EU DECLARATION OF CONFORMITY

According the in vitro Diagnostic Medical Device Directive 98/79/EC

Manufacturer:	Guangzhou Decheng Biotechnology Co., LTD
Address:	Room 218, Building 2, No.68, Nanxiang Road, Science City, Huangpu District, 510000, Guangzhou P.R.China
European Representative:	Caretechion GmbH Niederrheinstr. 71, 40474Duesseldorf, Germany.
Product Name:	2019-nCoV Ag Rapid Test Kit (Immunochromatography)
Cat. No.:	0555C2X001 0555C2X005 0555C2X010 0555C2X025 0555C3X025 0555C4X025
IVDD Classification:	Other, for professional use
Applied Common Specifications/ Standards:	EN ISO 18113-1:2011 EN ISO 18113-2:2011 EN ISO 15223-1:2016 EN 13641:2002 EN ISO 14971:2012 EN 62366 :2008 EN 23640:2015 EN 13612:2002 EN ISO 13485: 2016
Conformity assessment procedure:	Annex III, excluding 6
Notified Body (if consulted):	Not Applicable

CE

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.

Signature: 刘伟

Position:General Manager

Place:Guangzhou

Date:2021.03.26