EU wakes up to new medical device regulations

What will change under the EU's new medical device regulations?

■ After a three-year transition period and a delay of 12 months owing to the SARS-CoV-2 pandemic, new regulations for medical devices for human use in the European Union went into force on 26 May. The new and stricter rules mainly apply to those who manufacture, import and sell medical devices; however, dental professionals should be aware that distributors must keep a register of any complaints or reports received from health professionals and patients relating to devices and forward these complaints to the device manufacturer or importer.

Commonly referred to as the MDR (Medical Device Regulation), Council Regulation (EU) 2017/745 came into effect on 25 May 2017 with a grace period of three years. The MDR repealed Council Directive 93/42/EEC, known as the Medical Device Directive (MDD), and Council Directive 90/385/EEC, which regulated active implantable medical devices in the EU. An additional directive—Council Regulation (EU) 2017/746, known as the In Vitro Diagnostic Regulation (IVDR)—came into effect in tandem with the MDR and is set to regulate *in vitro* diagnostic medical devices when a five-year transition period expires in May 2022.

The European Commission, in April last year, announced a 12-month delay of the application of the MDR. A statement from the commission explained that the decision was made so that member states, health institutions and commercial operators in the medical devices industry could prioritise efforts to combat the pandemic. "Shortages or delays in getting key medical devices certified and on the market are not an option right now," commented Margaritis Schinas, vice president for promoting our European way of life, in the media release. Indeed, the MDR is denser and more complex than its predecessor and transposing the directive has been a mammoth task for all stakeholders.

Compared with the repealed MDD, the MDR changes device scope and the way that medical devices are classified. For example, the legislation includes new rules for devices that use hazardous substances and for software applications. Some devices have been reclassified under the MDR, and the directive regulates certain devices that were previously exempt from medical device regulations.

The MDR also brings changes to the oversight process. Under the new directive, only notified bodies that are designated under the MDR can verify medical devices as being fit for use in the EU. Notified bodies that were designated under the MDD must be newly designated under the MDR. According to a white paper published by the Brussels-based European business law firm contrast and the Association of Dental Dealers in Europe—seen by Dental Tribune International—the public health situation in Europe has hampered efforts to designate enough notified bodies. Since some notified bodies that were designated under the MDD may not receive designation under the MDR, it is expected that some medical device manufacturers will need to change notified bodies.

Other examples of the various changes brought by the MDR include a redefined economic operator concept, which differentiates between manufacturer, authorised representative, importer and distributor. All economic operators must conform to the directive and the responsibilities of these stakeholders are expected to increase.

The MDR also brings heightened post-market surveillance to the medical devices market, and EU member states are required to adopt penalties for any infringements of its requirements. Unique identifiers must be placed on medical devices so that they can be registered on a new European database. Named EUDAMED, the database will record the registration of devices, the accredited notified bodies, and also certificates and reports of incidents relating to the safety and clinical performance of devices.

Distributors will be required to keep a record of any complaints or reports that they receive from health professionals and immediately forward them to the manufacturer and/or importer of the device in question. Distributors of medical devices must also keep a register of non-conforming devices and devices that were recalled or withdrawn from sale.

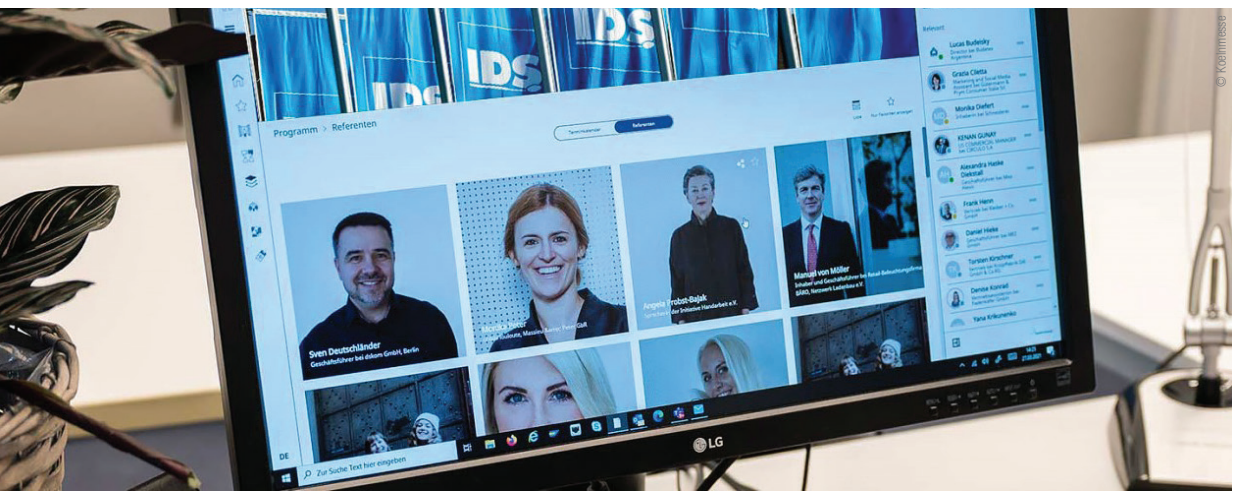
The full text of the MDR is available at https://eur-lex.europa.eu/eli/reg/2017/745/oj.

IDSconnect: The new digital event platform of IDS

Koelnmesse has stepped up its game to make IDS a successful event—online and offline.

■ In 2021, IDS is going hybrid, which means that more participants than ever before will attend the largest trade show in the dental industry from the comfort of their homes and not in person, owing to COVID-19 travel restrictions. To provide a digital enhancement to the classic physical event, the free platform IDSconnect intends to maintain IDS's extensive international reach together with a successful on-site trade fair experience.

At a trade fair or in day-to-day commercial business, a company's success is based on three essential building blocks: inspiration, interaction and business. IDSconnect provides innovative opportunities for you to reduce the effects of any current deficit in these crucial elements. Extensive features enable you to reach more potential customers easily, to experience trends and lectures on demand, and to establish valuable contacts—from anywhere in the world.



The experience starts in the Lobby, where users find an overview of all the features as well as initial recommendations for relevant contacts, exhibitors and upcoming scheduled trade fair items. Features include top experts on stage presenting on industry-relevant topics live from Cologne or streaming from locations throughout the world. The IDS Main Stage is the central platform for the official event programme of IDS 2021. This is where to find insight and motivation in the many presentations and official side events. Let yourself be inspired by the visionary programme.

The area Exhibitors and Products represents the exhibition hall. From there, users have access to the booths of the various exhibitors in so-called Showrooms in which relevant information about the exhibitor's company, products and services will be provided. On the Product Stage, exhibitors will present product innovations and highlights live to the audience. Alternatively, these can be watched later on demand.

At a Virtual Café, visitors, exhibitors, top decision makers, purchasers, industry experts and media representatives can come together to chat and network. In terms of networking, the Discovery Graph ensures networking with new contacts and achieving a direct exchange of ideas via the communication centre.

More information about IDSconnect can be accessed at https://www.english.ids-cologne.de/fair/idsconnect/.

Around 830 exhibitors from 56 countries to attend IDS 2021

High number of international companies underscores importance of global industry platform.

■ The International Dental Show (IDS) will be opening its doors for the 39th time from 22 to 25 September. Owing to the ongoing global SARS-CoV-2 pandemic, which led the organisers to postpone the event from March to September, this year's edition will be taking place under extraordinary circumstances. Although a considerable number of companies will not be exhibiting at IDS, about 830 companies have already confirmed their participation.

According to the latest figures by Koelnmesse, 74% of exhibitors come from abroad, including from France, Great Britain, Italy, South Korea, Switzerland and the US. Companies from Brazil, Bulgaria, China, France, Italy, South Korea, Russia and the US will have country-specific pavilions. In a recent press release, Koelnmesse stated that the high level of international participation underlines once again the outstanding significance of IDS as the most important global dental industry platform.

Overall, the organisers predict that IDS will play a key role in the successful restart of the market. Throughout 2020, dental companies around the globe reported the financial effects of government-imposed lockdowns and radical public health measures, including the partial or complete closure of dental practices. As revealed by the fourth-quarter results for 2020 and this year's first-quarter results, the industry is slowly but steadily recovering from the crisis.

In order to protect and ensure the health and safety of exhibitors and visitors alike, rigorous protective measures in line with the official requirements have been taken into account in the allocation of the exhibition floor. IDS 2021 will be staged in Halls 2, 3, 10 and 11, which are connected via a simple circular route. Visitors will be able to enter the fair through four entrances, which will allow for an even distribution of attendees across the exhibition halls. To meet social distancing rules, the existing restaurant and resting areas in the halls have been expanded and a new food area has been installed in Hall 4.1.

In addition, the organisers are extending the physical event in Cologne through the digital platform IDSconnect. This strategic move to make IDS 2021 a hybrid event will benefit both dental professionals and companies and, in particular, those who will not be able to travel to Cologne in September, as it includes a number of innovative features that will allow users to discover new products and connect with colleagues and partners online. More information about IDS can be found on the https://www.english.ids-cologne.de/.