



# EC Declaration of Conformity

according to the Directive 98/79/EC

Manufacturer WuHan UNscience Biotechnology Co., Ltd.  
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Donghu Hi-Tech Development, Wuhan, Hubei, P.R. China  
EC Representative CMC Medical Devices & Drugs S.L.  
Address 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  
Signature of General Manager

Place: Wuhan, Hubei, China

