

# BVMedReport № 04/17

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## German Healthcare Economy to Grow Extraordinarily

Wiesbaden. In comparison to the economy in general, the German healthcare economy shows above-average growth rates. Last year, it provided 7 million jobs and generated a revenue of about € 337 bn. This corresponds to a share of 12 percent in the gross domestic product. This is the result of a study by the economic research institute WifOR on behalf of the Federal Ministry of Economics and Technology.

## “Potential” – The New, Small Benefit Concept

Berlin. With financial pressure in the German healthcare system rising, the discussion about benefit assessment of innovative medtech has gained dynamics in the past years. The respective associations demand a high degree of evidence for new methods, usually to be provided by RCTs. In the new benefit assessment scheme introduced by the German legislature a new legal concept plays an important role: If there is no sufficient evidence, manufacturers and / or hospitals must prove that the innovation has the “potential” of becoming an alternative treatment method.

## SHI Total Reserves Rise to € 25 Bn

Berlin. According to preliminary results, the Statutory Health Insurance funds have realized a surplus of about € 1.38 bn in 2016. Together with the health pool, the financial reserves of the funds amounted to € 25 bn at the end of 2016.

## Andreas Gassen to Remain KBV Chairman; Board Members Elected

Berlin. The orthopedist has been confirmed as chairman of the National Association of Statutory Health Insurance Physicians.

## New Heart Surgeons' President

Berlin. Dr. Wolfgang Harringer, aged 56, chief physician of the Department of Heart, Thoracic, and Vascular Surgery of the Municipal Hospital in Braunschweig, has been elected the new president of the German Heart Surgeons' Society.

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## European Parliament Passed the MDR

Brussels. After the European Council passed the finalized version of the EU Medical Device Regulation – MDR – in March 2017, the European Parliament agreed on the MDR on April 5th, 2017. The regulation can be announced in the Official Journal of the European Union in the second quarter of 2017. The MDR will then enter into force 20 days after its announcement.

Once the MDR has entered into force, the transitional period of three years stipulated by the regulation begins. During this period the manufacturers can choose to receive their certification according to the old or already the new law.

The Notified Bodies can undergo renotification at the earliest six months after the MDR has entered into force and thus be able to perform certifications on the basis of the new law. Therefore, the transitional period for the manufacturers will be shortened. The recertification process will take at least another 12 months. In light of this unfortunate situation, manufacturers are well advised to renew their old certificates shortly before the end of the three-year transitional period as these will then be valid for up to four more years after the date of application of the MDR.

Read more at [www.medinsight.de](http://www.medinsight.de).

## Digitization: UDI and E-Invoice Are on Their Way

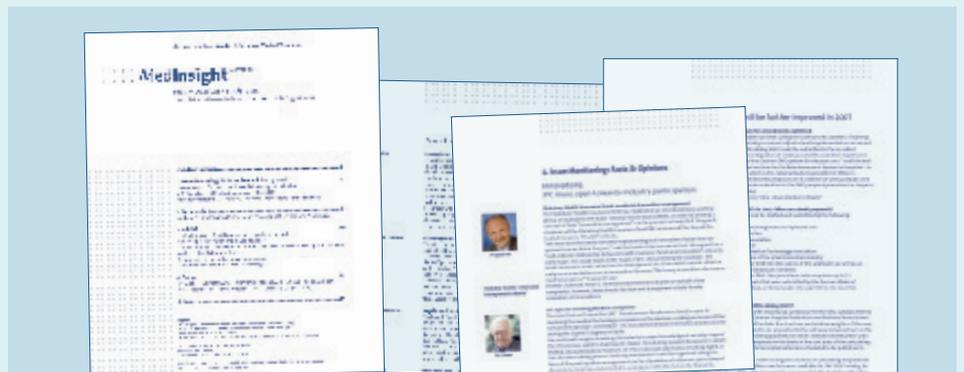
Dusseldorf. Digitization also goes along with new obligations for the manufacturers of medical devices. With the UDI obligations for the standardized labeling of medtech products, small and medium-sized medical device companies will face major challenges due to new regulatory requirements. In addition, the requirements for electronic invoicing and electronic procurement will become mandatory, the experts at BVMed's 19th eCommerce Conference explained.

Holger Clobes from B. Braun gave an introduction

into the importance of big data for the healthcare sector. “Nobody in the medtech industry can avoid the trend towards digitization, even though the healthcare sector is lagging behind other industries,” Holger Clobes said. Valid data were still the topic most underestimated by the companies. The challenge of big data was to collect, link, and analyze data. Technology was not the biggest challenge in this regard, but rather the organization of the data.

Read more at [www.medinsight.de](http://www.medinsight.de).

## MedInsight Germany: Latest News on Europe's Biggest Market!



MedInform has published a new issue of MedInsight Germany, a background report authored by the German medtech experts Joachim M. Schmitt and Manfred Beeres in cooperation with AdvaMed. MedInsight gives the latest news on Europe's biggest medtech market.

Topics of the new issue are e.g.: MDR on Its Way: Old CE Certificates Must Be Renewed; Digitization: UDI and E-Invoice Are on Their Way; “Potential” – The New, Small Benefit Concept; Healthcare Economy to

Grow Extraordinarily; SHI Total Reserves Rise to € 25 Bn; Data on Minimum Quantities “Inconclusive”, Surgeons Say; Definition of Surgical Dressings Includes Hydroactive Dressings; Wolfgang Harringer New Heart Surgeons' Society President.

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