



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



Product Service

EU Quality Management System Certificate (IVDR)

Pursuant to Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices,
Annex IX Chapters I and III (Class C and B Devices excluding self-/near-patient-testing and
Companion Diagnostics)

No. V12 102580 0004 Rev. 00

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

SRN Manufacturer: NL-MF-000000453

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (8) of the Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices. Details on devices covered by the quality management system are described on the following page(s).

The Report referenced below summarizes the result of the assessment and includes reference to relevant CS, harmonized standards, audit and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.

The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.

The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment includes an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples.

For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:V12 102580 0004 Rev. 00](http://www.tuvsud.com/ps-cert?q=cert:V12_102580_0004_Rev.00)

Report No.: 713221634

Valid from: 2022-05-06

Valid until: 2027-05-05

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2022-05-06



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Classification: C
Device Group: W0103 - HAEMATOLOGY / HAEMOSTASIS / IMMUNOHAEMATOLOGY / HISTOLOGY / CYTOLOGY
IVP Code: IVP 3011 - In vitro diagnostic devices which require knowledge regarding molecular biological testing including nucleic acid assays and next generation sequencing (NGS)
Intended Purpose: IVR 0201 - Devices intended to be used for tissue typing (HLA A, B, DR) to ensure the immunological compatibility of blood, blood components, cells, tissue or organs that are intended for transfusion or transplantation or cell administration

Classification: C
Device Group: W0205 - NUCLEIC ACID TESTING INSTRUMENTS
IVP Code: IVP 3011 - In vitro diagnostic devices which require knowledge regarding molecular biological testing including nucleic acid assays and next generation sequencing (NGS)
Intended Purpose: IVR 0201 - Devices intended to be used for tissue typing (HLA A, B, DR) to ensure the immunological compatibility of blood, blood components, cells, tissue or organs that are intended for transfusion or transplantation or cell administration

The validity of this certificate depends on conditions and/or is limited to the following: -none-