Press Release

The new EU In Vitro Diagnostic Medical Device Regulation 17 June 2020

TÜV SÜD designated as a Notified Body under the IVDR

Munich. The Central Authority of the German Länder for Health Protection with regard to Medicinal Products and Medical Devices (Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten, ZLG) has now designated TÜV SÜD Product Service as a Notified Body under the new In Vitro Diagnostics Regulation (IVDR). The IVDR regulates market access and monitoring of in vitro diagnostic medical devices and their accessories placed on the EU market. The new regulation came into force in 2017. Products which are already approved must be recertified by 26 May 2022.

"We are excited about our designation as Notified Body", says Dr. Andreas Stange, Vice President Medical & Health Services, TÜV SÜD. "In recent months we have expanded our team throughout the world, to deliver comprehensive IVDR activities." IVDR introduction increases the share of in-vitro diagnostic devices that will have to undergo assessment by a Notified Body in the future from 15 to 90 per cent. Dr. Andreas Stange: "Unless already done, manufacturers of in-vitro diagnostics should get ready for the IVDR immediately to avoid bottlenecks in the testing and certification of their devices."

The new EU Regulation, which replaces the previous IVD Directive, brings massive changes for manufacturers. In-vitro diagnostics are medical devices that enable specimens derived from the human body (such as blood, tissues or saliva) to undergo controlled examination in an artificial environment. In the future, the extended scope of the IVDR will also comprise high-risk devices manufactured and used within a single health institution as well as genetic tests and tests providing information on patients' genetic disposition.

The IVDR – what is new?

- Introduction of a new risk-based classification system:
  The new system extends from class D for high-risk devices (diagnostics used in transfusion medicine or for highly infectious diseases) to class A for non-critical devices (e. g. washing

solutions and general culture media). Other types of in-vitro diagnostics concern devices intended for near-patient testing or self-testing and companion diagnostics.

- Identification of a "person responsible for regulatory compliance":
  Manufacturers must appoint at least one person who is responsible for regulatory compliance in their companies and must furnish evidence of this person's qualifications.
- Increased involvement of Notified Bodies on the basis of a risk-based classification system
  With the exception of class A in-vitro diagnostics, the involvement of a Notified Body will be required for all other higher risk classes in the future. Another example is that Notified Bodies must carry out at least one unannounced audit every five years. This applies to all manufacturers with a certified QM system.
- Introduction of a unique device identification (UDI) to ensure traceability within the supply chain:
  A unique device identification (UDI) offers various advantages, including the fast and efficient recall of diagnostic devices with safety risks.
- Stricter demands imposed with respect to Technical Documentation and clinical evaluation:
  In the future, they will have to include more details, such as clinical studies and demonstration of compliance with the general safety and performance requirements of products (depending on the risk class). Manufacturers must ensure ongoing evaluation of potential safety risks including following up on clinical data.
- Increased monitoring of Notified Bodies (involvement of authorities and reference laboratories):
  Stricter requirements apply both to the designation of Notified Bodies and the monitoring of their work, in particular in the context of high-risk products. This will in all likelihood result in longer conformity assessment procedures and reduce the number of Notified Bodies.
- No 'grandfathering' provisions: Re-certification of in-vitro diagnostic medical devices according to IVDR requirements:
  Even in-vitro diagnostics which have already been approved must be recertified. Manufacturers have a transition period up to next year to do so. In individual cases the existing transition period for certified products can be extended by another two years.

International leading and long-standing experience

TÜV SÜD Product Service is one of the few Notified Bodies designated for both the new IVDR and the previous In-vitro Diagnostics Directive (IVDD). The international service provider is the world's largest Notified Body for medical devices and in-vitro diagnostic medical devices to be sold in the European Economic Area (EEA). Over authorized 80 experts support manufacturers and marketers, adding safety, quality and sustainability and ensuring the successful market launch of in-vitro diagnostic devices.
TÜV SÜD Product Service looks back on a track record of over 30 years in the testing, certification and

approval of medical devices and is familiar with the different local regulatory requirements on site. The organisation also has accredited testing laboratories throughout the world.

Further TÜV SÜD information on the 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

Note for editorial offices: The press release and an IVDR infographic can be downloaded from www.tuvsud.com/pressreleases.

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