Certificate CN20/42009

The management system of

WuHan UNscience Biotechnology Co., Ltd.

Building B18, 2nd Phase of Biomedical Park, #858 Gaoxin Road,
Donghu Hi-Tech Development , Wuhan, Hubei, P.R. China

has been assessed and certified as meeting the requirements of

ISO 13485:2016
EN ISO 13485:2016

For the following activities

Design and Manufacture of In Vitro Diagnostic Reagents(Colloidal gold Assay and Immunofluorescence Assay), including:Pathological Antibodies, Cardiovascular Test Reagent, Infectious Diseases Test Reagent, Kidney Disease Test Reagent, Reproductive Function Test Reagent, Rheumatoid Arthritis Test Reagent, Gastric Function Test Reagent.

This certificate is valid from 15 January 2020 until 14 January 2023
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 19 December 2022
Issue 1. Certified since 15 January 2020

Authorised by

SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

HC SGS 13485 2016 0118

SCIENCE

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 23640:2015
	EN ISO 15223-1:2016	EN 1041:2008
	EN ISO 14971:2012	
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