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Client Alert

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MDD Certificates Remain Valid: European Commission Proposes Longer Transition Periods for MDR Compliance

On Friday, January 6, 2023, the European Commission adopted a proposal to give more time to certify medical devices in hopes of mitigating the risk of shortages in the European Union (EU). The proposal introduces a longer transition period to adapt to the Regulation (EU) 2017/745 on medical devices (MDR). The new deadlines vary based on the medical devices' risk classification, and they work to ensure patients' continued access to medical devices. The proposal will also allow medical devices that are placed on the market in accordance with the current legal framework and that are still available to remain on the market (i.e., no 'sell-off' date).

Significant extension of the transition period (MDD/MDR)

The proposal foresees a longer transition period for medical devices, which have a certificate that was issued in accordance with the Council Directive 93/42/EEC concerning medical devices (MDD):

- **Class III devices** (other than custom-made implantable devices) may be placed on the market until **December 31, 2027**;
- **Class IIb implantable devices** (except sutures, stables, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors) may be placed on the market until **December 31, 2027**;
- **Class IIb devices** other than the above, may be placed on the market until **December 31, 2028**;
- **Class IIa devices** may be placed on the market until **December 31, 2028**;
- **Class I devices placed on the market in sterile condition or having a measuring function** may be placed on the market until **December 31, 2028**; and

- **Class I devices** for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to May 26, 2021 and **for which the conformity assessment procedure under the MDR requires the involvement of a notified body**, may be placed on the market until **December 31, 2028**.
- **Class I devices without sterile condition or measurement function** with a declaration of conformity under MDD without any involvement of a notified body placed on the market under the MDD before May 26, 2021 may be resold indefinitely. Since these Class I devices under MDD remain Class I devices under MDR, the declaration of conformity must be based on MDR since May 26, 2021.

Devices placed on the market until the above dates must meet the following conditions:

(i) the devices must continue to comply with the provisions of the MDD; with respect to post-market surveillance, market surveillance, vigilance, the registration of economic operators and of devices, devices must comply with MDR;

(ii) there are no significant changes in the design and intended purpose;

(iii) the devices do not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health;

(iv) no later than May 26, 2024, the manufacturer has put in place a quality management system in accordance with the MDR;

(v) no later than May 26, 2024, the manufacturer has lodged a formal application for conformity assessment, and no later than September 26, 2024, the notified body and the manufacturer have signed a written agreement on the conformity assessment.

Class III custom-made implantable devices may be placed on the market until **May 26, 2026** without a MDR certificate issued by a notified body, provided that not later than May 26, 2024, the manufacturer has lodged a formal application for the applicable conformity assessment, and no later than September 26, 2024, the notified body and the manufacturer have signed a written agreement.

Extended validity of certificates (MDD/MDR)

MDD certificates that were issued by notified bodies in accordance with the MDD as from May 15, 2017 that were valid on May 16, 2021 and that have not been withdrawn afterwards remain valid after the end of the period indicated on the certificate until the above dates.

Certificates that have expired before the date of entry of the proposed amendment will be considered valid until the above dates if the manufacturer and a notified body have signed a written agreement for the conformity assessment procedure under MDR. Alternatively, the competent authority of a Member State may also grant a derogation from the applicable conformity assessment procedure.

Cancellation of 'sell-of' date (MDD/MDR and IVDD/IVDR)

All products placed on the market under the MDD or the Directive 98/79/EC on *in vitro* diagnostic medical devices (IVDD) before May 26, 2021 may be resold indefinitely. The European Commission also proposes to remove the 'sell-off' date currently established in the MDR and the Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices (IVDR). The 'sell-off' date is the end date after which devices that have already been placed on the market, and remain available for purchase, should be withdrawn. Removing this 'sell-off' date will ensure that the safe and

essential medical devices that are already on the market remain available to healthcare systems and to patients in need.

The proposal now needs to be adopted by the European Parliament and the Council through an accelerated co-decision procedure. The proposal should lead to a sigh of relief for the medical device industry, as the bottleneck in the certification procedure caused many manufacturers to fear that they would not receive the required MDR certificates in time. Now, stakeholders cross their fingers that the proposed expansion of the transition periods will pass in the upcoming legislative process.

King & Spalding's team of life sciences lawyers advises medical device manufacturers with business in the European Union and can advise on how to best address the legal issues involved.