Mindpeak Earns IVDR Certification, Reinforcing Its Commitment to Quality and Regulatory Excellence

HAMBURG, GERMANY, September 11, 2026 /EINPresswire.com/ -- Certification under the EU's In Vitro Diagnostic Regulation validates Mindpeak's quality management system, confirming it meets the EU's most rigorous standard for cancer-related diagnostic devices - a milestone for the Hamburg-based AI diagnostics company as it deepens partnerships across Europe.

Mindpeak Recieves IVDR Certificate

Mindpeak, a leading developer of AI-powered software for digital pathology, today announced it has achieved certification under the EU In Vitro Diagnostic Medical Devices Regulation (IVDR). The certification, issued following rigorous assessment by BSI, a leading EU Notified Body, confirms that Mindpeak's quality management system meets the EU's most demanding regulatory standard for diagnostic software.

Setting a New Standard for AI-Powered Diagnostics

IVDR is widely regarded as one of the most demanding regulatory frameworks in the medical device world, requiring manufacturers to demonstrate robust, auditable quality processes across the full device lifecycle — from design and development through manufacturing, distribution, and post-market surveillance. Achieving this certification places Mindpeak's organizational infrastructure on the same regulatory footing required of every IVD device placed on the EU market.

"Achieving IVDR certification is a defining milestone for Mindpeak - it's proof that our technology doesn't just perform in the lab, it meets the same standard that governs every diagnostic device used in patient care across Europe. This is the foundation we'll build the next phase of our platform on." said Felix Faber, CEO and Founder of Mindpeak.

Built for Scale, Built for Trust
Mindpeak's certified quality management system meets the requirements of ISO 13485 and IVDR Annex IX, as confirmed by BSI Group - a reflection of the standards Mindpeak holds itself to as it builds AI diagnostics for high-stakes clinical use. This milestone reflects the maturity of Mindpeak's regulatory infrastructure as it continues to expand its footprint with laboratories and diagnostic partners across Europe.
By meeting IVDR requirements, Mindpeak reinforces its commitment to delivering AI-powered pathology tools that pathologists and laboratories can trust for high-stakes clinical decision-making - further solidifying the company's position at the forefront of AI-driven precision diagnostics.

About Mindpeak
Mindpeak is the leading company in AI-powered digital pathology, bridging the gap from biomarker development to clinical diagnostics. Founded in 2018, Mindpeak's AI technology enables laboratories to extract actionable insights from IHC, H&E, and mIF tissue images - ranging from subcellular biomarker quantification to predictive patient stratification. The solutions support both routine diagnostics as well as the discovery and translation of novel biomarkers into real-world clinical applications.
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