



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
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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](http://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



# 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