

## PRESS RELEASE

### **Gradientech receives IVDR certification for QuickMIC®**

*Uppsala, Sweden, October 30, 2025. The diagnostics company Gradientech today announces that its QuickMIC® diagnostic test for ultra-rapid antibiotic susceptibility testing (AST) of sepsis samples, has been officially certified under the European Union's In Vitro Diagnostic Medical Device Regulation (IVDR) – the new stringent regulatory framework for diagnostic devices.*

The IVDR is aimed at enhancing quality and ensuring safety by introducing more rigorous requirements for clinical performance, safety, and post-market surveillance, replacing the former European directive for In vitro diagnostic medical devices.

The IVDR certification, granted by leading Notified Body BSI, applies to Gradientech's Class B QuickMIC® GN AST panel for Gram-negative bacteria, along with its entire diagnostic platform — including the QuickMIC instrument, analysis software, and sample preparation kit. The entire QuickMIC system is now CE marked in accordance with the new IVDR.

"The IVDR certification marks a significant commercial milestone and reinforces Gradientech's position at the forefront of next-generation diagnostics that bring real value to sepsis patients through faster, more precise treatment decisions," says Sara Thorslund, CEO and co-founder of Gradientech. "It is of course a major validation of the robustness and quality behind every aspect of our technology, but it also unlocks broader access across European markets, opening up for additional market-specific antibiotic panels to be added to the QuickMIC system."

*QuickMIC® and its Gram-negative panel are CE marked and commercially available in Europe. QuickMIC is classified as a Breakthrough Device by the U.S. Food and Drug Administration and available for Investigational Use Only in the U.S., but not 510(k) cleared.*

#### **For further information, please contact:**

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#### **About Gradientech**

*Gradientech is a leader in ultra-rapid antibiotic susceptibility testing, developing next-generation diagnostics for infectious disease medicine. Our innovative diagnostic solutions aim to save lives, reduce healthcare costs, and combat the spread of antibiotic resistance - one of our greatest global health threats. Gradientech is headquartered in Uppsala, Sweden. Visit [gradientech.se](https://www.gradientech.se) for more information.*