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- 2016 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: Place: Hangzhou, Zhejiang, China

Signature (on behalf of the manufacturer) Kebin Qiu 2020.10.12

Name of authorized signatory: Kebin, Qiu

Position held in the company: General Manager

Seal/Stamp:

Anlage 2
(zu § 4 Abs. 1 Nr. 1 DIMDIV)
Formularnummer 00158610

Allgemeine Anzeigepflicht nach §§ 25 und 30 Abs. 2 MPG
General Obligation to Notify pursuant to §§ 25 and 30 (2) Medical Devices Act, MPG

Formblatt für In-vitro-Diagnostika / Form for In Vitro Diagnostic Medical Devices

Zuständige Behörde / Competent authority			
	Code **DE/CA11**		
	Bezeichnung / Name **Staatliches Gewerbeaufsichtsamt Oldenburg**		
	Staat / State **Deutschland**		Land / Federal state **Niedersachsen**
	Ort / City **Oldenburg**		Postleitzahl / Postal code **26122**
	Straße, Haus-Nr. / Street, house no. **Theodor-Tantzen-Platz 8**		
	Telefon / Phone **+49-441-7990**		Telefax / Fax **+49-441-7992700**
	E-Mail / E-mail **poststelle@gaa-ol.niedersachsen.de**		

Anzeige / Notification			
	Registrierdatum bei der zuständigen Behörde Registration date at competent authority **06.11.2020**		Registriernummer / Registration number **DE/CA11/923-4328**
	Typ der Anzeige / Notification type Erstanzeige / Initial notification Änderungsanzeige / Notification of change Widerrufsanzeige / Notification of withdrawal		
	Frühere Registriernummer bei Änderungs- und Widerrufsanzeige Previous registration number if notification has been changed or withdrawn		
	Anzeigender nach § 25 MPG / Reporter pursuant to § 25 Medical Devices Act, MPG Hersteller / Manufacturer Bevollmächtigter / Authorised Representative Einführer / Importer Verantwortlicher für das Zusammensetzen von Systemen oder Behandlungseinheiten nach § 10 Abs. 1 und 2 MPG \ Assembler of systems or procedure packs pursuant to § 10 (1) and (2) Medical Devices Act, MPG Betrieb oder Einrichtung (aufbereiten) nach § 25 Abs. 1 MPG i. V. m. § 4 Abs. 2 MPBetreibV Institution (processing) pursuant to § 25 (1) Medical Devices Act, MPG in connection with § 4 (2) MPBetreibV Betrieb oder Einrichtung (sterilisieren) nach § 25 Abs. 2 i. V. m. § 10 Abs. 3 MPG Institution (sterilizing) pursuant to § 25 (2) in connection with § 10 (3) Medical Devices Act, MPG		

Anzeigender / Reporting organisation (person)			
	Code **DE/0000049080**		
	Bezeichnung / Name **NIC GmbH**		
	Staat / State **Deutschland**		Land / Federal state **Niedersachsen**
	Ort / City **Osnabrück**		Postleitzahl / Postal code **49076**
	Straße, Haus-Nr. / Street, house no. **Erlenweg, 13**		
	Telefon / Phone **0541 9116706**		Telefax / Fax
	E-Mail / E-mail **info@nic-industry.com**		

Hersteller / Manufacturer			
	Bezeichnung / Name **Safecare Biotech (Hangzhou) Co., Ltd.**		
	Staat / State **CN**		
	Ort / City **Hangzhou, Zhejiang**		Postleitzahl / Postal code **311121**
	Straße, Haus-Nr. / Street, house no. **Building 2/203, No.18 Haishu Rd.Cangqian Sub-district, Yuhang District**		
	Telefon / Phone **0086-571-81389219**		Telefax / Fax **0086-571-80389223**
	E-Mail / E-mail **selinazhang@safecare.com.cn**		

Sicherheitsbeauftragter für Medizinprodukte nach § 30 Abs. 2 MPG 9) **Safety officer for medical devices pursuant to § 30 (2) Medical Devices Act, MPG**			
	Bezeichnung / Name **Kun Yang**		
	Staat / State **Deutschland**		Land / Federal state **Niedersachsen**
	Ort / City **Osnabrück**		Postleitzahl / Postal code **49076**
	Straße, Haus-Nr. / Street, house no. **Erlenweg, 13**		
	Telefon / Phone **017621317686**		Telefax / Fax
	E-Mail / E-mail **kun.yang@nic-industry.com**		

Vertreter / Deputy (optional)			
	Bezeichnung / Name		
	Telefon / Phone		Telefax / Fax
	E-Mail / E-mail		
	Erstanzeige / Initial notification Änderungsanzeige / Notification of change		

In-vitro-Diagnostikum / In vitro diagnostic medical device

Klassifizierung / Classification
- Produkt der Liste A, Anhang II / Device of List A, Annex II
- Produkt der Liste B, Anhang II / Device of List B, Annex II
- Produkt zur Eigenanwendung / Device for self-testing
- Sonstiges Produkt / Other device (all devices except Annex II and self-testing devices)

App (Software auf mobilen Endgeräten) ja / yes nein / no

Anzeige nach § 25 Abs. 3 Nummer 3 MPG
Notification pursuant to § 25 (3) number 3 Medical Devices Act, MPG
- "Neues In-vitro-Diagnostikum / New in vitro diagnostic medical device"

Handelsname des Produktes / Trade name of the device
COVID-19 Antigen Rapid Test Kit(Swab)

Produktbezeichnung / Name of device
COVID-19 Antigen Rapid Test Kit(Swab)

Angabe der benutzten Nomenklatur / Nomenclature used
- EDMS-Klassifikation / EDMS Classification
- GMDN

Nomenklaturcode / Nomenclature code
15-70-90-90-00

Nomenklaturbezeichnung / Nomenclature term
OTHER OTHER VIROLOGY RAPID TESTS

Kurzbeschreibung / Short description
In Deutsch / In German
Typ: Kassette(COV Ag-6012). Der COVID-19 Antigen-Schnelltest ist ein Lateral-Flow-Immunoassay, der für den qualitativen Nachweis von Nukleocapsid-Protein-Antigen in direkten Nasenabstrichen oder Nasopharyngealabstrichproben von Personen bestimmt ist, die von ihrem Arzt innerhalb der ersten sieben Tage nach Symptombeginn mit COVID-19 verdächtigt werden.
Der COVID-19 Antigen-Schnelltest unterscheidet nicht zwischen SARS-CoV und SARS-CoV- 2.
Die Ergebnisse sind für die Identifizierung von SARS-CoV-2-Nukleocapsid-Proteinantigen. Antigen ist in der Regel in Nasenabstrichen während der akuten Phase der Infektion nachweisbar. Positive Ergebnisse deuten auf das Vorhandensein von viralen Antigenen hin, aber eine klinische Korrelation mit der Patientengeschichte und anderen diagnostischen Informationen ist notwendig, um den Infektionsstatus zu bestimmen. Positive Ergebnisse schließen eine bakterielle Infektion oder Koinfektion mit anderen Viren nicht aus. Die nachgewiesene Substanz ist möglicherweise nicht die definitive Krankheitsursache. Negative Ergebnisse von Patienten mit Symptombeginn über sieben Tage hinaus sollten als anmaßend behandelt werden und gegebenenfalls mit einem molekularen Test für das Patientenmanagement bestätigt werden. Negative Ergebnisse schließen eine SARS-CoV-2-Infektion nicht aus und sollten nicht als alleinige Grundlage für Behandlungs- oder Patientenmanagemententscheidungen, einschließlich Infektionskontrollentscheidungen, verwendet werden. Negative Ergebnisse sollten im Zusammenhang mit den jüngsten Expositionen, der Vorgeschichte und dem Vorhandensein klinischer Anzeichen und Symptome eines Patienten im Einklang mit COVID-19 betrachtet werden.

	In Englisch / In English **Type: Cassette(COV Ag-6012). The COVID-19 Antigen Rapid Test is a lateral flow immunoassay intended for qualitative detection of nucleocapsid protein antigen in direct nasal swabs or nasopharyngeal swab specimens from individuals suspected of COVID-19 by their healthcare provider within the first seven days of symptom onset.** **The COVID-19 Antigen Rapid Test does not differentiate between SARS-CoV and SARS-CoV- 2.** **Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen. Antigen is generally detectable in nasal swabs during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.** **Negative results from patients with symptom onset beyond seven days, should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management, may be performed.** **Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of a patients recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.** **The COVID-19 Antigen Rapid Test is intended for use by medical professionals or trained operators who are proficient in performing rapid lateral flow tests.**

Zusätzliche Angaben im Falle der In-vitro-Diagnostika gemäß Anhang II und der In-vitro-Diagnostika zur Eigenanwendung / Addtional information for Annex II and self-testing in vitro diagnostic medical devices	
	Nummer(n) der Bescheinigung(en) / Certificate number(s)
	In Übereinstimmung mit den Gemeinsamen Technischen Spezifikationen (für Produkte gem. Anhang II, Liste A) In conformity with Common Technical Specifications (for Annex II List A devices)
	Ergebnisse der Leistungsbewertung Outcome of performance evaluation

Ich versichere, dass die Angaben nach bestem Wissen und Gewissen gemacht wurden.
I affirm that the information given above is correct to the best of my knowledge.

Ort
City **Osnabrück**

Datum
Date **2020-10-13**

Name **Kun Yang**

Unterschrift
Signature

Bearbeitungsvermerke / Processing notes Nur von der zuständigen Behörde auszufüllen / To be filled in only by the competent authority			
	Bearbeiter / Person responsible **Frau Diana Peters**		Telefon / Phone **0441 799-2529**

Stand 28.01.2021

Übersicht SARS-CoV-2 Antigenschnelltests, die als „dem derzeitigen Stand der Technik entsprechend“ bewertet wurden

Testname	Hersteller (Vertrieb)
Panbio™COVID-19 Ag Rapid Test Device (NASOPHARYNGEAL)	Abbott Rapid Diagnostics Jena GmbH
RIDA®QUICK SARS-CoV-2 Antigen	R-Biopharm AG
SARS-CoV-2 Rapid Antigen Test	SD BIOSENSOR (Roche Diagnostics GmbH)
NADAL® COVID-19 Ag Schnelltest	nal von minden gmbh
STANDARD™ F COVID-19 Ag FIA	SD BIOSENSOR
STANDARD™ Q COVID-19 Ag Test	SD BIOSENSOR
BIOSYNEX COVID-19 Ag BSS	BIOSYNEX SWISS SA
MEDsan® SARS-CoV-2 Antigen Rapid Test	MEDsan GmbH
TestNOW® - COVID-19 Antigen	Affimedix
NowCheck® COVID-19 Ag Test	BIONOTE
Coronavirus Ag Rapid Test Cassette (Swab)	Zhejiang Orient Gene Biotech Co.,Ltd
Sofia SARS Antigen FIA	Quidel Corporation
COVID-19 Ag Test Kit	Guangdong Wesail Biotech Co., Ltd.
CLINITEST® Rapid COVID-19 Antigen Test	Siemens Healthineers
ESPLINE® SARS-CoV-2	Fujirebio Inc. (Mast Diagnostica GmbH)
BD Veritor™ System for Rapid Detection of SARS-CoV-2	Becton Dickinson
GenBody COVID-19 Ag	IVC Pragen Healthcare
LumiraDx SARS-CoV-2 Ag Test	LumiraDX
Exdia COVID-19-Ag-Test	Precision Biosensor Inc. (Axon Lab AG)
SARS-CoV-2 Ag Rapid Test (FIA)	Wantai (Beijing Wantai Biological Pharmacy Enterprise Co., Ltd.)
SARS-CoV-2 Antigen Schnelltest	Xiamen Boson Biotech Co., Ltd (Medicovid-AG; technomed GmbH; Löwe Medizintechnik)
COVID-19 Antigen Schnelltest (Colloidal Gold)	Joinstar Biomedical Technology Co., Ltd (CIV care impuls Vertrieb)
mö-screen Corona Antigen Test	Mölab GmbH
Rapid SARS-CoV-2 Antigen Test Card	MP Biomedicals Germany GmbH
Lyher Novel Coronavirus (COVID-19) Antigen Test Kit (Colloidal Gold)	Hangzhou Laihe Biotech Co., Ltd. (Lissner Qi GmbH)
AMP Rapid Test SARS-CoV-2 Ag	Ameda Labordiagnostik GmbH
Clungene COVID-19 Antigen Rapid Test	Hangzhou Clongene Biotech Co., Ltd.
GensureTM COVID-19 Antigen Rapid Test Kit	GenSure Biotech Inc.
SARS-CoV-2 Antigen Rapid Test Kit	Beijing Lepu Medical Technology Co., Ltd

Hightop SARS-CoV-2 (Covid-19) Antigen Rapid Test	Qingdao Hightop Biotech Co., Ltd.
Rapid Covid-19 Antigen Test (Colloidal Gold)	Anbio (Xiamen) Biotechnology Co., Ltd
☆ **Safecare COVID-19 Ag Rapid Test Kit (Swab)**	Safecare Biotech Hangzhou Co., Ltd.

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

Clinical Evaluation Supplementary Report

1. Purpose:

Additional verify the clinical performance of the improved test (used sample matrix: nasal swab samples)

2. Material:

Fresh negative COVID-19 samples were collected from the hospital and validated by PCR.
Fresh positive COVID-19 samples were collected from CDC and validated by PCR.
Product used: COV20082701

3. Protocol:

3.1 Sample Size:
Positive Sample: >100
Negative Sample:>150

3.2 Sample's collection:
Two nasal swabs were collected from patients. All swabs were randomly blinded. One nasal swab was tested directly with Safecare COVID-19 Ag Card test kit according to product instructions. The other swab was assigned to testing with PCR assay as the comparator method for this study.

3.3 Sample Entry criteria:
The samples from hospital outpatient screening cases and COVID-19 Patients who presented within 7 days of symptom onset;
Samples of people that gender and age are not limited.

3.4 Sample Exclusion criteria:
Samples without PCR test results;
Samples that the quantity is not enough to complete the test;
Samples with failed test results (C-line has not appeared);
Freeze samples repeatedly.

3.5 Comparator method
All samples was confirmed by RT-PCR, Novel Coronavirus (2019-nCoV) Nucleia Acid Diagnostic Kit (PCR-Fluorescence Probing) manufactured by Sansure BioTech Inc.
PCR tests performed on ABI7500.

4. Operator and site:

Site 1: CDC-Immunology Laboratory
Researcher: Dr. Zhang Lei
Site 2: Hospital- Immunology Laboratory
Researcher: Dr.Xuwei

5. Statistical methods:

5.1 Statistical of test result

		Referencing reagent Test		Total
		Positive	Negative	
Research Reagent	Positive	A	B	A+B
	Negative	C	D	C+D
Total		A+C	B+D	A+B+C+D

Percent Positive Agreement=A/(A+C)*100%
Negative Percent Agreement=D/(B+D)*100%
Overall Agreement=(A+D)/(A+B+C+D)*100%

5.2 Statistical of Specimens correlation

Record and statistics the correlation of antigen-positive/PCR-positive and antigen-negative/ PCR-positive samples with the Ct values of the PCR to determine the mean Ct value of antigen-positive samples

6. Evaluation indicators:

The total PPA should be no less than 80%.
The total NPA should be no less than 90%.

7. Statistical results of the clinical evaluation

7.1 Test result

		Referencing Method (RT-PCR)		Total
		Positive	Negative	
Test-strip	Positive	118	1	119
	Negative	3	165	168
Total		121	166	287

Project	Value	Percentage (95% confidence interval)
Relative Sensitivity-PPA（%）	118/121	97.52% (92.93%～99.49%)
Relative Specificity-NPA（%）	165/166	99.40% (96.69%～99.98%)
Overall Agreement（%）	283/287	98.61% (96.47%～99.62%)

7.2 Kappa consistency test

Calculate the Kappa value and standard error; test hypothesis is established for Kappa: H0: k = 0, Kappa value comes from 0 population, H1: k > 0, Kappa value comes from non-0 population, α = 0.05.

Project	Value
Kappa Value	0.9714, Good consistency.
Standard Error Se(K)	0.0142
95% Confidence Interval	0.9435～0.9992
Standard Error Se0(K)	0.059
Test Value Z	Z=16.4575 Probability value P=0.0000
Test Result	P<0.05,refuse H0， Kappa values come from populations other than 0.

7.3 Specimens correlation

The performance of Safecare COVID-19 Antigen Rapid Test Kit(Swab) with positive results stratified by the comparator method (Ct) counts were collected and assessed to determine the correlation of assay performance to the Ct.

Safecare COVID-19 Antigen Rapid Test	Comparator Method (POS by Ct≦40)	
	Ct<30	Ct≧30
Positive	117	1
Negative	0	3
Total	117	4
Positive Agreement(95% CI)	100.00% (97.14%～100.00%)	25.00% (0.63%～80.59%)

Based on above table, the positive agreement of the Safecare COVID-19 Antigen Rapid Test Kit (Swab) is higher with samples of a Ct count <30.

8. Conclusion

8.1 A side-by-side comparison was conducted using the research reagent and referencing reagent. Compare with RT-PCR:

The Relative Sensitivity is 97.52%, the Relative Specificity is 99.40%, the Overall Agreement is 98.61%.

In summary, The study showed that there is a high coincidence rate between the test-strip and RT-PCR, and have the equivalence on the clinical usage.

Reporter: Wu Gang Date: 2021.02.19