

EU DECLARATION OF CONFORMITY

According to 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 N° 18, CP 29006,Málaga, Spain

Product Name: 2019-nCoV Saliva Ag EASY TEST
(Immunochromatography)

Cat. No.: 0674C4X001 0674C4X002 0674C4X005
0674C4X010 0674C4X020 0674C4X025

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



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 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:2021.03.15

