



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:



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

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 ♦ CERTIFICADO ♦ CERTIFIKAT ♦



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



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, Yuhang Economic
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, 5 tests/box, 25 tests/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
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

Applicable Standards:



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.

EU DECLARATION OF CONFORMITY

Manufacturer: Hangzhou Sejoy Electronics & Instruments Co., Ltd.
Area C, Building 2, No.365, Wuzhou Road, Yuhang
Economic 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 & Influenza A+B Antigen Combo Rapid Test
Cassette

Specification: COIF-522

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
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

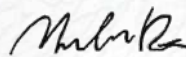
Applicable Standards:

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, April 09, 2021

Place, date



General Manager

Legally binding signature, Position

Declaration of Conformity

Manufacturer Hangzhou Sejoy Electronics & Instruments Co., Ltd.

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

European Representative Shanghai International Holding Corp.GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg,Germany

Product Name COVID-19 IgG/IgM Rapid Test Cassette

Classification Others/General

Conformity Assessment Route:IVDD 98/79/EC Annex III We herewith declare that the products mentioned above meet the provisions of the Directive 98/79/EC of the European Parliament and of the Council on in-vitro diagnostic medical device.All supporting documentations are retained at the premises of the manufacturer

Standards Applied EN 13612:2002
EN ISO 18113-1:2011
EN ISO 14971:2012
EN ISO 18113-2:2011
EN ISO 13614:2002
EN ISO 15223-1:2016
EN ISO 13485:2016
EN ISO 23640:2015
EN ISO 17511:2003



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

Hangzhou, March 24, 2020

Place , date

A handwritten signature in black ink, appearing to be 'Mubik'.

General Manager

Legally binding signature, Function

EU DECLARATION OF CONFORMITY

Manufacturer: Hangzhou Sejoy Electronics& Instruments Co.,Ltd.
Area C, Building 2, No.365, Wuzhou Road, Yuhang
Economic 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 Neutralizing Antibody Rapid Test Cassette

Specification: COVB-602

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

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, April 07, 2021

Place, date



General Manager

Legally binding signature, Position



Freie und Hansestadt Hamburg
Behörde für Justiz und Verbraucherschutz

9101/1E-020.33

Die Echtheit der Unterschrift der

Sachbearbeiterin Frau Frenzel

und die Echtheit des beigedruckten Dienstsiegels der Behörde für Justiz und Verbraucherschutz in der Ausfuhrbescheinigung Nummer 0784/2021 vom 6. Oktober 2021 werden hiermit bestätigt.

Zugleich wird bescheinigt, dass die Vorgenannte zur Vornahme der Amtshandlung befugt war.

Hamburg, den 22. Oktober 2021

Rehbeck

Rehbeck

Justizbeschäftigte

Behörde für Justiz und Verbraucherschutz Hamburg





Freie und Hansestadt Hamburg

Behörde für Justiz und Verbraucherschutz

Behörde für Justiz und Verbraucherschutz (V43), Postfach 302822, 20310 HH

Shanghai International Holding Corporation
GmbH (Europe)
Herrn Liang Jin
Eiffestraße 80
20537 Hamburg

Ministry of Justice and Consumer Protection
V4 - Pharmaziewesen und Medizinprodukte
Medizinprodukte - V43

Postfach 30 28 22
20310 Hamburg

Telefon: +49 40 428 37 - 2120
Zentrale: +49 40 428 28 - 0
E-Fax: +49 40 4279 - 48542
E-Mail: medizinprodukte@justiz.hamburg.de

Ansprechpartner/in: Sylvia Frenzel
Aktenzeichen: G517-80.01/07-01-, 0002

Hamburg, den 06.10.2021

Medizinproduktegesetz (MPG)

hier: **Ausfuhrbescheinigung für In-vitro-Diagnostika**
Bescheinigung Nummer 0784/2021

Ihr Antrag vom 19.09.2021

Bescheinigung der Verkehrsfähigkeit nach § 34 Abs. 1 des Medizinproduktegesetzes (MPG) zur Vorlage bei den zuständigen Behörden / Stellen des Staates Sozialistische Republik Vietnam Es wird bescheinigt, dass die nachfolgend genannten Medizinprodukte in Deutschland uneingeschränkt verkehrsfähig sind. Produkt / Produkte: Siehe Anlage, 1 Seite. Bevollmächtigter: Shanghai International Holding Corporation GmbH (Europe) Eiffestraße 80 20537 Hamburg Hersteller: Hangzhou Sejoy Electronics & Instruments Co., Ltd. Area C, Building 2, No.365, Wuzhou Road, Yuhang Economic Development Zone, 311100 Hangzhou City, Zhejiang, P. R. China	Certificate of Marketability according to § 34 (1) of the Medical Devices Act (MPG) for presentation to the competent authorities / bodies of the Socialist Republic of Vietnam It is certified that the following medical devices can be marketed without restriction within Germany. Product / Products: See enclosure, 1 page. Authorized Representative: Shanghai International Holding Corporation GmbH (Europe) Eiffestraße 80 20537 Hamburg Germany Manufacturer: Hangzhou Sejoy Electronics & Instruments Co., Ltd. Area C, Building 2, No.365, Wuzhou Road, Yuhang Economic Development Zone, 311100 Hangzhou City, Zhejiang, P. R. China
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Frenzel



Zusätzliche Information	Additional Information
Mit dem CE-Kennzeichen bringt der Hersteller zum Ausdruck, dass die Medizinprodukte die Grundlegenden Anforderungen der Richtlinie 98/79/EG des Europäischen Parlamentes und des Rates vom 27. Oktober 1998 über In-vitro-Diagnostika erfüllen und das vorgeschriebene Konformitätsbewertungsverfahren durchgeführt.	With the CE-mark the manufacturer confirms that the medical devices comply with the essential requirements of the Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices and that the required conformity assessment procedure has been completed.



Enclosure

Produktliste / Productlist	Modell / Model
Blood Glucose Monitoring Systems (Blood Glucose Meters, Blood Glucose Test Strips, Blood Glucose Test Controls)	BG-101,BG-201,BG-102,BG-202,BG-103,BG-203,BG-205,BG-108,BG-208,BG-207,BG-209,BG-707,BG-707b,BG-709,BG-207b,BG-209b,BG-709b BS-101,BS-102,BS-302,BS-602 CS-101,CS-201
Hemoglobin Monitoring Systems (Hemoglobin meters, Hemoglobin test strips, Hemoglobin control solution)	HB-101,HB-201,HB-202,HS-101,HC-101
Uric Acid Monitoring System(Uric Acid Meter, Uric Acid Test Strips, Control Solution)	UA-105,US-101,CS-301
hCG One Step Pregnancy Test	Strip, Cassette, Midstream
LH One Step Ovulation Test	Strip, Cassette, Midstream
FSH One Step Menopause Test	Strip, Cassette, Midstream
Influenza A+B Rapid Test	Flu-602
Syphilis Antibody Rapid Test	TP-401,TP-402
H.pylori Antibody Rapid Test	HP-301,HP-302
Multi-drug Rapid Test (Urine)	Strip, Cassette, Panel, Cup
COVID-19 IgG/IgM Rapid Test Cassette	COV-402
SARS-CoV-2 Antigen Rapid Test Cassette	COVG-602,COVG-602ST
SARS-CoV-2 Neutralizing Antibody Rapid Test Cassette	COVB-602
SARS-CoV-2 & Influenza A+B Antigen Combo Rapid Test Cassette	COIF-522
SARS-CoV-2 Antigen Saliva Lolly Test	COVG-603



**CHỨNG NHẬN/ HỢP PHÁP HÓA LÃNH SỰ
KONSULARISCHE BEGLAUBIGUNG/LEGALISIERUNG**

1. Quốc gia/Staat: **Việt Nam/Vietnam**

Giấy tờ, tài liệu này/Dieses Dokument

2. Với chữ ký của ông (bà)/U. von Herrn (Frau): **Rehbeck**

3. Với chức danh/Funktion: **Viên chức**

4. Và con dấu của/Dienstsiegel von: **Cơ quan Tư pháp và Bảo vệ người
tiêu dùng Hamburg**

**được chứng nhận/hợp pháp hóa lãnh sự/
wird hiermit konsularisch beglaubigt/legalisiert**

5. Tại/in: **Berlin**

6. Ngày/Datum: **16/11/2021**

7. Cơ quan cấp/Ausgestellt von: **Đại sứ quán nước CHXHCN Việt Nam
tại CHLB Đức Botschaft der SR Vietnam in der BR Deutschland**

8. Số/Nr.: **116-LS-HPH/2021**

TL. Đại sứ/i.A. der Botschafterin
Tham tán/Botschafrat



Phạm Hoàng Tùng



中国医药保健品进出口商会

China Chamber of Commerce for Import & Export of Medicines & Health Products

Add: 11-12/F, Bldg3, Beijing INN, No.6 Nanzhugan Hutong, Dongcheng Dist, Beijing, China P.C.100010

Tel: 0086 10 58036272/75/78/71/70

Fax: 0086 10 58036274

Website: www.cccmhpie.org.cn

E-mail: 110982739@qq.com 82579517@qq.com md@cccmhpie.org.cn

自由销售证书

CERTIFICATE OF FREE SALE

2021YB2441

产品名称: 新型冠状病毒(2019-nCoV)抗原检测试剂盒(胶体金法)
新型冠状病毒(2019-nCoV)抗体检测试剂盒(胶体金法)
新型冠状病毒(SARS-CoV-2)中和抗体检测试剂盒(胶体金法)
新型冠状病毒&甲/乙型流感病毒联合检测试剂(胶体金法)
新型冠状病毒(2019-nCoV)口含式抗原检测试剂盒(胶体金法)

Product(s): SARS-CoV-2 Antigen Rapid Test Cassette,
COVID-19 IgG/IgM Rapid Test Cassette
SARS-CoV-2 Neutralizing Antibody Rapid Test Cassette
SARS-CoV-2&Influenza A+B Antigen Combo Rapid Test Cassette
SARS-CoV-2 Antigen Saliva Lolly Test

规格型号: COVG-602、COVG-602ST、COV-402、COVB-602、COIF-522、COVG-603

Model: COVG-602、COVG-602ST、COV-402、COVB-602、COIF-522、COVG-603

销往国家: 泰国

Export to: Thailand

出口商: 杭州世佳电子有限公司

Exporter: Hangzhou Sejoy Electronics & Instruments Co., LTD.

出口商地址: 杭州市余杭区余杭经济技术开发区五洲路365号2幢C区

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

制造商: 杭州世佳电子有限公司

MANUFACTURER: Hangzhou Sejoy Electronics & Instruments Co., Ltd.

制造商地址: 杭州市余杭区余杭经济技术开发区五洲路365号2幢C区

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

兹证明上述产品符合相关标准, 未在中国注册, 该产品出口不受限制

THIS IS TO CERTIFY THAT THE ABOVE PRODUCT COMPLIES WITH THE RELEVANT STANDARDS, HAVE NOT BEEN REGISTERED IN CHINA. THE EXPORTATION OF THE PRODUCT IS NOT RESTRICTED.

此证明自签发时起有效期 2 年。

THIS CERTIFICATE IS VALID FOR TWO YEARS FROM THE DATE OF ISSUANCE.

中国医药保健品进出口商会

CHINA CHAMBER OF COMMERCE FOR IMPORT & EXPORT OF
MEDICINES & HEALTH PRODUCTS

证明日期: 2021 年 12 月 13 日

DATE OF ISSUE: December 13, 2021

[illegible]

Infarmed Atividade Nacional do Medicamento Atividade de Saúde PT citizens ▾ Health professionals ▾ Entities ▾ The ▾								
Results: Download								
Reference ▾	Manufacturer ▾	CDM ▾	Type ▾	Brand ▾	Model ▾	Class ▾	Name ▾	
COVG-602	Hangzhou Sejoy Electronics & Instruments Co., LTD	70412073	DM In Vitro Diagnostics (DIV)	SEJOY	SARS-CoV-2 Rapid Antigen Nasal Test	Others (DIV not listed in Annex II of Directive 98/79/EC and not intended for self-diagnosis)	SARS-CoV-2 Rapid Antigen Nasal Test	
MT-4333	Hangzhou Sejoy Electronics & Instruments Co., LTD	70654280	Active DM	Start by iHealth	Flexible Digital Thermometer	Ila (DM Class Ila)	Flexible Digital Thermometer	



Bundesinstitut
für Arzneimittel
und Medizinprodukte

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




Eine Marktübersicht nach §1 Satz 1 TestV zu Antigen-Tests zum direkten Erregernachweis des Coronavirus SARS-CoV-2, die vom Hersteller zur Eigenanwendung zweckbestimmt sind („Selbsttests“) finden Sie unter diesem Link.

Alle Daten gemäß Übermittlung des Herstellers, verbindlich sind ausschließlich die Angaben in den jeweiligen Gebrauchsinformationen.

Die Angabe „Evaluierung PEI“ bildet die entsprechende, auf der Webseite des Paul-Ehrlich-Instituts (PEI) veröffentlichte Übersicht zur dortigen vergleichenden Evaluierung der Sensitivität von SARS-CoV-2 Antigen Schnelltests 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 Mitgliedstaaten 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](#)

☒
☒
☒

France(self test & professional use)

MINISTÈRE DES SOLIDARITÉS ET DE LA SANTÉ

PLATEFORME COVID-19

Se connecter

VISUALISATION TESTS COVID-19

Nombre de tests

2/545

Dans le cadre de la stratégie nationale du schéma vaccinal complet à une dose chez les personnes immunocompétentes sans antécédent connu d'infection au SARS-CoV-2, les TROD sérologiques utilisés doivent détecter à minima les cibles suivantes : IgG anti protéine S ou IgG anti protéine N+S.

Cliquez pour accéder à la liste commune européenne TAG

Signalement

Accueil

Tests

Outil criblage

Projets

Veille

Eaux usées

Ressources

Surveillance épidémiologique

Contextes juridiques

Cliquez pour déplier et télécharger les fichiers des contextes juridiques

Statut: CE CNR UE HAS

Type de test: ---

Sous-type de test: ---

Cibles: --

Type prélèvement: ---

Rechercher: Q sejry

Tableau de bord des tests

Cliquez pour déplier et visualiser les graphes du tableau de bord

2 tests affichés

NOM	FABRICANT	DISTRIBUTEUR	CE	UE	CNR	SOUS-TYPE DE TEST	CIBLES	TYPE DE PRÉLÈVEMENT
SARS-CoV-2 Antigen Rapid Test Cassette	Hangzhou Sejoy Electronics, Instruments Co., Ltd.		✓	✓	✓	Antigénique non automatisé (dome TROD)	N	Nasopharyngé
Autotest antigénique SARS-CoV-2	Hangzhou Sejoy Electronics Instruments Co Ltd		✓	✓	✓	Autotest	N	Nasal

Switzerland(professional use)

Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Eidgenössisches Departement des Innern EDI
Bundesamt für Gesundheit BAG
Taskforce BAG Covid-19 AG Testung

22.12.2021

Listes der validierten SARS-CoV-2-Schnelltests zur Fachanwendung¹
Listes des tests rapides validés pour le SARS-CoV-2 pour usage professionnel
Liste dei test rapidi validati per il SARS-CoV-2 per uso professionale

Die Schnelltests sind ausschliesslich für bestimmte Probematerialien validiert und nur dementsprechend anzuwenden. In der Schweiz dürfen keine Antigen-Schnelltests mit Speichel als Probematerial ausserhalb von Laboratorien eingesetzt werden. Ausschiesslich Antigen-Schnelltests basierend auf einem Nasen-Rachen-Abstrich führen zu einem Covid-Zertifikat (ab den 16.11.21). Informationen bezüglich des Einsatzes der Schnelltests finden Sie auf der BAG-Webseite Covid-19-Testung.

Les tests rapides sont validés exclusivement pour certains types de prélèvements et ne doivent ainsi être utilisés que pour ceux-ci. En Suisse, aucun test antigénique rapide utilisant la salive comme matériel de prélèvement ne peut être utilisé en dehors des laboratoires. Seuls les tests rapides antigéniques pratiqués avec un frotis nasopharyngé permettent d'obtenir un certificat COVID (dès le 16.11.21). Des informations sur l'emploi prévu des tests rapides sont disponibles sur le site web de l'OFSP Tests COVID-19.

I test rapidi sono validati solo per certi tipi di campioni e possono essere utilizzati solo per questo scopo. In Svizzera, nessun test antigenico rapido che utilizza la saliva come materiale di campionamento può essere utilizzato al di fuori dei laboratori. Per ottenere un certificato COVID sono validi esclusivamente i test antigenici rapidi basati su un tampone nasofaringeo (dal 16.11.21). Le informazioni su come utilizzare i test rapidi sono disponibili sul sito internet dell'UFSP «Test COVID-19».

Validierte SARS-CoV-2-Schnelltests
Tests rapides SARS-CoV-2 validés
Test rapidi SARS-CoV-2 validati

[Webseite Covid-19 Testung](#)

[Site internet Tests COVID-19](#)

[Site web Test COVID-19](#)

Schweizerische Eidgenossenschaft Confédération suisse Confederazione Svizzera Confederaziun svizra	Eidgenössisches Departement des Innern EDI Bundesamt für Gesundheit BAG Taskforce BAG Covid-19 AG Testung
Glattigen CO., LTD., Novel Coronavirus (2019-nCoV) Antigen Test Kit (Colloidal gold immunochromatography)	2695
Goldsite Diagnostics Inc. SARS-CoV-2 Antigen Kit (Colloidal Gold)	1197
Green Cross Medical Science Corp., GENEDIA W COVID-19 Ag	1144
Guangdong Hecin Scientific, Inc., 2019-nCoV Antigen Test Kit (colloidal gold method)	1747
Guangdong Longsee Biomedical Co., Ltd., 2019-nCoV Ag Rapid Detection Kit (Immuno-Chromatography)	1216
Guangdong Wessai Biotech Co., Ltd., COVID-19 Ag Test Kit	1360
Guangzhou Decheng Biotechnology Co., LTD., V-CHEK, 2019-nCoV Ag Rapid Test Kit (Immunochromatography)	1324
Guangzhou Wondfo Biotech Co., Ltd., Wondfo 2019-nCoV Antigen Test (Lateral Flow Method)	1437
Hangzhou AllTest Biotech Co., Ltd., COVID-19 Antigen Rapid Test	1257
Hangzhou Biotech Co., Ltd., COVID-19 Antigen Rapid Test Cassette (Nasal Swab)	1876
Hangzhou Clongene Biotech Co., Ltd., COVID-19 Antigen Rapid Test Cassette	1610
Hangzhou Clongene Biotech Co., Ltd., Covid-19 Antigen Rapid Test Kit	1363
Hangzhou Clongene Biotech Co., Ltd., COVID-19/Influenza A+B Antigen Combo Rapid Test	1365
Hangzhou DIAN Biotechnology Co., Ltd., COVID-19 Antigen Test Cassette	2629
Hangzhou Immuno Biotech Co., Ltd., Immunobio SARS-CoV-2 Antigen ANTERIOR NASAL Rapid Test Kit (minimal invasive)	1844
Hangzhou Immuno Biotech Co., Ltd., SARS-CoV-2 Antigen Rapid Test	2317
Hangzhou Laihe Biotech Co., Ltd., LYHER Novel Coronavirus (COVID-19) Antigen Test Kit(Colloidal Gold)	1215
HANGZHOU LYSUN BIOTECHNOLOGY CO., LTD., COVID-19 Antigen Rapid Test Device (Colloidal Gold)	2139
Hangzhou Sejoy Electronics&Instruments Co.,LTD., SARS-CoV-2 Antigen Rapid Test Cassette	1945

Italy (self-testing)



Area tematica Dispositivi medici | Archivio banche dati

[Stampa](#) | [Scarica il dataset](#)

Elenco dei dispositivi medici

Criteri di ricerca:
 Denominazione fabbricante: **hangzhou Sejoy**
 Codice fiscale fabbricante:
 Partita IVA / VAT number fabbricante:
 Codice nazione fabbricante:
 Denominazione mandatario:
 Codice fiscale mandatario:
 Partita IVA / VAT number mandatario:
 Codice nazione mandatario:
 Tipologia dispositivo:
 Identificativo di registrazione attribuito dal sistema BD/RDM:
 Codice attribuito dal fabbricante:
 Nome commerciale e modello:
 Classificazione CND: **W0105099099**
 Descrizione CND:
 Normativa:
 Classe CE (valida solo per dispositivi medici di classe, impiantabili attivi e IVD): **ST - Test autodiagnostici (non inclusi nell'all. II)**

Elenco dispositivi individuati

Dati aggiornati al: 18/12/2021

Dispositivo	2179682	S	COVG-602ST - 25 TESTS	SARS-COV-2 ANTIGEN RAPID TEST CASSETTE	W0105099099 • VIROLOGIA • TEST RAPIDI E "POINT OF CARE" - ALTRI	D.L.vo 332/2000	ST - Test autodiagnostici (non inclusi nell'all. II)	04/12/2021		FABBRICANTE	SEJOY ELECTRONICS & INSTRUMENTS CO., LTD			CN
										MANDATARIO	SHANGHAI INTERNATIONAL HOLDING CORP.GMBH	166 892 350	DE	
Dispositivo	2179678	S	COVG-602ST - 3 TESTS	SARS-COV-2 ANTIGEN RAPID TEST CASSETTE	W0105099099 • VIROLOGIA • TEST RAPIDI E "POINT OF CARE" - ALTRI	D.L.vo 332/2000	ST - Test autodiagnostici (non inclusi nell'all. II)	04/12/2021		FABBRICANTE	HANGZHOU SEJOY ELECTRONICS & INSTRUMENTS CO., LTD			CN
										MANDATARIO	SHANGHAI INTERNATIONAL HOLDING CORP.GMBH	166 892 350	DE	
Dispositivo	2179679	S	COVG-602ST - 5 TESTS	SARS-COV-2 ANTIGEN RAPID TEST CASSETTE	W0105099099 • VIROLOGIA • TEST RAPIDI E "POINT OF CARE" - ALTRI	D.L.vo 332/2000	ST - Test autodiagnostici (non inclusi nell'all. II)	04/12/2021		FABBRICANTE	HANGZHOU SEJOY ELECTRONICS & INSTRUMENTS CO., LTD			CN
										MANDATARIO	SHANGHAI INTERNATIONAL HOLDING CORP.GMBH	166 892 350	DE	
Dispositivo	2179681	S	COVG-602ST - 7 TESTS	SARS-COV-2 ANTIGEN RAPID TEST CASSETTE	W0105099099 • VIROLOGIA • TEST RAPIDI E "POINT OF CARE" - ALTRI	D.L.vo 332/2000	ST - Test autodiagnostici (non inclusi nell'all. II)	04/12/2021		FABBRICANTE	HANGZHOU SEJOY ELECTRONICS & INSTRUMENTS CO., LTD			CN

https://www.salute.gov.it/interrogazioneDispositiviRicercaDispositiviServlet?action=ACTION_RICERCA#

2/

2021/12/23

Elenco dei dispositivi medici

DISPOSITIVO	MEDICO/ASSEMBLATO									FABBRICANTE/ASSEMBLATORE				
TIPOLOGIA DISPOSITIVO	IDENTIFICATIVO DI REGISTRAZIONE BD/RDM	ISCRITTO AL REPERTORIO	CODICE ATTRIBUITO DAL FABBRICANTE/ASSEMBLATORE	NOME COMMERCIALE E MODELLO	CND	NORMATIVA	CLASSE CE	DATA PRIMA PUBBLICAZIONE	DATA FINE IMMISSIONE IN COMMERCIO	RUOLO AZIENDA	DENOMINAZIONE	CODICE FISCALE	PARTITA IVA/VAT NUMBER	NAZIONE
										MANDATARIO	SHANGHAI INTERNATIONAL HOLDING CORP.GMBH		166 892 350	DE

Spain(self-testing)

Castellano | Català | Euskera | Galego | Valencià | English

  **agencia española de medicamentos y productos sanitarios**

SÍGUENOS     

La AEMPS ▾ Medicamentos de uso humano ▾ Medicamentos veterinarios ▾ Productos sanitarios ▾ Cosméticos y cuidado personal ▾

Acciones informativas ▾ Industria farmacéutica ▾ Profesional Sanitario ▾ Ciudadanía ▾ ON 0318 / Norma 13485

Información general sobre test de diagnóstico de COVID-19

Inicio ▾ La AEMPS ▾ Última información de la AEMPS acerca de la COVID-19 ▾ información general sobre test de diagnóstico de COVID-19

Compartir:    

Última actualización: 22 de diciembre de 2021

Existen diferentes tipos de test de diagnóstico de COVID-19 en función de su objetivo. Podemos distinguir entre los test que nos informan sobre si existe infección en el momento de realizar la prueba (infección activa) y aquellos que nos informan de la respuesta inmune frente al virus.

En función del objetivo deseado se utilizará un tipo de test u otro, con unas especificaciones propias.

SARS-CoV-2 Antigen Rapid Test Cassette	Hangzhou Sejoy Electronics & Instruments Co., Ltd. (China)	COVG-6025T	nº-1434	NASAL
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Common List



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Public health, country knowledge, crisis management
Health Security

EU health preparedness:

**A common list of COVID-19 rapid antigen tests;
A common standardised set of data to be included in COVID-19 test result certificates; and
A common list of COVID-19 laboratory based antigenic assays**

Agreed by the Health Security Committee

Manufacturer	RAT commercial name	Device ID # ¹⁵	Clinical performance As reported by independent validation studies	Clinical performance Data by manufacturer ¹⁶	Completed validation studies	SARS-CoV-2 Target protein	Specimen ¹⁷	Included in EU common list since:
Hangzhou Lysun Biotechnology Co. Ltd	COVID-19 Antigen Rapid Test Device (Colloidal Gold)	2139	<i>Retrospective in vitro study</i>					
			DE: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 100%	96.46% sensitivity 100% specificity Nasal swab	DEPI	Nucleo-protein	Nasal swab	10 May 2021
Hangzhou Sejoy Electronics & Instruments Co. Ltd	SARS-CoV-2 Antigen Rapid Test Cassette	1945	<i>Retrospective in vitro study</i> DE: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 100%	Sensitivity: 94.5%, Specificity: 100% Nasal swab	DEPI	Nucleo-capsid protein	Nasal swab	8 December 2021

China white list



中国医药保健品进出口商会

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English 登陆 | 注册

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开展不可抗力相关事实性证明

取得国外认证和注册企业查询

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杭州世佳

检索

企业名称 (中文)	企业名称 (英文)	产品类别	产品名称/型号	统一社会信用代码	国外注册认证情况
杭州世佳电子有限公司	Hangzhou Sejoy Electronics & Instruments Co.,Ltd	红外体温计	Infrared Ear/Forehead Thermometer (ET-306,ET-215,ET-206,ET-305) (有效期至2024年05月27日)	91330160742011788U	欧盟CE
杭州世佳电子有限公司	Hangzhou Sejoy Electronics & Instruments Co.,Ltd	新型冠状病毒检测试剂	COVID-19 IgG/IgM Rapid Test Cassette SARS-CoV-2 Antigen Rapid Test Cassette SARS-CoV-2 & Influenza A+B Antigen Combo Rapid Test Cassette SARS-CoV-2 Neutralizing Antibody Rapid Test Cassette SARS-CoV-2 Antigen Rapid Test Cassette (COVG-6025T) (Self-Testing) (有效期至2024年5月27日) SARS-CoV-2 Antigen Saliva Lolly Test	91330160742011788U	欧盟CE

友情链接

政府部门

副会长单位

国际机构

行业门户