

# BVMedReport № 02/20

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## Second MDR Corrigendum passed

Brussels. Following the decisions of the EU Commission and the EU Council, the second corrigendum to the Medical Device Regulation (MDR) has been accepted by the European Parliament, too. The corrigendum grants former class I medical devices with a higher classification under the MDR the same transitional period of four years that applies to other devices on the market. The German medtech industry welcomed the decision as an important step towards preventing bottlenecks in patient care. Nevertheless, BVMed advocates the restructuring of the existing procedures for special approvals in order to prevent such bottlenecks and to keep the additional workload for the competent authorities at a manageable level.

## Federal Joint Committee wants HTA for “high-risk medical apps”

The Federal Joint Committee (G-BA) claims authority over benefit assessment of digital “high-risk devices.” There was no interest in “fun apps,” said the non-partisan chairman, **Professor Josef Hecken**. “As long as the patient buys something on his own accord, it is their responsibility.” Such applications might be marketed without proven benefit. “Questions arise when we are dealing with medical devices,” Hecken emphasized.

## New Ministers of Health in Brandenburg and Saxony

Potsdam/Dresden. The new Minister of Health in Brandenburg is **Ursula Nonnemacher**, a 62-year-old specialist for internal medicine. **Petra Köpping** has become Minister of Social Affairs in Saxony, and thus is also responsible for healthcare politics.

## BVMed chair Meinrad Lugan again on the board of MedTech Europe

Brussels. BVMed chairman **Dr. Meinrad Lugan** (55) has again been elected to the board of the European medical devices umbrella association MedTech Europe. Dr. Lugan also remains in office as treasurer of the association and thus on the board of the seven-member Operations Management Committee (OMC), the top leadership body of MedTech Europe.

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## BVMed to seek a “Medtech Dialogue” in 2020

Berlin. BVMed is asking policy-makers to launch a new “Medtech Dialogue” in 2020 between the Ministry of Health, the industry, and the research sector. “We need to better coordinate regulatory measures for the medical device industry with economic and research policy activities. Research, economy, and healthcare policy should be aligned with each other: We want an integrated medtech strategy process,” said BVMed CEO **Dr. Marc-Pierre Möll** in a statement made at the turn of the year 2019/20. The Medical Technology Strategy Process is stalling. According to BVMed, the “Medtech Dialogue” should focus on the following topics:

- > stronger orientation towards comprehensive

- healthcare processes;
- > development of digital healthcare services; and
- > inclusion of artificial intelligence in order to support healthcare and nursing care.

“If we want to be able to provide optimized, state-of-the-art patient care, we need to evaluate and improve the regulatory and socio-legal framework conditions and eliminate unnecessary bureaucracy,” says BVMed.

This statement comes against the background that the “Medical Technology Strategy Process” envisaged in the coalition agreement continues to stall under the leadership of the Research Ministry.

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

## Fewer complication with experienced surgeons

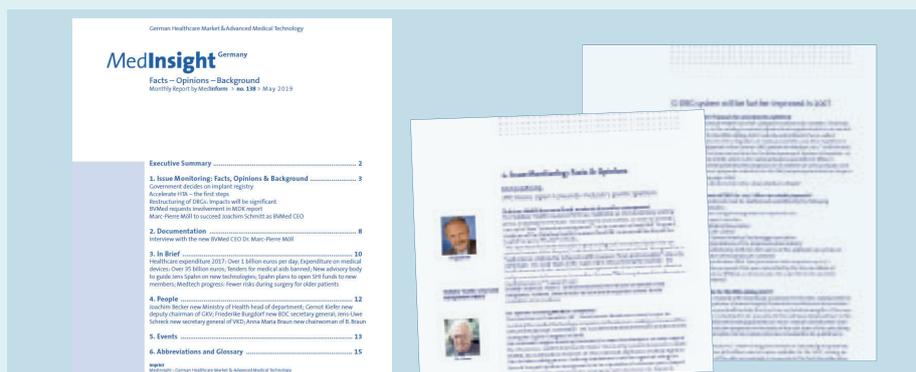
Berlin. Hospitals where a large number of hip and knee endoprostheses are implanted tend to have better surgical results than facilities with fewer procedures. Other factors influencing the life of a prosthesis are the components and materials used in a prosthesis as well as the patients in which they are implanted. These are the conclusions of the recent 2019 annual report published by the German Endoprostheses Register (EPRD). The EPRD registry is a joint initiative of the German Society for Ortho-

pedics, the SHI funds associations AOK and vdek, and BVMed.

According to current forecasts, joint replacement procedures will increase by around 27 percent by the year 2040. “This – mainly age-related – increase alone is reason enough to work at full speed on the further optimization of this procedure, which in itself is already very successful today,” says **Professor Dr. Carsten Perka** of Charité Hospital.

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 **Dr. Marc-Pierre Möll** and **Manfred Beerres** in cooperation with **Ralph Ives** and **Joe Gatewood** from AdvaMed. **MedInsight** gives the latest news on Europe’s biggest medtech market.

Topics of the new issue are e.g.: Second MDR Corrigendum passed; BVMed to seek a “Medtech Dialogue” in 2020; EPRD: Lower complication rates with experienced surgeons; Federal Joint Com-

mittee wants HTA for “high-risk medical apps”; Why UDI is still important for EU MDR despite EUDAMED delay; Jens Spahn plans greater focus on quality in hospitals; DIHK survey: Healthcare sector increasingly under pressure; Wound care: Experts present recommendations for new structures; Ursula Nonnemacher new Minister of Health in Brandenburg; Petra Köpping new Minister of Social Affairs in Saxony. You can order a free trial copy of **MedInsight** at [www.medinsight.de](http://www.medinsight.de).