CE-DOC-H152
Version 1.1

EC Declaration of Conformity

In accordance with Directive 98/79/EC

Legal Manufacturer: *Healgen Scientific Limited Liability Company*

Legal Manufacturer Address: *3818 Fuqua Street, Houston, TX 77047, USA.*

Declares, that the products
Product Name and Model(s)

See attachment

Classification: *Self-testing*
Conformity assessment route: *Annex III.6 (EC Design Examination)*

Notified Body' Name: TÜV SÜD Product Service GmbH

Notified Body Address: Ridlerstraße 65 80339 München Germany

Notified Body ID: 0123

EC Certificate Registration number: No.V9 092378 0008 Rev.00

Expiry date of EC certificate: 2024-05-26

We, the Manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

We hereby explicitly appoint

EC Representative's Name: Shanghai International Holding Corp. GmbH (Europe)

EC Representative's Address: Eiffestrasse 80, 20537 Hamburg, Germany

to act as our European Authorized Representative as defined in the aforementioned Directive.

I, the undersigned,hereby declare that the medical devices specified above conform with the directive 98/79/EC on in vitro diagnostic medical devices and pertinent essential requirements

Date Signed: 2020-04-30

Joyce Pang

Name of authorized signatory: Joyce Pang
Position held in the company: Vice-President

Attachment to CE-DOC-H152 Version 1.1

Product Name	Catalog No.	Siemens Material No.	Brand
Rapid COVID-19 Antigen Self-Test	GCCOV-502a-H1	11556333	CLINITEST®
Rapid COVID-19 Antigen Self-Test	GCCOV-502a-H5	11556327	CLINITEST®
Rapid COVID-19 Antigen Self-Test	GCCOV-502a-H20	11556331	CLINITEST®
Rapid COVID-19 Antigen Self-Test	GCCOV-502a-H5B	11556072	CLINITEST®
Rapid COVID-19 Antigen Self-Test	GCCOV-502a-H20B	11556236	CLINITEST®

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