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Waters ACQUITY UPLC I gets FDA & CE certification

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Waters Corporation has announced that the Waters ACQUITY UPLC I-Class IVD/Xevo TQ-S micro IVD System is now manufactured as a US FDA Class I medical device and is CE marked to the european directive 98/79/EC (IVDD). This development allows clinical laboratories to access leading innovations in liquid chromatography (LC) and mass spectrometry (MS) technology for the analysis of a variety of compounds that include diagnostic indicators in laboratory-developed tests.

"Waters pioneered the use of LC-MS as medical devices over a decade ago," said Mr Jeff Mazzeo, senior director, health sciences for Waters Division. "We are committed to expanding the number of Waters LC-MS systems listed as medical devices. Today we are pleased to announce that the ACQUITY UPLC I-Class IVD/Xevo TQ-S micro IVD System joins the family of Waters LC-MS in vitro diagnostic medical devices."

Using LC-MS technology, clinical laboratories perform qualitative and quantitative analyses of patients' samples to aid clinicians in many ways. Over recent years, the scope of use of LC-MS in the clinical environment has widened and the number of tests that can be developed and validated by diagnostic laboratory service providers has grown rapidly. Liquid chromatography separates analytes and interferences within a given sample, while mass spectrometry technology is used for detection and confirmation of those analytes.

The ACQUITY UPLC I-Class IVD/Xevo TQ-S micro IVD System features Waters' Ultra Performance LC technology coupled with a benchtop tandem-quadrupole mass spectrometer designed to provide the highest acquisition rates in UPLC-MS/MS

quantitative analysis. Xccelerated Ion Transfer (XIT) electronics, using SpaceWire technology, allow this instrument to acquire data at high speeds without compromising performance, and extensions to tried-and-tested StepWave ion optics continue Waters' long history in the delivery of sensitive and robust LC-MS systems.