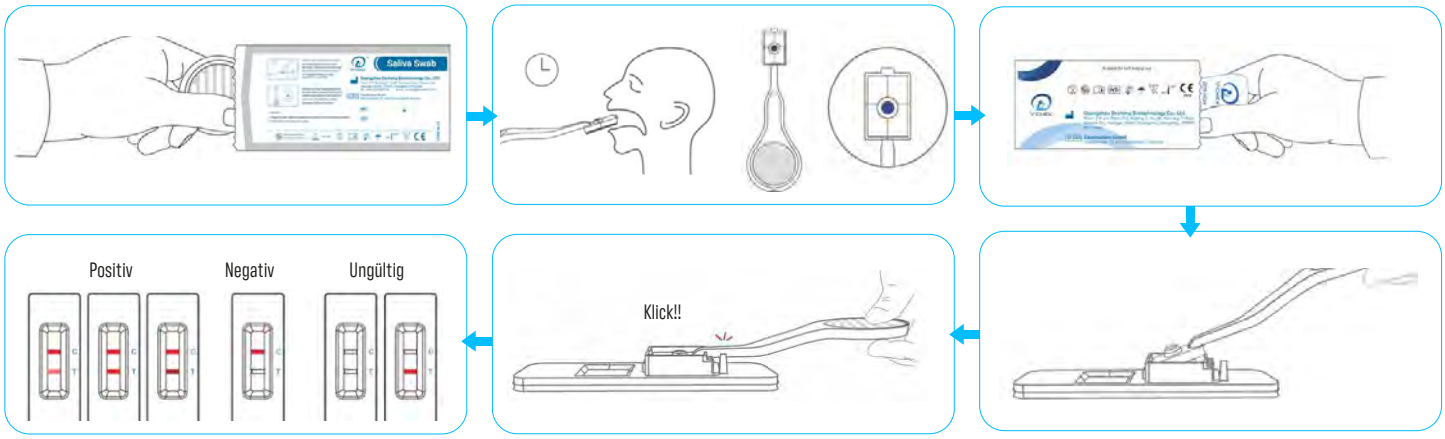
C·KES

V-CHECK™

2019-NCOV AG SPEICHEL SCHNELLTESTKARTE

Bei der Testkarte handelt es sich um einen Seitlichen-Strömungs-Immunotest für den qualitativen In-vitro-Nachweis des N-Protein-Antigens des 2019-nCoV in menschlichen Speichelproben. Die Testkarte kann bei Personen mit oder ohne Symptomen oder anderen epidemiologischen Gründen beim Verdacht einer COVID-19-Infektion verwendet werden.

So führen Sie den Test durch:



Test Prinzip	Immunochromatography
Probennahme	Speichelprobe
Probenmenge	Bis der Indikator die richtige Menge anzeigt
Test Zeit	10 Minuten
Gebrauchstemperatur	15-30 C°
Lagertemperatur	2-30 C°
Haltbarkeit (ungeöffnet)	24 Monate

Zur privaten Anwendung europaweite Laienzulassung

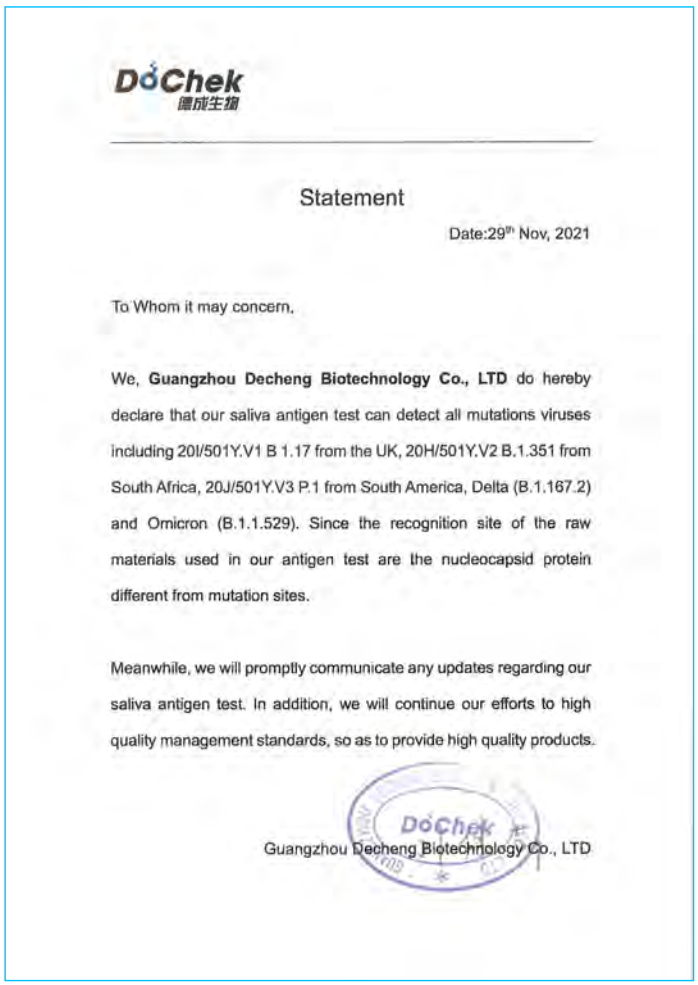
CE zertifiziert - EN 2854

C·KES

C-KES GmbH
Heinrich-Schütz-Straße 20 | 71065 Sindelfingen | Germany
Tel.: +49 7031 81 44 59 | Mobil: +49 171 31 55 420
Christian J. Weiss, GF | Amtsgericht: Stuttgart Handelsregister:
HRB 765879 | UST-ID DE315972975
vertrieb@c-kes.de | c.weiss@c-kes.de

ZERTIFIKATE

V-check™ 2019-nCoV Ag Speichel Schnelltestkarte



DoChek 德成生物

Statement

Date:29th Nov, 2021

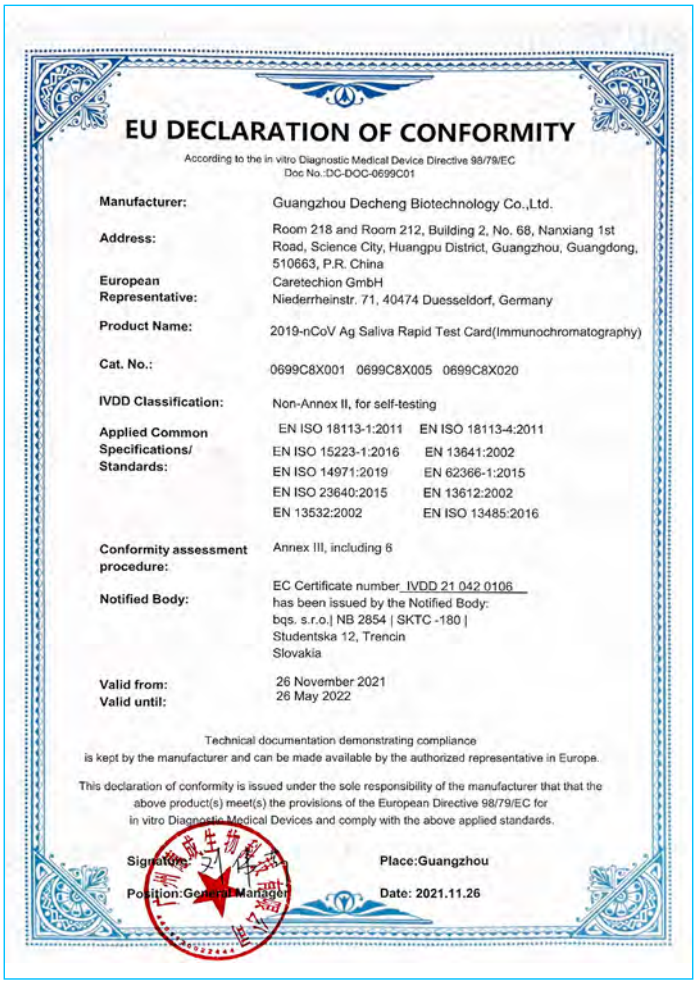
To Whom it may concern,

We, **Guangzhou Decheng Biotechnology Co., LTD** do hereby declare that our saliva antigen test can detect all mutations viruses including 20I/501Y.V1 B 1.17 from the UK, 20H/501Y.V2 B.1.351 from South Africa, 20J/501Y.V3 P.1 from South America, Delta (B.1.167.2) and Omicron (B.1.1.529). Since the recognition site of the raw materials used in our antigen test are the nucleocapsid protein different from mutation sites.

Meanwhile, we will promptly communicate any updates regarding our saliva antigen test. In addition, we will continue our efforts to high quality management standards, so as to provide high quality products.

DoChek

Guangzhou Decheng Biotechnology Co., LTD



EU DECLARATION OF CONFORMITY

According to the in vitro Diagnostic Medical Device Directive 98/79/EC
Doc No.:DC-DOC-0699C01

Manufacturer:	Guangzhou Decheng Biotechnology Co.,Ltd.
Address:	Room 218 and Room 212, Building 2, No. 68, Nanxiang 1st Road, Science City, Huangpu District, Guangzhou, Guangdong, 510663, P.R. China
European Representative:	Caretechion GmbH Niederrheinstr. 71, 40474 Duesseldorf, Germany
Product Name:	2019-nCoV Ag Saliva Rapid Test Card(Immunochromatography)
Cat. No.:	0699C8X001 0699C8X005 0699C8X020
IVDD Classification:	Non-Annex II, for self-testing
Applied Common Specifications/ Standards:	EN ISO 18113-1:2011 EN ISO 18113-4:2011 EN ISO 15223-1:2016 EN 13641:2002 EN ISO 14971:2019 EN 62366-1:2015 EN ISO 23640:2015 EN 13612:2002 EN 13532:2002 EN ISO 13485:2016
Conformity assessment procedure:	Annex III, including 6
Notified Body:	EC Certificate number IVDD 21 042 0106 has been issued by the Notified Body: bqs. s.r.o.| NB 2854	SKTC -180 | Studentska 12, Trencin Slovakia
Valid from: **Valid until:**	26 November 2021 26 May 2022

Technical documentation demonstrating compliance is kept by the manufacturer and can be made available by the authorized representative in Europe.

This declaration of conformity is issued under the sole responsibility of the manufacturer that that the above product(s) meet(s) the provisions of the European Directive 98/79/EC for in vitro Diagnostic Medical Devices and comply with the above applied standards.

Signature:

Position:General Manager

Place:Guangzhou

Date: 2021.11.26

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IVD CE 2854

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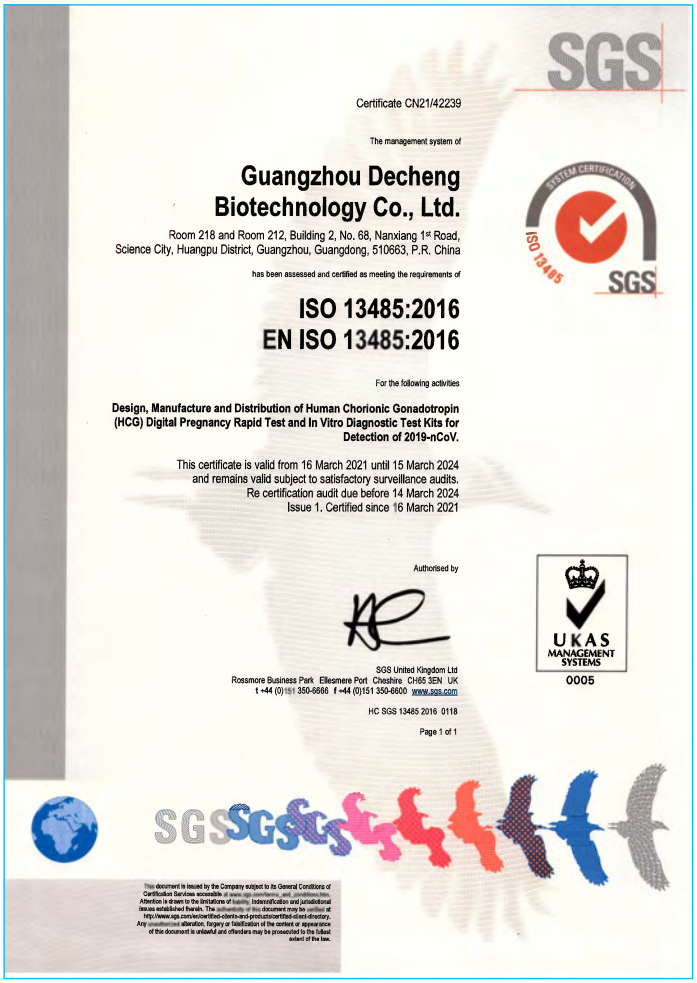
ZERTIFIKATE

V-check™ 2019-nCoV Ag Speichel Schnelltestkarte



SGS

Certificate CN21/42239

The management system of

Guangzhou Decheng Biotechnology Co., Ltd.

Room 218 and Room 212, Building 2, No. 68, Nanxiang 1st Road, Science City, Huangpu District, Guangzhou, Guangdong, 510663, P.R. China

has been assessed and certified as meeting the requirements of

ISO 13485:2016
EN ISO 13485:2016

For the following activities

Design, Manufacture and Distribution of Human Chorionic Gonadotropin (HCG) Digital Pregnancy Rapid Test and In Vitro Diagnostic Test Kits for Detection of 2019-nCoV.

This certificate is valid from 16 March 2021 until 15 March 2024 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 14 March 2024
Issue 1. Certified since 16 March 2021

Authorised by

SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

HC SGS 13485 2016 0118

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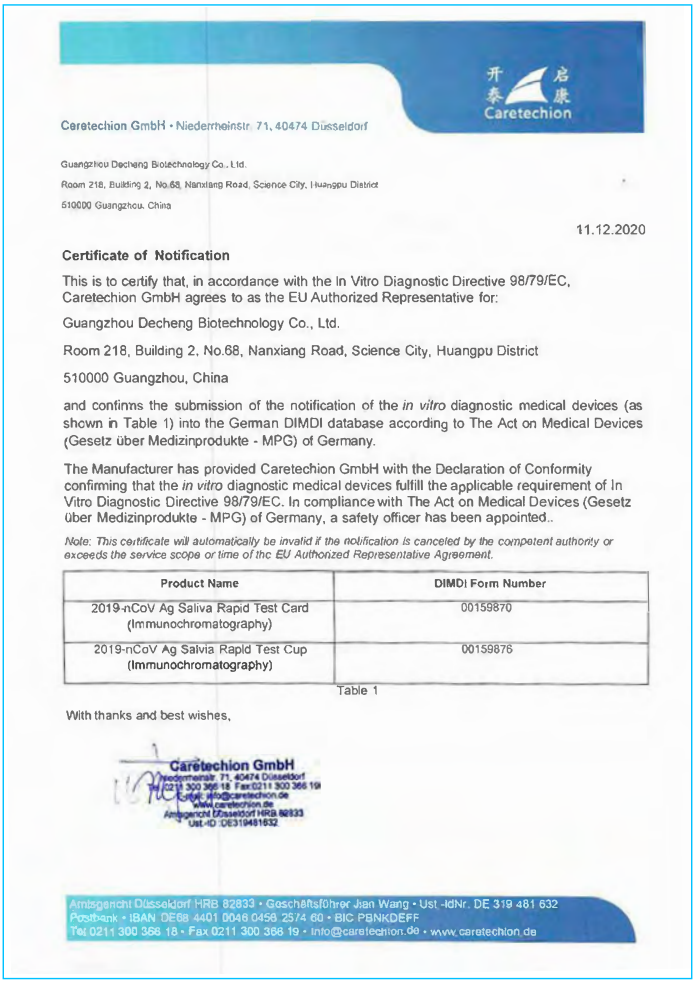
UKAS MANAGEMENT SYSTEMS 0005



Caretechion GmbH • Niederrheinstr. 71, 40474 Düsseldorf

Guangzhou Decheng Biotechnology Co., Ltd.
Room 218, Building 2, No.68, Nanxiang Road, Science City, Huangpu District
510000 Guangzhou, China

11.12.2020

Certificate of Notification

This is to certify that, in accordance with the In Vitro Diagnostic Directive 98/79/EC, Caretechion GmbH agrees to as the EU Authorized Representative for:

Guangzhou Decheng Biotechnology Co., Ltd.

Room 218, Building 2, No.68, Nanxiang Road, Science City, Huangpu District

510000 Guangzhou, China

and confirms the submission of the notification of the *in vitro* diagnostic medical devices (as shown in Table 1) into the German DIMDI database according to The Act on Medical Devices (Gesetz über Medizinprodukte - MPG) of Germany.

The Manufacturer has provided Caretechion GmbH with the Declaration of Conformity confirming that the *in vitro* diagnostic medical devices fulfill the applicable requirement of In Vitro Diagnostic Directive 98/79/EC. In compliance with The Act on Medical Devices (Gesetz über Medizinprodukte - MPG) of Germany, a safety officer has been appointed..

Note: This certificate will automatically be invalid if the notification is canceled by the competent authority or exceeds the service scope or time of the EU Authorized Representative Agreement.

Product Name	DIMDI Form Number
2019-nCoV Ag Saliva Rapid Test Card (Immunochromatography)	00159870
2019-nCoV Ag Salvia Rapid Test Cup (Immunochromatography)	00159876

Table 1

With thanks and best wishes,

Caretechion GmbH

Amtsgericht Düsseldorf HRB 82833 • Geschäftsführer Jian Wang • Ust.-IdNr. DE 319 481 632
Postbank • IBAN DE68 4401 0046 0458 2574 60 • BIC PBNKDEFF
Tel 0211 300 368 18 • Fax 0211 300 368 19 • info@caretechion.de • www.caretechion.de

CE zertifiziert - EN 2854

IVD CE 2854

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ZERTIFIKATE

V-check™ 2019-nCoV Ag Speichel Schnelltestkarte

bqs.
The Trust. We Make.

SNAS Reg. No. 575/P-051

Notified body 2854 | SKTC-180

bqs. s.r.o.
Studentska 12, 911 01
Trencin | Slovakia
www.bqsgroup.eu

EC Certificate IVDD 21 042 0106

EC Design-Examination Certificate

Directive 98/79/EC on In Vitro Diagnostic Medical Devices
Annex III section 6 (Devices for self-testing)

Certificate holder: **Guangzhou Decheng Biotechnology Co., Ltd**

Room 218 and Room 212, Building 2, No. 68, Nanxiang 1st Road, Science City, Huangpu District, Guangzhou, Guangdong, 510663, P.R. China

Related audit report: -

Other facility(ies): -

The certificate was issued with respect to the following scope:

2019-nCoV Ag Saliva Rapid Test Card (Immunochromatography)

This certificate is effective from 26 November 2021 until 26 May 2022 and remains valid subject to execution of regular examinations and continuous compliance.
Initial version of the certificate was effective from 26 November 2021.

Certification has been authorized by

Digitally signed by Radovan Máčaj

Radovan Macaj
Head of Notified body

bqs.
Certified In Vitro diagnostic medical device

bqs issued the certificate on the basis of performed examination in accordance with Council Directive 98/79/EC, Slovak government decree No. 569/2001 Coll. of Laws and EN ISO/IEC 17065:2012. Notified Body has performed an examination of the design dossier relating to the device in accordance with Annex III section 6 of the directive and found that the design of the device conforms to the requirements laid down by Annex III. Please see also notes overleaf if any.

CENB-01 ver. 1.0 Page 1 of 2

bqs.
The Trust. We Make.

SNAS Reg. No. 575/P-051

Notified body 2854 | SKTC-180

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www.bqsgroup.eu

Additional information on certification under 98/79/EC Annex III section 6

Related to certificate number:

IVDD 21 042 0106

Description of product(s) within the certification scope:

2019-nCoV Ag Saliva Rapid Test Card is an antigen rapid test on basis of lateral flow immunochromatographic assay intended for the rapid and qualitative detection of N-antigen of human coronavirus 2 (2019-nCoV) in saliva samples from individuals suspected of COVID-19.

Types/Categories/Models: 1 test per box, 5 tests per box, 25 tests per box (0699C8X001, 0699C8X005, 0699C8X020)

Classification: Devices for self-testing

Validity conditions: The manufacturer has a duty to submit to the Notified body testing results as per established procedure of each manufactured batch prior its releasing.

This certificate is effective from 26 November 2021 until 26 May 2022 and remains valid subject to execution of regular examinations and continuous compliance.
Initial version of the certificate was effective from 26 November 2021.

bqs.
Certified In Vitro diagnostic medical device

bqs issued the certificate on the basis of performed examination in accordance with Council Directive 98/79/EC, Slovak government decree No. 569/2001 Coll. of Laws and EN ISO/IEC 17065:2012. Notified Body has performed an examination of the design dossier relating to the device in accordance with Annex III section 6 of the directive and found that the design of the device conforms to the requirements laid down by Annex III. Please see also notes overleaf if any.

CENB-01 ver. 1.0 Page 2 of 2

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IVD CE 2854

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