CERTIFICADO ◆ 인증서 ◆ CERTIFICATO ◆ 認証書 ◆ CERTIFICATE ◆ 认证证书 ◆ ZERTIFIKAT

MDSAP
Medical Device Single Audit Program

C E R T I F I C A T E

No. QS6 102580 0003 Rev. 05

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

Certification Mark:

Scope of Certificate: **Design and 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): **Australia TGA, Brazil ANVISA, Health Canada, Japan MHLW / PMDA, USA FDA. 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. For details and certificate validity see:
www.tuvsud.com/ps-cert?q=cert:QS6 102580 0003 Rev. 05
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID: **F003019**
Report No.: **713403227**
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(Sofia Epshtein Elbrus)

ZERTIFIKAT ◆ 认证证书 ◆ CERTIFICATE ◆ 認証書 ◆ CERTIFICATO ◆ 인증서 ◆ CERTIFICADO

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Regulatory Requirements: **Audit/Certification Criteria**

Australia
Therapeutic Goods (Medical Devices) Regulations 2002
- Schedule 3, Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure

Brazil
- RDC ANVISA n. 665/2022 - Good Manufacturing Practices
- RDC ANVISA n. 551/2021
- RDC ANVISA n. 67/2009 - Vigilance

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

Japan
- MHLW Ministerial Ordinance No. 169 (2004), as amended by MHLW Ministerial Ordinance No.60 (2021)
- Japan PMD Act (as applicable)

United States
- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807 – Subparts A to D
- 21 CFR Part 820

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

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