NOBAMED Paul Danz AG

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 this year 2021, we had our MDR audit (stage 2). Numerous documents had to be submitted in advance (stage 1).
We successfully passed the audit without any non-conformities!

For the deadline of 26.05.2021, we have already placed the MDR DoC declarations of conformity class I on our website. Further declarations of conformity will follow step by step, depending on the receipt of the certificates.
MDD DoC declarations of conformity for classes Is to III will remain until the current certificates expire.
For this purpose, many of 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.
The customer must therefore be able to rely on the fact that the company has already implemented the content requirements of the MDR internally today. That is what we stand for!

On our website you will also find a **new 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, 29/04/2021

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