EC Declaration of Conformity

according to the Directive 98/79/EC

(For self-testing)

Manufacturer:	Safecare Biotech （Hangzhou）Co., Ltd.
Address:	Building 2/203, No.18 Haishu Rd.Cangqian Sub-district， Yuhang District, Hangzhou, Zhejiang China 311121 Tel/Fax:+86 571 81389219 Email:admin@safecare.com.cn
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) For Self-testing
	Type/model, identification of product allowing traceability (Where applicable)	Cassette (COV Ag-6012H)
of Category	Devices for **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 EN ISO 18113-4:2011 EN ISO 15223-1:2016 EN 62366-1:2015 EN 13532:2002
Conformity assessment procedure	**EC Declaration of Conformity (Annex III, -Section 6)**	
Notified Body (name & number)	POLSKIE CENTRUM BADAN I CERTYFIKACJI S.A. Notified Body number:1434	
Certificate & number		

Signed on: 2021.8.20 Place: Hangzhou, Zhejiang, China

Signature (on behalf of the manufacturer) Kebin Qiu

Name of authorized signatory: Kebin Qiu

Position held in the company: General Manager

Seal/Stamp: