ZERTIFIKATE / LISTUNGEN

Konformitätserklärung

EC Declaration of Conformity

Manufacturer:
Name: JOYSBIO (Tianjin) Biotechnology Co., Ltd.
Address: Tianjin International Joint Academy of Biotechnology & Medicine 9th floor, No.220, Dongting Road, TEDA 300457 Tianjin China.
Tel: +86-022-65378415
Email: molly@joysbio.com

Whose Authorized Representative:
Name: Lotus NL B.V.
Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.
E-mail: peter@lotusnl.com

We, the manufacturer, here with declare that the product(s)

Product Name	SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)	**Specification**	20Tests/box (1Test/bag ×20 Bags) , 40 Tests /box (1Test / bag ×40 Bags)
Intended Use	For in vitro qualitative detect of SARS-CoV-2 nucleocapsid antigen in nasal(NS) swab specimens directly from individuals who are suspected of COVID-19 by their healthcare provider within the first 5 days of the onset of the symptoms. This test is only provided for use by clinical laboratories or to healthcare workers for point-of-care testing, and not for at home testing.		
Classification	Others		

Conformity Assessment Route: IVDD98/79/EC Annex III.

Applicable Standards:

ISO 13485:2016	*EN ISO 18113-3:2011*	*EN 13612:2002*
ISO 14971:2019	*EN 13641:2002*	*ISO 23640:2015*
EN ISO 18113-1:2011	*ISO 15223-1:2016*	*EN 62366-1:2015*
EN ISO 18113-2:2011		

CE

We, the manufacturer, here 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.

We agree to develop,implement and maintain a documented post-production monitoring process.

Name of General Manager	王森
Signature	
Date	2020-06-05
Place	Tianjin, China
Seal (Manufacturer)	

EU Registrierung „In Vitro Diagnostic Products“

CIBG
Ministry of Health, wellbeing and sports

> Return address PO Box 16114 2500 BC The Hague

Lotus NL B.V.
Attn. Mr. X. Wei
Koningin Julianaplein 10
2595 AA The Hague

Farmatec
Visiting address:
Hoftoren
Rijnstraat 50
2515 XP The Hague
T 070 340 6161

http//hulpmiddelen.farmatec.nl

Information about:
M.P. Meijer - Michiels

Medische_hulpmiddelen@minvws.nl
registration number:
CIBG-20204011

Attachments

Date of Application
Aug 13, 2020

Correspondence should only be addressed to the return address, stating the date and reference of this letter.

Date : Aug 18, 2020
Subject : Notification In-vitro diagnostics

Dear Mr. Wei
I hereby acknowledge receipt on 29 April 2020 of the Article 4. 1st paragraph of the Dutch Decree in vitro diagnostics (BIVD) that company name JOYSBIO (Tianjin) Biotechnology Co., Ltd with European authorized Lotus NL B.V. market the product below as an in vitro diagnostic product on the European market.

The product is registered as an in vitro diagnostic under number:

SARS-CoV-2 IgG/Neutralizing antibody Rapid Test Kit(Colloidal Gold) ,
SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold),
Immunochromatography analyzer (no brand name) (NL-CA002-2020-53008)

Tuberculosis Antibody Test Kit (Colloidal Gold) ,
Mycoplasma Pneumonia IgM Antibody Test Kit (Colloidal Gold),
Treponema Pallidum Antibody Test Kit (Colloidal Gold),
Morphine/Methamphetamine/Ketamine Test Kit (Colloidal Gold)
(no brand name) (NL-CA002-2020-53009)

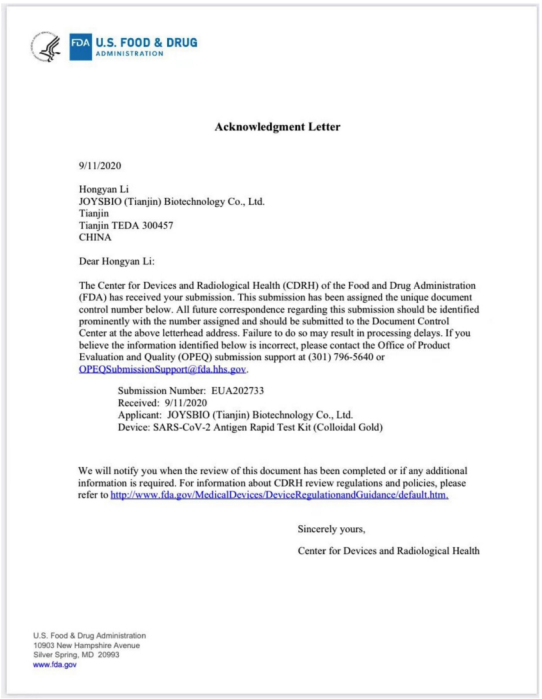
It means that you have fulfilled your obligation under Article 4 of the BIVD.

In all further correspondence regarding the above-mentioned product, I request that you state this number. No further rights can be derived from this number, it only serves to facilitate the administrative notification.

The registration of in vitro diagnostics as a medical device under the Classification Criteria (Annex II) to Directive 98/79/EC on medical devices for in vitro diagnostics is subject to possible revisions of European regulations on the classification of medical devices and to advancing scientific understanding (see Article 10 (1) of Directive 98/79/EC).

Page 1 of 2

FDA Einreichung



FDA U.S. FOOD & DRUG ADMINISTRATION

Acknowledgment Letter

9/11/2020

Hongyan Li
JOYSBIO (Tianjin) Biotechnology Co., Ltd.
Tianjin
Tianjin TEDA 300457
CHINA

Dear Hongyan Li:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the unique document control number below. All future correspondence regarding this submission should be identified prominently with the number assigned and should be submitted to the Document Control Center at the above letterhead address. Failure to do so may result in processing delays. If you believe the information identified below is incorrect, please contact the Office of Product Evaluation and Quality (OPEQ) submission support at (301) 796-5640 or OPEQSubmissionSupport@fda.hhs.gov.

Submission Number: EUA202733
Received: 9/11/2020
Applicant: JOYSBIO (Tianjin) Biotechnology Co., Ltd.
Device: SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)

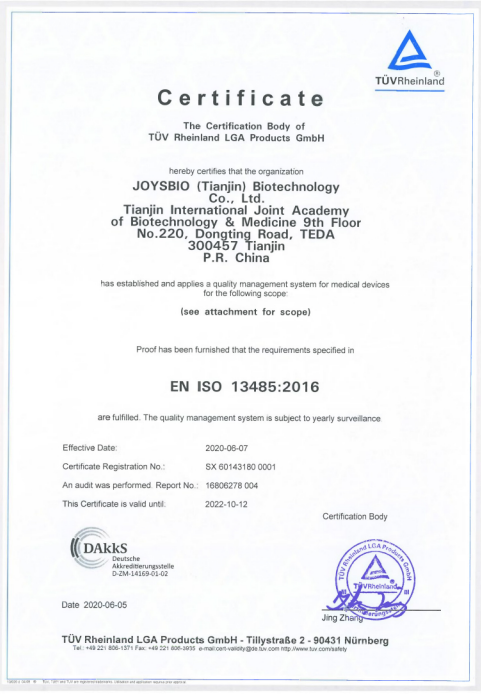
We will notify you when the review of this document has been completed or if any additional information is required. For information about CDRH review regulations and policies, please refer to http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm.

Sincerely yours,

Center for Devices and Radiological Health

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

EN ISO 13485: 2016 Qualitätsnachweis



TÜVRheinland

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

**JOYSBIO (Tianjin) Biotechnology Co., Ltd.
Tianjin International Joint Academy of Biotechnology & Medicine 9th Floor
No.220, Dongting Road, TEDA
300457 Tianjin
P.R. China**

has established and applies a quality management system for medical devices for the following scope:

(see attachment for scope)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2020-06-07
Certificate Registration No.: SX 60143180 0001
An audit was performed. Report No.: 16806278 004
This Certificate is valid until: 2022-10-12

Certification Body

DAkkS
Deutsche Akkreditierungsstelle
D-ZM-14169-01-02

Date 2020-06-05

Jing Zhang

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel: +49 221 806-1371 Fax: +49 221 806-3935 e-mail:cert-validity@de.tuv.com http://www.tuv.com/safety

ZERTIFIKATE / LISTUNGEN

WHO Prequalification

World Health Organization

20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – TEL CENTRAL +41 22 791 2111 – FAX CENTRAL +41 22 791 3111 – WWW.WHO.INT

Prequalification Unit Inspection services
WHO DESK ASSESSMENT REPORT
Emergency Use Listing (EUL)
Review of Quality Management System Documentation

Part 1	**General information**
Company information	
Name of manufacturer	Joysbio (Tianjin) Biotechnology Co., Ltd
Corporate address of manufacturer	Tianjin International Joint Academy Biotechnology & Medicine 9th Floor, No. 220, Dongting Road, TEDA 300457 Tianjin, China
Contact person	Ms Yang Man Director Registration Department Email: molly@joysbio.com Tel: +86-13821759311
Manufacturing site(s) under assessment	
Address of manufacturing site if different from that given above	Same as above
Desk assessment details	
Date of review	18-23 November 2020
EUL number(s)	EUL 0582-223-00
Inspector(s)	Conrad Mark
Products covered by this desk assessment	SARSV-2 Antigen Rapid Test Kit (Colloidal Gold)
List of documents submitted	WHO-EUL Quality System Information 312 pages
Any documents missing?	

Abbreviations	**Meaning**
NC	Non-conformity
QC	Quality control
QMS	Quality management system

Part 2	**Summary of the assessment of supporting documentation**

1. Certification and audit reports:
ISO 13485:2016 certificate number SX 60143180 0001 was provided.

Organization:F
JOYSBIO (Tianjin) Biotechnology CO., Ltd.

WHO Prequalification

World Health Organization

20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – TEL CENTRAL +41 22 791 2111 – FAX CENTRAL +41 22 791 3111 – WWW.WHO.INT

Tel. direct: +41 22 791 47 61
Fax direct: +41 22 791 47 30
Email: prequalinspection@who.int
In reply please refer to: P5-447-3/KR/SL/1

Your reference:

Ms Yang Man
Joysbio (Tianjin) Biotechnology Co. Ltd
Tianjin International Joint Academy of Biotechnology & Medicine
9th floor, No. 220 Dongting Road
TEDA 300457, Tianjin
République Populaire de Chine

24 November 2020

Dear Ms Man,

OUTCOME OF DESK ASSESSMENT
EUL Emergency Use Listing
WHO Prequalification Unit – Inspection Services
Joysbio (Tianjin) Biotechnology Co. Ltd

Thank you for your email correspondence dated 12 October 2020 and the documents that were sent to the WHO PQT: Inspections Team for the Emergency Use Listing of SARS-CoV-2 (EUL) desk assessment of the Quality Management System of Joysbio (Tianjin) Biotechnology Co. Ltd. Kindly be advised that your application for a desk assessment was reviewed as described in the desk assessment report (enclosed). These related to the site, indicated as:

Name: Joysbio (Tianjin) Biotechnology Co. Ltd
Address: Tianjin International Joint Academy of Biotechnology & Medicine, 9th floor, No. 220 Dongting Road, TEDA 300457, Tianjin, China

The documents submitted for the desk assessment were found to be satisfactory and are considered to constitute adequate evidence of compliance with ISO 13485 and the requirements described in the "*Instructions and requirements for Emergency Use Listing (EUL) submission: In vitro diagnostics detecting SARS-CoV-2 nucleic acid and rapid diagnostics tests detecting SARS-CoV-2 antigens* (PQDx_ 347 version 4; 09 June 2020)".

Furthermore, this desk assessment allows Prequalification Inspection Team to recommend to the Prequalification Assessment Team that the site may be named as a manufacturing site in the dossier for the following product:

PQT Number	**Product**
EUL 0582-223-00	SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)

Please do not hesitate to send an email to **prequalinspection@who.int** should you require any further information regarding the closure of this inspection.

Yours sincerely,

Dr Joey Gouws
Team Lead, Inspection Services
Prequalification Unit
Regulation and Prequalification Department
Access to Medicines and Health Products Division

Bestätigung der Wirksamkeit bei neuartigen Mutationen

JOYSBIO(Tianjin)Biotechnology Co., Ltd.

Address: Tianjin International Joint Academy of Biotechnology& Medicine 9th floor, No.220, Dongting Road, TEDA 300457 Tianjin China
TEL: 86-22-65378415
Web: en.joysbio.com
E-mail: bd@joysbio.com

To: The Federal Institute for Drugs and Medical Devices
1/20/2020

Letter of Declaration

We, JOYSBIO (Tianjin) Biotechnology Co., Ltd. (hereinafter "JOYSBIO"), with the address of Tianjin International Joint Academy of Biotechnology& Medicine 9th floor No.220, Dongting Road TEDA 300457 Tianjin, China, hereby declare that our product "JOYSBIO SARS-COV-2 Antigen Rapid Test Kit (Colloidal Gold)" is compatible with the new virus strain VUI – 202012/01.

This product is for qualitative detection of SARS-CoV-2 nucleocapsid antigen. We confirm this information is available on the IFU under section [Verwendungszweck], described as "Dieses Produkt wird zum extrakorporalen qualitativen Test der Infektion mit neuartiger Coronavirus-Pneumonie (COVID-19) oder des Proteins aus Nucleocapsid des neuartigen Coronavirus (SARS-CoV-2) ..... ".

If you have any questions or concerns, please feel free to contact us.

Sincerely Yours,

JOYSBIO (Tianjin) Biotechnology Co., Ltd.

JOYSBIO(Tianjin)Biotechnology Co.,Ltd. 正元盛邦(天津)生物科技有限公司 Authorized Signature

BfArM-Listung

Bundesinstitut für Arzneimittel und Medizinprodukte

Antigen-Tests zum direkten Erregernachweis des Coronavirus SAF | Impressum

Liste der Antigen-Tests zum direkten Erregernachweis des Coronavirus SARS-CoV-2.

die Gegenstand des Anspruchs nach § 1 Satz 1 gemäß "Dritte Verordnung zur Änderung der Verordnung zum Anspruch auf bestimmte Testungen für den Nachweis des Vorliegens einer Infektion mit dem Coronavirus SARS-CoV-2 (Coronavirus-Testverordnung – TestV)" sind.

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

Weitere Hinweise zur vom BfArM bereitgestellten Liste sowie zu den der Listung und ggfs. auch Streichung von der Liste zugrundeliegenden Kriterien finden Sie auf unserer Webseite zu Antigentests auf SARS-CoV-2.

gesine | Los | Aktionen | Zurücksetzen

Nach "gesine" suchen

	Hersteller			Deutscher Vertreiber	Europäischer Bevollmächtigter						Sensitivität		Spezifität	
Testkit	Name	Stadt	L...	Name	Name	Stadt	L...	Handelsname des Tests	Testart *	Artikelnr...	%	95%i... Vertr... Inter...	%	95%i... Vertr... Inter...
AT...	BEIJING KEWEI CLINICAL DIAGNOSTIC REAGENT INC.	BEIJING	CN	GESINO GmbH	Lotus NL B.V.	Den Haag	NL	COVID-19 Antigen Rapid Test Kit(Colloidal Gold)		CBG-20205033	96,18	91,91 - 98,24	100,00	98,54 - 100
AT...	Hangzhou Clongene Biotech Co.Ltd.	Hangzhou	CN	GESINO GmbH	Shanghai International Holding Corporation GmbH (Europe)	Hamburg	DE	COVID-19 Antigen Rapid Test Cassette		ICOV5002-100040	91,40	82,5 - 96,0	100,00	98,2 - 100
AT...	Hangzhou Realy Tech Co.,ltd	Hangzhou	DE	GESINO GmbH	Lucia Lebensweit GmbH	Willich	DE	Novel Coronavirus (SARS-CoV-2) Antigen Rapid Test Cassette (Swab)		RX114180	96,17	92,51 - 98,17	99,90	98,96 - 100
AT...	JOYSBIO (Tianjin) Biotechnology CO., LTD.	Tianjin	CN	GESINO GmbH	Lotus NL B.V.	The Hague	NL	SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold) / Test Kit für neuartiges Coronavirus-Antigen (kolloidale Gold-Methode)	POC (ohne Gerät)	COV-AG-20 / G10313	95,10	88,9 - 98,4	100,00	98,6 - 100,0

Gesamt 4

letzte Änderung: 22.01.2021 10:32

* POC = Point of Care