



Specific Diagnostics Announces Designation as an ISO-13485-Compliant Medical Device Manufacturer

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Specific Diagnostics today announced that it has successfully received its ISO-13485 certification through the International Organization for Standardization. A QMS conforming to ISO-13485 meets the highest FDA standards applicable to businesses operating in the medical device sector.

Specific, which manufactures the Reveal rapid antimicrobial susceptibility testing system and associated disposables, has already started its European market launch. While not required for European sales, the ISO-13485 quality management system certification will give European hospital customers the added assurance that Specific's instruments and disposables have been manufactured under the highest standards applicable to medical devices.

"Our team has worked incredibly hard to implement our ISO-13485-compliant quality system," said Dr. Paul A. Rhodes, Specific's CEO. "This designation, along with our CE-IVD registration, have made us a better engineering and manufacturing organization, and will continue to positively impact the Company's operations as we begin to supply the Reveal rapid AST system to our customers in Europe."

Specific's Reveal furnishes a phenotypic MIC directly from a positive blood culture sample in an average of less than 5 hours, as reported in a to-be-published preclinical study of 104 patient samples conducted at the Henry Ford Health System in Detroit, Michigan. Based upon arrays of printed sensors responsive to the volatiles emitted by growing microorganisms, the Reveal system has the high throughput, low cost, antibiotic menu, and ease of use to prompt wide adoption.

"As we move to make Reveal available to clinics in Europe, we were determined to complete the ISO-13485 certification process to ensure we meet the highest standards applicable to medical device manufacturers, and we have done-so," said Specific COO Raymond Martino. "The Reveal system, which is currently available in Europe, will rapidly make an impact on clinical best practice for bacteremia and other time-sensitive infections."

About Specific

Specific Diagnostics has developed *in vitro* diagnostic systems based upon a unique, patented metabolomic signature technology that enables rapid detection and identification of microorganisms as they grow in culture. Its first commercial application applies this fundamental new platform to the rapid determination of antimicrobial susceptibility directly from positive blood cultures, as well as isolate dilutions. Specific is based in Mountain View, CA.

For press inquiries, please contact: press@specificdx.com