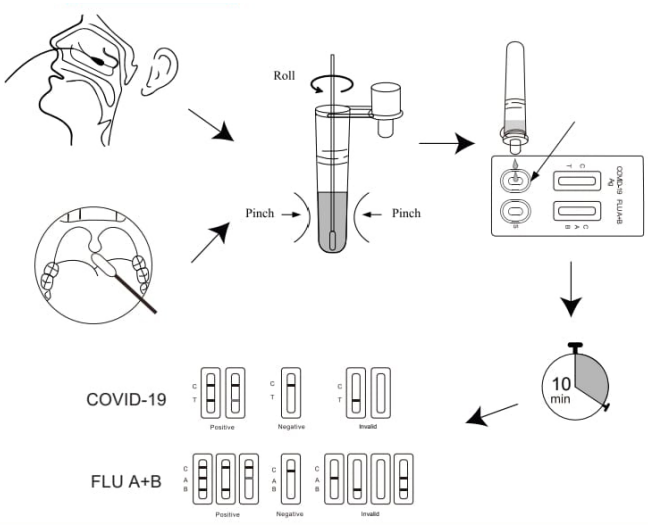
GisMédical®
L'Hygiène au cœur de votre quotidien

FICHE TECHNIQUE

TEST ANTIGÉNIQUE COMBO

Permet en un seul prélèvement de savoir si le patient est atteint du Covid ou d'une grippe A ou B.





PERFORMANCES

SARS-CoV-2 Test:

SARS-CoV-2 Antigen Rapid Test		RT-PCR		Total Results
		Positive	Negative	
SARS-CoV-2 Antigen	Positive	113	2	115
	Negative	3	212	215
Total		116	214	330
Relative Sensitivity		97.41%(95%CI*:92.67%-99.12%)		
Relative Specificity		99.07%(95%CI*:96.66%-99.74%)		
Accuracy		98.48% (95%CI*: 96.50%~99.35%)		

Influenza A+B Test:

Influenza A+B Antigen Combo Rapid Test		Type A			Type B		
		RT-PCR		Total	RT-PCR		Total
		Positive	Negative		Positive	Negative	
Flu A+B	Positive	100	2	102	85	2	87
	Negative	1	180	181	2	200	202
Total		101	182	283	87	202	289
Relative Sensitivity		99 0% (95%CI*: 94. 6%~99. 8%)			97.7% (95%CI*: 92. 0%~99. 4%)		
Relative Specificity		98.9% (95%CI*: 96. 1%~99. 7%)			99.0% (95%CI*: 96. 5%~99. 7%)		
Accuracy		98.9% (95%CI*: 96. 9%~99. 6%)			98.6% (95%CI*: 96. 5%~99. 5%)		

CONTENU ET LOGISTIQUE

1 TEST

Materials Required and Provided:

- Test Cassette
- Extraction Kit
- Sterile Swab
- Package Insert
- Tube Holder
- Biohazard Waste Bag
- Qualification Certificate



Sejoy SARS-CoV-2 Antigen Rapid Test Cassette-Export Packing Cartons			
Measurement of Gift Box	Measurement of Carton	Weight of Carton	Packing Quantity
185*75*15mm	39.5*39*62.5cm	GW: 15 KGS NW: 14 KGS	400 tests/carton

25 TESTS

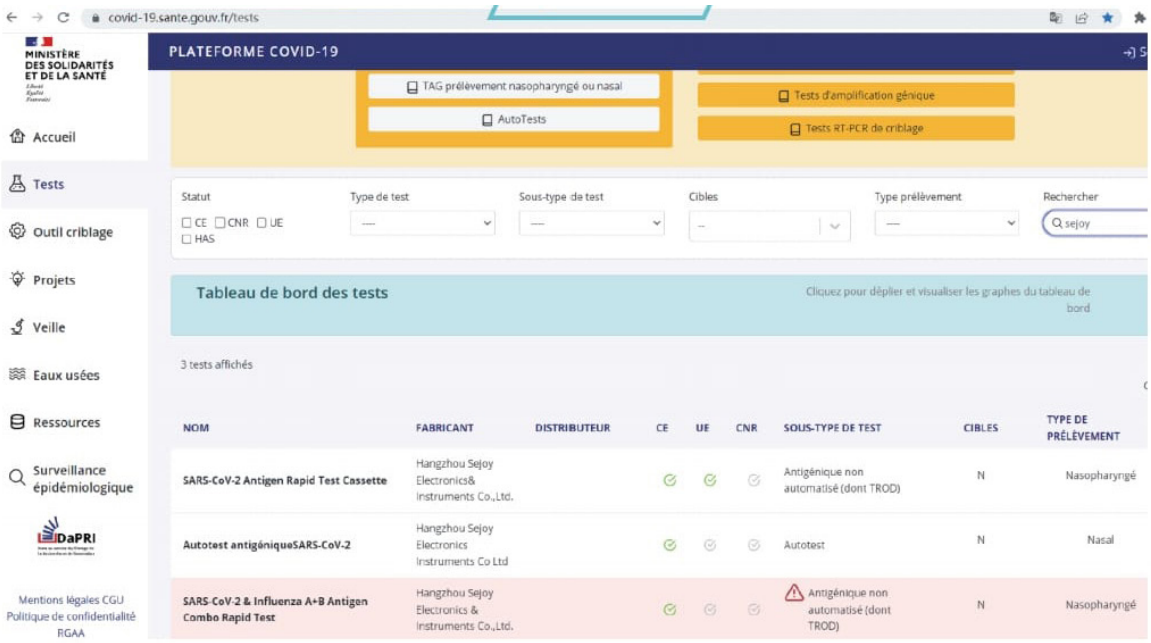
Materials Required and Provided:

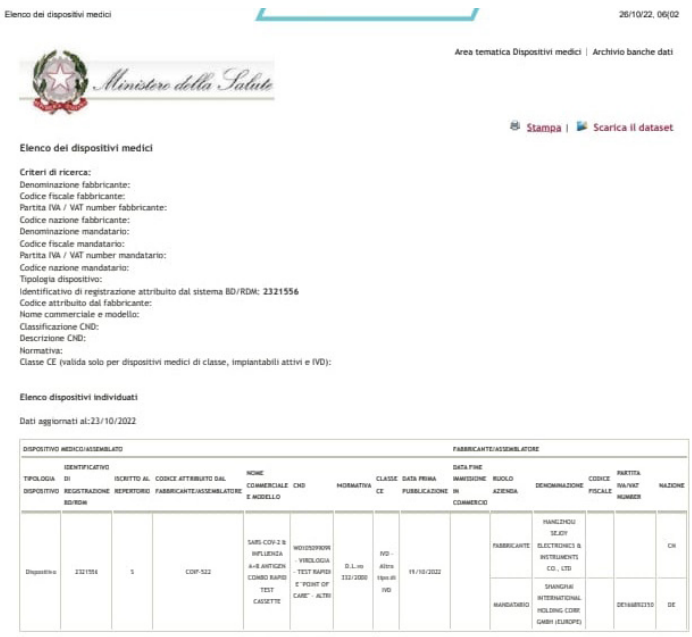
- 25*Test Cassette
- 25*Extraction Kit
- 25*Sterile Swab
- 1*Package Insert
- 1*Tube Holder
- 1*Biohazard Waste Bag
- 1*Qualification Certificate



Sejoy SARS-CoV-2 Antigen Rapid Test Cassette-Export Packing Cartons			
Measurement of Gift Box	Measurement of Carton	Weight of Carton	Packing Quantity
210*150*70mm	62*44*30.5cm	GW:12.5 KGS NW:11.5 KGS	800 tests/carton

CONFORMITÉ




Elenco dei dispositivi medici

26/10/22, 06(02

Ministero della Salute

Area tematica Dispositivi medici | Archivio banche dati

Stampa | Scarica il dataset

Elenco dei dispositivi medici

Criteri di ricerca:
Denominazione fabbricante:
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: **2321556**
Codice attribuito dal fabbricante:
Nome commerciale e modello:
Classificazione CND:
Descrizione CND:
Normativa:
Classe CE (valida solo per dispositivi medici di classe, impiantabili attivi e IVD):

Elenco dispositivi individuati

Dati aggiornati al:23/10/2022

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
Dispositivo	2321556	S	COVF-522	SARS-COV-2 & INFLUENZA A+B ANTIGEN COMBO RAPID TEST CASSETTE	W0105099099 - VIROLOGIA - TEST RAPIDI E "POINT OF CARE" - ALTRI	D.L.vo 332/2000	IVD - Altro tipo di IVD	19/10/2022		FABBRICANTE	HANGZHOU SEJOY ELECTRONICS & INSTRUMENTS CO., LTD			CN
										MANDATARIO	SHANGHAI INTERNATIONAL HOLDING CORP GMBH (EUROPE)		DE368892350	DE

CONFORMITÉ (SUITE)

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/CA05

Bezeichnung / Name
Behörde für Justiz und Verbraucherschutz, Referat V43

Staat / State	Land / Federal state
Deutschland	Hamburg
Ort / City	Postleitzahl / Postal code
Hamburg	20310

Straße, Haus-Nr. / Street, house no.
Postfach 30 28 22

Telefon / Phone	Telefax / Fax
+49-40-428280	+49-40-427310017

E-Mail / E-mail
medizinprodukte@justiz.hamburg.de

Anzeige / Notification

Registrierdatum bei der zuständigen Behörde Registration date at competent authority	Registriernummer / Registration number

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

Anzeigender / Reporting organisation (person)

Code
DE/0000040627

Bezeichnung / Name
Shanghai International Holding Corporation GmbH (Europe)

Staat / State	Land / Federal state
Deutschland	Hamburg
Ort / City	Postleitzahl / Postal code
Hamburg	20537

Straße, Haus-Nr. / Street, house no.
Eiffestrasse 80

Telefon / Phone	Telefax / Fax
+49-40-2513175	+49-40-255726

E-Mail / E-mail
shholding@hotmail.com

Hersteller / Manufacturer

Bezeichnung / Name
Hangzhou Sejoy Electronics& Instruments Co., Ltd.

Staat / State
CN

Ort / City	Postleitzahl / Postal code
Hangzhou City, Zhejiang	311100

Straße, Haus-Nr. / Street, house no.
Area C, Building 2, No.365, Wuzhou Road, Yuhang Economic Development Zone

Telefon / Phone	Telefax / Fax
+86-571-81957767	+86-571-81957750

E-Mail / E-mail
zhangyy@sejoy.com

Sicherheitsbeauftragter für Medizinprodukte nach § 30 Abs. 2 MPG 9)
Safety officer for medical devices pursuant to § 30 (2) Medical Devices Act, MPG

Bezeichnung / Name
Liang Jin

Staat / State	Land / Federal state
Deutschland	Hamburg
Ort / City	Postleitzahl / Postal code
Hamburg	20537

Straße, Haus-Nr. / Street, house no.
Eiffestr.80

Telefon / Phone	Telefax / Fax
+49-40-2513175	+49-40-255726

E-Mail / E-mail
shholding@hotmail.com

Vertreter / Deputy (optional)

Bezeichnung / Name

Telefon / Phone	Telefax / Fax

E-Mail / E-mail

☐ Erstanzeige / initial notification
☒ Änderungsanzeige / Notification of change

In-vitro-Diagnostikum / In vitro diagnostic medical device

Klassifizierung / Classification
☐ Produkt der Liste A, Anhang II / Device of List A, Annex II
☐ Produkt der Liste B, Anhang II / Device of List B, Annex II
☐ Produkt zur Eigenanwendung / Device for self-testing
☒ Sonstiges Produkt / Other device (all devices except Annex II and self-testing devices)

App (Software auf mobilen Endgeräten) ☐ ja / yes ☒ nein / no

Anzeige nach § 25 Abs. 3 Nummer 3 MPG
Notification pursuant to § 25 (3) number 3 Medical Devices Act, MPG
☐ "Neues In-vitro-Diagnostikum / New in vitro diagnostic medical device"

Handelsname des Produktes / Trade name of the device
Sejoy

Produktbezeichnung / Name of device
Influenza A+B Rapid Test

Angabe der benutzten Nomenklatur / Nomenclature used
☒ EDMS-Klassifikation / EDMS Classification
☐ GMDN

Nomenklaturcode / Nomenclature code
15-70-90-90-00

Nomenklaturbezeichnung / Nomenclature term
OTHER OTHER VIROLOGY RAPID TESTS

Kurzbeschreibung / Short description
In Deutsch / In German

In Englisch / In English
The Influenza A+B Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of influenza A and B antigens in nasal swab or throat swab or nasal aspirate specimens. It is intended to aid in the rapid differential diagnosis of influenza A and B viral infections.

Zusätzliche Angaben im Falle der In-vitro-Diagnostika gemäß Anhang II und der In-vitro-Diagnostika zur Eigenanwendung / Addtional information for Annex II and self-testing in vitro diagnostic medical devices

Nummer(n) der Bescheinigung(en) / Certificate number(s)

☐ In Übereinstimmung mit den Gemeinsamen Technischen Spezifikationen (für Produkte gem. Anhang II, Liste A) In conformity with Common Technical Specifications (for Annex II List A devices)

Ergebnisse der Leistungsbewertung
Outcome of performance evaluation

Ich versichere, dass die Angaben nach bestem Wissen und Gewissen gemacht wurden.
I affirm that the information given above is correct to the best of my knowledge.

Ort / City: Hamburg
Datum / Date: 2020-12-21
Name: Liang Jin
Unterschrift / Signature

Bearbeitungsvermerke / Processing notes
Nur von der zuständigen Behörde auszufüllen / To be filled in only by the competent authority

Bearbeiter / Person responsible	Telefon / Phone

CONFORMITÉ (SUITE)

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
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 09, 2021
Place,date

General Manager
Legally binding signature, Position

Device ID # [19]	REF number [20, 21]	Name of submitting company [22]	Commercial name of the device [22]	Clinical performance of the device *As evaluated by independent validation studies, meeting the agreed criteria*	Specimen type(s) [22]	SARS-CoV-2 Target protein	Included in the EU common list since *D/M/Y*
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
2063	COIF-522	**Hangzhou Sejoy Electronics & Instruments Co.,Ltd.**	**SARS-CoV-2 & Influenza A+B Antigen Combo Rapid Test Cassette**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 99.1%.*	Nasopharyngeal, Oropharyngeal	Nucleocapsid protein	05/10/2022
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
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