Press Release

New EU In Vitro Diagnostic Medical Device Regulation (IVDR) 29 October 2020

First IVDR certificate issued by TÜV SÜD

Munich. TÜV SÜD Product Service has issued their first In Vitro Medical Device Regulation (IVDR) certificate since receiving notification in June 2020 – and the first IVDR certificate worldwide. The IVDR, which came into force in May 2017, must be implemented by late May 2022.

The new In Vitro Diagnostic Medical Device Regulation (IVDR, EU 2017/746) of the European Union replaces Directive 98/79/EC on In Vitro Medical Devices (IVDD). It represents a significant regulation change which imposes stricter demands on medical device manufacturers and Notified Bodies. To date, 4 of the 11 Notified Bodies which have applied for designation under IVDR have received designation and are published on the NANDO webpage.

TÜV SÜD is pleased to announce that it has issued the first IVDR certificate, a certificate for a Class B device.

“Since receiving designation and notification, TÜV SÜD has been working hard on reorganising and preparing resources to provide services under the new legislative framework. We have continued to clarify open questions and implement newly published information about the IVDR into our processes. The release of our first IVDR certificate is a significant milestone. The challenge now lies in balancing our existing IVDD projects with the strong demand for IVDR services in this transition period”, says Dr Andreas Stange, Vice President / Medical & Health Services at TÜV SÜD.

"Our issue of the first IVDR certificate in such a short time after receiving our designation as a Notified Body, demonstrates our commitment under this new status to support effective implementation of the IVDR and a smooth transition from the old directive to the new regulation. It is critical that a continued supply of safe and effective medical devices is available for patients and healthcare professionals”, adds Dr Royth von Hahn, Senior Vice President / Global Head of Medical & Health Services at TÜV SÜD.

TÜV SÜD's international expertise

TÜV SÜD is one of the world's leading Notified Bodies providing conformity assessment services related to medical devices. Its 900-plus medical device professionals can be found at more than 30 locations throughout the world. Manufacturers benefit from both TÜV SÜD's technical expertise and its extensive international accreditations and recognitions, including NRTL, INMETRO and the Medical Device Single Audit Program (MDSAP). These benefits considerably reduce the efforts involved in accessing international markets and time to market.

Further information about the EU In Vitro Diagnostic Medical Device Regulation, the key changes it involves and TÜV SÜD's services in this context can be found at https://www.tuvsud.com/ivdr.

Note for editorial staff: This press release is available at https://www.tuvsud.com/en/press-and-media

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