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Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-IVDR-099

EU Quality Management System Certificate

Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices, Annex IX Chapter I

Certificate No. V13 102580 0005 Rev. 00

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

SRN Manufacturer - NL-MF-000000453

The quality management system has been evaluated in accordance with Regulation (EU) 2017/746, Annex IX Chapter I with a positive result.

Details on devices covered by the quality management system are described on the following page(s). The report referenced below summarises the results of the assessment and includes reference to relevant CS, harmonised standards and test reports.
The certified quality management system is subject to periodical surveillance.

If class A devices in sterile conditions are covered by this certificate, the audit was limited to the aspects relating to establishing, securing, and maintaining sterile conditions.
If class B or C excluding self-/near-patient-testing, or class C companion diagnostics devices are covered by this certificate, the quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis. The periodical surveillance includes further assessment of the technical documentation on the basis of representative samples.
If class D devices, class B or C self-/near-patient testing, or class C companion diagnostics devices are covered by this certificate, an EU Technical Documentation Assessment Certificate in accordance with Annex IX Chapter II is required before placing them on the market.

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:V13 102580 0005 Rev. 00

Report No.: 713392833
Preceding Certificate No.: V12 102580 0004 Rev. 00

Valid from: 2026-10-08
Valid until: 2027-05-05

Marta Carnielli
Head of Certification IVD

Issue date: 2026-10-08

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Certificate No. V13 102580 0005 Rev. 00

Classification:	Class C
Device Group:	W0103 + IVP 3011 - Haematology / Haemostasis / Immunohaematology / Histology / Cytology
Intended Purpose:	IVD Reagents for Haematology, Haemostasis, Immunohaematology, Histology and Cytology
Classification:	Class C
Device Group:	W0106 + IVP 3011 - Genetic testing
Intended Purpose:	IVD Reagents for genetic testing
Classification:	Class C
Device Group:	W0205 + IVP 3011 - Nucleic acid testing Instruments
Intended Purpose:	IVD Medical device Software for Nucleic acid testing
The validity of this certificate depends on conditions and/or is limited to the following:	-none-

Revision History:

Rev.	Dated	Report	Description
00	2026-10-08	713392833	Supplemented: Device(s)/group of device(s) added Administrative merge / transfer to new Certificate Type

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