CE CE

EC Declaration of Conformity

according to the Directive 98/79/EC

(applicable to IVD Devices of **NOT Annex II and NOT self-test***)*

Manufacturer: **Koch Biotechnology (Beijing) Co., Ltd**

Address: No.16 Chunlin street, Daxing District, Beijing, China

EC Representative: WellKang Ltd (www.CE-marking.eu)

Enterprise Hub, NW Business Complex,1 Beraghmore Road,Derry, BT48 8SE, Northern Ireland,UK

Product **COVID-19 Antigen Rapid Test Strip**

Product Code and Type: NCV10: 50Tests/Kit NCV10-2: 100Tests/Kit

Classification **Others**

We, the manufacture, declares the product as specified above meets the applicable provisions of the following the Directive and Standards and fulfils the obligations imposed by Annex III of Directive 98/79/EC. All supporting documentation is retained under the premise of authorized representative.

DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 1998 on in-Vitro diagnostic medical devices.

Standards	EN ISO 18113-1:2011	EN ISO 18113-2:2011	EN 13612:2002
	EN ISO 23640:2015	EN ISO 15223-1:2016	EN 13641:2002
	EN ISO 14972:2012	EN ISO 13485:2016	EN 13975:2003
	EN ISO 17511:2003	EN 62366-1:2015	

Conformity assessment procedure Module A (EC Declaration of Conformity) (Annex III, except point 6)

Signed on: 23 March 2020 Place: Beijing, China

Signature (on behalf of the manufacturer) Yu Song

Name of authorized signatory: Yu Song

Position held in the company: General Manager

Company Seal/Stamp:

Version Number: NCV-AGS-50-2.1