

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization
Healgen Scientific Limited
Liability Company
3818 Fuqua Street
Houston, TX 77047
USA

has established and applies a quality management system for medical devices
for the following scope:

**Design and Development, Manufacture and Distribution of
In Vitro Diagnostic Reagents for Cardiac Diseases,
Infectious Diseases, Oncology and for Biochemistry
as well as Rapid Tests for Fertility and Drugs of Abuse**

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2019-03-01
Certificate Registration No.: SX 60135029 0001
An audit was performed. Report No.: 15090679 004
This Certificate is valid until: 2022-02-28

Certification Body



Date 2018-12-29



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

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CE-DOC-H070
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)

Coronavirus Ag Rapid Test Cassette (Swab)	GCCOV-502a
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Classification: *Other*

Conformity assessment route: *Annex III (EC DECLARATION OF CONFORMITY)*

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: July 20, 2020

Name of authorized signatory: Joyce Pang

Position held in the company: Vice-President