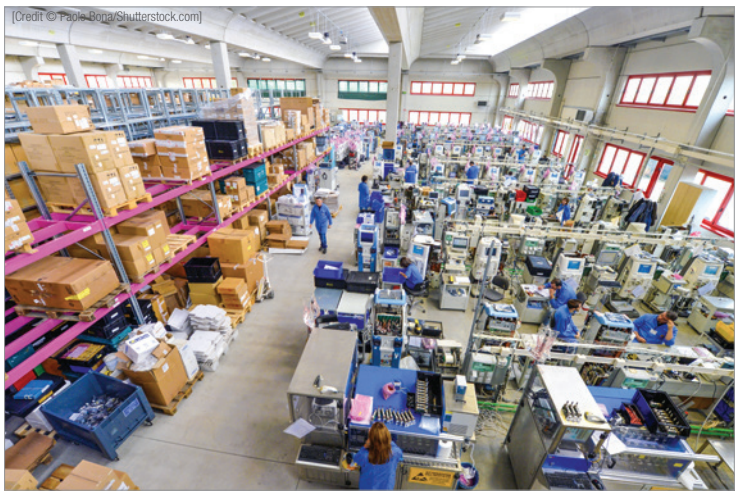
EU grants more time to certify medical devices

European Commission gives manufacturers more time to bring products into compliance with new EU rules.

■ Europe is struggling with the effects of the SARS-CoV-2 pandemic and the war in Ukraine, and the bloc could not have picked a worse time to transition to its overhauled medical device regulation. The European Commission (EC) now wants to give manufacturers more time in order to avoid the real threat of device shortages, but will the extensions make a difference for companies who are withdrawing devices from the market as a result of increasing costs and bureaucracy.

The EC has adopted a proposal to amend the transitional provisions of Regulation (EU) 2017/745 on medical devices (MDR)–giving manufacturers of medical devices more time to certify their products and bring them into compliance with the new rules. Under the amendments, manufacturers now have at least three more years to have their products certified. The new deadlines are December 2027 for high-risk devices and December 2028 for devices deemed medium or low risk. These extensions apply to devices that are considered "safe" and for which the manufacturers have already taken steps to transition towards gaining certification under the MDR.

Having come into law in 2017, the MDR became applicable in May 2021, after being delayed by one year owing to the global pandemic. A transition period of three years was provided for the MDR and its partner regulation, Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices (IVDR), to supersede the existing Council Directive (EEC) 93/42 concerning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medical devices (MDD) and Council Directive (EEC) 90/385 on active implantable medical devices (AIMDD).

An additional "sell-off" provision in the MDR specified a date after which products already placed on the market and certified under the MDD and AIMDD would have to be withdrawn. The EC has now scrapped that provision, emphasising that essential medical devices that are already on the market should remain available to patients in need.

European Health Commissioner Stella Kyriakides proposed the changes in Brussels in December, citing multiple issues. She said: "A combination of factors has left healthcare systems across the EU facing a risk of shortages of life-saving medical devices for patients." Admitting that most manufacturers were struggling to meet the certification requirements in the time given, the commission stated in January that the limited progress made posed a threat to device availability. It cited a number of factors, such as the limited capacity of notified bodies (entities that check compliance with medical device regulations), the ongoing effects of the COVID-19 pandemic, global supply chain disruptions and limited preparedness on the part of manufacturers. These factors were "causing a risk of shortages of life-saving medical devices for patients," the EC said.

The commission stated: "Many manufacturers are not sufficiently prepared to meet the robust requirements of the MDR by the end of the current transition period. This threatens the availability of medical devices on the EU market."

Figures provided by the EC show lacklustre progress. By October 2022, notified bodies had received just 8,120 applications for MDR certification and fewer than 2,000 certificates had been issued. At that time, a total of 22,793 MDD and AIMDD certificates had been due to expire before the supersession of these regulations by the MDR and IVDR.

It all began in France in 2010 with a breast implant scandal that forced EU lawmakers into crisis mode. Many say that the resulting regulatory overhaul was necessary, but others have labelled the MDR as reactionary and overburdensome. Staff at Osypka, a German company which has manufactured surgical devices in Europe for decades, told Reuters in December that the company could not afford the costly MDR certification process and had been forced to withdraw five lines of its devices from sale. The company estimated that certification for one of its products, which has already undergone clinical trials, would cost the company over €1 million.

Mark Stephen Pace, chairman of the Association of the German Dental Industry, told attendees at an IDS press conference in Cologne in January that dentists and dental manufacturers needed more support from their politicians. He said that the MDR had made daily operations at clinics and manufacturing sites more complicated and more expensive, and he emphasised that a balance must be struck. Pace said: "In recent years, many requirements, guidelines and laws have been added, and these have enormously increased the bureaucratic effort for companies. Costs are rising and staff is scarce. In order to be able to offer affordable products and services, bureaucracy has to be reduced, because what it essentially does is create problems for manufacturers and for dental professionals." ◂◂

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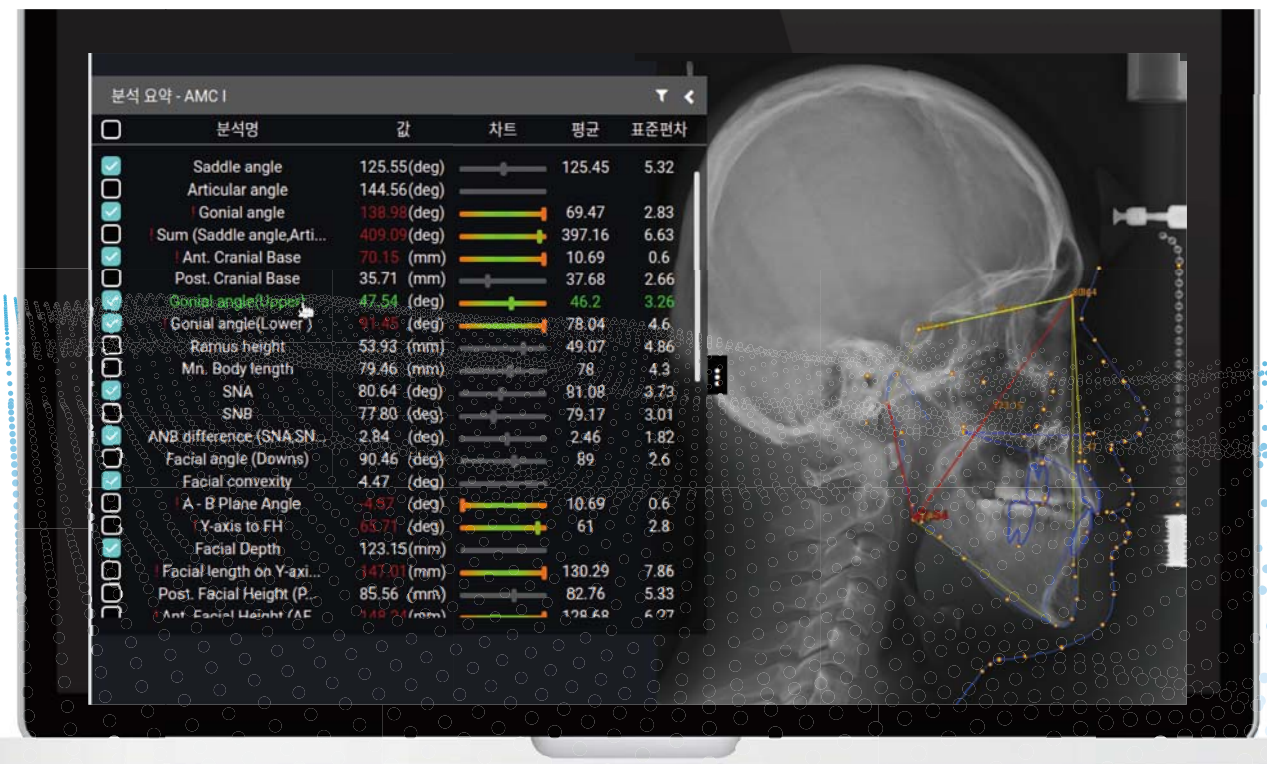

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