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Client Alert

Life Sciences Practice Group

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New European Medical Device Regulations Will Become Effective on May 25, 2017

On May 05, 2017 the European Union legislator published Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices – the EU-Medical Devices Regulations (MDRs) in the Official Journal of the European Union. The new MDRs provide an entirely new legal framework for the EU medical device sector. The Regulations provide numerous new obligations for manufactures and distributors, incl. parallel importers, as well as Notified Bodies which will have to adjust internal processes and procedures in order to ensure compliance at the distribution of medical devices.

The new Regulations will become effective on May 25, 2017. Regulation (EU) 2017/745 on medical devices will apply from 26 May 2020 and Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices will apply from 26 May 2022 on.

The MDRs will replace the current EU Medical Device Directives, Council Directive 93/42/EEC on medical devices and Directive 98/79/EC on *in vitro* diagnostic medical devices (Medical Device Directives – MDDs). As so-called "European Regulations" the MDRs will become immediately enforceable as applicable law in all EU member states simultaneously and do not need to be mediated into national law by means of implementing measures. When the MDRs become effective, they will repeal the current MDDs and override all national laws of the EU member states dealing with the same subject matter. Thus, the MDRs provide a completely new legal framework for the EU medical device sector.

Both manufacturers and distributors of medical devices or *in vitro* diagnostic medical devices will have to make good use of the short period of time until the MDRs become applicable, as both the Medical Device Regulation and the *In Vitro* Diagnostic Medical Device Regulation provide a number of new statutory provisions on an EU-wide level and introduce higher requirements for the placing of medical devices on the EU market.

MDRs tighten the requirements on market access: the Regulations set stricter requirements at the evaluation of clinical data and introduce a higher classification of certain substance-based devices and implantable devices. Manufacturers also will have to produce additional plans and

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reports such as Post Market Surveillance Plan/Report (PMS), Post Market Clinical Follow-up Report (PMCF), Periodic Safety Update Report (PSUR), Summary of Safety and Clinical Performance (SSCP). Manufacturers will have to up-date their vigilance procedures and processes as the MDRs introduce new regulations on market surveillance and are *i.a.* tightening current reporting time lines for the initial reporting of an incident recommended by the European Commission in its MEDDEV-Guideline 2.12-1 rev 8 on a Medical Devices Vigilance System. Also, manufacturers will have to appoint a person responsible for regulatory compliance, who possesses the requisite expertise in the field of medical devices. The person responsible for regulatory compliance has to be at least responsible for supervision and control of the manufacturing of devices, and the post-market surveillance and vigilance activities concerning them.

Manufacturers will have to examine the status of their conformity assessment certificates issued by Notified Bodies and will have to apply for (re-)examination by a Notified Body under the new MDRs where necessary. From 26 May 2020 on in case of medical devices and from 26 May 2022 on in case of *in vitro* diagnostic medical devices, devices may only be placed on the market where they comply with the new Regulations. It is expected that Notified Bodies will be available for certification under the new MDRs from 2019 on.

With view to the short period of time, MDRs foresee a derogation for medical devices where certificates were issued by Notified Bodies prior to May 25, 2017 under the current MDDs. These certificates remain valid until the end of the period indicated on the certificate (except for certificates issued in accordance with Annex 4 of the MDDs which become void at the latest on 27 May 2022). Certificates issued by Notified Bodies in accordance with MDDs from 25 May 2017 remain valid until the end of the period indicated on the certificate, which shall not exceed five years from its issuance. They will however become void at the latest on 27 May 2024. However, such medical devices may only be placed on the market where from the date of application of the MDRs the device continues to comply with either of the MDRs, and provided there are no significant changes in the design and intended purpose. However, the requirements of the MDRs relating to post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices apply in place of the corresponding requirements in the MDDs.

MDRs also newly introduce general obligations for distributors of medical devices. When making a medical device available on the EU market, distributors have to verify *i.a.* that the device has been CE marked and that the EU declaration of conformity has been drawn up. For imported medical devices distributers must ensure that the devices are labeled and accompanied by instructions for use in accordance with the applicable labeling regulations. Also, distributors have to report complaints or reports about suspected incidents related to a medical device they have made available to the manufacturer, respectively the manufacturer's authorized representative, and the importer.

Medical devices lawfully placed on the market prior to 26 May 2020 (respectively 26 May 2022 in case of *in vitro* diagnostic medical devices) and medical devices placed on the market from 26 May 2020 (respectively 26 May 2022 in case of *in vitro* diagnostic medical devices) by virtue of a certificate issued under the current MDDs as referred to above, may continue to be made available on the market until 27 May 2025. Medical devices which comply with the new MDRs may be placed on the market before 26 May 2020 (26 May 2022 in case of *in vitro* diagnostic medical devices).

The European Commission will set up a central database (Eudamed) that will integrate different electronic systems to collate and process information regarding medical devices on the market and the relevant economic operators, certain aspects of conformity assessment, Notified Bodies, certificates, clinical investigations, vigilance and market surveillance and the MDRs foresee the introduction of a Unique Device Indentification-System (UDI), similar to the US FDA UDI-System.

As the MDRs provide an entirely new framework for the EU medical device market, all stakeholders in the device market will have to engage with the new obligations and requirements following from the new MDRs. Especially manufacturers will have to begin with the implementation of the new regulations and the adjustment of internal procedures and processes at an early stage in order to ensure compliance with the numerous requirements when the new MDRs apply.