Special edition

Medical Device Regulation (MDR)

EUDAMED postponed by two years

Current status of EUDAMED

Following to last week's rumors, the EU commission has now taken an official position on the status of EUDAMED. On their webpage it now says: "EUDAMED's launch will be done together for medical and in-vitro medical devices, at the original date foreseen for in-vitro medical devices i.e. May 2022". This means that the European Databank on Medical Devices (EUDAMED) which is required to meet MDR requirements will go online for the first time only two years after the end of the transition period of the MDR.

For more information about the reason of postponing please refer to the following link: https://ec.europa.eu/growth/sectors/medical-devices/new-regulations/eudamed_en

General information relating to EUDAMED

EUDAMED is the European database for medical devices. It is intended to improve market observation in addition to administration. Authorities should have quick access to information on manufacturers and European Authorized Representatives, on products and certificates and on vigilance. EUDAMED is thus not only important for manufacturers of medical devices, but also for other actors such as European Authorized Representatives. With MDR, manufacturers are obliged to enter product data in EUDAMED before placing their products on the European market.

What does that mean for the MDR?

Despite the non-usable EUDAMED, the date of application of the MDR still remains May 2020. All MDR requirements that are not related to EUDAMED are to be implemented by this date.

MedNet's statement

Currently, it is not clear how the registration process under MDR will be preceded without EUDAMED. We will of course keep you up to date and inform you as soon as there are any news.

For more detailed information, please do not hesitate to contact us!

MedNet GmbH • Borkstraße 10 • 48163 Muenster • Germany
Phone +49 251 32266-0 • Fax +49 251 32266-22 • www.mednet-eurep.com • info@medneteurope.com