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	CMC Medical Devices & Drugs S.L C/Horacio Lengo N 18 CP 29006, M á laga-Spain

We, the manufacturer, declare under our sole responsibility that

the medical device(s)	SARS-CoV-2 Antigen Rapid Test Kit
	Type/model 20T/25T/40T/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: 10 October, 2020 **Place: Wuhan, Hubei, China**

Signature of General Manager

Wuhan UNscience Biotechnology Co., Ltd 武汉优赛生物科技有限公司

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