

FOR IMMEDIATE RELEASE

Medicover Genetics Announces compliance of TarCET Kit with the In Vitro Diagnostic Regulation (IVDR) (EU) 2017/746

Nicosia, Cyprus – December 2nd, 2024 – Medicover Genetics, a leader in genetic testing and diagnostics, is proud to announce that **TarCET Kit**, NGS-based genetic kit assays and their accompanied accessories **UltraVerse Index Oligos**, have been officially CE certified under In Vitro Diagnostic Regulation (IVDR) (EU) 2017/746. TarCET Kit is classified as Class A which denotes that it is categorized as a low-risk device. Compliance with the In Vitro Diagnostic Regulation (IVDR) indicates that our product meets stringent regulatory standards, ensuring product efficacy and patient safety across the European market.

Medicover Genetics' CE-IVD TarCET Kit provides a comprehensive suite of panels, covering a wide range of genetic conditions, including Metabolic disorders, Cardiovascular diseases, Hereditary cancers, Infertility and Neonatal screening.

"Securing IVDR compliance for the TarCET Kit Panels is a significant milestone for Medicover Genetics," said Dr. Stefan Mehrle, Head of Business Unit Medicover Genetics. "This accomplishment underscores our commitment to advancing genetic science while ensuring the highest standards of safety and quality. By providing reliable tools, we empower healthcare professionals to make better-informed decisions that improve patient outcomes."

TarCET Kit Intended Use:

TarCET Kit is a reagent kit including library preparation and targeted capture enrichment. The kit is intended for use with genomic DNA from human cells for library preparation and capture enrichment for Next Generation Sequencing (NGS) applications. The kit can be used to target specific regions of the genome with validated DNA hybridization probe panels supplied in the kit. All further downstream analyses can be performed in conjunction with the IVD VEGA analysis software, not provided in this kit, or using an independent IVD analysis software.

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About Medicover Genetics

Medicover Genetics is a leading healthcare company specialising in genetic medicine, with over 25 years of experience in genetics diagnostics. Medicover Genetics offers genetic testing services and genetic counselling, proprietary CE-IVD Next Generation Sequencing solutions and a versatile Technology Transfer Platform which enables partners to perform high-fidelity genetic tests in-house. With services across Europe, Asia, and Africa, the company empowers laboratories, healthcare professionals and patients to place genetics at the core of medical decisions. Committed to enhancing health and well-being, Medicover Genetics provides meaningful and actionable diagnostic solutions, improving disease prognosis, clinical management, and therapy selection for genetic disorders. The laboratories are CAP and ISO 15189 accredited, CLIA, ISO 9001, and ISO 13485 certified, and comply with GMP and GCP, ensuring the highest quality standards. www.medicover-genetics.com

Medicover Genetics is part of Medicover, a leading international healthcare and diagnostic services company founded in 1995 and listed on Nasdaq Stockholm. <u>www.medicover.com</u>







