Extended transition period for the EU Medical Device Regulation does not help

MDR: Deadline extension a drop in the ocean

The problems of implementing the requirements of the EU's Medical Device Regulation (MDR) for device manufacturers have been pressing ever since the regulation came into force. Now, after much hesitation, EU Health Commissioner Stella Kyriakides has finally reacted. However, according to BDIZ EDI, her "solutions" are just a drop in the ocean.

While the further extension of the transitional provisions of Art. 120 MDR, which are intended to alleviate the massive problems associated with the recertification of existing products, is certainly welcome, BDIZ EDI continues to criticise the EU Commission's ironclad adherence to the bureaucratic monster that is the MDR. Nothing of substance will change.

Still not enough Notified Bodies

There are still too few Notified Bodies. The certification process is as complicated as it is expensive. Small and medium-sized enterprises are particularly affected. In an anonymous survey of the dental industry conducted by BDIZ EDI in 2019, more than 45 per cent of participating manufacturers said they would withdraw products from the market because of the MDR. BDIZ EDI fears that the situation is even worse today.

BDIZ EDI President Christian Berger said: "This will of course also have an impact on many dental treatments. We fear—and we are not the only ones—that small and medium-sized device manufacturers and manufacturers of niche products will not be able to survive much longer."

BDIZ EDI forecast

The new deadlines depend on the risk class of the medical device and are designed to ensure that users such as dentists and physicians continue to have access to medical devices for their patients. Higher-risk devices, such as implants, will have a shorter transition period, until December 2027, than medium- and lower-risk devices, such as syringes, which will have until December 2028 to obtain MDR certification. There will also be no mandatory phase-out date, meaning that products marketed under the current regulatory framework that are still available can remain on the market.

Even before the COVID-19 pandemic, BDIZ EDI had called for the implementation to be postponed by several years, citing a lack of Notified Bodies and a non-functioning central EUDAMED database. None of the objectives of the MDR can be achieved by the original effective date, BDIZ EDI predicted at the time.

Source: BDIZ EDI press release

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