SAFECARE BIO-TECH

Safecare

Rapid Test Antigen

NASEN-RACHEN-ABSTRICH

Bundesinstitut
für Arzneimittel
und Medizinprodukte

Paul-Ehrlich-Institut

Bundesinstitut für Impfstoffe
und biomedizinische Arzneimittel

BfArM gelistet und vom Paul-Ehrlich-Institut getestet

EN ISO 13485:2016

Zur professionellen Anwendung

25er Verpackung

Merkmale:

- ✓ Nur bis zu 2,5cm in die Nase einführen oder alternativ in den Nasopharynx.
- ✓ Schnelle und zuverlässige Testergebnisse in 15 Minuten
- ✓ BfArM gelistet und vom Paul-Ehrlich-Institut getestet.

Spezifität
99,42%

Sensitivität
97,27%

Schnelle Testergebnisse In 15 Min

Eine Packung enthält:

01 25xTupfer

02 25xPuffer

03 25x Testkassetten

04 25x Röhrchen

05 1x Ständer

Zertifikate

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

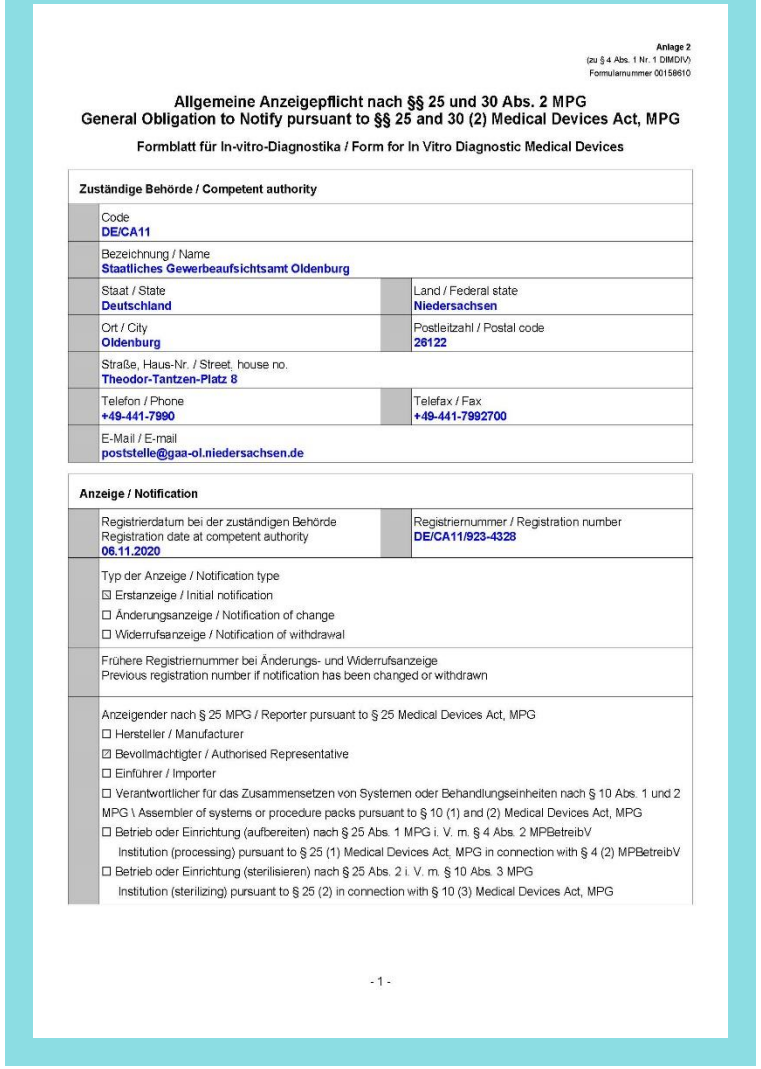
Signature (on behalf of the manufacturer): Kebin Qiu 2020.9.28

Name of authorized signatory: Kebin Qiu

Position held in the company: General Manager

Seal/Stamp:

EU-Konformitätserklärung



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

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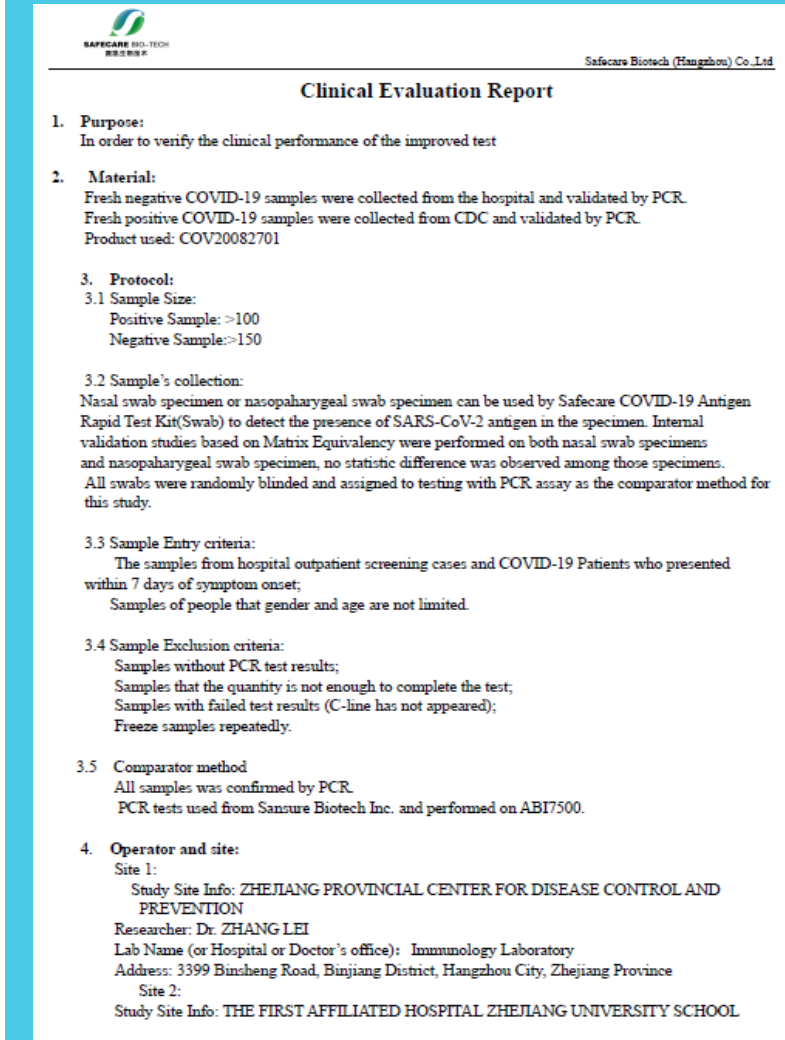
MDR-Zertifikat



SAFECARE BIO-TECH

Safecare Biotech (Hangzhou) Co.,Ltd

Clinical Evaluation Report

1. **Purpose:**
In order to verify the clinical performance of the improved test

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:
Nasal swab specimen or nasopaharygeal swab specimen can be used by Safecare COVID-19 Antigen Rapid Test Kit(Swab) to detect the presence of SARS-CoV-2 antigen in the specimen. Internal validation studies based on Matrix Equivalency were performed on both nasal swab specimens and nasopaharygeal swab specimen, no statistic difference was observed among those specimens. All swabs were randomly blinded and 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.

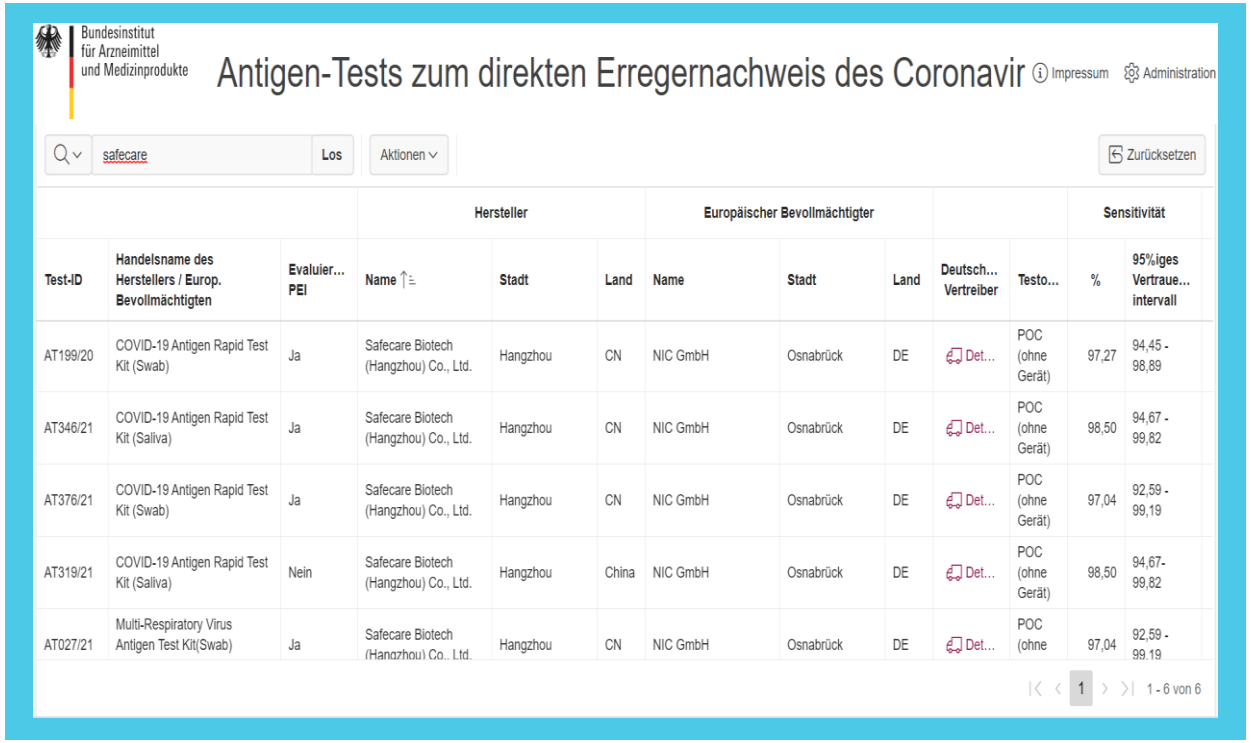
3.4 Sample Exclusion criteria:
Samples without PCR test results;
Samples that the quantity is not enough to complete the test;
Samples with failed test results (C-line has not appeared);
Freeze samples repeatedly.

3.5 Comparator method
All samples was confirmed by PCR.
PCR tests used from Sansure Biotech Inc. and performed on ABI7500.

4. **Operator and site:**
Site 1:
Study Site Info: ZHEJIANG PROVINCIAL CENTER FOR DISEASE CONTROL AND PREVENTION
Researcher: Dr. ZHANG LEI
Lab Name (or Hospital or Doctor's office): Immunology Laboratory
Address: 3399 Binsheng Road, Binjiang District, Hangzhou City, Zhejiang Province
Site 2:
Study Site Info: THE FIRST AFFILIATED HOSPITAL ZHEJIANG UNIVERSITY SCHOOL

klinischer Bericht

Auflistungen



Bundesinstitut für Arzneimittel und Medizinprodukte

Antigen-Tests zum direkten Erregernachweis des Coronavir

Impressum Administration

safecare Los Aktionen Zurücksetzen

			Hersteller			Europäischer Bevollmächtigter					Sensitivität	
Test-ID	Handelsname des Herstellers / Europ. Bevollmächtigten	Evaluier... PEI	Name	Stadt	Land	Name	Stadt	Land	Deutsch... Vertreiber	Testo...	%	95%iges Vertraue... intervall
AT199/20	COVID-19 Antigen Rapid Test Kit (Swab)	Ja	Safecare Biotech (Hangzhou) Co., Ltd.	Hangzhou	CN	NIC GmbH	Osnabrück	DE	Det...	POC (ohne Gerät)	97,27	94,45 - 98,89
AT346/21	COVID-19 Antigen Rapid Test Kit (Saliva)	Ja	Safecare Biotech (Hangzhou) Co., Ltd.	Hangzhou	CN	NIC GmbH	Osnabrück	DE	Det...	POC (ohne Gerät)	98,50	94,67 - 99,82
AT376/21	COVID-19 Antigen Rapid Test Kit (Swab)	Ja	Safecare Biotech (Hangzhou) Co., Ltd.	Hangzhou	CN	NIC GmbH	Osnabrück	DE	Det...	POC (ohne Gerät)	97,04	92,59 - 99,19
AT319/21	COVID-19 Antigen Rapid Test Kit (Saliva)	Nein	Safecare Biotech (Hangzhou) Co., Ltd.	Hangzhou	China	NIC GmbH	Osnabrück	DE	Det...	POC (ohne Gerät)	98,50	94,67- 99,82
AT027/21	Multi-Respiratory Virus Antigen Test Kit(Swab)	Ja	Safecare Biotech (Hangzhou) Co., Ltd.	Hangzhou	CN	NIC GmbH	Osnabrück	DE	Det...	POC (ohne	97,04	92,59 - 99,19

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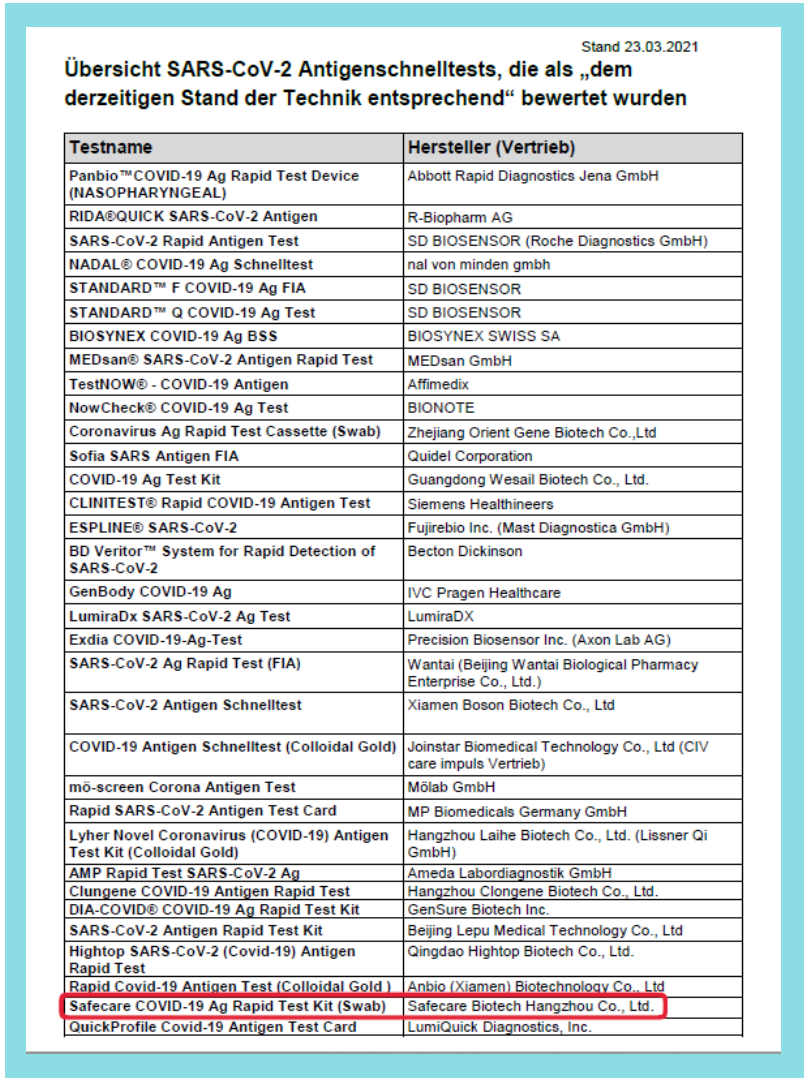
Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM)



Stand 23.03.2021

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
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.
DIA-COVID® COVID-19 Ag 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.
QuickProfile Covid-19 Antigen Test Card	LumiQuick Diagnostics, Inc.

Paul-Ehrlich-Institut-Listung