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:	26 November 2021
Valid until:	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