Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-245.10.07

Product Service

EC Certificate

Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 102580 0001 Rev. 02

Manufacturer:

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

Product Category(ies): **Reagents for determination of HLA tissue types: DR, A, B**

Model(s): **Reagents for HLA tissue typing based on DNA sequencing**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device families in accordance with IVDD Annex IV. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of List A devices an additional Annex IV (4) certificate is mandatory. See also notes overleaf.

Report no.: 713182215

Valid from: 2020-08-02
Valid until: 2024-05-26

Date, 2020-05-04

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany