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:	CMC Medical Devices & Drugs S.L. C/ Horacio Lengo Nº 18, CP 29006,Málaga, Spain
Product Name:	2019-nCoV Ag Saliva Rapid Test Kit (Fluorescence Immunochromatographic Assay)
Cat. No.:	0639C4X010 0639C4X015 0639C4X020 0639C4X025
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:

Place:Guangzhou

Position:General Manager

Date:2020.12.01