MDR: Roadblock to innovation

Dear reader,

one year ago, the European Commission ended the due to corona one-year-transition period and the European Medical Device Regulation (MDR) came into effect on 26 May 2021. The comprehensive reform of the entire European medical device law obviously affects also dental practices and dental laboratories and of course the medical device industry.

It was even before the Corona pandemic when BDIZ EDI demanded a delay of two to three years to ensure the MDR's viability. Nothing really happened. In the meantime, all predicted implementation problems came true. Among other things, there is still a lack of Notified Bodies and a non-functional central EUDAMED database. None of the objectives of the MDR can be achieved, even though EUDAMED was postponed. Market observers and especially the entire dental sector see the MDR as a roadblock to innovation – with serious repercussions for the practice of medicine and dentistry and ultimately for patients as the steam of new and innovative products dries up. Our fear still is that especially small and medium-sized manufacturers of medical devices will be at risk.

A few weeks ago the Medical Device Regulation was on the agenda at the meeting of the Employment, Social Policy, Health and Consumer Affairs Council (EPSCO), where the health ministers of the European member states discussed implementation problems. However, the EU Commission will probably not present any solutions until the end of 2022. BDIZ EDI welcomes the fact that the EU Commission is moving. However, time is too short to guarantee the functionality of the MDR. It's a good thing that the EU Commission and the member states are taking the concerns of clinics, doctors and med-tech companies seriously and striving for pragmatic solutions. But: we need concrete solutions and measures now!

EU Commissioner Stella Kyriakides had to admit that only 1,000 MDR certificates have been issued so far. By the end of the transition period in May 2024, however, some 24,000 certificates will expire. The German Medical Technology Association (Verband Medizintechnologie, BV-Med) is calling for immediate action: increasing number of Notified Bodies, issuing conditional certificates, exemption for niche products and sufficient resources for innovations and finally: more time!

We from BDIZ EDI call again for postponement – otherwise we all would have to swallow the bitter pill: lack of innovation, lack of many medical devices we're using in our offices. Proper treatment of our patient's will then be at risk!

Christian Berger
President BDIZ EDI