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:**	Wondfo 2019-nCoV Antigen Test (Lateral Flow Method)
	Cat. No.:	W196, W196P0005, W196P0006, W196P0007, W196P0008, W196P0009, W196P0010, W196P0011, W196P0012
	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 18, 2021	Yaqin Chi, Vice-President of Regulatory Affairs Yaqin Chi
(Place and date of issue)	(name and signature or equivalent marking of authorized person)