

SphingoTec's Innovative IVD Product sphingotest® penKid® Receives First IVDR Certificate

- *SphingoTec GmbH has received its IVDR certificate for its sphingotest® penKid® confirming the quality and compliance of this product with regulatory requirements.*
- *Sphingotest® penKid® aids in the diagnosis of acute kidney injury and meets rigorous safety standards to ensure the best possible outcomes for critically ill patients.*

Hennigsdorf/Berlin, Germany, May 9, 2023 - Diagnostic company SphingoTec has been successfully re-certified according to ISO 13485 and received its first IVDR certificate for its IVD product sphingotest® penKid®. The certificates awarded by its Notified Body TÜV SÜD Product Service GmbH demonstrate the commitment of SphingoTec to meet the high-quality requirements of the ISO 13485 and the (EU) 2017/746 (IVDR).

The IVDR-compliant and CE IVD-released product sphingotest® penKid® is used as an aid in the diagnosis of kidney injury in patients with sepsis or septic shock and meets the regulatory requirements to ensure the safety of critically ill patients to the utmost extent possible.

Dr. Angelo Moesslang, Managing Director and CFO of SphingoTec commented, "Ensuring compliance in all aspects of our clinical biomarker validation processes is an absolute requirement for our company and our licensing partners. This includes robust quality management, setting up and maintaining technical documentation, continuous biomarker evaluation, and diligent manufacturing of products. By maintaining these quality standards, we are able to offer our partners valuable business opportunities and a strong competitive advantage in the marketplace."

As a company committed to innovation in the field of diagnostic testing, SphingoTec plans to continue collaborating with official regulatory bodies in the future to certify further products and expand existing certifications. By building up on the success with sphingotest® penKid®, SphingoTec aims to lead the way in developing diagnostic tools that meet the highest standards of quality, safety, and regulatory compliance.

About SphingoTec

SphingoTec GmbH ("SphingoTec"; Hennigsdorf near Berlin, Germany) is a commercial-stage diagnostic company focusing on innovative critical care biomarkers for the diagnosis, prediction, and monitoring of acute medical conditions. SphingoTec's innovative markers are made available on different IVD platforms. SphingoTec's proprietary biomarker portfolio includes Proenkephalin A 119-159 (penKid), a biomarker for the assessment of kidney function in critical diseases, and bioactive Adrenomedullin 1-52 (bio-ADM), a biomarker for the assessment of endothelial function in conditions like sepsis.

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