Devyser's quality management system and fetal diagnostics product approved under the new European IVD Regulation

Devyser has today been certified under the new, more comprehensive IVD Regulation that came into force on May 26, 2022. The certification, issued by the notified body TÜV SÜD, covers Devyser's quality management system and fetal diagnostics product. The approval strengthens Devyser's position in the market and confirms the company's long-term focus on quality and patient safety.

From May 26, 2022, all new medical devices to be sold in Europe will have to comply with the new IVD Regulation that defines enhanced quality and safety requirements for diagnostic use of medical devices to ensure the highest level of public health protection. For a product to meet the requirements, the company's quality management system must, among other things, be certified in accordance with the regulation.

"We have worked intensively over the past two years to meet the more comprehensive requirements of the IVD Regulation. Our customers can be reassured to know that our fetal diagnostics product has already been approved. Further, it shows that Devyser has a development and quality organization that can compete with the best in Europe," says Fredrik Alpsten, CEO of Devyser.

In Europe, medical devices for in vitro diagnostics must be CE marked in accordance with Directive 98/79/EC of the European Parliament and of the Council in order to be sold on the market. The new regulation, known as the IVDR (EU) 2017/746, replaced the previous directive on May 26, 2022, which means that products need to undergo a new approval process. Devyser's fetal diagnostics product has been approved under the new regulation and the company is now certified to continue registering new and existing products in accordance with the new EU regulation.

"The transition to the IVD Regulation is a major challenge for the industry in general. This certification is a sign of our relentless commitment to and focus on quality and patient safety. We are proud to be able to offer our customers this assurance," says Theis Kipling, CCO of Devyser.

This is information that Devyser Diagnostics AB (publ) is obliged to publish in accordance with the EU Market Abuse Regulation 596/2014. The information was submitted for publication by the contact persons below on August 29, 2022 at 14:30 CET.

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About Devyser Diagnostics AB (publ)
Devyser develops, produces, and sells genetic testing kits to laboratories in more than 45 countries. The products are used for advanced DNA 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 monitoring. Devyser's products simplify complex genetic testing processes, improve sample throughput, minimize hands-on time and deliver rapid results. The company was founded in 2004 and is based in Stockholm, Sweden.

Devyser's shares are listed on the Nasdaq First North Growth Market Stockholm (ticker: DVYSR). The company's Certified Adviser is Redeye AB. For more information, visit www.devyser.com.