Press Release

EU Regulation on in-vitro diagnostic medical devices 25 July 2022

TÜV SÜD issues first IVDR certificate for a class D medical device

Munich. Notified Body TÜV SÜD Product Service GmbH is happy to announce that it has issued the world's first certificate in accordance with the new EU Regulation on in vitro diagnostic medical devices (IVDR) for a new device in risk class D produced by Roche Diagnostics GmbH. TÜV SÜD was already the issuer of the world's first IVDR certificate, in October 2020.

The IVDR brought a reorganisation of the approval process of in vitro diagnostics (IVD). On the basis of the new rules, IVDs are now classified in one of four risk classes, A, B, C or D, with devices in class A posing the lowest risks and those in class D the highest. The IVDR has been in force since May 2017. For manufacturers of medical devices that had already been certified, a transitional period of five years was originally defined. After the recent modification of the IVDR transition periods, manufacturers of high-risk products now have until May 2025 to gain IVDR certification for products which had already been certified under the old procedure.

To place class D IVDs on the market, these products must be approved by the manufacturers with a Notified Body such as TÜV SÜD Product Service GmbH. EU reference laboratories are involved in this process and the harmonised standards and "common specifications" are taken into consideration. Since these laboratories had not yet been designated when the IVDR was published and the standards and specifications do not yet apply in full, a view from an expert panel of the EU Commission had to be obtained for this early conformity assessment procedure. "The certificate now issued marks the first time that this procedure has been brought to successful completion and represents an important milestone in IVDR implementation", says Dr Andreas Stange, Vice President Medical & Health Services (MHS) at TÜV SÜD Product Service.

The certified diagnostic product, manufactured by Roche Diagnostics GmbH, Mannheim, is a qualitative immunoassay intended to detect antibodies to SARS-CoV-2 in human blood plasma and serum.
Dr Andreas Stange comments, "What makes this certification so exciting, in addition to the special procedure, is the fact that it concerns a diagnostic product without prior certification under the In-Vitro

Diagnostic Device Directive (IVDD), but which is the first example of a class D diagnostic device certified under the IVDR."

More devices, fewer Notified Bodies

Introduction of the new risk-based classification system also means that manufacturers now have to involve a Notified Body in the approval of most IVDs. Where this previously applied to only about 15 per cent of IVDs, this percentage has now grown to more than 80 per cent. Only low-risk devices in class A are excluded from this obligation. At the same time, the IVDR establishes significantly stricter requirements for Notified Bodies: they now need to consult reference laboratories and other competent authorities – or, as in this case, an expert panel; this will extend the time taken up by conformity assessment processes. Stricter designation rules have likewise had a negative impact on the number of available Notified Bodies. Regarding the number of MedTech experts, TÜV SÜD has acted with remarkable foresight. To prepare for the regulation, TÜV SÜD has increased and qualified its resources over the last 4 to 5 years at a compound annual growth rate (CAGR) of almost 20 per cent.

Notified Body TÜV SÜD Product Service GmbH

Notified by the EU in June 2020, TÜV SÜD Product Service GmbH is one of the few Notified Bodies authorised to carry out certification according to both the new Regulation and the previous In-Vitro Diagnostics Directive (IVDD). As the largest Notified Body for Medical Devices and In Vitro Diagnostic Medical Devices, TÜV SÜD has more than 30 years of experience in providing certification of manufacturers and suppliers, which is one of the requirements for placing medical devices on the market. More than 130 authorised experts work on enhancing safety and security, quality and sustainability at every stage, from product design and development to testing, certification and ultimately approval. As they are represented at various locations in different countries, they are familiar with the local regulatory requirements – an essential feature for the success of the certification process.

More information from TÜV SÜD about the new IVDR can be found at:
https://www.tuvsud.com/en/industries/healthcare-and-medical-devices/medical-devices-and-ivd/medical-device-market-approval-and-certification/eu-in-vitro-diagnostic-medical-device-regulation

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