MedRhein TN25. S01

Antigen Schnelltest (Nasal, Nase-Rachen)

COVID-19 Antigen Rapid Test Kit (Swab)

gelistet und somit erstattungsfähig

BfArM gelistet und PEI Prüfung bestanden

Bundesinstitut
für Arzneimittel
und Medizinprodukte

Paul-Ehrlich-Institut

EU-weit anerkannt

EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFE

Public health, country knowledge, crisis management
Health Security and Vaccination

BfArM Nr: AT199/20

PZN: 17393995

MedRhein

Impressum Administration

Bundesinstitut für Arzneimittel und Medizinprodukte

Antigen-Tests auf SARS-CoV-2 zur professionellen Anwendung

die Gegenstand des Anspruchs nach §1 Satz 1 Coronavirus-Testverordnung (TestV) sind („Schnelltests“)

Allgemeine Hinweise

AT199/20 Los Aktionen Zurücksetzen

Nach 'AT199/20' suchen

				Hersteller			Europäischer Bevollmächtigter				Sensitivität		Spezifität		
Test-ID	Handelsname	Evaluierung PEI	Omikron-Erkennung entsprechend der Bridging-Prüfung des PEI	Name	Stadt	L...	Name	Stadt	La...	Testort*	%	95%iges Vertrauens-intervall	%	95%iges Vertrauens-intervall	Gebra anwei
AT199/20	COVID-19 Antigen Rapid Test Kit (Swab)	Ja	Ja	Safecare Biotech (Hangzhou) Co., Ltd.	Hangzh...		NIC GmbH	Osnabrück	DE	POC (ohne Gerät)	96,62	94,17 - 98,24	99,74	98,54 - 99,99	

letzte Änderung am: 02.06.2022 16:10 * POC = Point of Care

Release 1.2.2

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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:

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:	2023-08-08

Certification Body

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

Date: 2020-08-02

Herbert Zhang

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
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SAFECARE BIO-TECH

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www.safecare.com.cn

Declaration

Date: 1. June. 2022

To whom it may concern,

We, **Safecare Biothech (Hangzhou) Co., Ltd.**, having our office at Fl.2 Blog.2, No.18 Haishu Road, Hangzhou 311121 China, as a manufacturer of COVID-19 Antigen Rapid Test Kit(swab), hereby declare that our COVID-19 Antigen Rapid Test Kit(swab) remains effective for the detection of SARS-CoV--2 antigen even in the emergence of newly discovered variants including those found in the UK, India, South Africa and Brazil.

According to our investigation, several site mutations have occurred in the spike protein at the position of B.1.1.7, N501Y, E484K, K417N in the UK, Delta, B.1.617 in India, N501Y, P681H, 69-70 in the S.A. and E484K, K417N/T, N501Y, D614G in the Brazial, BA.4 and BA.5. Since the recognition site of the raw materials used in our antigen test is the nucleocapsid protein (nucleoprotein or protein N) antigens, which is different from the mutation sites, we expect our products are theoretically able to detect variants including those in UK, India, South Africa and Brazil.

Lastly, We Safecare will strictly implement our quality management system and strive to provide the best products to the customers. We will also inform you officially if there is any update information of our COVID-19 Antigen Rapid Test Kit.

杭州赛凯生物技术有限公司
HANGZHOU SAFECARE BIOTECH CO.,LTD.

Yours sincerely,

SAFECARE BIOTECH (HANGZHOU) CO., LTD.