FORUM
The Stiegelmeyer-Group's company magazine

Despite postponement – Stiegelmeyer and Burmeier are ready for the MDR

27. April 2020 // **Articles & Reports**

Many manufacturers and users in the healthcare sector have been preparing for 26 May 2020 for years. On this day, the new EU Medical Device Regulation (abbreviation MDR) was supposed to come into effect. However, the corona crisis has put a damper on the plans. In order to avoid putting even more pressure on the medical industry players during the pandemic, the EU Parliament has agreed to postpone the deadline by one year to May 26, 2021. This is probably a relief not least to the responsible EU authorities themselves, who have been repeatedly accused by the industry of lack of preparation. For Stiegelmeyer and Burmeier, on the other hand, nothing will change as a result of the postponement: We have already completed the implementation of the MDR.

EU Medical Devices Regulation will not become binding until 2021

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This means strong advantages and planning security for our partners, who deal with our beds in purchasing associations and medical supply stores. After all, the MDR also imposes some new obligations on dealers. They are compiled in the 14th article of the regulation text.

CE labelling and "UDI"

What does this mean in concrete terms for the handling of care beds? For example, dealers are required to

check certain bed labels. Products from Stiegelmeyer and Burmeier have always carried the prescribed CE label. Originally, the Unique Device Identification (UDI) was to be added to the identification label at the start of the MDR, with the help of which a lot of information about the bed can be obtained. However, this project was postponed until 2025 because the associated European database EUDAMED has not yet been released for Class I medical devices, which also includes care beds.

The mandatory EU declarations of conformity for our beds, on the other hand, are already available. They contain the "Basis UDI DI" as well as the declaration of compliance with the MDR specifications. Depending on whether our partners deal with beds from Stiegelmeyer or Burmeier, they can request the EU Declarations of Conformity from the Stiegelmeyer Customer Centre or download them from the Burmeier dealer area. The same applies to the user manuals for the beds. Links and telephone numbers can be found at the end of this article.

Feedback from our partners is important to us – in the course of the MDR we will soon contact you annually and ask for your feedback and wishes regarding our products.

Certified quality

The current ISO certifications of our quality management according to EN ISO 9001 and EN ISO 13485 are already available for download at www.stiegelmeyer.com/en/information/certificates. Such a certified quality management will only now become mandatory for Class I medical device manufacturers for the first time from the start of MDR validity. The Stiegelmeyer-Group, however, has been voluntarily applying such a system for more than 20 years, thus underlining its commitment to quality. Other data relevant for dealer documentation are handed over upon delivery of the bed to the hospital or nursing home or are located directly on the product, e.g. an identification label with model designation, date of manufacture etc. and a barcode label with the specific product identification number (PID).

Beds and furniture from the Stiegelmeyer-Group are manufactured in the EU, which means that dealers do not have to carry out the mandatory testing of imported products from third countries. What is important, however, is compliance with the storage or transport conditions – these can be found on the outer packaging of the beds.

We all have a great interest in ensuring that our beds function smoothly. The MDR requires dealers to document error messages about medical products in a register and to forward them to the manufacturers. As always, we will be listening to our partners. We would also like to support the dealers in this feedback obligation: Once a year we will contact them and ask them specifically about their experiences and suggestions for improvement. By observing the market, we are making sure together that our beds are getting better and better.

Anyone who wants to purchase beds from us can do so without any worries, regardless of when the MDR comes into effect. All our beds delivered starting in May 2020 are already MDR-compliant. All models acquired before that date and still in operation are under unlimited protection.

The MDR is causing many concerns throughout Europe, but for the Stiegelmeyer-Group's business we can assure all partners: The new regulation will in no way impair our cooperation; on the contrary, it will make it even more reliable, transparent and successful.

EU declarations of conformity and user manuals

For Stiegelmeyer beds:

Please contact our customer centre:
Email: service@stiegelmeyer.com
Phone: +49 (0) 5221 185 - 777

For Burmeier beds:

Download in the dealer section:
partner.burmeier.com/en/