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 092378 0008 Rev. 00

Manufacturer:

Healgen Scientific Limited Liability Company
3818 Fuqua Street
Houston TX 77047
USA

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 092378 0008 Rev. 00

Report No.: SH20178302

Valid from: 2021-04-30
Valid until: 2024-05-26

Date, 2021-04-30

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 092378 0008 Rev. 00

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

Facility(ies):

Healgen Scientific Limited Liability Company
3818 Fuqua Street, Houston TX 77047, USA

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

Model	REF
Healgen Rapid COVID-19 Antigen Self-Test	GCCOV-502a-H1
Healgen Rapid COVID-19 Antigen Self-Test	GCCOV-502a-H2
Healgen Rapid COVID-19 Antigen Self-Test	GCCOV-502a-H3
Healgen Rapid COVID-19 Antigen Self-Test	GCCOV-502a-H5
Healgen Rapid COVID-19 Antigen Self-Test	GCCOV-502a-H7
Healgen Rapid COVID-19 Antigen Self-Test	GCCOV-502a-H10
Healgen Rapid COVID-19 Antigen Self-Test	GCCOV-502a-H15
Healgen Rapid COVID-19 Antigen Self-Test	GCCOV-502a-H20
CLINITEST Rapid COVID-19 Antigen Self-Test	11556333
CLINITEST Rapid COVID-19 Antigen Self-Test	11556327
CLINITEST Rapid COVID-19 Antigen Self-Test	11556331
CLINITEST Rapid COVID-19 Antigen Self-Test	11556072
CLINITEST Rapid COVID-19 Antigen Self-Test	11556236

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