






Shenzhen Reagent Technology Co.,Ltd.
R7777, Hangcheng Wisdom Science Park, Hangcheng street, Bao'an District Shenzhen 518128, China
0755-23006622 Email: reagenkits@gmail.com
Web :www.reagen.cn
www.reagen.us

Dichiarazione di Conformità

DECLARATION of CONFORMITY

Complies with the applicable essential requirements of the council directive 98/79/EC in vitro diagnostics as amended

	Manufacturer:	Shenzhen Reagent Technology Co.,Ltd.
	Add :	R7777, Hangcheng Wisdom Science Park, Hangcheng street, Bao'an District Shenzhen 518128, China
Medical Device:		1. COVID-19 Real-Time Fluorescence PCR Detection Kit (lyophilized) 2. COVID-19 & Influenza A/B Antigen Combo Test Kit 3. COVID-19 IgM ELISA Test Kit 4. COVID-19 IgG ELISA Test Kit 5. COVID-19 Neutralizing Antibody ELISA Test Kit 6. COVID-19 Neutralizing Antibody Rapid Test Kit 7. Zilpaterol ELISA Test Kit 8. SARS-CoV-2 antigen IVD kit SWAB 9. SARS-CoV-2 antigen IVD kit NASAL 10. SARS-CoV-2 antigen IVD kit SALIVA
Classification:		Others/General
We, Shenzhen Reagent Technology Co.,Ltd. Herewith declare that the stated medical devices meet the transposition into national law, complies with the applicable essential requirements of the council directive 98/79/EC in vitro diagnostics as amended, All supporting documentation is retained at the premises of the manufacturer.		
EC REP	CMC Medical Devices & Drugs S.L.	
European Representative:	C / Horacio Lengo Nr. 18, 29006, Malaga, Spain +34 951214054 Info@cmcmedicaldevices.com	
Place, Date of Declaration:	China, Mar 19, 2021	
Signature:	 	
	Managing Director	