



Information on the implementation status of MDR (EU) 2017/745 at NOBAMED Paul Danz AG

Since 2016, we have been preparing intensively for the implementation of MDR 2017/745. It all started in 2014 with the strategic search for a Notified Body that would probably still be designated under the MDR. To be absolutely sure, we decided on TÜV Süd Product Service GmbH 0123 and switched there in 2015.

In the first quarter of 2021, we successfully passed our MDR audit (stage 2). Numerous documents had to be submitted in advance (stage 1).

We successfully completed the audit without any deviations.

Due to the generally known overload of the Notified Bodies, the final processing of the documents and the issuing of the certificate at TÜV Süd was now delayed until the first quarter of 2022.

As of today, you can find the certificates for the MDR under Knowledge Connects.

For the deadline of 26.05.2021, we have already placed the MDR DoC Class I declarations of conformity on our website. The other declarations of conformity will follow step by step.

MDD DoC declarations of conformity for classes Is to III remain valid until the expiry of the current certificates.

Our product data sheets have already been revised and contain further important text modules.

Please note that from the date of application of the MDR (26.05.2021), products with MDD 93/42 EEC labelling may remain in the trade chain until 27.05.2025 and can still be used by the end user thereafter.

Therefore, we have additionally placed the declarations of conformity of the products under MDD next to the product data sheets on the website.

It is also important that the UDI code, which immediately shows on the labelling that the product has already been assessed under the MDR, does not have to be applied to the product until 2025 for all Class I products.

On our website you will also find the **tab: 'Knowledge connects'**.

This contains a lot of useful regulatory information on our products:

- our QM certificates
- Information on new symbols on packaging
- Translation of the body of the DoC
- Instructions for set packers
- Reprocessing instructions for clinics
- Quality assurance information for distributors

Wetter, 10/03/2022

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