



Certificate

No. Q5 102580 0002 Rev. 00

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

Genome Diagnostics B.V.
Yalelaan 1, 3584 CL 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

Applied Standard(s):

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

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). See also notes overleaf.

Report No.: 713147842

Valid from: 2019-07-18

Valid until: 2022-07-17

Date, 2019-07-18

Stefan Preiß
Head of Certification/Notified Body