

祺氏 KISSH

EC Declaration of Conformity

We,
 Manufacturer Name: Shenzhen Kisshealth Biotechnology Co., Ltd.
 Address: 301, Building B, No. 16-1 Jinhui Road, Jinsha Community, Kenzi Sub-district
 Office, Pingshan District, 518118 Shenzhen, P.R.China

as the Manufacturer of
 Product Name: SARS-CoV-2 Antigen Test Kit(GICA)
 Analyte: SARS-CoV-2 antigen(protein)
 Classification:Others
 Conformity assessment: IVDD 98/79/EEC Annex III

herewith declare under our sole responsibility that the mentioned products meet the provisions of the Council Directive 98/79/EC concerning In-Vitro Diagnostic Medical Devices and the following standards which apply to them.

The following standards were used to prove conformity:

- EN ISO 13485:2016
- ISO 14971:2007
- EN ISO 14971:2012
- EN 13640:2002
- EN ISO 18113-2:2011
- EN ISO 18113-3:2011
- EN ISO 18113-4:2011
- EN ISO 18113-5:2011
- EN ISO 15223-1:2012
- BSEN 13612-2002
- EN ISO 15223-4:2012

The authorized representative within the EU who has been empowered to enter into commitments on our behalf:

MedNet GmbH
 Borkstrasse 10, 48163 Muenster, Germany

Place, Shenzhen, China

Date: October 14, 2020

Name,

5.1.2e

Position

5.1.2e

