APRIL 24, 2020

For more information, contact:

Ulf Grundmann
+ 49 69 257 811 400
ugrundmann@kslaw.com

Geneviève Michaux
+32 2 898 0202
gmichaux@kslaw.com

Elisabeth Kohoutek
+ 49 69 257 811 401
ekohoutek@kslaw.com

King & Spalding

Frankfurt
TaunusTurm
Taunustor 1
60310 Frankfurt am
MainTel: +49 69 257 811 000

Brussels
Bastion Tower
5 Place du Champ de Mars
1050 Brussels
Belgium
Tel: +32 2 898 0200

One More Year: EU Medical Device Regulation Fully Applies on May 26, 2021

As of today, the "REGULATION (EU) 2020/561 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 23 April 2020 amending Regulation (EU) 2017/745 on medical devices, as regards the dates of application of certain of its provisions" applies and is fully binding in all EU Member States. This measure creates significant opportunities for device manufacturers.

In sum, as a result of today's amendments:

1. the EU Medical Device Regulation ("MDR") will begin to apply one year later on 26 May 2021;
2. the Medical Device Directive and national laws shall apply until 25 May 2021; and
3. the Regulation provides the right of EU Member States and the European Commission for a "Union-wide derogation" as of today.

The COVID-19 outbreak and the associated public health crisis presents an unprecedented challenge to Member States and constitutes an immense burden for national authorities, health institutions, Union citizens, and economic operators. The public health crisis has created extraordinary circumstances that demand substantial additional resources, as well as an increased availability of vitally important medical devices, that could not reasonably have been anticipated at the time of adoption of Regulation (EU) 2017/745. Those extraordinary circumstances have a significant impact on various areas covered by Regulation (EU) 2017/745, such as the designation and work of notified bodies, as well as the placing on the market and making available on the market of medical devices in the Union.

Given the unprecedented magnitude of the current challenges, and taking into account the complexity of Regulation (EU) 2017/745, it is very likely that Member States, health institutions, economic operators and other

relevant parties will not be in a position to ensure the proper implementation and application of that Regulation from 26 May 2020 as laid down therein.

As such, today's amendment helps to ensure the continuous availability of medical devices on the EU market, including medical devices that are vitally important in the context of the COVID-19 outbreak and the associated public health crisis.

The application should be deferred for provisions of Regulation (EU) 2017/745 that would otherwise start to apply from 26 May 2020. To ensure the continuous availability of medical devices on the EU market, including medical devices that are vitally important in the context of the COVID-19 outbreak and the associated public health crisis, it is also necessary to adapt certain transitional provisions of Regulation (EU) 2017/745 that would otherwise no longer apply.

Highlights from the new Regulation include:

- **The MDR applies starting 26 May 2021 (Art. 123 Para 1 MDR).**
- **The Regulation provides for Class I Devices under MDD (Art. 120 Para. 3 MDR):**

  A device which is a class I device pursuant to MDD, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body, or which has a certificate that was issued in accordance with MDD and that is valid, may be placed on the market or put into service until 26 May 2024, provided that from 26 May 2021 it continues to comply with either of those Directives, and provided there are no significant changes in the design and intended purpose. **However, the requirements of this MDR relating to post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices shall apply in place of the corresponding requirements in those Directives**.
- **Transition period (Art. 120 Para. 4, 5, 10 MDR):**

  Devices lawfully placed on the market pursuant to MDD prior to 26 May 2021, and devices placed on the market on or after 26 May 2021 pursuant to paragraph 3 of this Article, may continue to be made available on the market or put into service until 26 May 2025.

  Devices which comply with MDR may be placed on the market prior to 26 May 2021.

  Notified Bodies which comply with the MDR may be designated and notified prior to 26 May 2021. Notified Bodies which are designated and notified in accordance with the MDR may carry out the conformity assessment procedures in the MDR and issue certificates in accordance with this Regulation prior to 26 May 2021.
- **Timelines regarding UDI (Unique Device Identification system; Art. 123 Para. 3, Art. 27 Para 4 MDR):**

  Reusable devices that are required to bear the UDI carrier on the device itself need to be labeled in accordance with MDR:

  (i) implantable devices and class III devices from 26 May 2023;

  (ii) class IIa and class IIb devices from 26 May 2025;

  (iii) class I devices from 26 May 2027

- **The Member States may grant exceptions for needed medical devices without carrying a CE mark in the Member State, and the Commission may grant a Union-wide derogation for such products (Art. 59 MDR):**

  Any competent authority of a Member State may authorize, on a duly justified request, the placing on the market or putting into service, within the territory of the Member State concerned, of a specific device for which the applicable procedures under MDD have not been carried out, but use of which is in the interest of public health or patient safety or health. The Member State may inform the Commission and the other Member States of any authorization granted before 24 April 2020. Following a notification of a Member State, the Commission, in exceptional cases relating to public health or patient safety or health, may, by means of implementing acts, extend for a limited period of time the validity of an authorization granted by a Member State when granted before 24 April 2020, to the territory of the Union and set the conditions under which the device may be placed on the market or put into service.

The impacts of the Regulation (EU) 2020/561 for device manufacturers are the following:

1. Devices that are legally placed on the market may be distributed after 26 May 2020.
2. The assessment of devices under MDR need to be finished by 26 May 2021; manufacturers and Notified Bodies will have one more year to finish the necessary assessments.
3. Manufacturers have the opportunity to apply for placing devices on the market for which an assessment under MDD or MDR has not been finished or even conducted.