

TREND REPORT

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An attractive market: New MDR creates uncertainty for suppliers

Anyone currently involved with the medical technology sector as a supplier can no longer ignore the new regulation that will take effect in 2020. In addition to a QM system, the peculiarities of the MDR also pose a real challenge to the SME-dominated supplier industry. Quality and regulation are therefore two of the major themes at the Medtech Summit and MedtecLIVE.

The challenge of MDR

Anyone seeking to become a supplier on the medical technology market would be well advised to get to grips with the MDR as swiftly as possible. Following a three-year transitional period, the European Medical Device Regulation (MDR) will be binding with effect from 26 May 2020. Its wide-ranging provisions differ in many details from the Medical Products Act, which previously applied in Germany, and make it necessary to recertify all medical products in accordance with the new provisions of the MDR. Although trade and professional associations are currently trying to influence policy-makers to have the transitional period extended, at the urging of SMEs in particular, it is unclear whether these efforts will ultimately be rewarded with success. Many information services and platforms – such as MedtecLIVE and the Medtech Summit – are therefore actively tackling this subject and offering practical advice about the impending challenges.

For development service firms, too, the changed requirements under the MDR will mean major challenges affecting their work with collaborative partners. “Manufacturers that want to have a medical device certified or recertified with our support are often surprised at the huge amount of work that is required,” comments Reiner Witt, CEO of Mechatronic AG. “Extensive information is required, along with sensitisation, to ensure that

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services offered by firms can be assessed realistically and with professional understanding.”

For further information about MedtecLIVE exhibitor Mechatronic AG, see [here](#).

Dialogue and sharing of knowledge

For Leoni, success comes from proximity to the customer. For Bytec the key lies in extensive know-how about the regulatory framework, such as the MDR and the registration process. Discussion and a broader perspective – beyond their own shop floor – are equally important for ideas people, suppliers and OEMs. And this is exactly what MedtecLIVE, the trade fair that grew from the combination of Medtec Europe and MT-CONNECT, aims to initiate and enliven. It will be held for the first time at the Exhibition Centre Nuremberg from 21 to 23 May 2019. “By working together, the two organizers, NürnbergMesse and UBM, hope to create a major platform in southern Germany for the entire medical technology value chain,” assures Alexander Stein, Director of Exhibitions for MedtecLIVE at NürnbergMesse. “The three core values, ‘Innovate, Connect and Do Business’, set the direction: MedtecLIVE brings the latest trends and technologies into the exhibition halls, while being THE networking platform for the medical technology scene in Europe. And last but not least, MedtecLIVE is a trade fair where experts – from developers to purchasers – can share ideas, find new solutions, and establish business relationships.”

Making new contacts at the congress

Additional stimulation for the intensive dialogue between manufacturers and suppliers comes from the presentations and interactive formats that characterise the MedTech Summit. “Suppliers can leverage the strong appeal of the medical technology sector for the long term only if they are familiar with the specific challenges of the sector and work closely with their partner entities to develop good solutions,” says Dr Matthias Schier, CEO of Forum MedTech Pharma e.V., the honorary sponsor of the overall event. “That’s why we will be giving a special emphasis to these questions.” The event will deal in detail with the challenges posed by the medical technology sector as identified by technology suppliers and service firms like Bytec, Leoni and Mechatronic. These include the relevance of

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certification, the joint elaboration of specifications, and implementing the best possible design transfer. Of central interest is the question of how the changes brought about by the MDR will influence the way manufacturers and suppliers work together. Information and platforms for sharing information help give shape to collaborative efforts, to ensure the maximum benefit for everyone involved.

Further information on the MedTech Summit Congress & Partnering is available [here](#).

One thing that's certain is that the effort is worth it for suppliers and service firms alike. The medical technology sector has enjoyed constant growth for a number of years and is benefiting more than almost any other from the advances in technology and digitalisation being made in healthcare. Successful and beneficial long-term business relationships await software suppliers or component manufacturers whose own work is focused on the interests of patients and users, and are prepared to take on the regulatory peculiarities of this strong and globally prosperous sector. Figures from a study by the Landshut University of Applied Sciences clearly show that once a business has successfully entered the market, it will often become a supplier to several manufacturers.

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