Press Release

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TÜV SÜD releases the worldwide first certificate for aesthetic products according to Annex XVI of the MDR

Munich. The Notified Body TÜV SÜD Product Service GmbH released the first certificate for a non-medical purpose device according to Annex XVI of Regulation (EU) 2017/745. The certified device – a hyaluronic acid based dermal filler – is covered by group 3 of Annex XVI and fulfils the strict requirements of MDR and the Common Specifications 2022/2346.

On 2nd December 2022, the long awaited Common Specification (CS) 2022/2346 for the groups of products without an intended medical purpose was published by the European Commission laying down strict requirements for risk management and information for safety especially for those products. To obtain a MDR certificate the requirements of CS 2022/2346 need to be fulfilled. With the release of the worldwide first Annex XVI certificate, TÜV SÜD Product Service GmbH positively assessed the compliance of a hyaluronic acid based dermal filler to the requirements for a Class III product.

A major group of Annex XVI are dermal fillers, which are injectable substances used to restore volume, smooth wrinkles, and enhance facial contours. They are typically made from hyaluronic acid, a naturally occurring substance in the body, and are injected beneath the skin's surface to improve the appearance of aging signs, such as fine lines and sagging. The certified device is a hyaluronic based dermal filler provided by Croma-Pharma GmbH based in Austria.

The release of the certification marks another chapter in TÜV SÜD's track record as a key driver for successful implementation of the new MDR and IVD regulations and ensures the availability of safe and effective devices for the patients. The testing and certification company had already issued its first MDR certificate in September 2019, the world's first IVDR certificate in October 2020 and has since issued numerous MDR and IVD certificates to support the transition to MDR- and IVDR-compliant products. Now, TÜV SÜD is proud to support manufacturers as a strong and reliable Notified Body in obtaining market approval for their devices without an intended medical purpose in accordance with the requirements of the MDR and CS 2022/2346.

“The certificate that has now been issued is a milestone because it shows that two different pieces of EU legislation are successfully interlinked,” explains Dr. Andreas Stange, Global Head for Regulatory and Quality, Medical & Health Services at TÜV SÜD.

TÜV SÜD in the MedTech industry

TÜV SÜD is one of the first Notified Bodies worldwide to be authorised for MDR and IVDR conformity assessments. As a global leading company in this field, TÜV SÜD has been certifying manufacturers and suppliers for over 30 years as a requirement for market entry. The authorised experts ensure increased safety, quality and sustainability from product design through testing and certification to approval. Thanks to their extensive presence in many different countries, they are familiar with the local regulatory requirements - a basic prerequisite for successful certification processes.

The Medical & Health Services division at TÜV SÜD has continuously expanded its capacities over the past five years (CAGR of almost 20 %) and now has more than 1,400 medical device experts at over 30 locations worldwide. Thanks to this long-term and forward-looking resource planning, the company offers short-term availability for conformity assessment procedures in accordance with the MDR and IVDR - both for existing products and for new approvals. New customers can be accepted and projects can be started quickly, reliably and transparently. At a time when innovation and patient safety are of utmost importance, early testing and collaboration with experienced bodies such as TÜV SÜD can make all the difference.

Further information:

- https://www.tuvsud.com/mdr

Note for editorial staff: The press release can be downloaded from https://www.tuvsud.com/newsroom.

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