

TÜV SÜD
 ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ CERTIFICADO ◆ CERTIFIKAT ◆ CERTIFICATE



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



CE registration 欧盟注册文件



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

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 10, eerste lid van Richtlijn 98/79/EG).

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.*

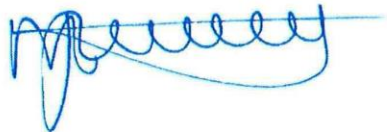
Notificatie van in-vitro diagnostische medische hulpmiddelen impliceert dat de fabrikant, Joinstar Biomedical Technology Co.,Ltd de CE-conformiteitsmarkering heeft aangebracht op het desbetreffende product alvorens het in een EU-lidstaat in de handel te brengen. Zodoende garandeert Lotus NL B.V. dat 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



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

Xu Yi ZHOU

General Manager

Joinstar Biomedical Technology Co.,Ltd.



Joinstar Biomedical Technology Co.,Ltd.

Exporting White List 出口白名单商务部备案

说明:

地市

序号	企业名称 (中英文)	经营企业 代码	产品名称 (中英文) (含规格 、型号)	产品分类 (按选项 填写)	复核意见	专家初审 意见	来源
7	中翰盛泰 生物技术 股份有限 公司 Joinstar Biomedic al Technolo gy Co.,Ltd.	9133010 0566061 4000	新型冠状 病毒抗原 检测试剂 盒(乳胶 法) COVID- 19 Antigen Rapid Test (Latex)	新冠病毒 试剂盒	欧盟CE认 证完成	欧盟: 1、新冠病 毒检测试 剂盒在欧 盟的分类 是 Others, 需要企业 按照体外 诊断医疗 器械指令 98/79/EC 出具符合 性声明 DoC, 并 由欧盟授 权代表在 对应欧盟 成员国 的主管当 局进行登 记注册 2、企业通 过地方商 务部门 (浙江) 提交的材 料中包 括:	浙江25-8 家

杭州



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 (1 Page)

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)



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
空白 Blank	空白 Blank	空白 Blank



Registration in Italy 意大利注册文件

9/11/2020

Elenco dei dispositivi medici

Area tematica Dispositivi medici | Archivio banche dati



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

Elenco dei dispositivi medici

Criteri di ricerca:

Denominazione fabbricante: **Joinstar Biomedical Technology Co.,Ltd.**

Codice fiscale fabbricante:

Partita IVA / VAT number fabbricante:

Codice nazione fabbricante:

Denominazione mandatario: **Lotus**

Codice fiscale mandatario:

Partita IVA / VAT number mandatario:

Codice nazione mandatario:

Tipologia dispositivo: **Dispositivo**

Identificativo di registrazione attribuito dal sistema BD/RDM: **2000587**

Codice attribuito dal fabbricante:

Nome commerciale e modello: **COVID-19 ANTIGEN RAPID TEST (LATEX)**

Classificazione CND: **W0105099099**

Descrizione CND:

Classe CE (valida solo per dispositivi medici di classe, impiantabili attivi e IVD): **IVD - Altro tipo di IVD**

Elenco dispositivi individuati

Dati aggiornati al:07/11/2020

DISPOSITIVO MEDICO/ASSEMBLATO							FABBRICANTE/ASSEMBLATORE					
TIPOLOGIA	DI	ISCRITTO AL	CODICE ATTRIBUITO DAL	NOME	CLASSE	DATA PRIMA	DATA FINE	RUOLO	DENOMINAZIONE	CODICE	PARTITA	NAZIONE
DISPOSITIVO	REGISTRAZIONE	REPERTORIO	FABBRICANTE/ASSEMBLATORE	COMMERCIALE CND E MODELLO	CE	PUBBLICAZIONE	IMMISSIONE IN COMMERCIO	AZIENDA		FISCALE	IVA/VAT NUMBER	
	BD/RDM											
Dispositivo	2000587	S	RPBH1234 0	COVID-19 ANTIGEN RAPID TEST (LATEX)	W0105099099 - VIROLOGIA - TEST RAPIDI E "POINT OF CARE" - ALTRI	IVD - Altro tipo di IVD	02/10/2020	FABBRICANTE	JOINSTAR BIOMEDICAL TECHNOLOGY CO.,LTD.			CN
								MANDATARIO	LOTUS NL BV	857879145801		NL

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

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.



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)

- [InTec Products, Inc.](#) Rapid SARS-CoV-2 Antibody (IgM/IgG) (CE-IVD) [Contact.1](#) [Contact.2](#)
- [InTec Products, Inc.](#) Rapid SARS-CoV-2 Antibody Test (CE-IVD) [Contact.1](#) [Contact.2](#)
- [Jetta Labs LLP](#) COVID Diamond SARS-CoV2 (COVID-19) IgG/IgM Test (Latex Method) (CE-IVD) [Contact](#)
- [Jetta Labs LLP](#) COVID India SARS-CoV2 (COVID-19) IgG/IgM Test (Colloidal Gold Method) (CE-IVD) [Contact](#)
- [Jiangsu Biopurfectus Technologies Co., Ltd](#) PerfectPOC Novel Corona Virus (SARS-CoV-2) Ag Rapid Test Kit (CE-IVD) [Contact](#)
- [Jiangsu Biopurfectus Technologies Co., Ltd](#) PerfectPOC Novel Corona Virus (SARS-CoV-2) (IgM/IgG) Rapid Test Kit (CE-IVD) [Ca](#)
- [Jiangsu Superbio Biomedical Technology \(Nanjing\) Co., Ltd](#) SARS-CoV-2 (COVID-19) IgM/IgG Antibody Fast Detection Kit (Contact)
- [Jinhuan Medical Instrument Co., Ltd](#) (COVID-19) IgM/IgG Antibody Fast Detection Kit (Colloidal Gold) (CE-IVD) [Contact](#)
- [Joinstar Biomedical Technology Co., Ltd](#) SARS-CoV-2 /MERS-CoV/ Influenza A&B Antigen Rapid Test (CE-IVD) [Contact](#)
- [Joinstar Biomedical Technology Co., Ltd](#) COVID-19 Antigen Rapid Test (Latex) (CE-IVD) [Contact](#)
- [Joinstar Biomedical Technology Co., Ltd](#) SARS-CoV-2 IgM/IgG Antibody Test (Colloidal Gold) (CE-IVD) [Contact](#)
- [JOYSEBO \(Tianjin\) Biotechnology Co., Ltd](#) COVID-19 (SARS-CoV-2) Antigen Rapid Test Kit (Colloidal Gold) (CE-IVD) [Contact](#)
- [JOYSEBO \(Tianjin\) Biotechnology Co., Ltd](#) COVID-19 (SARS-CoV-2) Antigen Rapid Test Kit (Colloidal Gold) (CE-IVD) [Contact](#)
- [JOYSEBO \(Tianjin\) Biotechnology Co., Ltd](#) COVID-19 Neutralizing Antibody Test Kit (Lateral Flow Rapid Test) (CE-IVD) [Contact](#)
- [Keaphera Diagnostics](#) iDx COVID-19 IgG/IgM Rapid Detection Test Kit (in development) [Contact](#)
- [Keaphera Diagnostics](#) iDx Rapid SARS-CoV-2 Antigen Test (in development) [Contact](#)
- [Keaphera Diagnostics](#) iDx SARS-CoV-2 IgG/IgM ELISA (in development) [Contact](#)
- [Koch Biotechnology \(Beijing\) Co., Ltd](#) SARS-CoV-2 Antigen Lateral Flow Assay (MHRA UK) [Contact](#)
- [KRISHGEN BioSystems](#) SARS-CoV-2 Surrogate Virus Neutralization Test (SNT) ELISA (CE-IVD) [Contact](#)

COVID-19 In Vitro Diagnostic Devices and Test Methods Database

欧盟官网新冠体外诊断设备和测试方法数据库

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



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:

[Download as CSV](#)

CE Marking	Detection Principle	Manufacturer	Commercial Name	Target	Format	Commercial Status	
Yes	ImmunoAssay-Antigen	Zhuohai Lian Biotechnology Co., Ltd	COVID-19 Antigen Detection Kit (Colloidal Gold Method)	Antigen	Rapid diagnostic test	Commercialized	>
Yes	ImmunoAssay-Antigen	Zhuohai Lian Biotechnology Co., Ltd	COVID-19 Antigen Detection Kit (Immunochromatography)	Antigen	Rapid diagnostic test	Commercialized	>
Yes	ImmunoAssay-Antigen	Zhejiang Key Biotech Biotech Co., Ltd	COVID-19 Antigen Rapid Test	antigen	Rapid diagnostic test	Commercialized	>
Yes	immunoAssay-Antigen	Joinstar Biomedical Technology Co.,Ltd	COVID-19 Antigen Rapid Test (Latex)	antigen	Rapid diagnostic test	Commercialized	>
Yes	ImmunoAssay-Antigen	Lifetech AG	COVID-19 Antigen Rapid Test Device: SARS-CoV-2 (Nucleocapsid Protein) rapid test (Fluorescence Immunochromatography assay)	Antigen	Rapid diagnostic test	Commercialized	>
Yes	ImmunoAssay-Antibody	Zylin Inc	SARS-CoV-2 IgM and IgG Antibody Assay Kit	IgG, IgM	Rapid diagnostic test	Commercialized	>
Yes	ImmunoAssay-Antibody	Sure Bio-Tech (USA) Co., Ltd	SARS-CoV-2 IgM/IgG Ab Rapid Test	IgG, IgM	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	>
Yes	ImmunoAssay-Antibody	BIOHT HealthCare (Hefei) Co., Ltd	SARS-CoV-2 IgM/IgG antibody test kit (Colloidal IgG, IgM Gold Method)	IgG, IgM	Rapid diagnostic test	Commercialized	>
Yes	ImmunoAssay-Antibody	Guangzhou Fenghua Bioengineering Co., LTD	SARS-CoV-2 IgM/IgG Combo Rapid Test Kit	IgG, IgM	Rapid diagnostic test	Commercialized	>

Registration in Germany 德国注册

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

 Bundesinstitut für Arzneimittel und Medizinprodukte

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

[Impressum](#)

Suchen: Alle Textspalten

Test-ID	Hersteller			Deutscher Vertreter	Europäischer Bevollmächtigter			Handelsname des Tests	Testort *	Artikelnum...	Sensitivität		Spezifität		Gebrauc... anweisung
	Name ↑	Stadt	Land	Name	Name	Stadt	Land				%	95%iges Vertra... intervall	%	95%iges Vertra... intervall	
AT03...	Lexiplex Liability Company	Huadon	US	A. Menarini Diagnostics				Coronavirus Ag Rapid Test (antigen) (fluid)	POC (ohne Gerät)		96,30	87,25 - 99,55	98,06	96,53 - 99,80	
AT19...	Hecin Scientific, Inc	Guangdong	CN	Stephana GmbH	Stephana GmbH	Manchen	DE	SARS-CoV-2 Antigen-Testkit (kollektive Goldmethode)	POC (mit Gerät)	109031003	98,11	89,93 - 99,95	99,53	97,44 - 99,99	
AT08...	Humass Co. Ltd	Gyeonggi-do	KR	godiscare GmbH	MT Promess Consulting GmbH	St. Ingbert	DE	Humass COVID-19 Ag Test			95,50	90,0 - 98,1	100,00	98,0 - 100,0	Link öffn
AT17...	Joinstar Biomedical Technology, Co., Ltd	Hangzhou	CN	Praxisdienst GmbH & Co. KG	LOTUS NL BV	's-Gravenhage	NL	Joinstar Covid-19 Antigen-Rapid Test	POC (ohne Gerät)	FLCOVA200	95,00	86,08 - 98,96	100,00	88,43 - 100	Link öffn
AT18...	JOYSBIO (Tianjin) Biotechnology Co., Ltd	Tianjin	CN	New Mobility AG	Lotus NL B.V.	Den Haag	NL	SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold) / Test Kit for reusable Coronavirus-Antigen (colloidal Gold Methode)	POC (ohne Gerät)	GOV-AG-20 / G10313	98,89	75,8 - 98,3	99,05	94,8 - 100,0	Link öffn
AT17...	JOYSBIO (Tianjin) Biotechnology Co., Ltd	Tianjin	CN	InsuGeX GmbH	Lotus NL B.V.	The Hague	NL	SARS-CoV-2 Antigen-Rapid Test Kit (Colloidal Gold)	POC (ohne Gerät)	IOX-IS-01	98,72	93,0 - 100,0	97,32	92,4 - 99,4	
AT04...	JOYSBIO (Tianjin) Biotechnology Co., Ltd	Tianjin	CN		Lotus NL B.V.	The Hague	NL	SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold) / Test Kit for reusable Coronavirus-Antigen (colloidal Gold Methode)	POC (ohne Gerät)	GOV-AG-20 / G10313	98,72	93,0 - 100,0	97,32	92,4 - 99,4	Link öffn
	Korh Bioteknologi							COVID-19 Antigen-Test	POC			97,9		98,4	