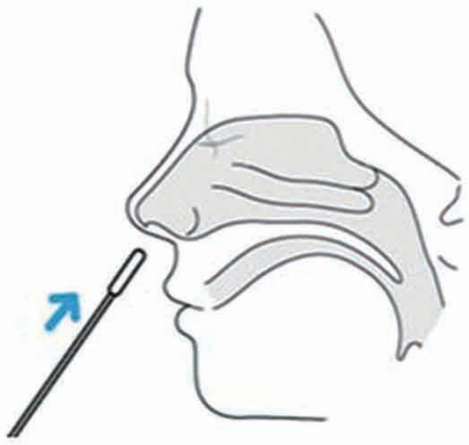
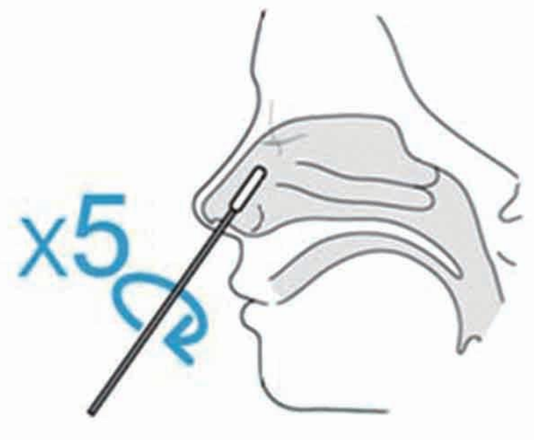
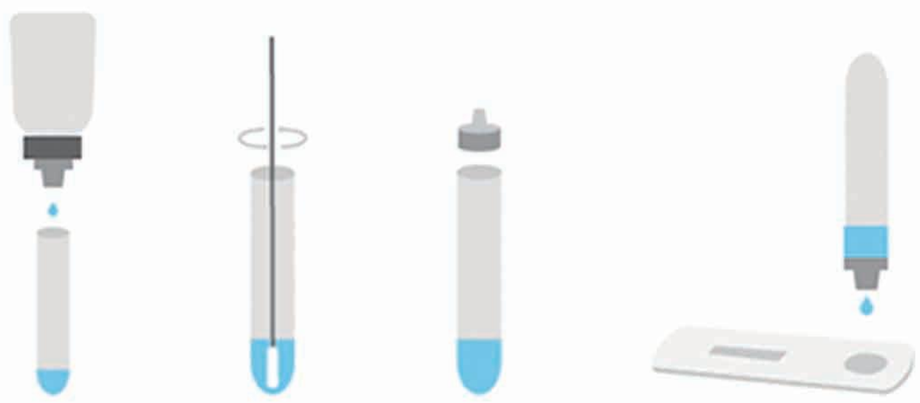
SARS-CoV-2 Antigen Rapid Test Cassette

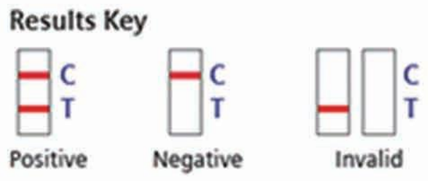
a. Führen Sie die gesamte Tupferspitze vorsichtig etwa **2,5 cm** in das linke Nasenloch ein.



b. Streichen Sie in einer kreisförmigen Bewegung mindestens 5-mal fest gegen die Innenseiten des linken Nasenloches.







SEJOY®

Area C, Building 2, No.365, Wuzhou Road, Yuhang Economic Development Zone,
Hangzhou City, 311100, Zhejiang, China

CERTIFICATE

EC Certificate No. 1434-IVDD-474/2021

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

Polish Centre for Testing and Certification certifies
that manufactured by:

Hangzhou Sejoy Electronics & Instruments Co., Ltd
Area C, Building 2, No. 365, Wuzhou Road, Yuhang Economic Development Zone, 311100 Hangzhou City, Zhejiang, China

in vitro diagnostic medical devices
for self-testing

SARS-CoV-2 Antigen Rapid Test Cassette
COVG-602ST

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 22.10.2021 to 27.05.2024

The date of issue of the Certificate: 22.10.2021

The date of the first issue of the Certificate: 22.10.2021

CE 1434

Issued under the Contract No. MD-100/2021
Application No: 192/2021
Certificate bears the qualified signature.
Warsaw, 22/10/2021
Module A1
FBM-30-E_10

Vice-President

EU DECLARATION OF CONFORMITY

Manufacturer:	Hangzhou Sejoy Electronics & Instruments Co.,Ltd. Area C, Building 2, No.365, Wuzhou Road, Yuhang Economic Development Zone, 311100 Hangzhou,Zhejiang,China
European Authorized Representative:	Shanghai International Holding Corp.GmbH (Europe) Eiffestrasse 80, 20537 Hamburg, Germany
Product Name:	SARS-CoV-2 Antigen Rapid Test Cassette
Model:	COVG-602ST
Classification:	Self-testing device not listed under Annex II of Directive 98/79/EC
Notified Body:	Polish Centre for Testing and Certification 469 Puławska Street, 02-844 Warsaw
Notified Body No.:	1434
EC Certificate No.:	1434-IVDD-474/2021
Conformity assessment route:	Annex III section 6 of Directive 98/79/EC
Applicable Standards:	EN ISO 13485:2016, EN ISO 14971:2012, EN 13532:2002, EN ISO 23640:2015, EN ISO 13612:2002, EN ISO 17511:2003, EN 13975:2003, EN ISO 18113-1:2011, EN ISO 18113-4:2011, EN ISO 15223-1:2016, EN 13641:2002,EN 62366:2008

We, the Manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

杭州世佳电子有限公司
HANGZHOU SEJOY ELECTRONICS & INSTRUMENTS CO.,LTD.

Hangzhou, October 23, 2021
Place , date

General Manager
Legally binding signature, Position

Shanghai International Holding Corporation GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg Germany

Confirmation

of EU product notifications

Herewith we confirm that

Shanghai International Holding Corp. GmbH (Europe)
Eiffestraase 80, 20537 Hamburg, Germany

has taken over the function of an European Authorised Representative according to the requirements of IVD Directive 98/79/EC for:

Hangzhou Sejoy Electronics& Instruments Co., Ltd.
Area C, Building 2, No.365, Wuzhou Road, Yuhang Economic Development Zone
311100 Hangzhou City, Zhejiang, China

for their in-vitro diagnostic device:
SARS-CoV-2 Antigen Rapid Test Cassette

and has submitted the product notifications at the relevant German Competent Authority according to Article 10(3) of the above mentioned IVD Directive and all supporting technical documents showing the devices' conformity with the Directive are deposited in our office.

15,04,2021

Shanghai International Holding Corporation GmbH (Europe) Eiffestrasse 80 20537 Hamburg

Mr. Liang Jin
-- on behalf of --
Shanghai International Holding
Corp. GmbH (Europe)

Tel.:(49) 40 2513175
Mail:
shholding@hotmail.com

Amtsgericht Hamburg
HRB 56 583
Geschäftshührer:
Liang Jin

Finanzamt Hamburg
Steuer-Nr.22/795/00590
Ust-ID-Nr.DE166892350

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

Certificate

No. Q5 095295 0001 Rev. 00

Holder of Certificate: **Hangzhou Sejoy Electronics & Instruments Co., Ltd.**
Area C, Building 2, No. 365, Wuzhou Road
Yuhang Economic Development Zone
311100 Hangzhou City, Zhejiang
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

tuv-sud.com/ps-cert

Scope of Certificate: **Design and Development, Production and Distribution of In Vitro Diagnostic Medical Device based on Immunochromatography, Dry Chemistry and Electrochemistry Method, Include Instrument, Test Strip and Control Solution**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see:
www.tuvsud.com/ps-cert?q=cert:Q5 095295 0001 Rev. 00

Report No.: SH20167601

Valid from: 2020-10-30
Valid until: 2023-10-29

Date, 2020-10-30

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 095295 0001 Rev. 00

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

Hangzhou Sejoy Electronics & Instruments Co., Ltd.
Area C, Building 2, No. 365, Wuzhou Road, Yuhang Economic Development Zone, 311100 Hangzhou City, Zhejiang, PEOPLE'S REPUBLIC OF CHINA

.

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

SARS-CoV-2 Antigen Rapid Test Cassette

Bundesinstitut für Arzneimittel und Medizinprodukte

Antigen-Tests zum direkten Erregernachweis des Coronavirus SARS-CoV-2

Impressum Administration

ab (siehe Webseite des PEI).

- „Ja" bedeutet, dass der Test bereits mit positivem Ergebnis durch das PEI evaluiert wurde.
- „Nein" bedeutet, dass bislang keine entsprechenden Testergebnisse vorliegen.

Im Falle einer negativen Evaluierung durch das PEI streicht das BfArM den entsprechenden CE-gekennzeichneten Test von seiner Liste. Für eine Sonderzulassung ist eine positive Evaluierung des PEI eine zwingende Voraussetzung.

Hinweis: Eine aktuelle Übersicht der SARS-CoV-2-Tests, die von den europäischen Mitgliedsstaaten gegenseitig für COVID-19-Testergebnisbescheinigungen anerkannt werden und damit für das „EU Digital COVID-19 Certificate" berücksichtigt werden können, finden Sie im entsprechenden Dokument der Europäischen Kommission: Link zum Dokument

sejoy | Los | Aktionen | Zurücksetzen

Nach 'sejoy' suchen

			Hersteller			Europäischer Bevollmächtigter				Sensitivität		Spezifität		
Test-ID	Handelsname	Evaluierung PEI	Name	Stadt	Land	Name	Stadt	Land	Testort*	%	95%iges Vertraue... intervall	%	95%iges Vertraue... intervall	Gebrauchs...
AT653/21	SARS-CoV-2 Antigen Rapid Test Cassette	Nein	Hangzhou Sejoy Electronics & Instruments Co., Ltd.	Hangzhou City	CN	Shanghai International Holding Corporation GmbH (Europe)	Hamburg	DE	POC (ohne Gerät)	95,76	90,39 - 98,61	99,38	98,20 - 99,87	
AT615/21	SARS-CoV-2 Antigen Rapid Test Cassette	Ja	Hangzhou Sejoy Electronics & Instruments Co.,Ltd.	Hangzhou	CN	Shanghai International Holding Corp.GmbH (Europe)	Hamburg	DE	POC (ohne Gerät)	95,65	90,14 - 98,75	99,26	97,84 - 99,85	
AT629/21	SARS-CoV-2 Antigen Rapid Test Cassette	Nein	Hangzhou Sejoy Electronics & Instruments Co.,Ltd.	Hangzhou	CN	Shanghai International Holding Corp.GmbH (Europe)	Hamburg	DE	POC (ohne Gerät)	95,76	90,39 - 98,61	99,38	98,20 - 99,87	
AT628/21	SARS-CoV-2 Antigen Rapid Test Cassette	Ja	Hangzhou Sejoy Electronics & Instruments Co.,Ltd.	Hangzhou	CN	Shanghai International Holding Corp.GmbH (Europe)	Hamburg	DE	POC (ohne Gerät)	97,40	90,39 - 98,61	99,10	98,20 - 99,87	Link...
AT1062/21	SARS-CoV-2 & Influenza A+B Antigen Combo Rapid Test Cassette	Nein	Hangzhou Sejoy Electronics & Instruments Co.,Ltd.	Hangzhou	CN	Shanghai International Holding Corp.GmbH (Europe)	Hamburg	DE	POC (ohne Gerät)	97,40	90,39 - 98,61	99,10	98,20 - 99,87	Link...

1 Zeilen ausgewählt

1 - 5 von 5

Bundesinstitut für Impfstoffe und biomedizinische Arzneimittel
Federal Institute for Vaccines and Biomedicines

Paul-Ehrlich-Institut

SARS-CoV-2 Antigen Rapid Detection Kit (Colloidal Gold Method)	Jinan Babio Biotechnology Co., Ltd.
GLINE-2019-nCoV Ag	Shenzhen YHLO Biotech Co. Ltd.
SARS-CoV-2 Rapid Antigen Test (Colloidal Gold Method)	Sansure Biotech Inc.
SARS-CoV-2 Antigen Schnelltestkassette	Hangzhou Sejoy Electronics & Instruments Co.,Ltd.
SARS-CoV-2-Antigen-Schnelltest	Hangzhou Careomedic Tech Co., Ltd.
AS-check COVID-19 Antigen Schnelltest	Asterion Otel Insaat Bilisim Medikal Maden Tic.Ltd.Sti.
Kanzone COVID-19 Antigen Rapid Test	Weihai Kangzhou Biotechnology Engineering Co., Ltd.

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