



Information on MDR (EU) 2017/745 at NOBAMED Paul Danz AG

Since 10.03.2022 we are certified according to MDR (EU) 2017/745.

Our Notified Body is TÜV Süd Product Service GmbH, 0123, and you can find the MDR certificates under 'Knowledge connects'.

We prepared intensively for the implementation of MDR 2017/745 back in 2016.

It all began in 2014 with the strategic search for a notified body that would probably still be designated under the MDR. To be absolutely sure, we opted for TÜV Süd Product Service GmbH 0123 and switched to it 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 delayed until the first quarter of 2022.

We have placed the MDR DoC declarations of conformity on our website and will always keep them up to date for our customers to download.

Our product data sheets are part of the declaration of conformity and contain further important information.

Please note that from the date of application of the MDR (2021-05-26), products labeled according to MDD 93/42 EEC may remain in the supply chain and can then continue to be used by the end user. We have therefore added the declarations of conformity of the products under MDD to the product data sheets on the website.

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, 2025-05-23

Dr. A. Danz MBA
Vice Chair of the Executive Board, PRRC