ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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

EC Design-Examination Certificate
Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex III (6)
(Devices for self-testing)

No. V9 092305 0003 Rev. 00

Manufacturer:

Zhejiang Orient Gene Biotech Co., Ltd.
3787#, East Yangguang Avenue, Dipu Street Anji
313300 Huzhou, Zhejiang
PEOPLE'S REPUBLIC OF CHINA

Product: **In Vitro diagnostic devices for self testing**

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with IVDD Annex III (6). The design of the devices conforms to the requirements of this Directive. 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:V9 092305 0003 Rev. 00

Report No.: SH2198801

Valid from: 2021-07-30
Valid until: 2024-05-26

Date, 2021-07-30

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

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

EC Design-Examination Certificate
Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex III (6)
(Devices for self-testing)

No. V9 092305 0003 Rev. 00

Model(s): **Rapid COVID-19 (Antigen) Self-Test**

Facility(ies):

Zhejiang Orient Gene Biotech Co., Ltd.
3787#, East Yangguang Avenue, Dipu Street Anji, 313300
Huzhou, Zhejiang, PEOPLE'S REPUBLIC OF CHINA

Model	REF
Rapid COVID-19 (Antigen) Self-Test	GCCOV-502a-H1OGE
Rapid COVID-19 (Antigen) Self-Test	GCCOV-502a-H2OGE
Rapid COVID-19 (Antigen) Self-Test	GCCOV-502a-H3OGE
Rapid COVID-19 (Antigen) Self-Test	GCCOV-502a-H5OGE
Rapid COVID-19 (Antigen) Self-Test	GCCOV-502a-H7OGE
Rapid COVID-19 (Antigen) Self-Test	GCCOV-502a-H8OGE
Rapid COVID-19 (Antigen) Self-Test	GCCOV-502a-H10OGE
Rapid COVID-19 (Antigen) Self-Test	GCCOV-502a-H15OGE
Rapid COVID-19 (Antigen) Self-Test	GCCOV-502a-H20OGE
Rapid COVID-19 (Antigen) Self-Test	GCCOV-502a-H25OGE

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