



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 ISO 18113-1:2011
	EN 13612:2002	EN ISO 18113-4:2011
	EN 13641:2002	EN ISO 15223-1:2016
	EN ISO 14971:2019	EN 62366-1:2015
	ISO13485:2016	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)



Name of authorized signatory: Kebin Qiu

Position held in the company: General Manager

Seal/Stamp: