EC Declaration of Conformity

according to the Directive 98/79/EC

Manufacturer	WuHan UNscience Biotechnology Co., Ltd.
Address	Building B18, 2nd Phase of Biomedical Park, #858 GaoXin Road, Donghu Hi-Tech Development, Wuhan, Hubei, P.R. China
EC Representative Address	Wellkang Ltd. 16 Castle Street, Dover, CT16 1PW, England, UK

We, the manufacturer, declare under our sole responsibility that

the medical device(s)	COVID-19 IgG/IgM Rapid Test Kit
	Type/model 20T/40T/50T/100T
Classification	Others in vitro diagnostic device (IVD)

is/are in conformity with the relevant provisions and requirements of Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

Applied harmonised standards, national standards or other normative documents	EN ISO 13485:2016 EN ISO 15223-1:2016 EN ISO 14971:2012	EN ISO 23640:2015 EN 1041:2008
Conformity assessment procedure	Module A (EC Declaration of Conformity) (Annex III, except point 6)	

Signed on: 19 March 2020 Place: Wuhan, Hubei, China

Signature of General Manager

CE