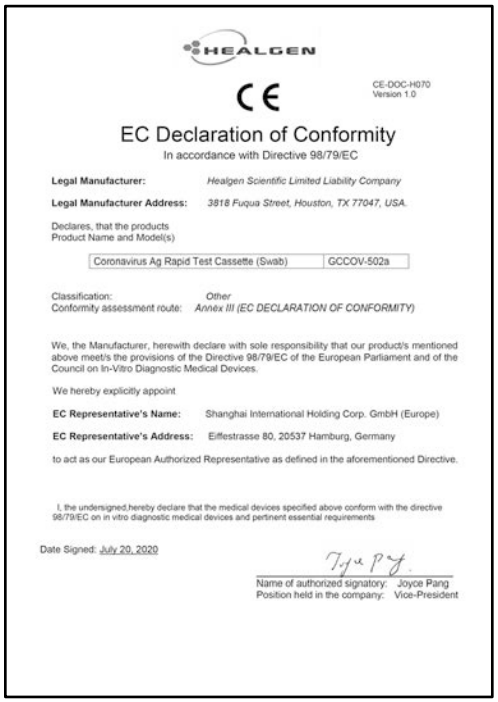
COVID-19

CE Declaration, Letter of authority and Certification



HEALGEN

CE

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

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

浙江东方基因生物制品股份有限公司
Zhejiang Orient Gene Biotech Co., Ltd

Letter of Authorization

Dear Sir/Madam,

Subject: Letter of Authorization for ulti med Products (Deutschland) GmbH

We, **Zhejiang Orient Gene Biotech Co., Ltd.** with our factory address at: #3787 East Yangguang Avenue, Dipu Street, Anji 313300, Huzhou, Zhejiang, China, as the official manufacturer of Healgen brand rapid diagnostic test, hereby authorize **ulti med Products (Deutschland) GmbH** with address: Reeshoop 1, 22926 Ahrensburg, Germany, to be our non-exclusive distributor for **Healgen brand Coronavirus Ag Rapid Test Cassette (Swab)**, (catalogue number GCCOV-502a), and to submit all documents necessary for registration, sale and monitoring of above products in Germany (excluding purchase orders from German government).

This authorization shall remain in effect for a period of one (1) year from November 17th, 2020. The authorization can be renewed for a period of another one (1) year if both parties agrees mutually in writing at least 30 days before the expiry of the agreement.

If there is an exclusive agent signed during the period from Zhejiang Orient Gene Biotech Co., Ltd., therefore this letter will be invalid and the final interpretation right shall be owned by Zhejiang Orient Gene Biotech Co., Ltd.

We undertake to provide post-market support and assistance to the distributor as may be required in relation to any matter involving the above medical device.

Your Sincerely,

浙江东方基因生物制品股份有限公司
ZHEJIANG ORIENT GENE BIOTECH CO.,LTD

Fang Xiaoliang

Chairman Board

November 17th, 2020

地址：安吉县递铺街道阳光大道东段 3787 号
Add: 3787#, East Yangguang Avenue, Dipu Street, Anji,313300 Zhejiang,China
电话 Tel:+86-572-5226111 传真 Fax: +86-572-5226222 邮编 PC:313300

TÜVRheinland

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.:	15090579 004
This Certificate is valid until:	2022-02-28

Certification Body

DAkkS
Deutsche Akkreditierungsstelle
D-ZM-14169-01-02

Date 2018-12-29

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg