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 IgG/IgM Rapid Test Kit (Whole Blood/serum/plasma)
	Type/model, identification of product allowing traceability (Where applicable)	Cassette(NCO-4022)
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 ISO 18113-1:2011
	EN 13612:2002	ISO 18113-2：2009
	EN 13641:2002	EN1041- 2008
	EN ISO 14971:2012	EN ISO15223-1:2016
	ISO13485:2016	
Conformity assessment prccedure	**Module A (EC Declaration of Conformity) (Annex III, except point 6)**	
Notified Body (name & number)	**NOT applicable**	
Certificate & number		

Signed on: 6 March, 2020. Place: Hangzhou, Zhejiang, China

Signature (on behalf of the manufacturer) Kebin Qiu 2020.3.6

Name of authorized signatory: Kebin, Qiu
Position held in the company: General Manager
Seal/Stamp: