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ASIA EDITION

Waters announces US FDA 510(k) clearance of BD BACTEC FXI Culture System

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Enabling broader access to bloodstream infection diagnostics

Waters Corporation has announced that the BD BACTEC FXI Culture System has received US Food and Drug Administration (FDA) 510(k) clearance. This clearance enables commercialisation in the US and provides a new option for laboratories seeking a fully automated blood culture system designed to improve the speed, consistency, and accuracy of sepsis and bloodstream infection diagnostics in modern microbiology laboratories.

The BD BACTEC FXI Culture System features a first-of-its-kind capability in a blood culture platform – an automated gravimetric measurement of individual blood culture vial volume. By objectively confirming blood volume in each vial, the system reduces pre-analytical variability and supports more consistent diagnostics and adherence to recommended collection practices.

The BD BACTEC FXI Culture System was recently CE marked under the European Union's In Vitro Diagnostic Regulation (IVDR) and licensed by the Japan Pharmaceuticals and Medical Devices Agency (PMDA) for availability in Europe and Japan.

Designed for high-throughput microbiology labs, the BD BACTEC FXI Culture System fully automates vial loading, unloading, incubation, and detection alerts, with an industry-leading automated loading capacity of up to 60 vials at a time, 50% more vials than the leading competitior.