4. EU-Konformitätserklärung

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:	NIC GmbH Erlenweg 13,49076 Osnabrück,Germany

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: