The European Parliament has voted to implement two new regulations concerning medical devices with the aim of improving safety in medicine and dentistry. The regulations were proposed in 2012 by the European Commission and experienced several delays before being officially endorsed at the begging of 2017. They will be applied after a transitional period of three years from publication for medical devices and five years for *in vitro* diagnostic medical devices. Publication is expected to take place shortly in the Official Journal of the European Union.

Though the rules regarding the safety and performance of medical devices were standardised throughout the EU in the 1990s, significant progress in technology rendered these standards in need of updating. In addition, manufacturers could interpret the three existing directives on medical devices—which will be replaced by these regulations—in different ways, thereby creating inconsistencies in adherence to these rules. The new regulations aim to remedy this by ensuring that this progress and innovation continue in a way that is beneficial to the safety of all involved. At the same time, smaller and medium-sized companies are facing the challenge of meeting the new requirements for clinical data, new legal requirements and certifications for all dental products.

Some of the main elements of the regulations include:
- Stricter measures on the quality, safety and performance of devices released into the marketplace, with a particular emphasis on perceived high-risk devices.
- A scrutiny mechanism for Class III implants and Class IIb active products.
- The introduction of a comprehensive database for medical devices sold in the EU (EUDAMED), to be set up by 2020 at the latest.
- Higher requirements for clinical data and technical documentation before and after placement of the respective product on the market.
- A universal device identification system that will permit medical devices to be traced more easily.
- An implant card that will be given to patients so that they, along with medical professionals, have access to information about any implants they receive.
- A set of guidelines for providing appropriate financial recompense to patients for faulty products (the payment will vary according to the risk class and type of device, as well as the size of the company that manufactures the device, and will ideally expedite the remunerative process).
- Guidelines for manufacturers of substances that are carcinogenic, mutagenic or toxic for reproduction, as well as substances that can disrupt the endocrine system, to provide alternative and less harmful products.

The regulations will be applicable in each of the EU member states and aim to provide a clearer framework regarding device standards to patients, professionals, and relevant domestic and international regulatory bodies. A Medical Device Coordination Group, formed of experts from member states and chaired by the European Commission, will be established to help organise and enforce the correct implementation of these regulations.

In addition, conformity assessment procedures by notified bodies—intranational organisations that evaluate medium- and high-risk devices—will continue to be performed through joint assessments conducted with the assistance of other member states.