Features

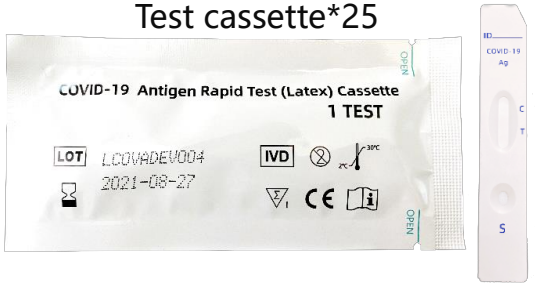
Patent Application No. (USA) : T13520.PROV

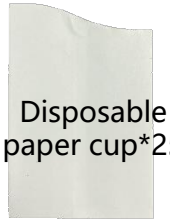
COVID-19 ANTIGEN RAPID TEST (Latex)

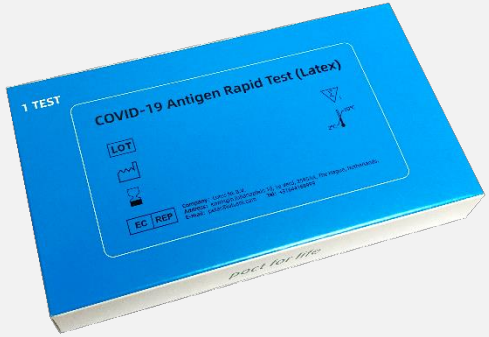
JOINSTATR COVID-19 ANTIGEN RAPID TEST has complete export qualifications; non-invasive; saliva (oropharyngeal), sputum and stool can be detected, early diagnosis reassures your mind

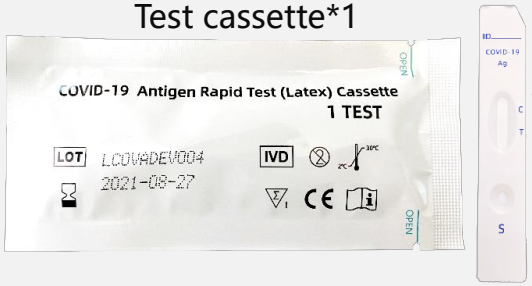
- **Internationally innovative,** direct detection of pathogen S protein, not affected by virus mutation, high sensitivity & specificity, and can be used for early screening;
- **Convenient and non-invasive sampling**. Specimen type: oropharyngeal saliva/sputum/stool, which can be used for home self-inspection during the quarantine, and screening before resumption of work and school; Non-invasive testing is particularly suitable for continuous monitoring of children and the elderly;
- **One-step method**, easy to operate, reducing missed or false inspections caused by operator errors;
- **No equipment required**, fast detection, results are available in 10-15 minutes;
- **Storage temperature: 2~30℃**. No cold-chain transportation needed;
- **Specification:** 25 tests/box, 1 test/box; **Diverse cooperation modes**: OEM/ODM accepted.

Specification	P/N	Components
25Tests/Box 800Tests/CTN (61*32*39CM 13/14KG)	**FLCOVA200**	Test cassette*25 Package insert*1 Sample Extraction Tube*25 Dropper*25 Disposable paper cup*25
1Test/Box 400Tests/CTN (61*40*43CM 6/7KG)	**FLCOVA100**	Test cassette*1 Package insert*1 Sample Extraction Tube*1 Dropper*1 Disposable paper cup*1

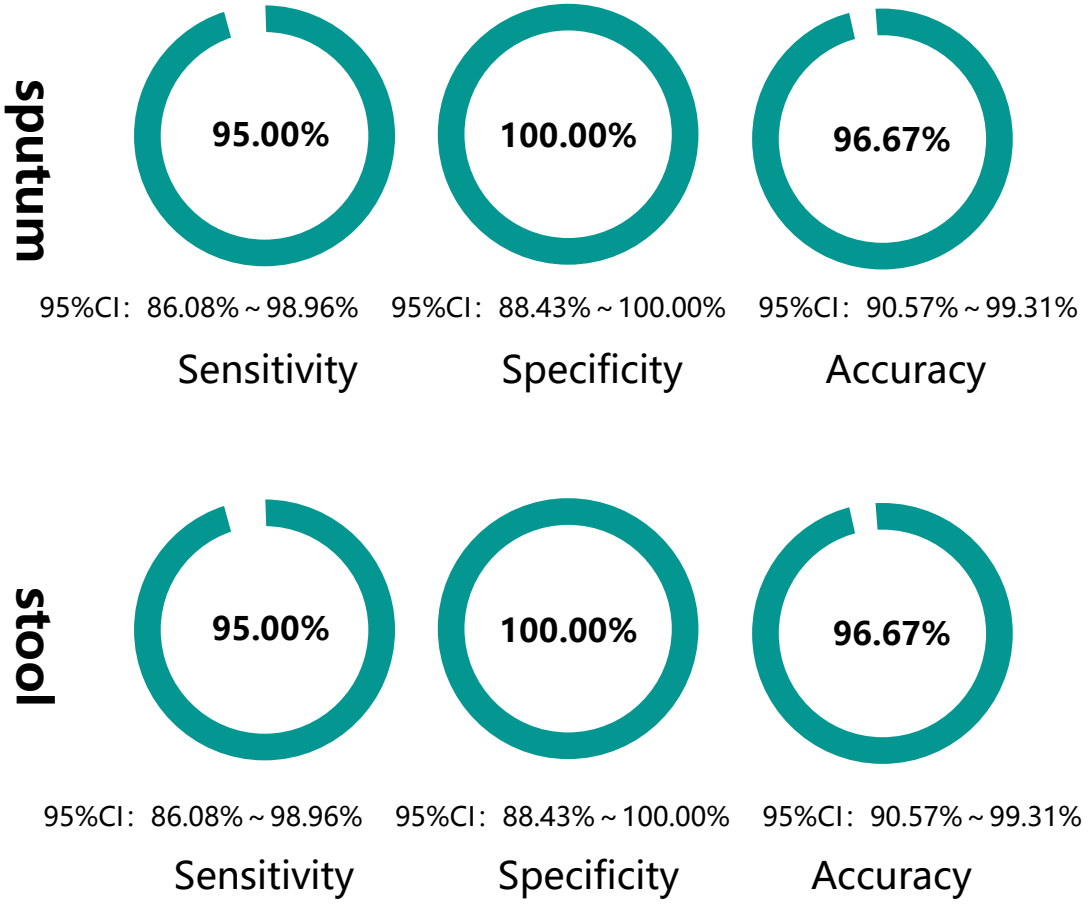




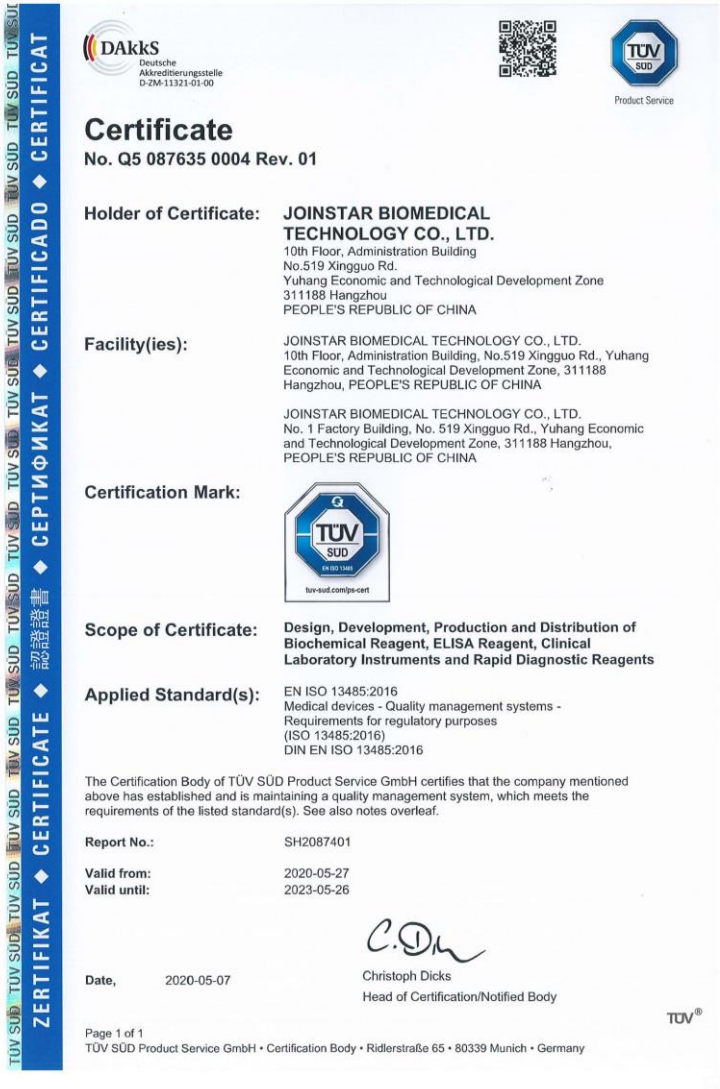




Performance Characteristics



CERTIFICATE



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

TÜV SÜD Product Service

Certificate
No. Q5 087635 0004 Rev. 01

Holder of Certificate: **JOINSTAR BIOMEDICAL TECHNOLOGY CO., LTD.**
10th Floor, Administration Building
No.519 Xingguo Rd.
Yuhang Economic and Technological Development Zone
311188 Hangzhou
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):
JOINSTAR BIOMEDICAL TECHNOLOGY CO., LTD.
10th Floor, Administration Building, No.519 Xingguo Rd., Yuhang Economic and Technological Development Zone, 311188 Hangzhou, PEOPLE'S REPUBLIC OF CHINA

JOINSTAR BIOMEDICAL TECHNOLOGY CO., LTD.
No. 1 Factory Building, No. 519 Xingguo Rd., Yuhang Economic and Technological Development Zone, 311188 Hangzhou, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate: **Design, Development, Production and Distribution of Biochemical Reagent, ELISA Reagent, Clinical Laboratory Instruments and Rapid Diagnostic Reagents**

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

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). See also notes overleaf.

Report No.: SH2087401

Valid from: 2020-05-27
Valid until: 2023-05-26

Date, 2020-05-07

Christoph Dicks
Head of Certification/Notified Body

Page 1 of 1
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

ISO13485

CIBG
Ministerie van Volksgezondheid, Welzijn en Sport

> Retouradres Postbus 16114 2500 BC Den Haag

Lotus NL B.V.
T.a.v. de heer X. Wei
Koningin Julianaplein 10
2595 AA 's-Gravenhage

Farmatec
Bezoekadres:
Hoftoren
Rijnstraat 50
2515 XP Den Haag
T 070 340 6161
http://hulpmiddelen.farmatec.nl

Inlichtingen bij:
M.P. Meijer - Michiels
medische_hulpmiddelen@minvws.nl

Ons kenmerk:
CIBG-20204350

Bijlagen
-

Uw aanvraag
5 september 2020

Correspondentie uitsluitend richten aan het retouradres met vermelding van de datum en het kenmerk van deze brief.

Datum: 8 september 2020
Betreft: aanmelding In-vitro diagnostica

Geachte heer Wei,

Op 5 september 2020 ontving ik uw notificatie krachtens artikel 4, eerste lid van het Nederlandse Besluit in-vitro diagnostica (BIVD) om onder de bedrijfsnaam Joinstar Biomedical Technology Co.,Ltd met Europees gemachtigde Lotus NL B.V. onderstaand product als in-vitro diagnosticum op de Europese markt te brengen.

Het product staat geregistreerd als in-vitro diagnosticum onder nummer:

COVID-19 Antigen Rapid Test (Latex)
(geen merknaam) (NL-CA002-2020-53351)

Hiermee heeft u voldaan aan uw verplichting op grond van artikel 4, BIVD.

In alle verdere correspondentie betreffende bovenvermeld product verzoek ik u dit nummer te vermelden. Aan dit nummer kunnen geen verdere rechten ontleend worden, het dient alleen om de notificatie administratief te vergemakkelijken.

De registratie van in-vitro diagnostica als medisch hulpmiddel op grond van de Classificatiecriteria (Bijlage II) bij Richtlijn 98/79/EG betreffende medische hulpmiddelen voor in-vitro diagnostiek is onderhevig aan mogelijke revisies van Europese regelgeving inzake de classificatie van medische hulpmiddelen en aan voortschrijdend wetenschappelijk inzicht (zie artikel artikel 10, eerste lid van Richtlijn 98/79/EG).

Pagina 1 van 2

Notificatie van in-vitro diagnostische medische hulpmiddelen impliceert dat de fabrikant, Joinstar Biomedical Technology Co.,Ltd de CE-conformiteitsmarkering heeft aangebracht op het desbetreffende product alvorens het in een EU-lidstaat in de handel te brengen. Zodoende garandeert Lotus NL B.V. dat het in-vitro diagnosticum voldoet aan de essentiële eisen zoals opgenomen in bijlage I bij Richtlijn 98/79/EG (en in het daarmee corresponderende onderdeel 1 bij het besluit)

Volledigheidshalve wijzen wij u erop dat een in-vitro diagnosticum moet voldoen aan de eisen uit het BIVD. Het BIVD is gebaseerd op Richtlijn voor in-vitro diagnostiek, 98/79/EG. Met name wijzen wij u op de Nederlandse-taaleis zoals deze in Nederland geldt, de eisen voor het ter beschikking houden van de technische documentatie en de plicht tot het hebben van een Post Marketing Surveillance- en vigilantiesysteem.

Tot slot merk ik op dat met uw notificatie - de administratieve notificatie als fabrikant - en deze brief geen sprake is van een oordeel over de status of kwalificatie van uw product: notificering betekent niet dat daadwerkelijk sprake is van een in-vitro diagnosticum in de zin van de onderhavige wet- en regelgeving. In voorkomende gevallen kan de Inspectie Gezondheidszorg en Jeugd (IGJ), belast met het toezicht op de naleving van het bij of krachtens de wet bepaalde, een standpunt innemen over de status van een product, waarbij het volgens vaste jurisprudentie uiteindelijk aan de nationale rechter is om te bepalen of een product onder de definitie van in-vitro diagnosticum valt.

De Minister voor Medische Zorg en Sport,
namens deze,

Afdelingshoofd
Farmatec

Dr. M.J. van de Velde

Pagina 2 van 2

CE Registration

CERTIFICATE

CE

DECLARATION OF CONFORMITY

Manufacturer: Joinstar Biomedical Technology Co.,Ltd.

Address: 10th Floor, Administration Building, NO.519, XingGuo RD., Yuhang Economic and Technological Development Zone,Hangzhou, Zhejiang,China,311188

EC Representative's Name: Lotus NL B.V.

EC Representative's Address: Koningin Julianaplein 10,1e Verd, 2595AA,The Hague,Netherlands.

Declares, that the product

Product Name and Model:

COVID-19 Antigen Rapid Test (Latex)
1 Test/Kit, 25 Tests/Kit

as described above are in conformity with the requirements as defined in IVDD98/79/EC Annex III.

Additional information:

Conformity assessment route: Directive 98/79/EC, Annex III
Classification: List Others

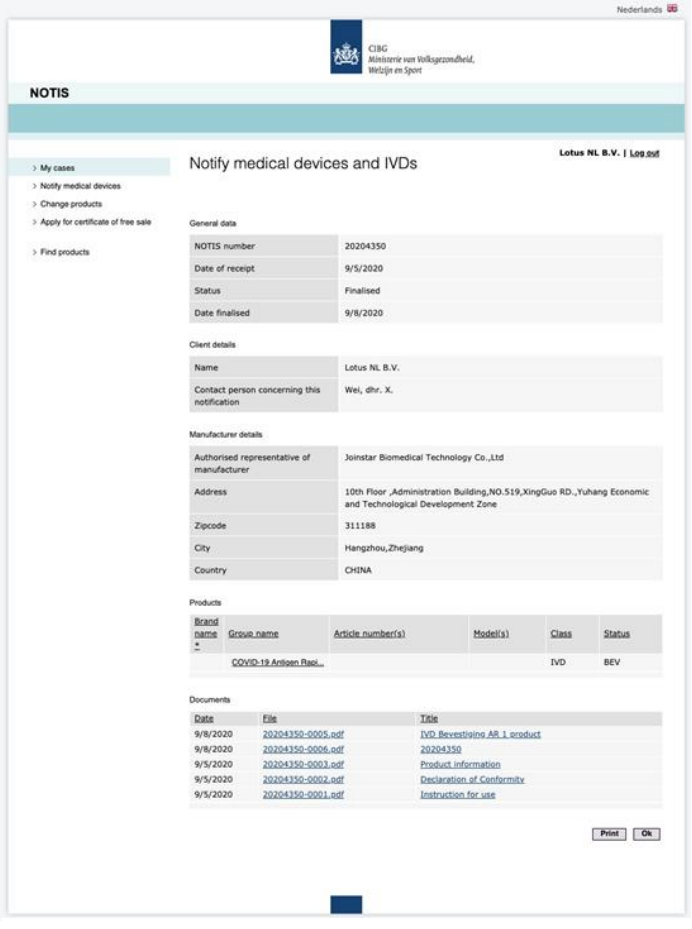
I, the undersigned, hereby declare that the medical devices specified above conform with the Directive 98/79/EC on in vitro diagnostic medical devices and pertinent essential requirements.

Date Signed: 2020.09.02

Xuyi ZHOU
General Manager
Joinstar Biomedical Technology Co.,Ltd.

Joinstar Biomedical Technology Co.,Ltd.

Version:0.0



Nederlands

CIBG
Ministerie van Volksgezondheid, Welzijn en Sport

NOTIS

Lotus NL B.V. | Log out

- My cases
- Notify medical devices
- Change products
- Apply for certificate of free sale
- Find products

Notify medical devices and IVDs

General data

NOTIS number	20204350
Date of receipt	9/5/2020
Status	Finalised
Date finalised	9/8/2020

Client details

Name	Lotus NL B.V.
Contact person concerning this notification	Wei, dhr. X.

Manufacturer details

Authorised representative of manufacturer	Joinstar Biomedical Technology Co.,Ltd
Address	10th Floor ,Administration Building,NO.519,XingGuo RD.,Yuhang Economic and Technological Development Zone
Zipcode	311188
City	Hangzhou,Zhejiang
Country	CHINA

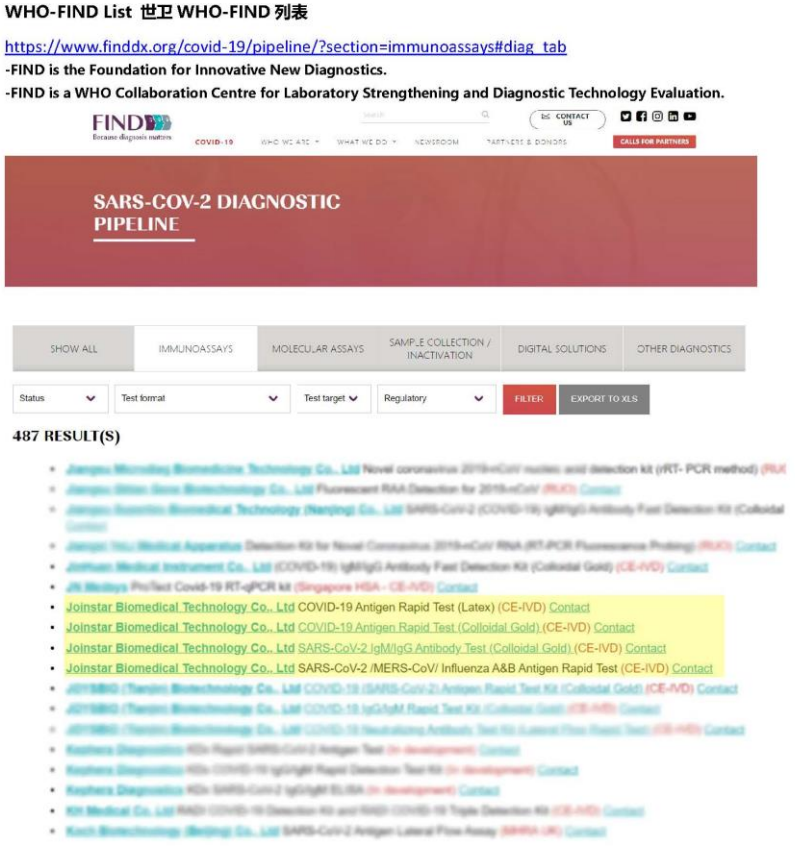
Products

Brand name *	Group name	Article number(s)	Model(s)	Class	Status
	COVID-19 Antigen Rapi...			IVD	BEV

Documents

Date	File	Title
9/8/2020	20204350-0005.pdf	IVD Bevestiging AR 1 product
9/8/2020	20204350-0006.pdf	20204350
9/5/2020	20204350-0003.pdf	Product information
9/5/2020	20204350-0002.pdf	Declaration of Conformity
9/5/2020	20204350-0001.pdf	Instruction for use

Print Ok



WHO-FIND List 世卫 WHO-FIND 列表

https://www.finddx.org/covid-19/pipeline/?section=immunoassays#diag_tab

-FIND is the Foundation for Innovative New Diagnostics.

-FIND is a WHO Collaboration Centre for Laboratory Strengthening and Diagnostic Technology Evaluation.

FIND
Because diagnosis matters

COVID-19 | WHO WE ARE | WHAT WE DO | NEWSROOM | PARTNERS & DONORS | CONTACT US | CALLS FOR PARTNERS

SARS-COV-2 DIAGNOSTIC PIPELINE

SHOW ALL | IMMUNOASSAYS | MOLECULAR ASSAYS | SAMPLE COLLECTION / INACTIVATION | DIGITAL SOLUTIONS | OTHER DIAGNOSTICS

Status | Test format | Test target | Regulatory | FILTER | EXPORT TO XLS

487 RESULT(S)

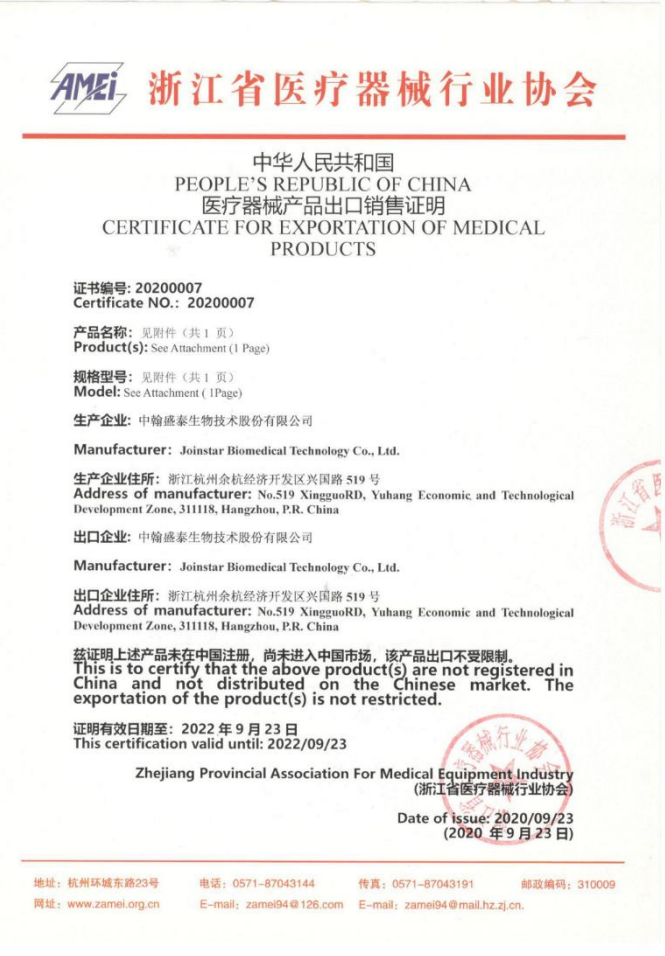
- [redacted] Novel coronavirus 2019-nCoV nucleic acid detection kit (rRT- PCR method) (RUO) Contact
- [redacted] Fluorescent RAA Detection for 2019-nCoV (RUO) Contact
- [redacted] SARS-CoV-2 (COVID-19) IgM/IgG Antibody Fast Detection Kit (Colloidal Gold) Contact
- [redacted] Detection Kit for Novel Coronavirus 2019-nCoV RNA (RT-PCR Fluorescence Probing) (RUO) Contact
- [redacted] (COVID-19) IgM/IgG Antibody Fast Detection Kit (Colloidal Gold) (CE-IVD) Contact
- [redacted] ProTect Covid-19 RT-qPCR kit (Singapore HSA - CE-IVD) Contact
- Joinstar Biomedical Technology Co., Ltd COVID-19 Antigen Rapid Test (Latex) (CE-IVD) Contact
- Joinstar Biomedical Technology Co., Ltd COVID-19 Antigen Rapid Test (Colloidal Gold) (CE-IVD) Contact
- Joinstar Biomedical Technology Co., Ltd SARS-CoV-2 IgM/IgG Antibody Test (Colloidal Gold) (CE-IVD) Contact
- Joinstar Biomedical Technology Co., Ltd SARS-CoV-2 /MERS-CoV/ Influenza A&B Antigen Rapid Test (CE-IVD) Contact
- [redacted] COVID-19 (SARS-CoV-2) Antigen Rapid Test Kit (Colloidal Gold) (CE-IVD) Contact
- [redacted] COVID-19 IgG/IgM Rapid Test Kit (Colloidal Gold) (CE-IVD) Contact
- [redacted] COVID-19 Neutralizing Antibody Test Kit (Lateral Flow Rapid Test) (CE-IVD) Contact
- [redacted] Rapid SARS-CoV-2 Antigen Test (In development) Contact
- [redacted] COVID-19 IgG/IgM Rapid Detection Test Kit (In development) Contact
- [redacted] SARS-CoV-2 IgG/IgM ELISA (In development) Contact
- [redacted] RADI COVID-19 Detection Kit and RADI COVID-19 Triple Detection Kit (CE-IVD) Contact
- [redacted] SARS-CoV-2 Antigen Lateral Flow Assay (MHRA UK) Contact

CE Declaration of Conformity

CE Notify medical devices and IVDs

WHO-FIND List

CERTIFICATE



浙江省医疗器械行业协会

中华人民共和国
PEOPLE'S REPUBLIC OF CHINA
医疗器械产品出口销售证明
CERTIFICATE FOR EXPORTATION OF MEDICAL PRODUCTS

证书编号: 20200007
Certificate NO.: 20200007

产品名称: 见附件（共 1 页）
Product(s): See Attachment (1 Page)

规格型号: 见附件（共 1 页）
Model: See Attachment (1Page)

生产企业: 中翰盛泰生物技术股份有限公司

Manufacturer: Joinstar Biomedical Technology Co., Ltd.

生产企业住所: 浙江杭州余杭经济开发区兴国路 519 号
Address of manufacturer: No.519 XingguoRD, Yuhang Economic and Technological Development Zone, 311118, Hangzhou, P.R. China

出口企业: 中翰盛泰生物技术股份有限公司

Manufacturer: Joinstar Biomedical Technology Co., Ltd.

出口企业住所: 浙江杭州余杭经济开发区兴国路 519 号
Address of manufacturer: No.519 XingguoRD, Yuhang Economic and Technological Development Zone, 311118, Hangzhou, P.R. China

兹证明上述产品未在中国注册，尚未进入中国市场，该产品出口不受限制。
This is to certify that the above product(s) are not registered in China and not distributed on the Chinese market. The exportation of the product(s) is not restricted.

证明有效日期至: 2022 年 9 月 23 日
This certification valid until: 2022/09/23

Zhejiang Provincial Association For Medical Equipment Industry
(浙江省医疗器械行业协会)

Date of issue: 2020/09/23
(2020 年 9 月 23 日)

地址：杭州环城东路23号 电话：0571-87043144 传真：0571-87043191 邮政编码：310009
网址：www.zamei.org.cn E-mail：zamei94@126.com E-mail：zamei94@mail.hz.zj.cn.

附件
ATTACHMENT

证书编号:20200007 （共 1 页 第 1 页）
Certificate No.:20200007 （Page 1 of 1 Page）

序号 SN	产品名称 Product(s)	规格型号 Model
1	新冠病毒抗原检测试剂盒(乳胶法) COVID-19 Antigen Rapid Test (Latex)	25 人份/盒,FLCOVA200, FLCOVA200 25TESTS/KIT,FLCOVA200, FLCOVA200 1 人份/盒,FLCOVA100, FLCOVA100 1TESTS/KIT,FLCOVA100, FLCOVA100
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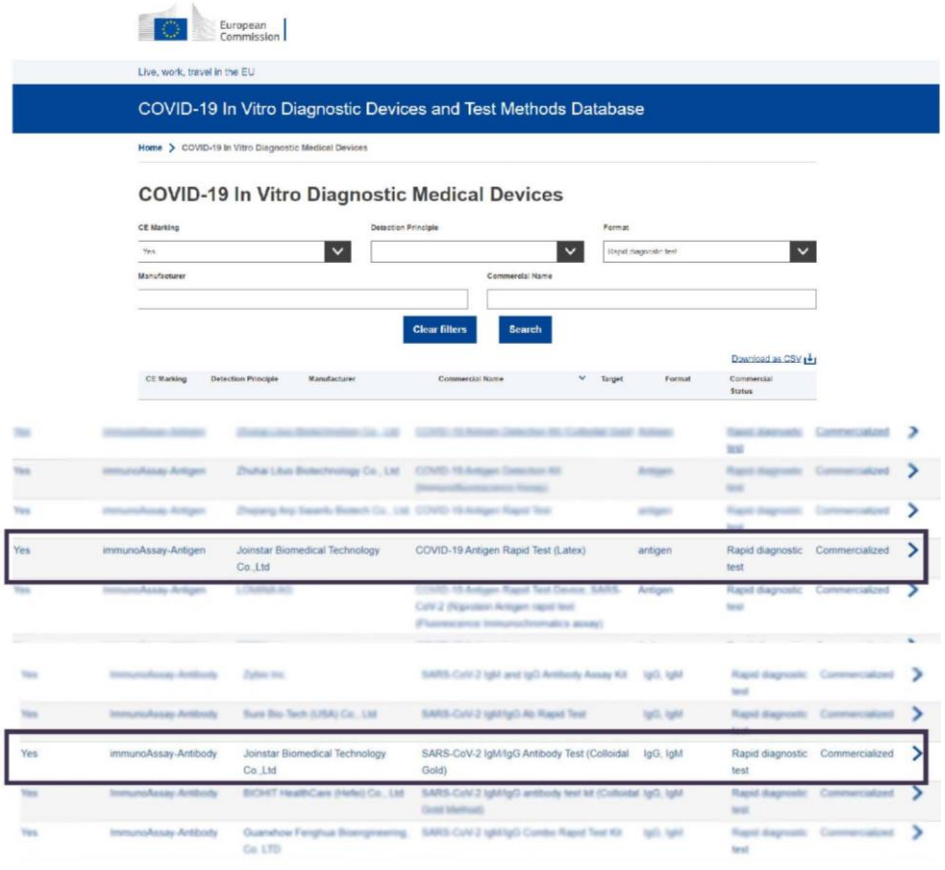
FSC

https://covid-19-diagnostics.jrc.ec.europa.eu/devices?marking=&principle=&format=&manufacturer=Joinstar&text_name=#form_content



European Commission

Live, work, travel in the EU

COVID-19 In Vitro Diagnostic Devices and Test Methods Database

Home > COVID-19 In Vitro Diagnostic Medical Devices

COVID-19 In Vitro Diagnostic Medical Devices

CE Marking | Detection Principle | Format | Manufacturer | Commercial Name

Clear filters | Search

Download as CSV

CE Marking	Detection Principle	Manufacturer	Commercial Name	Target	Format	Commercial Status
Yes	immunoAssay-Antigen	Joinstar Biomedical Technology Co.,Ltd	COVID-19 Antigen Rapid Test (Latex)	antigen	Rapid diagnostic test	Commercialized
Yes	immunoAssay-Antibody	Joinstar Biomedical Technology Co.,Ltd	SARS-CoV-2 IgM/IgG Antibody Test (Colloidal Gold)	IgG, IgM	Rapid diagnostic test	Commercialized

Listed in COVID-19 In Vitro Diagnostic Devices and Test Methods Database

CERTIFICATE

9/10/2020 Elenco dei dispositivi medici

Area tematica Dispositivi medici | Archivio banche dati

Ministero della Salute

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: **2000587**
Codice attribuito dal fabbricante:
Nome commerciale e modello:
Classificazione CND:
Descrizione CND:
Classe CE (valida solo per dispositivi medici di classe, impiantabili attivi e IVD):

Elenco dispositivi individuati

Dati aggiornati al:03/10/2020

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	CLASSE CE	DATA PRIMA PUBBLICAZIONE	DATA FINE IMMISSIONE IN COMMERCIO	RUOLO AZIENDA	DENOMINAZIONE	CODICE FISCALE	PARTITA IVA/VAT NUMBER	NAZIONI
Dispositivo	2000587	S	RPBH1237 0	COVID-19 ANTIGEN RAPID TEST (LATEX)	W0105099099 - VIROLOGIA - TEST RAPIDI E "POINT OF CARE" - ALTRI	ST - Test autodiagnostici (non inclusi nell'all. II)	02/10/2020		FABBRICANTE	JOINSTAR BIOMEDICAL TECHNOLOGY CO.,LTD.			CN
									MANDATARIO	LOTUS NL BV		857879145B01	NL

<< < Pagina:1 > >> Num. Pagine:1 Num. Dispositivi:1

https://antigentest.bfarm.de/ords/antigen/r/antigentests-auf-sars-cov-2/liste-der-antigentests?session=11940645182854

Registration in Italy

Registration in Germany