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:**	2019-nCoV RBD Antibody Rapid Test
	Cat. No.:	W632P0002, W632P0003, W632P0004, W632P0005, W632P0006, W632P0007, W632P0008, W632P0009, W632P0010, W632P0011
	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 62366:2008
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:

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:

Qarad BV, Cipalstraat 3, 2440 Geel, Belgium

Guang Zhou, January 5, 2021	Yaqin Chi, Vice-President of Regulatory Affairs
(Place and date of issue)	(name and signature or equivalent marking of authorized person)