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: Caretechion GmbH
Niederrheinstr 71,40474 Duesseldorf, Germany

Product: COVID-19 Antigen Rapid Test Kit

Product Code and Type: NCV11: 25Tests/Kit; NCV12: 1Test/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 13485-2016	EN ISO 18113-1:2011	EN 13612-2002
EN ISO 14971:2019	EN ISO 18113-2-2011	EN 13641-2002
EN ISO 15223-1-2016	EN ISO 23640-2015	EN 62366-1-2015
EN ISO 17511-2003		

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

Signed on: 6th January 2021 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: