Press Release
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Prostatype Genomics obtains IVDR certification, an important regulatory milestone

Prostatype Genomics AB announces that the company has obtained certification in accordance with the EU regulation for medical devices for in vitro diagnostics (IVDR), following a comprehensive evaluation process by its notified body TÜV SÜD. The certification asserts that the company's operations within prognostic gene testing for diagnosed prostate cancer meet high standards in safety, quality and performance, and thus constitute an important regulatory milestone.

The EU's IVDR regulation has been designed to ensure that all diagnostic products meet strict requirements in terms of safety, quality and performance. IVDR certification for medium risk devices (such as cancer tests) will be required in the European market from December 2028. This date has been postponed from May 2026 due to the fact that many companies would have had difficulties to meet the earlier deadline because of how demanding the IVDR regulation is.

The IVDR regulation replaces the less strict IVDD regulation and significantly raises the requirements. In order to obtain IVDR certification, a comprehensive evaluation by an external and independent notified body is required, and then recurring reviews to ensure ongoing regulatory compliance. In the case of Prostatype Genomics, the evaluation and issuing of the certification was conducted by TÜV SÜD, a globally recognized testing, inspection and certification entity.

“Our IVDR certification not only reflects that we meet strict regulatory demands, but also underscores our dedication to long-term value creation. By adhering to high-quality standards, we minimize our risks related to product design, product performance and compliance, which is important from both a medical and a financial perspective. With this certification, we are well-positioned to continue to build trust among healthcare providers and patients, paving the way for sustainable growth in the European market,” says Prostatype Genomics' CEO Fredrik Rickman.

“This project has internally been ongoing for a couple of years, and we are both happy and proud to have reached this significant milestone well ahead of the time schedule. All the hard work and investments enable us to benefit from significant regulatory synergies also in the light of expected higher quality and regulatory standards also in the US market. Achieving IVDR certification confirms our dedication to patient safety, efficient operations, and ethical practices moving forward,” says Fredrik Rickman.

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About Prostatype Genomics AB
Prostatype® is a genomic test that is available to patients and treating urologists as a complementary decision basis for the question of treatment or no-treatment of prostate cancer. The test was developed by a leading research group at Karolinska Institute and is provided by Prostatype Genomics AB.