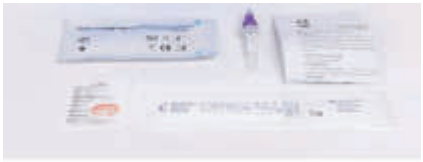
Datenblatt: Joinstar COVID-19 Antigen-Schnelltest (Colloidales Gold)

Der Joinstar COVID-19 Antigen-Schnelltest (Colloidales Gold) eignet sich zum qualitativen Nachweis neuartiger Coronaviren in Proben aus dem vorderen Nasenabstrich.



Technische Daten:

- BfArM-gelistet (Test-ID: AT236/20), 100% erstattungsfähig
- Vom Paul-Ehrlich-Institut evaluiert und geprüft
- Sensitivität: 96,10%
- Spezifität: 98,10%
- Testdurchführung nur durch medizinisches Fachpersonal

Vorteile:

- Kurzer Nasenabstrich (2 - 2,5 cm)
- Leicht zu bedienen
- Testergebnis in 10-15 Minuten
- Alle Testkomponenten sind enthalten
- Ergebnisse zeigen keine Kreuzreaktivität

Bestandteile:

- Abstrichtupfer
- Testkassette
- Probennahmerohr mit Extraktorpuffer
- Tropfer

Bundesinstitut für Arzneimittel und Medizinprodukte GELISTET

Paul-Ehrlich-Institut Bundesinstitut für Impfstoffe und biomedizinische Arzneimittel GEPRÜFT

Haltbarkeit und Lagerung:

Der Test 1 Jahr haltbar, wenn alle Komponenten in dem versiegelten Beutel bleiben und der Test vor Licht geschützt bei 2°C bis 30°C aufbewahrt wird

Hersteller:

Joinstar Biomedical Technology Co., Ltd., China

EC Rep:

Lotus NL B.V., Niederlande

Bestellinformation:

Artikelnummer	Bezeichnung	Verpackungseinheit
	Joinstar COVID-19 Antigen-Schnelltest (Colloidales Gold)	25er Packung

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

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:

tuv-sud.com/ps-cert

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

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

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 (Colloidal Gold)

1Test/Kit,20Tests/Kit, 25Tests/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: 2020.11.02

Zhong Wang

Management Representative

Joinstar Biomedical Technology Co.,Ltd.

Joinstar Biomedical Technology Co.,Ltd.

Version:0.0

CIBG
Ministry of Health, Welfare and Sport

> Return address PO Box 16114 2500 BC The Hague

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

Farmatec
Visiting address:
Court Tower
Rijnstraat 50
2515 XP Den Haag

T 070 340 6161

http://hulpmiddelen.farmatec.n1

Information at:
M.P. Meijer - Michiels

Medische_hulpmiddelen@
minvws.nl

Attachments

Our reference:
CIBG-20204350

Your request
September 5, 2020

Correspondence only to the return address with date indication and the hallmark of this letter.

Date: October 16, 2020
Subject: Registration In vitro Diagnostics

Dear Mr. Wei,

On October 14, 2020 I received your notification pursuant to Article 4, paragraph 1 of the Dutch Decree in vitro diagnostics (BIVD) under the company name Joinstar Biomedical Technology Co., Ltd with European Authorized Lotus NL BV market the product below as an in-vitro diagnostic agent on the European market.

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

COVID-19 Antigen Rapid Test (Colloidal Gold)
(geen merknaam) (NL-CA002-2020-53843)

With this you have fulfilled your obligation on the basis of article 4 BIVD.

I request you in all further correspondence regarding the above product mention this number. No further rights can be attached to this number, It only serves to keep the notification administrative ease.

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

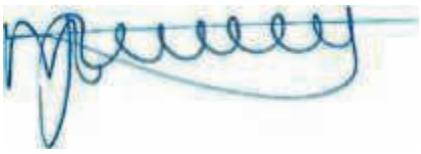
Notification of in vitro diagnostic medical devices implies that the manufacturer, Joinstar Biomedical Technology Co., Ltd has affixed the CE conformity marking to the respective product before placing it on the market in an EU Member State. In this way Lotus NL B.V. guarantees that the in vitro diagnostic meets the essential requirements as included in Annex I to Directive 98/79/EC (and in the corresponding section 1 of the decision)

For the sake of completeness, we would like to point out that an in vitro diagnostic must suffice to the requirements of the BIVD. The BIVD is based on the guidelines for in vitro diagnostics, 98/79/EC. In particular, we draw your attention to the Dutch language requirement such as this applies in the Netherlands, the requirements for keeping the technical documentation and the obligation to have a Post Marketing Surveillance and vigilance system.

Finally, I note that with your notification - the administrative notification as manufacturer - and this letter does not constitute a judgment on the status or qualification of your product: In some cases, the Health and Youth Care Inspectorate (IGJ), charged with supervising compliance with the provisions by or pursuant to the law, take a position on the status of a product, according to fixed case law is ultimately for the national court to determine whether a product falls within the definition of in vitro diagnostic.

The Minister for Medical Care and Sport,
on their behalf,

Department head
Farmatec



Dr. MJ van de Velde