CERTIFICATE

EC Certificate No. 1434-IVDD-460/2021

EC Design-examination
Directive 98/79/EC concerning
***in vitro* diagnostic medical devices**

Polish Centre for Testing and Certification certifies
that manufactured by:

Safecare Biotech (Hangzhou) Co., Ltd
311121 Hangzhou, Building 2/203, No. 18 Haishu Rd.Cangqian Subdistrict, Yuhang District, China

in vitro diagnostic medical devices
for self-testing

COVID-19 Antigen Rapid Test Kit (Swab)

in terms of design documentation, comply with requirements
of Annex III (Section 6) to Directive 98/79/EC (as amended)
implemented into Polish law,
as evidenced by the audit conducted by the PCBC
Validity of the Certificate: from 23.09.2021 to 27.05.2024

The date of issue of the Certificate: 23.09.2021

The date of the first issue of the Certificate: 23.09.2021

CE 1434

Issued under the Contract No. MD-117/2021
Application No: 218/2021
Certificate bears the qualified signature.
Warsaw, 23.09.2021
Module A1

Anna Małgorzata Wyroba
Elektronicznie podpisany przez Anna Małgorzata Wyroba
Data: 2021.09.23 14:29:35 +02'00'
Vice-President

POLISH CENTRE FOR TESTING AND CERTIFICATION 02-844 Warsaw, 469 Puławska Street, tel. +48 22 46 45 200, e-mail:pcbc@pcbc.gov.pl

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Safecare Biotech (Hangzhou) Co., Ltd.
Building 2/203,No. 18 Haishu Rd.
Cangqian Sub-district,Yuhang District
Hangzhou
311121 Zhejiang
P.R. China

has established and applies a quality management system for medical devices for the following scope:

Design and Development, Manufacture and Distribution of In Vitro Diagnosis of Rapid Test of Fertility, Drug of Abuse, Cardiac Markers, Infectious Diseases

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:	2020-08-02
Certificate Registration No.:	SX 60149068 0001
An audit was performed. Report No.:	15096152 005
This Certificate is valid until:	2023-06-06

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

Date 2020-08-02

Herbert Zhong

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail:cert-validity@de.tuv.com http://www.tuv.com/safety

CE

EC Declaration of Conformity

CE

according to the Directive 98/79/EC
(For self-testing of ANNEX II of IVDD)

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	: **Self-test** of **Annex II**	

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 18114-1:2011
	EN 13612:2002	EN ISO15223-1:2016
	EN 13641:2002	EN13532：2002
	EN ISO 14971:2019	EN 62366:2015
	ISO13485:2016	EN ISO 17511:2003

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

Signed on: 2021.6.10 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: