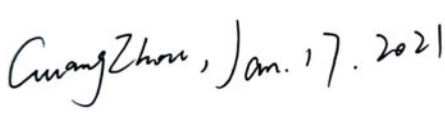



Guangzhou Wondfo Biotech Co., Ltd.
RF-008-00

Effective date: 2017-11-2

EC DECLARATION OF CONFORMITY
According the In Vitro Diagnostic Medical Device Directive 98/79/EC

Manufacturer:	Guangzhou Wondfo Biotech Co., Ltd.	
Address:	No.8, Lizhishan Road, Science City, Luogang District, 510663, Guangzhou, P.R. China	
In vitro diagnostic device(s):	Product Name:	Cat. No.:
	2019-nCoV Antigen Saliva/Sputum Test	W633P0001, W633P0002, W633P0003, W633P0004, W633P0005, W633P0006
	IVDD Classification:	Other, for professional use
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.		
The following (harmonized) standards have been applied:		
EN ISO 13485: 2016	EN ISO 14971: 2012	EN 13612:2002
EN ISO 15223-1:2016	EN ISO 18113-1: 2011	EN ISO 18113-2: 2011
EN ISO 23640: 2015	EN 13641: 2002	EN 62366-1: 2015
EC 1272/2008		
The conformity with the requirements of the Directive has been assessed following the procedure(s) outlined in the following annexes of the Directive: <u>Annex III, excluding 6</u>		
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: <u>Qarad BV, Ciplastraat 3, 2440 Geel, Belgium</u>		
 _____	Yaquin Chi, Vice-President of Regulatory Affairs  _____	
(Place and date of issue)	(name and signature or equivalent marking of authorized person)	