

Devyser receives IVDR approval for post-transplant monitoring software

Devyser has received IVDR approval for Advyser Solid organs, its software for the post-transplant product One Lambda Devyser Accept cfDNA. This is Devyser's first European approval for post-transplant monitoring software under the new, more comprehensive IVD regulation that came into force in May 2022, and it confirms Devyser software meets the established safety, efficacy, and quality requirements.

"Achieving IVDR-certification for our software demonstrates Devyser's commitment to pioneering genetic testing. This approval is another confirmation of our strong regulatory expertise and testament to the high quality, safety, and compliance of Devyser products," says CEO Fredrik Alpsten. "We are confident this approval will further enhance the growth potential of our transplantation products."

Advyser Solid organs is an IVD software for monitoring donor-derived cell-free DNA (dd-cfDNA) in patients following kidney transplantation. The software is intended for use with One Lambda Devyser Accept cfDNA, a novel NGS test for detecting dd-cfDNA in blood samples from kidney transplant patients. The assay received IVDR approval in 2023.

The product mentioned is CE-IVD marketed but not FDA-cleared. Availability in each country depends on local regulatory marketing authorization status. Please consult your local sales representative for details.

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About Devyser

Devyser develops, manufactures and sells diagnostic solutions and analysis services to clinical laboratories in more than 65 countries. Our products are used for advanced genetic testing in the hereditary disease, oncology and transplant fields, to enable targeted cancer treatment, the diagnosis of a large number of genetic diseases, and transplant patient follow-up. Devyser's products, and unique, patented solution requiring only one test tube, simplify genetic testing processes, improve sample throughput, minimize hands-on time and deliver rapid results. Our goal is for every patient to receive a correct diagnosis in the shortest possible time. Sustainability is a central part of our business and an important prerequisite for long term value creation.

Devyser was founded in 2004 and is based in Stockholm, Sweden with eight in-house sales offices in Europe and the US. The company also runs Devyser Genomic Laboratories, a CLIA certified laboratory in Atlanta, US. In 2022, Devyser's quality management system was certified according to the IVDR and a number of the company's products have since been certified according to the IVDR.

Devyser's shares are listed on the Nasdaq First North Premier Growth Market Stockholm (ticker: DVYSR). The company's Certified Adviser is Redeye AB.

For more information, visit www.devyser.com.