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.:		
	Wondfo SARS-CoV-2 A	Vondfo SARS-CoV-2 Antigen Test (Lateral Flow Method)		W196	
	IVDD Classification: Other, for professional use				
	of conformity is issued roduct(s) meet(s) the product Devices.				
The following (ha	rmonized) standards ha	we been applied:			
EN ISO 13485: 20	016 EN ISO	EN ISO 14971: 2012		EN 13612:2002	
EN ISO 15223-1:	2016 EN ISO	EN ISO 18113-1: 2011		EN ISO 18113-2: 2011	
EN ISO 23640: 20	D15 EN 1364	EN 13641: 2002 EN		2008	
Notified Body (if Technical docume made available by	consulted): Not apple the authorized representation demonstrating of the authorized REEL, Bottom 1981.	icable. compliance is kept but attive in Europe:	ve: Annex III, ex	scluding 6	
	7				
GranyZhou	Aug 1100/92020		gulatory Affairs Dire	ector	