

CERTIFICATE

No. QS6 102580 0003 Rev. 00

Regulatory Requirements: **Audit/Certification Criteria**

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

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
DUNS No: 41-349-3037

Genome Diagnostics B.V.

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