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

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

C E R T I F I C A T E

No. QS6 102580 0003 Rev. 02

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

Certification Mark:

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**

Standard(s): **ISO 13485:2016**

Regulatory Authority(ies): **Brazil ANVISA, Health Canada. See attached for listing of specific regulatory requirements.**

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. Validity of this certificate can be obtained by visiting the website www.tuvsud.com/ps-cert
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID: **F003019**

Effective Date: **2022-10-07**

Expiry Date: **2025-10-06**

Date of Issue: 2022-10-24

(Renee Walker)
Manager, US Certification Body,
Medical and Health Services

TÜV®

TÜV SÜD America, Inc. • 401 Edgewater Place Suite #500 • Wakefield • MA 01880 • USA • www.tuvsud.com

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

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

C E R T I F I C A T E

No. QS6 102580 0003 Rev. 02

Regulatory Requirements: **Audit/Certification Criteria**

Brazil
- RDC ANVISA n. 16/2013
- RDC ANVISA n. 23/2012
- RDC ANVISA n. 67/2009

Canada
- Medical Device Regulations – Part 1- SOR 98/282

Facility(ies):

Genome Diagnostics B.V.
Yalelaan 48, 3584CM Utrecht, THE NETHERLANDS

Genome Diagnostics B.V.
Yalelaan 1, 3584 CL Utrecht, THE NETHERLANDS

Facility Scopes:

Genome Diagnostics B.V.
Yalelaan 48, 3584CM Utrecht, THE NETHERLANDS

Manufacture of In-Vitro Diagnostic Medical Devices (Reagents) used in Genetic Testing in relation to Compatibility Testing, Disease Status, Donor Screening, Tissue Typing and Immunological Typing; Distribution of In-Vitro Diagnostic Medical Devices (Reagents and Software)
REPs Facility ID: F003019

Genome Diagnostics B.V.
Yalelaan 1, 3584 CL Utrecht, THE NETHERLANDS

Design, Development, Manufacture 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
REPs Facility ID: F003019

Date of Issue: 2022-10-24

(Renee Walker)
Manager, US Certification Body,
Medical and Health Services

TÜV®

TÜV SÜD America, Inc. • 401 Edgewater Place Suite #500 • Wakefield • MA 01880 • USA • www.tuvsud.com