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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. 03

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): **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. For details and certificate validity see:
www.tuvsud.com/ps-cert?q=cert:QS6 102580 0003 Rev. 03
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID: **F003019**
Report No.: **713331456**
Effective Date: **2025-04-11**
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(Renee Walker)
Director, US Certification Body, MHS

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CERTIFICATE

No. QS6 102580 0003 Rev. 03

Regulatory Requirements: **Audit/Certification Criteria**

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

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

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