FORUM
The Stiegelmeyer-Group's company magazine

What does MDR mean for care and hospital beds?

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In 2020, an important date awaits all companies that manufacture or handle medical devices. On 26 May, the new European Medical Device Regulation (MDR) will enter into force after a transitional period. Stiegelmeyer and Burmeier have been preparing for this deadline for a long time. Also, for the medical specialised trade new requirements result. We have compiled the most important changes for you.

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European Medical Devices Regulation becomes binding in 2020

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The MDR is intended to make medical devices safer. It therefore increases the requirements both for the manufacturers and for the so-called "Notified Bodies", which check the manufacturing process – this includes, for example, the TÜV (Technical Inspection Authority). The increased monitoring and recertification of the 90 Notified Bodies in Europe to date is also one of the biggest points of criticism, as there is a lack of specialists needed for this. Many manufacturers therefore fear long delays in market access and the approval of new products. This applies above all to medical devices with a high-risk classification, such as implants.

The Stiegelmeyer Group has been fulfilling several requirements for years

Hospital and care beds, on the other hand, are considered low-risk products and are for the most part in the lowest class I, together with wheelchairs or walking aids. This means that manufacturers continue to declare the conformity of these products themselves. In the Stiegelmeyer Group, these documents are regularly

checked by DEKRA (a German auditing and testing firm), which has already been listed as a Notified Body for the MDR. We have been voluntarily fulfilling parts of the higher requirements that MDR now places on manufacturers for years, for example through a comprehensive quality management system in accordance with EN ISO 13485.

The medical supply trade must monitor its medical products even more closely than before in everyday life. Burmeier is a strong and reliable partner. Our care beds – here the Dali low-entry – stand for high quality.

UDI – the unique product key

An important innovation of the MDR is the "Unique Device Identification" (UDI), a unique product key for every medical product, which will also be found on our beds and their packaging in the future. The UDI will gradually become mandatory for certain classes of medical devices from 2021 and for Class I beds from 2025. It will provide information about the product and its manufacturing route. Some of this information will also be publicly accessible in the new European database EUDAMED, which is currently being set up. This will make it easier, for example, to recall defective products and prevent the sale of illegal products.

Distributors selling medical devices from countries outside the EU must ensure that these products meet the requirements of the MDR. This also includes the fact that the manufacturer has appointed an authorised representative in the EU to act as the manufacturer's contact person and fulfil manufacturer obligations. In addition, of course, the manufacturer must also provide a declaration of conformity in accordance with the MDR, the UDI label if applicable and instructions for use in the respective EU country’s language. If dealers offer medical devices under their own model name or with their own packaging, they should carefully check whether this could make them a manufacturer themselves. This is the case, for example, if the original manufacturer's type plates and the associated identification options for the medical device are no longer used.

Dealers must be vigilant

The specialist dealers also play an important role in the systematic monitoring of their medical products in everyday life. If, for example, customers complain about defective products, the specialist dealers must document this and forward it to the manufacturer. For this purpose, it may also be necessary to collect customer data.

The specialist trade is obliged to comply with the manufacturer's prescribed storage and transport conditions and to reprocess the medical devices according to a validated procedure. New goods which have not yet been certified according to the MDR regulations may only be brought onto the market until 27 May 2025. Used products are not affected by this restriction.

Even greater safety for residents and patients is the main objective of MDR.

Many manufacturers concerned

As much as the higher safety standards for medical devices are to be welcomed, many manufacturers are concerned about their implementation. The expected bottleneck at the Notified Bodies and the simultaneous higher classification of many products brings uncertainty. According to surveys, every third medical device manufacturer fears for its existence. In many cases, the introduction of innovative products could be postponed or even discontinued altogether.

On the retailer side, the medical supply trade has the advantage that it can more easily collect data and document information through close contact with customers and the case-based compensation system. The medical device trade in supermarkets, on the other hand, is likely to present greater challenges.

Whatever the future holds: Stiegelmeyer and Burmeier are reliable partners. Our customers can rely on the fact that our beds comply with all applicable guidelines and regulations.

The complete wording of the MDR can be found here:

https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1571117483543&uri=CELEX:32017R0745