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

Effective date: 2017-11-2

Manufacturer:	Guangzhou Wondfo Biotech Co. Ltd.				
Address:	No.8, Lizhishan Road, Science City, Luogang District, 510663, Guangzhou, P.R. China				
In vitro	Product Name:				Cat. No.:
diagnostic device(s):	Wondfo 2019-nCoV Antigen Test (Lateral Flow Method)			W196	
device(s).	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)2
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					08
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					
			Yaqin Chi, Regulatory Affairs Director		
Gungzhon Nov. 6, 2020		- ~ ~	Yagin Chi		
(Place and date of issu	ce and date of issue)		(name and signature or equivalent marking of authorized person)		