Infermedica Achieves MDR Class IIb Certification for its AI-Powered Medical Guidance Platform

Infermedica earns EU MDR Class IIb certification, validating its AI platform's safety, clinical rigor, and regulatory compliance.

WROCLAW, POLAND, September 22, 2025 /EINPresswire.com/ -- Infermedica, a leading provider of AI-powered digital health solutions, announced that its Medical Guidance Platform—including Triage, Intake, and Follow-up modules—has received Class IIb certification under the European Union Medical Device Regulation (MDR). This certification represents one of the most rigorous levels of regulatory compliance for software as a medical device (SaMD) in the European market.

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>
> *Piotr Orzechowski, CEO of Infermedica*

MDR Class IIb certification applies to software that provides high-impact information for treating or diagnosing serious conditions, or for managing critical conditions. Achieving this certification affirms that Infermedica's technology meets the strictest requirements for safety, performance, quality management, and clinical validation.

"This milestone reinforces Infermedica's long-standing commitment to clinical excellence, regulatory integrity, and the responsible use of AI in healthcare," said Piotr Orzechowski, CEO of Infermedica. "We believe that the future of digital health must be both innovative and trustworthy. With this certification, we're proud to demonstrate that our solutions not only push the boundaries of technology but also meet the highest standards of medical safety and reliability."

Infermedica's platform is used by healthcare organizations worldwide to streamline symptom assessment, route patients to appropriate care, and improve clinical workflows. With the MDR Class IIb certification, healthcare providers and patients gain additional assurance that the platform is safe, effective, and compliant with European regulatory frameworks governing medical software.

Unlike general-purpose AI tools or wellness apps that operate without medical oversight, Infermedica's solutions are classified as regulated medical devices. This certification signifies that the platform has undergone independent evaluation by a Notified Body and meets the robust technical, clinical, and quality MDR requirements expected for software as a medical device used in patient care.

The path to certification involved an extensive and multi-layered process, including detailed clinical evidence generation, end-to-end validation of software functionality, and a thorough audit of the product's technical documentation and the company's quality management systems, based on ISO 13485:2016 standard. Infermedica successfully completed this process in six months, with zero non-conformities, underscoring the maturity and robustness of its internal practices and product development lifecycle.

For healthcare organizations, this certification offers confidence that the AI technology they adopt has been designed and tested to meet the highest standards for patient safety and clinical reliability. For patients, it reinforces the trustworthiness of the digital tools they increasingly rely on to understand symptoms and make decisions about seeking care.

This achievement comes at a critical time in healthcare, as organizations globally seek out AI-powered solutions to increase efficiency, reduce the burden on clinical teams, and improve access to care. As the use of medical AI accelerates, the need for validated, compliant, and transparent solutions is more important than ever.

Infermedica views MDR Class IIb certification not only as a regulatory milestone but as a reflection of its core mission: to combine technological innovation with clinical responsibility. The company remains committed to ongoing compliance, continuous product improvement, and supporting the future of safe, trusted AI in healthcare.

To learn more about Infermedica, visit www.infermedica.com.

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Explore our technology in real time at Symptomate – powered by Infermedica's AI.

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