Press Release

New EU In Vitro Diagnostic Medical Device Regulation (IVDR) 20 April 2021

TÜV SÜD issued the first IVDR certificate in Japan

Tokyo. TÜV SÜD, a globally acclaimed safety and quality expert, issued a certificate to FUJIFILM for IVDR, which regulates the sale of in vitro diagnostic products to the European marketplace. This is the first review project conducted by TÜV SÜD Japan to issue IVDR certification.

Japan

In order to manufacture and sell medical devices, including in vitro diagnostic products (IVDs), it is necessary to meet international regulations and standards. The requirements differ from country to country, and TÜV SÜD Japan provides testing and certification services as well as training services to meet these regulations.

The European In Vitro Diagnostic Medical Devices Regulation (IVDR), which is mandatory in Europe, was officially issued and enforced in May 2017, and IVD manufacturers have a five-year transition period until May 26, 2022* to comply with the IVDR requirements. TÜV SÜD has designated TÜV SÜD Product Service as the Notified Body** to conduct the IVDR conformity assessment.

We are pleased to announce that TÜV SÜD Product Service issued IVDR certification on March 30, 2021 to Fujifilm Co., Ltd.'s DRI-CHEM SLIDE Clinical-Chemical Analyzer. This device has been issued IVDR certification as Near Patient Testing (NPTs).

This certification review project was conducted by the Japanese Review Team at TÜV SÜD Japan for technical document review and practical review. TÜV SÜD issued the first IVDR certification in October after it was designated as a IVDR notified body in June 2020, but it is the first in Japan.

TÜV SÜD Japan will continue to provide audits and services conducted by our Japanese audit team, to help customers comply with regulations without delay.

*Under the previous European legislation (IVDD), many IVD products could be sold only with a self-declaration by the manufacturer, but under the IVDR, most IVD reagent products will be required to be certified by a Notified Body. Products that were previously able to be shipped with self-declaration will be required to undergo an audit by a Notified Body and obtain a certificate after May 26, 2022.

**What is a Notified Body?

An organization accredited to conduct compatibility assessments by an accreditation body, in accordance with laws and regulations. TÜV SÜD Product Service GmbH is accredited by ZLG (The Central Authority of the German Länder for Health Protection) as a Notified Body for conducting conformity assessments of IVDR.

TÜV SÜD IVDR services

TÜV SÜD is capable of certification for all classes of products in IVDR and has a system that allows the Japanese Review Team to conduct reviews for nearly all class C, B, NPT (near-patient testing) and self-testing (ST) products. Several IVDR certification reviews are ongoing by Japanese examiners, and additional certificates will be issued in recent days.

Click here for service details: https://www.tuvsud.com/ja-jp/industries/healthcare-and-medical-devices/medical-devices-and-ivd/medical-device-market-approval-and-certification/eu-in-vitro-diagnostic-medical-device-regulation

Media Relations:

TÜV SÜD Japan
Marketing Department
Contact: www.tuvsud.com/ja-jp
160-0023 Nishi-Shinjuku, Shinjuku-ku, Tokyo 4-33-4
Sumitomo Realty & Development Nishi-Shinjuku Building No. 4 8F

Dirk Moser-Delarami	Tel. +49 (0) 89 / 57 91 – 15 92
TÜV SÜD AG	Fax +49 (0) 89 / 57 91 – 22 69
Corporate Communications	Email dirk.moser-delarami@tuvsud.com
Westendstr. 199, 80686 Munich, Germany	Internet www.tuvsud.com

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