Press Release

EU Regulation on in-vitro diagnostic medical devices 21 December 2022

TÜV SÜD issues the first IVDR certificate for an IVD companion diagnostic (CDx) device

Munich. Notified Body TÜV SÜD Product Service GmbH is happy to announce the issue of the world's first CDx certificate in accordance with the EU Regulation on in vitro diagnostic medical devices, IVDR (EU) 2017/746. The CDx is a cancer biomarker assay used to identify patients who are most likely to benefit from a specific therapeutic treatment. The CDx is used in the oncology care pathway and is manufactured by Roche Diagnostics GmbH.

Companion diagnostics (CDx) are key diagnostic tools to further enhance the emerging field of personalised medicine. CDx devices are clinically validated to identify patient populations, allowing more individualised treatment based on a specific patient's likelihood of response.

Today's announcement further builds on TÜV SÜD's strong track record in IVDR implementation, as the issuer of the world's first IVDR certificate in October 2020 and the world's first Class D certificate in July 2022. TÜV SÜD is proud to serve as a strong and reliable Notified Body for manufacturers and to help bring compliant IVDs to market by performing the implementation of the additional consultation procedures required for high-risk products such as Class D and/or CDx within an efficient timeframe.

The IVDR introduced a new concept of risk classification for IVDs as well as a reorganisation of the conformity assessment process. In general, the mandatory Notified Body involvement for IVDs to achieve CE-mark approval has increased significantly, from approximately 15 per cent of IVDs with NB certification to the present level of more than 80 per cent of IVDs.

Companion diagnostics is one of the device categories that could be placed on the EU market by the manufacturer without Notified Body involvement under the previous EU regulatory framework (IVD Directive, 98/79/EC). These clinically valuable products are now classified as Class C and need to undergo a newly established Notified Body conformity assessment, in which the Notified Body is

required to consult the respective Competent Authority (CA) for medicinal products according to the 2001/83/EC directive or the European Medicines Agency (EMA).

The involvement of an additional stakeholder – in the form of the EMA or the respective CA – increases the time needed for the overall Notified Body conformity assessment process, and this must be taken into consideration by companion diagnostic manufacturers. After the recent modification of the IVDR transitional provisions in January 2022 set out in Regulation (EU) 2022/112, the IVDR now requires Class C CDx products to be CE-marked with the involvement of a Notified Body such as TÜV SÜD Product Service GmbH by May 2026.

The consultation of the EMA or the respective CA for a medicinal product is a new concept in the IVD EU regulatory framework on which representatives of the EMA and Notified Bodies have been working for some years. “The certificate now issued marks a major milestone, demonstrating that two different EU legislations are working effectively together and that this additional IVDR consultation procedure has been successfully implemented by TÜV SÜD”, says Dr Andreas Stange, Vice President IVD global at Medical & Health Services at TÜV SÜD.

The certified CDx is a qualitative immunohistochemical cancer biomarker assay designed to detect the programmed death-ligand 1 (PDL1) expression pattern to identify patients who will benefit from a specific therapeutical treatment. Dr Heike Möhlig-Zuttermeister, Head of Business Unit Line IVD at Medical & Health Services at TÜV SÜD comments, “It is great to see this highly patient-critical CDx being placed on the EU market in compliance with the IVDR with a CE-marking based on a conformity assessment procedure. The CDx thus can now provide actual direct clinical benefit – such as higher tumour survival rates – for an identified patient population undergoing a specific therapeutical treatment. This first CDx certification also demonstrates the effectiveness of IVDR implementation activities by all the stakeholders involved: the manufacturer, the EMA and TÜV SÜD Product Service GmbH as the Notified Body.”

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, the company 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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