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MDR into Force:

Last Deadline Ends in 2024

Brussels. The European Medical Device Regulation, MDR, came into force on May 25, 2017. The MDR will apply from May 26, 2020, after a three-year transitional period. Experts believe that owing to the large scope of new standards applied to the Notified Bodies and the clinical evaluation of medical devices, as well as new planning and reporting requirements and the new EUDAMED/UDI database system, this transitional schedule is very tight.

Study: Medtech and Pharma Continue to Expand in Germany

London. The German medical technology market will increase from around 25 billion euros (2016) to almost 31.5 billion euros, the market research company Global Data forecasts. The driving force behind the market growth, apart from the aging population, is the increasing awareness that it is necessary to diagnose and treat diseases as early as possible. Commercially, Germany continued to offer good conditions as well: low corporate taxes, low interest rates, well-trained specialist staff and hardly any restrictions for foreign investors.

Fraunhofer Center for Active Implants Opened

Hanover. At the end of April 2017 the Fraunhofer High-Performance Center Translational Medical Engineering in Hanover was opened. The center aims to bring research ideas into the phase of clinical development. The center will focus on the development of active implants such as cochlear and retinal implants. The facility aims to support small and medium-sized enterprises during the complex processes of transferring the results of fundamental research into the clinical phase.

Montgomery Vice-Chairman of World Medical Association

Hamburg. The Council of the World Medical Association has re-elected Prof. Dr. Frank Ulrich Montgomery, president of the German Medical Association, as vice-chairperson.

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Medtech Benefit Assessment Put to Test

Berlin. The early benefit assessment for medical devices of high classes used in hospitals does not sufficiently recognize the innovative potential of new methods. This was the criticism voiced by the German medtech industry association BVMed after the first decisions by the Federal Joint Committee, G-BA, became public. This concern is now shared by the Federal Ministry of Health, BMG.

To this day G-BA has examined eight methods under the new scheme. Only two were considered to have sufficient potential for providing

a treatment alternative. Ministry officials were surprised by these results, Dr. Ulrich Orłowski, head of the BMG healthcare department, said. One might ask how the exclusion of methods can be reconciled with the constitutional provision that patients suffering from severe illness should not be denied access to yet unapproved medical treatment methods if they promise cure or attenuation. The ministry official expressed doubts whether the mechanism of the new law provides sufficient basis to gain evidence. Read more at www.medinsight.de.

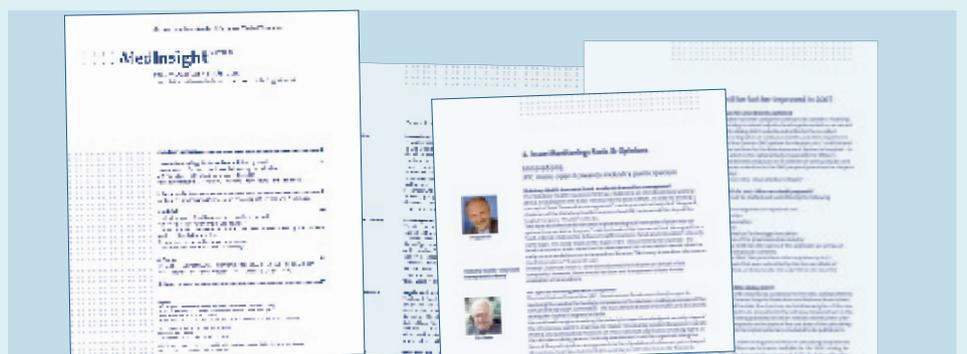
Start of Election Campaign: Advantage For Merkel

Berlin. After the parliament election in North Rhine Westphalia, the German federal state with the largest population, on May 14, 2017, the crucial phase of the federal election campaign has now started. The federal elections will be held on September 24, 2017. Its momentum is being driven by Federal Chancellor and CDU leader **Angela Merkel**, because in North Rhine-Westphalia—as happened in Schleswig-Holstein a week before—the SPD-led state government was voted out. After the elections in the federal states of Saarland and Schleswig-Holstein, the CDU, surprisingly, became the strongest party

again in the third election in a federal state this year. The right-wing populist AfD only had single-digit results. The Liberals have recovered strongly. Hence, the conservative camp in Germany has been strengthened. For the medtech industry, these are generally positive news as they make further regulatory interference by the government less likely.

The SPD election program will only be adopted on June 25, 2017. The CDU health committee has prepared an election paper which provides insights for the medtech industry. Read more at 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.: Start of the Federal Election Campaign: Advantage for Merkel; MDR Has Come into Force: Last Deadline Ends in 2024; Medtech Benefit Assessment Put to Test; G-BA Leadership:

Mr. Hecken Will Get New Vice-Chairs; Study: Medtech and Pharma Continue to Expand in Germany; Bariatric Surgery to Become Usual Therapy Option for Diabetics?; Größe at the conhIT Fair: More Benefits for Patients through Digitalization.

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