



Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00



Product Service

Certificate

No. Q5 102580 0002 Rev. 03

Holder of Certificate: **Genome Diagnostics B.V.**

Yalelaan 48
3584CM Utrecht
THE NETHERLANDS

Facility(ies):

Genome Diagnostics B.V.

Yalelaan 48, 3584CM Utrecht, THE NETHERLANDS

See Scope of Certificate

Certification Mark:



Scope of Certificate:

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

Applied Standard(s):

ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems -
Requirements for regulatory purposes

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). 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:Q5 102580 0002 Rev. 03](http://www.tuvsud.com/ps-cert?q=cert:Q5_102580_0002_Rev_03)

Report No.: 713371167

Valid from: 2025-07-18

Valid until: 2028-07-17

Date, 2025-07-09

Christoph Dicks

Head of Certification/Notified Body