ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

Product Service

Certificate

No. Q5 102580 0002 Rev. 02

Holder of Certificate: **Genome Diagnostics B.V.**
Yalelaan 48
3584CM Utrecht
THE NETHERLANDS

Facility(ies): **Genome Diagnostics B.V.**
Yalelaan 48, 3584CM Utrecht, THE NETHERLANDS

See Scope of Certificate

Certification Mark:

TÜV SÜD EN ISO 13485 tuvsud.com/ps-cert

Scope of Certificate: **Design, Development, Manufacture and Distribution of In-Vitro Diagnostic Medical Devices (Reagents and Software) used in Genetic Testing in relation to Compatibility Testing, Disease Status, Donor Screening, Tissue Typing and Immunological Typing**

Applied Standard(s): ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems - Requirements for regulatory purposes

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 102580 0002 Rev. 02

Report No.: 713331456_CN

Valid from: 2025-04-04
Valid until: 2025-07-17

Date, 2025-04-04

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany