

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: Caretechion GmbH
Niederrheinstr. 71, 40474 Duesseldorf, Germany

Product Name: 2019-nCoV Ag Saliva Rapid Test Card
(Immunochromatography)

Cat. No.: 0589C4X001 0589C4X005 0589C4X010
0589C4X015 0589C4X020

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 that the above product(s) meet(s) the provisions of the European Directive 98/79/EC for in vitro Diagnostic Medical Devices.

Signature: 
Position: General Manager

Place: Guangzhou

Date: 2020.11.21

