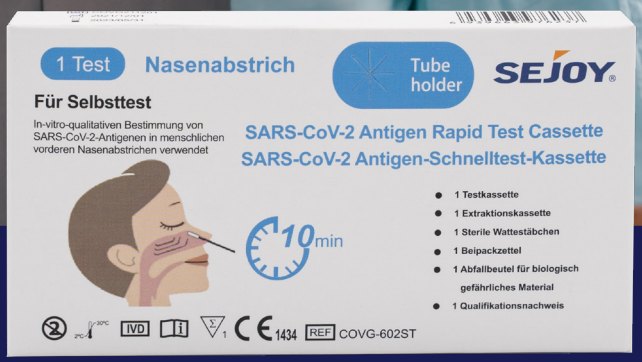
KINGLINE GMBH



SEJOY

SARS-COV-2 ANTIGEN SCHNELLTEST

Zertifiziert und Evaluiert

Zuverlässig sehr genaue Ergebnisse

Persönliche Experten-Beratung

verkauf@kingline.de | +49 (0) 9135 - 5718390

Version: 1.1 | Freigabe: 11.08.2022

Kingline GmbH | Gewerbering 32a | 91341 Röttenbach

KINGLINE
GMBH

EINFACHE UND SICHERE ANWENDUNG

ZUVERLÄSSIG SEHR GENAUE ERGEBNISSE

HYGIENISCHER ENTSORGUNGSBEUTEL

CE-ZERTIFIZIERT (CE-1434)

PRODUKTBILDER

Vorderansicht

Packungsinhalt

verkauf@kingline.de | +49 (0) 9135 - 5718390
Version: 1.1 | Freigabe: 11.08.2022
Kingline GmbH | Gewerbering 32a | 91341 Röttenbach

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DETAILINFORMATIONEN

CE-Kennzeichnung	CE-1434
Art der Probe	Anterior nasal
Anwendungsart	Laien
LoD-Wert	4000 TCID 50/ml
Sensitivität/Spezifität	97,9% (bei einem Ct-Wert von ≤32)/99,9%
Haltbarkeit (ab Produktionsdatum)	18 Monate
Verfügbare Sprachen des Gebrauchsanweisung	Deutsch, Englisch, Italienisch, Spanisch, Französisch, Niederländisch**

** Für Verfügbarkeiten wenden Sie sich bitte an einen unserer Vertriebsmit-

LOGISTIKDATEN

VPE	600 Stk. (1er-Packung) 720 Stk. (5er-Packung) 1000 Stk. (25er-Packung)
VPE Gewicht	17 kg (1er-Packung) 11,5 kg (5er-Packung) 12 kg (25er-Packung)
VPE Maße	62x42x38 cm (1er-Packung) 61,7x39,5x35 cm (5er-Packung) 62x42x37,5 cm (25er-Packung)
EPAL Gewicht	350 kg (1er-Packung) 245 kg (5er-Packung) 255 kg (25er-Packung)
EPAL Maße (B x H x T)	124x198x84 cm (1er-Packung) 124x190x80 cm (5er-Packung) 124x190x80 cm (25er-Packung)
Lagertemperatur	min. 2 °C; max. 30°C
Vereinzelbar	ja

DISTRITBUTION

Hersteller	Hangzhou Sejoy Electronics & Instruments co., Ltd. Area C. Building 2, No. 365, Wuzhou Road, Yuhang Economic Development Zone, 311100 Hangzhou City, Zhejiang, China
EC-REP	Shanghai International Holding Corp. GmbH (Europe) Eiffestraße 80 20537 Hamburg, Deutschland

verkauf@kingline.de | +49 (0) 9135 - 5718390
Version: 1.1 | Freigabe: 11.08.2022
Kingline GmbH | Gewerbering 32a | 91341 Röttenbach

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

Anna Małgorzata Wyroba
Elektronicznie podpisany przez Anna Małgorzata Wyroba
Data: 2021.10.22 11:26:29 +02'00'

Vice-President

EU DECLARATION OF CONFORMITY

Manufacturer:	Hangzhou Sejoy Electronics& Instruments Co.,Ltd. Area C, Building 2, No.365, Wuzhou Road,YuhangEconomic Development Zone,Hangzhou City 311100 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
Specification:	1 test/ box， 5tests/ box， 25tests/ box
Classification:	Other device not listed under Annex II and self-testing of Directive 98/79/EC
Conformity assessment route:	Annex III,except Point 6,of Directive 98/79/EC
Applicable Standards:	EN ISO 13485:2016, EN ISO 14971:2012, EN ISO 23640:2015, EN ISO 13612:2002, EN ISO 17511:2003, EN 13975:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN ISO 15223-1:2016, EN 13641:2002

CE

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.

Hangzhou, March 22, 2021
Place,date

General Manager
Legally binding signature, Position

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

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

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