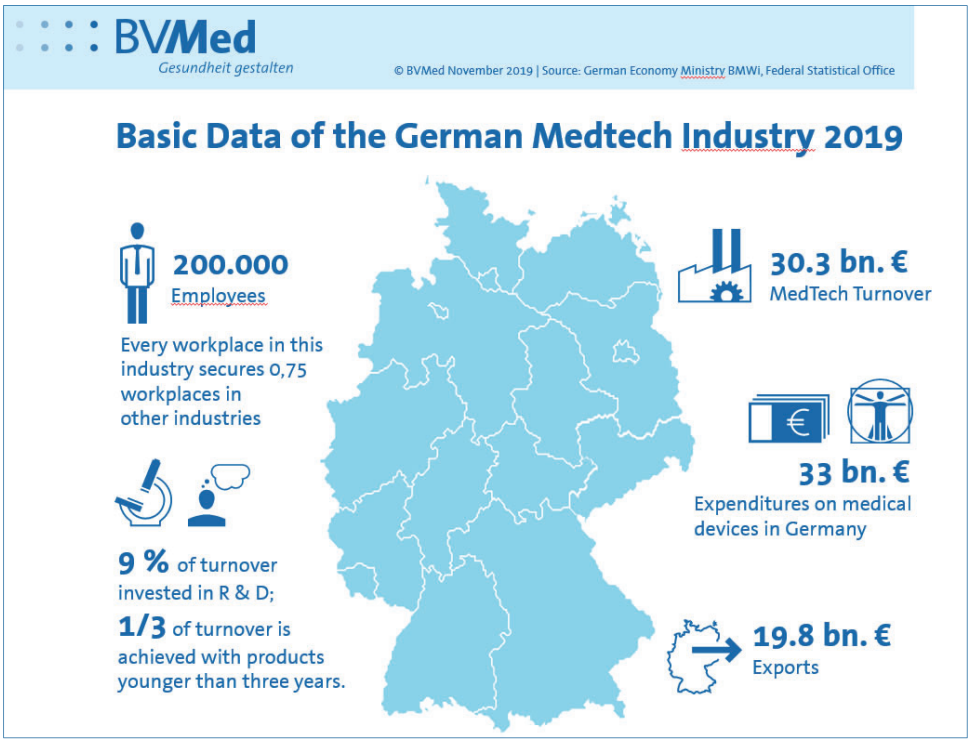
Bonn. The new provisional head of the German Institute for Medical Documentation and Information (DIMDI) is **Prof. Karl Broich**, who is also president of the Federal Institute for Drugs and Medical Devices (BfArM). Both authorities are to merge in the first quarter of 2020.

Parliament passes fast track for digital health

Berlin. On November 7, the Federal Parliament passed the digital care law Digitale Versorgung-Gesetz (DVG). Approval by the Federal Council is not necessary. Thus, the law can come into effect on January 1, 2020. The law contains, among other things, a provision that digital medical devices, or digital healthcare applications, of the lower classes I and IIb can be prescribed by a physician and must be remunerated by the health insurance funds. The inclusion of applications in a central register will not be decided by the G-BA committee but through a fast track procedure conducted by the Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM). In addition, the digital care law creates the basis for digital prescriptions of medical technical aids.
The digital care law is an important step in the right direction. It must be followed by further steps. BVMed, for instance, advocates the inclusion of combination devices by well-established medical devices manufacturers as well as the addition of classes IIb and III to the approved list.
The crucial point is the proof of benefit. The Federal Ministry of Health will pass an ordinance in order to regulate the details of the required proofs. Here the special challenge lies in developing new evaluation concepts for digital healthcare applications that fulfill the particular characteristics of these applications such as agility and faster life cycles.
Read more at **www.medinsight.de**.

MDR: Focus on shortfalls in Notified Bodies

Berlin. A persistent shortfall in Notified Bodies remains among the biggest problems concerning the rollout of the new European Medical Device Regulation (MDR), according to experts at a special BVMed event in Cologne on questions of practical implementation of medical devices law, where 150 participants were welcomed. "The MDR is voluminous and difficult to interpret. This alone will slow down market access for new products – because the scarce availability of Notified Bodies will create bottlenecks," said **Dr. Joachim Wilke** of Medtronic. **Salvatore Scalzo**, an officer with the European Commission, expects that by the end of this year, a total of 20 Notified Bodies will be accredited in accordance with the MDR. According to **Martin Witte** of TÜV Süd, however, the sheer number of Notified Bodies bears little significance. The real problem was that only few Notified Bodies cover all risk classes and that there is a general lack of experts for the assessment schemes.
Read more at **www.medinsight.de**.
All relevant documents and downloads on the MDR implementation can be found in BVMed's MDR portal at **www.bvmed.de/mdr**.



The German medtech industry has a total turnover of over 30 billion euros and provides 200,000 jobs.