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Press Release

In-vitro Diagnostic Medical Devices

July 3, 2025

Manufacturers Assured of Seamless UKCA and CE Certification with TÜV SÜD's expanded UK Approved Body Designation

Fareham/Munich. TÜV SÜD has expanded its designation as a UK Approved Body (UKAB) to include in-vitro diagnostic medical devices under Part IV of the UK Medical Devices Regulations 2002 (UK MDR 2002). This designation enables TÜV SÜD to provide seamless UKCA and CE certification services for all types of medical devices.

UKABs are responsible for conducting medical device conformity assessments under the UKCA scheme, which allows manufacturers to market their products in the UK. TÜV SÜD's UKAB designation will help to relieve some market pressure, as the industry is concerned by the limited capacity to conduct UKCA medical device conformity assessments. The designation means that medical device manufacturers can optimise effort and time to market across Europe for new products by gaining UKCA and CE certification simultaneously.

Monisha Phillips, Head of MHS Certification Body at TÜV SÜD UK, said: "Our designation with a full scope for in-vitro diagnostic medical devices mirrors TÜV SÜD's existing EU Notified Body scope. This will enable us to provide comprehensive support to our in-vitro medical devices clients for market access in both the EU and the UK helping them to streamline processes and optimise efficiencies."

TÜV SÜD is a designated UKAB for Part II, Part III and Part IV of the UK Medical Devices Regulations 2002 (SI 618, as amended) for general, active implantable and in-vitro diagnostic medical devices. Full details of the scope of designation can be accessed here:

[List of UK approved bodies for medical devices - GOV.UK](#)

More information: tuvsud.com/en-gb/industries/healthcare-and-medical-devices

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Founded in 1866 as a steam boiler inspection association, the TÜV SÜD Group has evolved into a global enterprise. Around 30,000 employees work at over 1,000 locations in about 50 countries to continually improve technology, systems and expertise. They contribute significantly to making technical innovations such as Industry 4.0, autonomous driving and renewable energy safe and reliable. tuvsud.com