



# Certificate

No. Q5 102580 0002 Rev. 01

**Holder of Certificate:** **Genome Diagnostics B.V.**  
Yalelaan 48  
3584CM Utrecht  
THE NETHERLANDS

**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**

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 and certification regulation of 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. 01](http://www.tuvsud.com/ps-cert?q=cert:Q5_102580_0002_Rev.01)

**Report No.:** 713257060

**Valid from:** 2022-07-19  
**Valid until:** 2025-07-17

**Date,** 2022-07-19



Christoph Dicks  
Head of Certification/Notified Body

# Certificate

No. Q5 102580 0002 Rev. 01

**Applied Standard(s):** EN ISO 13485:2016  
Medical devices - Quality management systems -  
Requirements for regulatory purposes  
(ISO 13485:2016)  
DIN EN ISO 13485:2016

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

Manufacture of In-Vitro Diagnostic Medical Devices (Reagents)  
used in Genetic Testing in relation to Compatibility Testing,  
Disease Status, Donor Screening, Tissue Typing and  
Immunological Typing. Distribution of In-Vitro Diagnostic Medical  
Devices (Reagents and Software)

**Genome Diagnostics B.V.**  
**Yalelaan 1, 3584 CL Utrecht, THE NETHERLANDS**

Design, Development and Manufacture 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

./.