Press Release

EU Regulation on in vitro diagnostic medical devices 17 December 2020

Comprehensive IVDR certificate issued in record time

Mannheim. TÜV SÜD Product Service, a Notified Body for Medical Devices, has issued a comprehensive EU quality management system certificate (IVDR) in less than four months. Certification covered the extensive range of products of an internationally leading pharmaceutical and diagnostic devices company. TÜV SÜD was already the issuer of the world's first IVDR certificate in October 2020.

"Our review covered around 700 class B and C in vitro diagnostics in record time", says Dr Andreas Stange, Vice President Medical & Health Services (MHS) at TÜV SÜD Product Service. "Certification was completed roughly six weeks after the initial IVDR audit and four months after the company filed the certification application. Further certifications of the company are already in preparation."

The In Vitro Diagnostics Regulation (IVDR), which recently came into force, presents significant changes for both manufacturers and Notified Bodies. Within the scope of this certification, the experts reviewed random samples of the technical documentation for each category of devices in class B and for each generic device group in class C. Key changes presented by the regulation include more detailed technical documentation and stricter requirements for clinical evaluation and post-market surveillance. "Contacting us at an early stage is critical for quick certification", points out Dr Andreas Stange. "The larger the portfolio of products, the more important it is to keep an eye on the deadlines that apply to the various risk classes of devices." By doing so, manufacturers can avoid supply bottlenecks.

More devices, fewer Notified Bodies

Introduction of the new risk-based classification system also means that in future, manufacturers will have to involve a Notified Body in the approval of most IVDs. While the requirement applied to only about 15 per cent of IVDs in the past, this is expected to rise to more than 90 per cent in future as only low-risk devices in class A will be excluded. At the same time, the IVDR establishes significantly stricter requirements for Notified Bodies: they need to consult reference laboratories and other competent

authorities, which will extend the time taken up by conformity assessment processes. Stricter designation rules might likewise impact on the number of available Notified Bodies in the future.

TÜV SÜD – largest of the five Notified Bodies designated to date

Notified by the EU in June 2020, TÜV SÜD 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 80 authorised experts work on ensuring more 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 – which is essential for a successful certification process.

More information by 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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