PRESS RELEASE
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Devyser achieves Class D IVDR approval for its RHD product

Devyser has received IVDR approval for its non-invasive fetal RHD screening product. This marks the first approval of a Class D product, the highest risk class under the new, comprehensive European regulation that came into force in May 2022. This approval confirms that Devyser's RHD product meets the stringent safety, efficacy, and quality requirements.

"Successfully meeting the rigorous requirements for Class D certification showcases Devyser's great organizational capabilities and underscores our strong regulatory expertise. It also reflects our commitment to providing high-quality, compliant products both in Europe and globally," says CEO Fredrik Alpsten. "National and regional screening programs present significant opportunities for Devyser RHD, one of our fastest-growing products, with an increasing number of users in Europe. We are confident that this approval will further enhance the growth potential of this product. The certification guarantees that our pioneering product continues to deliver trusted results of highest quality to clinicians and patients."

Devyser RHD is a highly sensitive CE-IVD labelled QPCR test to conduct accurate non-invasive screening for fetal RHD that helps clinicians avoid untargeted and unnecessary treatment.

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**.