PRESS RELEASE
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Devyser CFTR achieves IVDR compliance, strengthening clinical confidence in cystic fibrosis diagnostics

Devyser, a pioneer in advanced genetic testing solutions, is pleased to announce that its next-generation sequencing (NGS) based CFTR assay is now compliant under the European In Vitro Diagnostic Regulation (IVDR). This marks a major regulatory advancement for Devyser's cystic fibrosis testing portfolio and underscores the company's commitment to safety, quality, and patient-centric innovation.

This move ensures that clinical laboratories using Devyser CFTR tests can operate with enhanced regulatory certainty, trusted conformity, and alignment with the latest European standards. This regulatory upgrade builds on Devyser's earlier successes in securing IVDR designation across its broader product range, including RHD (Class D) and post-transplant monitoring solutions.

"Achieving full IVDR compliance for our CFTR NGS portfolio is a major milestone in our mission to deliver diagnostics of the highest standard," said **Olle Myrberg, VP QA/RA, Devyser**. "It demonstrates our regulatory maturity and our deep dedication to product performance and patient safety."

What this means for users and stakeholders
With IVDR compliance, Devyser's CFTR assays now adhere to a robust set of requirements around analytical performance, clinical evidence, scientific validity, and ongoing post-market surveillance. For clinicians, genetic counselors, and patients, this regulatory step reinforces the reliability and traceability of test results and fosters greater confidence in diagnostics supporting patient analysis as well as cystic fibrosis screening, carrier testing, and therapeutic decision-making.

Devyser supports its users all the way through the transition to IVDR ensuring a seamless implementation "This IVDR approval represents not only regulatory excellence but also a clear advantage for our laboratory partners," said **Jan Wahlström, CEO, Devyser**. "With CFTR now IVDR-certified, labs can continue to offer high-quality cystic fibrosis testing with full confidence, while patients benefit from the reliability and speed that define Devyser's genetic testing solutions. It reinforces our leadership in bringing clinically proven, market-ready diagnostics to customers across Europe."

About Devyser CFTR
Devyser CFTR is an NGS-based assay designed for comprehensive analysis of the CFTR gene, providing clinicians and laboratories with a complete genetic picture of each patient.

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About Devyser
Devyser is redefining how laboratories approach genetic testing. As your true one-stop shop, we offer streamlined solutions for a wide range of conditions, helping labs overcome complexity, reduce turnaround times, and maximize efficiency.

Our technologies simplify workflows, minimize hands-on time, and deliver fast, accurate results. Every test is designed to empower labs to do more with less, freeing up resources while supporting better patient outcomes.

We specialize in diagnostic kits and advanced analysis services for clinical genetics and post-transplantation laboratories - two critical areas where accuracy and speed matter. With customers in 65+ countries, we also operate our own CLIA-certified laboratory, Devyser Genomic Laboratories, in Atlanta and maintain sales offices across Europe and the US.

Devyser is committed to regulatory excellence under IVDR, ensuring the highest quality standards across our growing product portfolio.

Founded in 2004 and headquartered in Stockholm, Devyser is listed on the Nasdaq First North Premier Growth Market Stockholm (ticker: DVYSR). The company´s Certified Adviser is Redeye AB.

Discover how we're shaping the future of lab diagnostics at **www.devyser.com**.