

Press Release

Brno, 17 January 2023

GeneProof a.s. is one of the first companies in Europe to obtain the EU Quality Management System Certificate according to the European IVDR Regulation

Our products' quality, safety, and performance are fully compliant with the new rules for in vitro diagnostics in the EU.

"The path to IVDR certification was extremely challenging and financially demanding, but we were one of the first in Europe to achieve it", says Kamil Šplíchal, Director of Quality Assurance and Regulatory Affairs at GeneProof, with pleasure and pride. "We started preparations about 5 years ago and invested tens of millions of Czech crowns. For the manufacturer of *in vitro* diagnostic devices, it is mainly about creating extensive technical documentation, including clinical validations of products. So now we have reached one of the major milestones for the further successful operations of our company in the European and global markets. This sends a clear signal to our business partners that we are a reliable partner and manufacturer of *in vitro* diagnostic devices in the future."

The **EU Quality Management System Certificate number IVDR733600**, issued on 11 January 2023 by the notified body **BSI Group** The Netherlands B.V. BSI (NB 2797), confirms that GeneProof's **quality management system complies with the requirements of Regulation (EU) 2017/746 - IVDR**.

The system covers all components and areas of GeneProof that affect the quality of processes and procedures that ensure the safety and performance of the GeneProof IVD devices, which is a prerequisite for compliance with the IVDR requirements.

The Certificate obtained includes:

- **Class C IVD** devices that require knowledge of molecular biological testing, including DNA/RNA testing for infectious diseases,
- **Class B IVD** devices, which represent controls without an assigned quality value that allow control of the entire diagnostic process.

Founded in 2005, **GeneProof** develops, manufactures, and distributes high-quality, user-friendly biotechnology products and solutions. In 2022, GeneProof merged with **American Laboratory Products Company** to create a global market leader in the diagnostic product market.

GeneProof, partnered with ALPCO, is now a leading **Global Diagnostics Company**.

See more at www.geneproof.com www.geneproof.com

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