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Press Release

TÜV SÜD expands its testing infrastructure for medical devices in Frankfurt

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New testing laboratory expands biosafety services and supports access to international markets

Munich. Chemical characterisation is becoming an increasingly important factor in the successful authorisation of medical devices. The regulatory requirements set out in the European Medical Devices Regulation (MDR), the US Food and Drug Administration (FDA) guidelines and the ISO 10993-18 standard all stipulate that robust biological safety data must be available from the outset of product development. With a new testing laboratory for Biological Safety, Reusable Device & Lot Release (BRL) services at its Frankfurt site, TÜV SÜD is expanding its testing infrastructure and helping manufacturers to identify regulatory risks at an early stage and to plan their entry into international markets more effectively.

The new testing laboratory is accredited to ISO/IEC 17025. This internationally recognised standard confirms the technical competence of testing laboratories, as well as the quality and validity of their testing procedures. For manufacturers, this provides a robust basis for technical documentation and supports the use of test results within the framework of regulatory conformity assessment procedures.

The BRL testing laboratory in Frankfurt expands TÜV SÜD's existing portfolio of services for the testing, assessing and certifying medical devices. The testing services provided there support manufacturers in assessing the biological safety of their products, complementing TÜV SÜD's existing expertise in the areas of chemical characterisation, chemical safety assessment, certification and global market access. Customers also benefit from the close links between the Frankfurt testing facilities and TÜV SÜD's international medical technology experts and laboratory sites.

This expansion strengthens Frankfurt's position as a centre of excellence for the testing of medical devices and broadens the range of testing services available to manufacturers requiring robust test results for their technical documentation and international market access. The scope of services also includes state-of-the-art analytical methods such as gas

chromatography-mass spectrometry (GC-MS) and quadrupole time-of-flight liquid chromatography-mass spectrometry (QTOF-LC/MS) for chemical characterisation.

“Regulatory expectations regarding the demonstration of the biological safety of medical devices have evolved significantly in recent years,” says Ralf Gansel, Head of Sales DACH in the Medical Devices division at TÜV SÜD. “Chemical characterisation planned at an early stage lays the foundation for robust biological risk assessments and helps to identify regulatory risks as early as the initial development phases. This makes it easier to plan development projects and reduces potential delays in the authorisation process.”

Chemical characterisation forms the basis for regulatory safety

Chemical characterisation is a key component of the biological safety assessment of medical devices. It provides reliable information on the chemical substances that may be released from materials or products, and thus forms the basis for biological assessments in accordance with the ISO 10993 series of standards.

At the same time, regulatory requirements are constantly increasing. In addition to MDR and FDA requirements, manufacturers must also consider the REACH Regulation and the guidelines on per- and polyfluoroalkyl substances (PFAS) and persistent organic pollutants (POPs), amongst other things. An early assessment of the materials used can help to address regulatory issues at the product development stage, avoiding subsequent additional requirements or project delays.

“Today, chemical characterisation is far more than a single laboratory test,” says Christoph Lindner, BRL Team Leader at TÜV SÜD. “It provides the scientific basis for biological risk assessment and reveals important information about substances that could be released from a medical device. If these investigations are integrated into product development at an early stage, manufacturers can meet regulatory requirements more effectively and streamline development and authorisation processes.”

Comprehensive support throughout the product life cycle

By combining chemical characterisation, chemical safety assessment, biological risk assessment, BRL testing services, certification, and global market access, TÜV SÜD supports manufacturers throughout the entire product life cycle – from early-stage product development right through to international market access.

Close collaboration between the various teams of experts enables a holistic approach to regulatory requirements, helping manufacturers to identify potential risks early on and prepare products efficiently for international markets.

Customer Day in Frankfurt showcases new testing capabilities

TÜV SÜD will present its new BRL testing services on 16 September 2026 in Frankfurt as part of its Customer Day, under the theme ‘Chemical Characterisation Supporting Market Access’. Specialist presentations on chemical characterisation, chemical safety and MDR certification, as well as laboratory tours and live demonstrations, will provide practical insights into current regulatory requirements and modern testing methods. The event is aimed at specialists and managers from the fields of regulatory affairs, quality management and research and development, as well as manufacturers of Class IIa, IIb and III medical devices, including implantable and combination products.

Further information:

- tuvsud.com/en/industries/medical-devices
- tuvsud.com/en/industries/medical-devices/chemical-testing-for-medical-devices
- tuvsud.com/en/events-and-webinar-hub/customer-events/frankfurt-customer-day-2026

Note for editorial staff: The press release is available on the Internet at:
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