

Techcyte Achieves CE Marking Under IVDR for Fusion AP Digital Pathology Platform

OREM, UT, UNITED STATES, March 2, 2026 /EINPresswire.com/ -- [Techcyte](https://www.techcyte.com), a leading provider of AI-powered digital diagnostics for anatomic and clinical pathology, today announced that its Fusion AP platform has achieved CE marking under the European In Vitro Diagnostic Regulation (IVDR) (EU) 2017/746. The device is now registered with the German Competent Authority and authorized for commercialization across the European Economic Area.



The IVDR represents one of the most significant regulatory shifts in European diagnostics in decades, raising requirements for clinical evidence, risk management, post-market surveillance, and quality systems. Achieving CE marking under IVDR confirms that Fusion AP meets these strengthened standards and is approved for clinical use within its intended purpose across Europe.

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Ben Cahoon, CEO Techcyte

Fusion AP is designed to support digital pathology workflows through high-performance slide viewing, enterprise scalability, and truly integrated AI-driven analysis support. With the CE-IVDR marking, European laboratories can adopt Fusion AP with regulatory assurance aligned to current EU requirements.

“IVDR compliance is a critical milestone not only for regulatory readiness, but for the long-term sustainability of digital pathology in Europe,” said Ben Cahoon, Chief Executive Officer of Techcyte. “This achievement reflects our commitment to rigorous quality systems, robust clinical validation, and responsible AI deployment. It provides European laboratories with confidence that Fusion AP meets the highest regulatory standards.”

As laboratories across Europe transition from legacy directives to IVDR-compliant systems, regulatory clarity has become a key factor in vendor selection. By securing CE marking under

IVDR, Techcyte positions Fusion AP as a compliant and future-ready solution for digital pathology programs seeking scalability, performance, and regulatory alignment.

The CE-IVDR mark enables Techcyte to market and deploy Fusion AP throughout the European Economic Area, supporting hospitals, laboratory networks, and pathology groups in their transition to digital-first workflows.

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About Techcyte

Founded in 2013, Techcyte is transforming the practice of pathology with a unified pathology platform that digitizes lab workflows and offers AI tools that aim to improve the efficiency and accuracy of diagnostic testing.

Our mission is to positively impact the health of humans, animals, and the environment through the use of artificial intelligence.

We do that by partnering with best-in-class labs, whole slide scanner manufacturers, AI vendors, diagnostic companies, hardware manufacturers, and solution providers. Together, we aim to deliver a unified anatomic and clinical pathology platform to labs and clinics around the world. Visit techcyte.com for more information.

Techcyte's anatomic and clinical pathology platform is for Research Use Only in the United States.

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