SAFECARE BIO-TECH

Dokumentation

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(Saliva)

Type/model, identification of product allowing traceability (Where applicable): COV Ag-7012

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 ISO 18113-1:2011, EN 13612:2002, ISO 18113-2：2009, EN 13641:2002, EN1041- 2016, EN ISO 14971:2019, EN ISO15223-1:2016, ISO13485:2016

Conformity assessment procedure: Module A (EC Declaration of Conformity) (Annex III, except point 6)

Notified Body (name & number) Certificate & number: **NOT applicable**

Signed on 3th Feb.,2021 Place: Hangzhou, Zhejiang, China

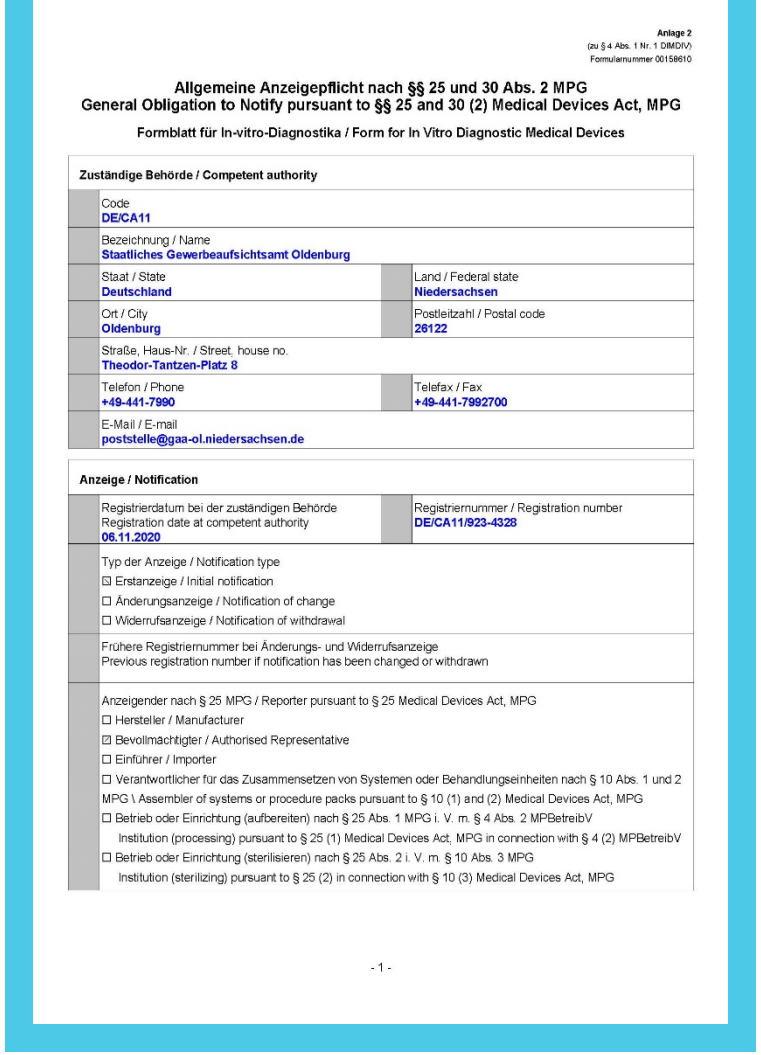
Signature (on behalf of the manufacturer)

Name of authorized signatory: Kebin, Qiu

Position held in the company: General Manager

Seal/Stamp:

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	Land / Federal state
Deutschland	**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	Registriernummer / Registration number
06.11.2020	**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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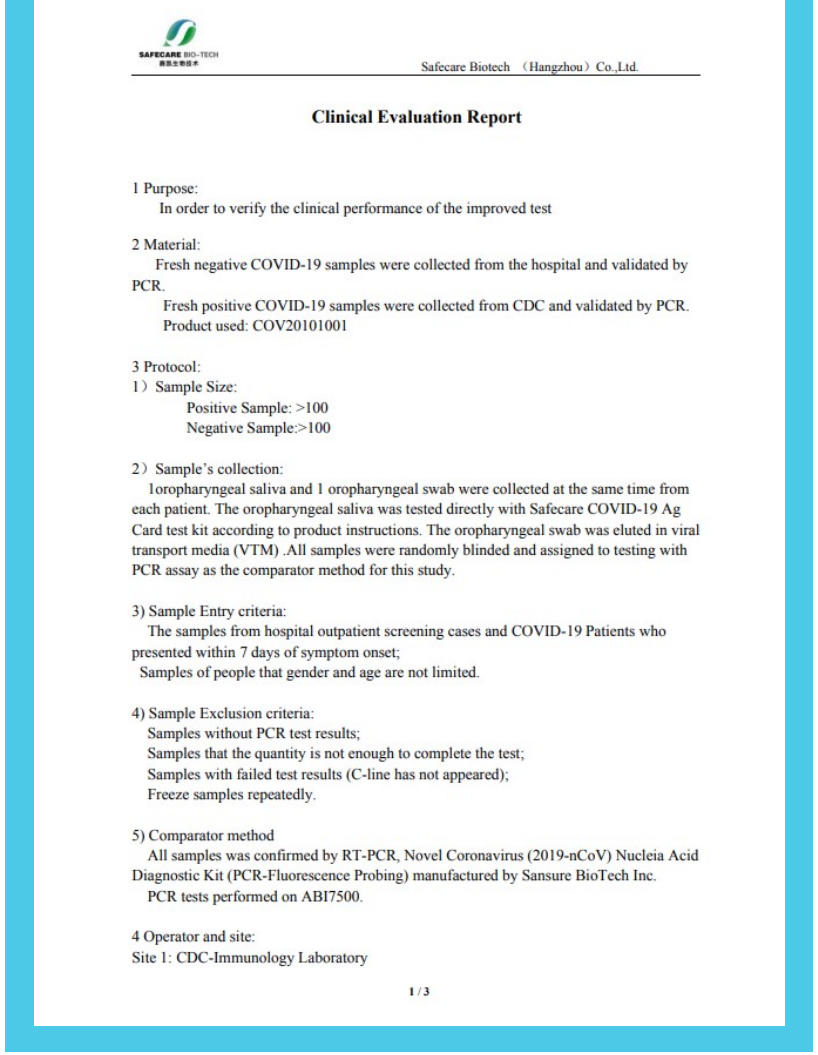
MDR-Zertifikat



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: COV20101001

3 Protocol:
1）Sample Size:
Positive Sample: >100
Negative Sample:>100

2）Sample's collection:
1oropharyngeal saliva and 1 oropharyngeal swab were collected at the same time from each patient. The oropharyngeal saliva was tested directly with Safecare COVID-19 Ag Card test kit according to product instructions. The oropharyngeal swab was eluted in viral transport media (VTM) .All samples were randomly blinded and assigned to testing with PCR assay as the comparator method for this study.

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.

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.

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

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klinischer Bericht