DECLARATION of CONFORMITY

The products comply with the essential requirements in accordance with Annex I of Medical Devices Directive 98/79/EC

Manufacturer:	Shenzhen Reagent Technology Co.,Ltd. Add : R777,Hangcheng Wisdom Science Park, Hangcheng street, Bao′an District Shenzhen 518128,China.
Medical Device:	1. Monkeypox Virus Antigen Rapid Test Kit 2. Nine Respiratory Pathogens Antigen Rapid Test Kit
IVDD Classification:	IVD OTHERS
Standards Applied:	EN ISO 13485:2016 EN ISO13612:2002 EN ISO 15223-1-2016 EN ISO 14971:2019
Conformity Assessment Procedure:	Annex I, including 6
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 European Representative:	CMC Medical Devices&Drugs S.L. C/Horacio Lengo Nr. 18, 29006, Malaga, Spain +34 951214054 Info@cmcmedicaldevices.com
Place, Date of Declaration:	China, Mar, 20, 2022
Signature:	Managing Director