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Waters announces CE Mark for next-generation fully automated BD BACTEC FXI Culture System

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Achieves a ~3â??hour faster time to detection (~15% reduction) versus the prior generation system



US-based Waters Corporation has announced that the BD BACTEC™ FXI Culture System has received CE marking under the European Union's In Vitro Diagnostic Regulation (IVDR), enabling commercialisation in Europe and representing a key milestone in the Company's clinical microbiology portfolio expansion.

The BD BACTEC FXI System is a next-generation, fully automated blood culture system designed to improve the speed, consistency, and accuracy of bloodstream infection diagnostics in modern microbiology laboratories.

Clinical study data show that the BD BACTEC FXI System delivers a mean time to detection approximately three hours faster (~15% reduction) than the previous generation BD BACTEC™ FX System, supporting earlier detection of pathogens and more timely initiation of targeted antimicrobial therapy in patients with suspected bloodstream infections and sepsis.

In 2021, sepsis-related deaths represented 31.5% of total global deaths, with studies showing that each hour of delay in antibiotic administration is associated with increased odds of mortality.

A key innovation of the BD BACTEC FXI System is its automated gravimetric measurement of individual blood culture vial volume, the first-of-its-kind capability in a blood culture platform. Studies indicate up to 85% of blood culture vials are inappropriately filled in routine clinical practice, negatively impacting diagnostic accuracy. By objectively confirming blood volume in each vial, the system addresses a well-established source of pre-analytical variability and supports improved diagnostic consistency and adherence to recommended collection practices.

The BD BACTEC FXI System is designed for modern, high-throughput microbiology laboratories, featuring fully automated workflows including vial loading, unloading, incubation, and detection alerts.