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: Safecare Biotech (Hangzhou) Co., Ltd.

Address: Building 2/203, No.18 Haishu Rd.Cangqian Sub-district, Yuhang District, Hangzhou, Zhejiang China 311121

EC Representative: Wellkang Ltd,
16 Castle St,Dover, Kent, CT16 1PW,England,UK

We, the manufacturer, declare under our sole responsibility that

the medical device(s)

Product Name	COVID-19 Antigen Rapid Test Kit(Swab)
Type/model, identification of product allowing traceability (Where applicable)	Cassette(COV Ag-6012)

of Category: **Common/Others IVD**
(Devices of **NOT Annex II** and **NOT self-test**)

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 ISO23640:2015
EN 13612:2002
EN 13641:2002
EN ISO 14971:2019
ISO13485:2016
EN ISO 18113-1:2011
ISO 18113-2: 2009
EN1041- 2008
EN ISO15223-1:2016

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

Notified Body (name & number) Certificate & number: **NOT applicable**

Signed on 28th Sep.,2020 Place: Hangzhou, Zhejiang, China

Signature (on behalf of the manufacturer) Kebin Qiu 2020.9.28

Name of authorized signatory: Kebin Qiu

Position held in the company: General Manager

Seal/Stamp: