



CE-DOC-H157  
Version 1.0

# 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

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



Attachment to CE-DOC-H157 Version 1.0

<b>Product Name</b>	<b>Catalog No.</b>	<b>Brand</b>
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	Healgen

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