# Manufacturers, dentists, patients – all are affected

The EU Medical Device Regulation (MDR) is the sword of Damocles hanging over manufacturers of medical devices and will have an impact on the entire health care system and the economy – including dentists. Pessimism is spreading. Small and medium-sized manufacturers in particular feel overwhelmed by the new requirements. We spoke with Professor Ulrich M. Gassner, Founding Director of the Research Center for Medical Device Law (Forschungsstelle für Medizinprodukterecht, FMPR) at the University of Augsburg, the only research institution of its kind in Europe.

***The MDR has been in force since 25 May 2017. Pessimism is spreading throughout the market. But why now? Why not much earlier?***

There have been sceptical voices from the beginning. Criticism was levelled at the excessively tight transitional provisions and the fact that hardly any Notified Bodies could be re-accredited in the short time available. But now people are starting to be more nervous. Warning signals aimed at Brussels are increasing because it is now that the fears are actually materializing. This applies in particular to the bottleneck that has arisen: Numerous observers have remarked that there will be too few Notified Bodies to certify products under the new law as the MDR takes full effect on 26 May 2020.

Anita Wuttke, BDIZ EDI Editor-in-Chief, during her conversation with Professor Ulrich M. Gassner.

***Do you share this pessimism?***

I tend to. We are already experiencing a significant drop in the number of Notified Bodies. In addition, just like the manufacturers, Notified Bodies are subject to new requirements, which will slow down certification procedures.

***Who is particularly affected and what effects do you think this will have on the medical device market in Germany and in Europe?***

The major manufacturers have done their homework. But the medical device market is mostly medium-scale in nature. Small and medium-sized enterprises in particular find it difficult to cope with the much more exacting requirements and the associated exorbitant costs. The MDR has already contributed to some concentration tendencies on the market, and this trend will persist. I am aware of small manufacturers who have withdrawn from the market completely or are getting ready to do so. One would rather not have to think about what this means for the affected patients.

***How does the regulation affect manufacturers from non-European countries – say from Asia or North America – who export their medical products to Europe?***

These manufacturers must adapt to the new circumstances. Incidentally, importers are treated the same as manufacturers with regard to their obligations under the MDR.

***Based on estimates by the industry associations Spectaris and BVMed, which are supported by market surveys – including those conducted by the Fraunhofer Institute – it would appear that 40 per cent of companies have already withdrawn their medical products previously on the market. Is the MDR acting as a brake on innovation?***

Certainly; added product safety has its price. The higher the regulatory hurdles, the costlier the certification process, and the greater the delays before an innovative product reaches the patient. Unfortunately, this interrelationship is often overlooked in the public debate. Moreover, it remains to be seen whether the MDR and all its regulations will actually result in greater patient safety or whether the only effect is ever more paperwork.

***Who and where are those "Notified Bodies" that approve the consultation procedures in connection with the clinical evaluation for Class IIb medical devices and Class III implants, or monitor compliance with the extensive regulations?***

As things stand now (at the end of May 2019), only two Notified Bodies are currently accredited under the new law: BSI (London) and TÜV Product Service (Munich). The respective certification authority is not based on risk classes, but on product categories and technical cross-sectional competencies.

***The marketing of products certified under the previous law will have to cease completely by May 2024 at the latest. In your experience, how far have manufacturers come in their implementation of the MDR?***

Like I said, the large manufacturers are relatively well prepared. Some small manufacturers seem to prefer to bury their heads in the sand, even though this may often be mostly due to a lack of available qualified staff.

***To what extent is dentistry or oral implantology affected by the EU regulation?***

Implantologists with in-office laboratories are manufacturers of custom-made products. There are no transitional arrangements that apply to them. As of 26 May 2020, for example, they must meet exactly the same requirements that apply to industrial manufacturers of medical devices with regard to clinical evaluations.

And clinical evaluations are not even all there is to it. Under the heading of "post-market surveillance" (PMS), the MDR demands that implantologists continue to monitor whether their implants are safe and therapeutically useful once implanted and whether there are any incidents related to them. Furthermore, they have to demonstrate that a person responsible for regulatory compliance is available on a permanent and continuous basis.

***Professor Gassner, thank you very much for this interesting interview.***

*This interview was conducted by Anita Wuttke, Editor-in-Chief.* ■