



Press release

Tribun Health Announces CaloPix® 6, Its First IVDR-Certified Version for Routine Diagnostic Use

A major new milestone in the digital transformation of pathology, benefiting laboratories, clinicians, and patients. Following FDA clearance in 2025, [CaloPix's®](#) IVDR certification confirms Tribun Health's ability to serve the global digital pathology market.

PARIS, France, June 30, 2026 (Newswire.com)

Tribun Health, a global leader in digital pathology and artificial intelligence orchestration software solutions, today announced the availability of CaloPix® 6, the first version of its platform certified under the European In Vitro Diagnostic Medical Devices Regulation (IVDR) for routine diagnostic use.

This new milestone marks the culmination of several years of investment in quality, cybersecurity, risk management, and regulatory excellence. It confirms Tribun Health's ability to meet the highest standards set by health authorities while providing laboratories with a robust, scalable platform ready to support the widespread adoption of digital pathology.

Already deployed in more than [30 hospitals and laboratories across Europe and North America](#), the CaloPix® platform enables pathologists to access their cases remotely, collaborate across institutions, integrate the artificial intelligence algorithms of their choice, and accelerate diagnostic workflows without compromising security or performance.

For customers, this IVDR certification provides additional assurance that the entire cycle of software development, clinical validation, and post-market surveillance meets the most stringent standards in the medical industry. "Obtaining IVDR certification for CaloPix® 6 represents much more than a regulatory milestone. It demonstrates the maturity of our quality system and our ability to develop and maintain diagnostic solutions that comply with the most stringent requirements of the European market, making them readily deployable in international markets that recognize IVDR certification. Laboratories that choose CaloPix® now benefit from a platform designed to the same standards of safety, traceability, risk management, and performance as expected of the most critical medical devices. This certification reflects our teams' daily commitment to quality, patient safety, and the trust of our users." **Françoise Veyriac, Head of Quality Assurance & Regulatory Affairs, Tribun Health**

This certification comes amid a global surge in the adoption of digital pathology. Faced with rising test volumes, a shortage of pathologists, and the emergence of companion biomarkers and artificial intelligence, laboratories are seeking platforms capable of ensuring operational performance, regulatory compliance, and interoperability. Thanks to its open and independent architecture, CaloPix® allows institutions to maintain their freedom of choice regarding scanners, information systems, and [AI algorithm providers](#), while benefiting from centralized governance and an efficient infrastructure at the regional or national level.

The announcement of CaloPix® 6 also comes one year after [Tribun Health received 510\(k\) clearance from the FDA in the United States](#), further strengthening Tribun Health’s ability to serve the world’s leading digital pathology markets. “Following our FDA clearance, the IVDR certification of CaloPix® 6 is further validation of our vision: to build the open digital infrastructure that will enable pathology to fully harness the potential of artificial intelligence and precision medicine. For our customers, this means greater security, sustainability, and trust in their technology partner. For our partners, it confirms that CaloPix® is a platform capable of supporting large-scale deployments and delivering significant organizational and clinical value to our customers.” **Jean-François Pomerol, Chief Executive Officer, Tribun Health**

With CaloPix® 6, Tribun Health is continuing to pursue its goal of becoming the leading platform for orchestrating digital diagnostics in oncology by connecting pathologists, laboratories, information systems, and artificial intelligence solutions within an open, secure, and scalable ecosystem.

About Tribun Health

Tribun Health is a global leader in Digital Pathology, providing the foundation that enables healthcare organizations to digitize pathology, integrate pathology into enterprise imaging ecosystems, and accelerate AI-enabled cancer diagnostics.

Its flagship platform, CaloPix®, is FDA-cleared, CE-IVDR marked, and Health Canada licensed for clinical use. Recognized by KLAS Research among the highest-rated Digital Pathology platforms worldwide, CaloPix earned Best in KLAS honors for three consecutive years (2022–2024) and maintained a top-tier ranking in 2025 and 2026.

Designed as an open, vendor-neutral platform, CaloPix connects pathologists, laboratories, scanners, enterprise imaging systems, and AI applications within a single interoperable environment. Supporting the complete pathology workflow, from image review and diagnosis to reporting and AI orchestration, CaloPix helps healthcare organizations standardize workflows, improve collaboration, and advance precision medicine.

Headquartered in Paris, Tribun Health serves leading healthcare organizations across Europe and North America, enabling them to deploy digital pathology at scale and helping shape the future of AI-enabled cancer diagnostics. For more information, visit [Tribun Health](#).

Media Contact

Andreia Beyer

VP Global Marketing & Managing Director, North America, Tribun Health

abeyer@tribun.health