PRESS NEWS

Gradientech achieves transition accreditation to ISO 13485:2016

Uppsala, February 15, 2019. Gradientech AB has successfully transitioned to the latest revision of ISO 13485:2016, an important regulatory requirement for CE-marking of our *in vitro* diagnostic system QuickMIC™ for ultra-rapid antibiotic susceptibility testing (AST).

"We are very pleased to have obtained this certification, since it accredits that our company has the ability to provide medical devices that meet customer and international regulatory requirements", said Sara Thorslund, co-founder and CEO of Gradientech.

ISO 13485 is the world's most widely used international standard for quality management system for medical devices. The 2016 version of the international standard is a major revision of the 2003 version, with a heavy focus on risk management and risk-based decision-making processes at both the quality management system and product levels. This certification demonstrates that Gradientech has a quality management system that ensures high-quality and consistent design, development, manufacturing, sales and support for microfluidic-based products for the determination of cell responses to concentration gradients.

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TO THE EDITORS

About Gradientech

Gradientech is a Swedish biotech company based on innovative microfluidic product development. To help our customers discover, we provide precision assays and software solutions for high-quality analysis of cell behavior in response to gradients of signalling molecules. Driven by the increased global prevalence of antibiotic resistance, Gradientech is developing its microfluidic platform QuickMIC™ - the most rapid IVD system for antibiotic susceptibility testing of sepsis patients.