

# BVMedReport № 10/19

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## Another MDR corrigendum on its way

Brussels. The European Commission has decided to initiate another “corrigendum” that will amend or modify some parts of the EU Medical Device Regulation (MDR). The key issue is a transitional period that will be introduced for class I devices that are classified higher by the MDR, like class II. In this way the “hard deadline” in May 2020 could be avoided, a BVMed delegation headed by chairman **Dr. Meinrad Lugan** and CEO **Dr. Marc-Pierre Möll** confirmed after holding talks with the German EU Commissioner **Günther Oettinger**, the relevant EU Directorate General, and parliamentary staff as well as government experts in Brussels.

## MDR immediate aid program in Baden-Wuerttemberg

Stuttgart. The Ministry of Economics in Baden-Wuerttemberg has made available an MDR immediate aid program in order to assist the medical technology industry in the federal state. It is the first German federal state to do so.

## MDR portal:

### All the documents in one place

Berlin. BVMed makes available important information and relevant documents regarding the implementation of the new EU Medical Device Regulation (MDR) through its MDR information portal at [www.bvmed.de/mdr](http://www.bvmed.de/mdr). The documents include flowcharts, publications, and links to relevant documents, guidelines, and implementation aids of the EU Commission as well as guidelines by various organizations.

## Doctors revolt against the German DRG system

Hamburg. In a large-scale campaign published by the nationwide magazine “Stern,” 30 organizations and individuals from the healthcare sector have called for fundamental changes in financing hospital services. The signatories claim that the DRG system by which hospitals are compensated for their services on the basis of flat rates per case offers many incentives to generate “profit through unnecessary activities to the detriment of patients.”

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## Digital medical devices: “Gathering experience”

Berlin. With the new approach for digital medical devices based on the Digital Care Law (DVG), “we now want to gain experience without delay and improve patient care.” These were the words of **Prof. Dr. Jörg Debatin**, head of the new “Health Innovation Hub” of the Federal Ministry of Health at BVMed’s first Digital Talk in Berlin.

In terms of providing a starting point from where to ensure swift access to digital solutions, BVMed recognizes many valuable approaches in the Digital Care Law (DVG), though it proposes more comprehensive regulations with regard to the scope and support of telemedicine solutions, in particular, an extension to class IIb and III medical devices, said BVMed managing director **Dr. Marc-Pierre Möll**. In

the discussion, Debatin viewed the limitation to classes I and IIa as justifiable, as small steps were easily implementable and would allow to gain experience with the new approach without delay. If the approach proves successful, Debatin is not opposed to an extension to include classes IIb and III. In April 2019, Federal Health Minister **Jens Spahn** launched the Health Innovation Hub under the leadership of Prof. Dr. Jörg Debatin in order to actively search the digital scene for new ideas and solutions and thus to improve healthcare. The former head of the Hamburg-Eppendorf University Hospital (UKE) had consistently digitized the clinic during his time as medical director and chairman of the board. Read more at [www.medinsight.de](http://www.medinsight.de).

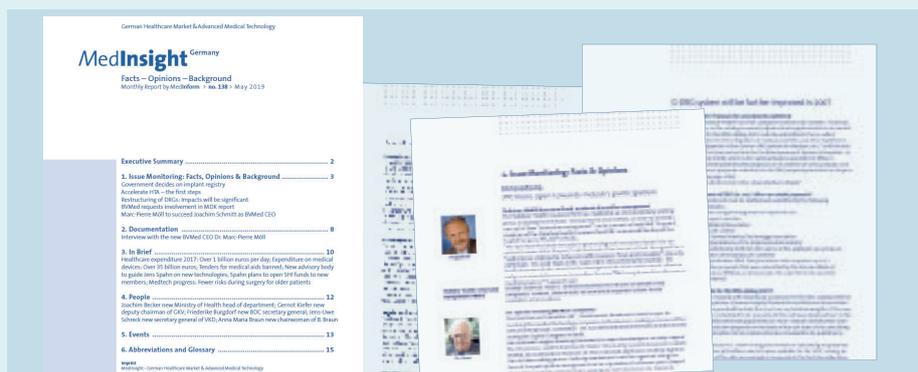
## Call for reimbursement of remote monitoring

Berlin. Cardiology companies in BVMed are calling for the reimbursement of continuous remote monitoring for patients with active cardiac implants. In view of the current recommendations on the remote monitoring of cardiac patients published by the “Telemonitoring” working group of the German Cardiac Society (DGK), it remains incomprehensible why continuous remote monitoring is denied reimbursement while the benefit assessment procedure with the Federal Joint Committee (G-BA) has been

ongoing for more than three years, says BVMed CEO **Dr. Marc-Pierre Möll**. “The benefit has long been proven, clinical evidence is available. It is high time that remote monitoring is made routinely available to affected cardiac patients.”

Over 600,000 patients are currently living with cardiac implants in Germany. Of these, approximately 470,000 are cardiac pacemakers, and approximately 130,000 are ICD and CRT systems. 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.: Another MDR corrigendum on its way; Digital medical devices: “Gathering experience”; Doctors revolt against the German DRG system; Call for reimbursement

of remote monitoring; MDR immediate aid program in Baden-Wuerttemberg; MDR portal: All the documents in one place; Financial results of SHI funds for first half of 2019; Hospitals forced to temporarily close intensive care beds; BVMed: Avoiding sepsis through the prevention of infections; Claudia Bernhard new Senator for Health in Bremen; Dr. Dirk Heinrich confirmed as Spifa chairman; Boris Velter heads “Health City Berlin”.

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