ZERTIFIKAT ■ CERTIFICATE ■ СЕРТИФИКАТ ■ CERTIFICADO ■ CERTIFICAT

RIOMAVIX

CERTIFICATE OF NOTIFICATION

This is to certify that, according to the European Council Directive 98/79/EC, Riomavix S.L. performed all notification duties and responsibilities as the European Authorized Representative:

MANUFACTURER: Shanghai Liangrun Biomedicine Technology Co., Ltd.

ADDRESS: Level 4, Building 1, No. 271, Gang'ao Road, Pilot Free Trade Zone, Shanghai, China

The manufacturer has provided Riomavix S.L. with all the appropriate declaration according to the European Council Directive 98/79/EC including the Declaration of Conformity confirming that its in vitro diagnostic medical device, as stipulated here below, is fulfilling the essential requirements of the European Council Directive 98/79/EC.

IVD Devices: LionRun™ SARS-CoV-2 Antigen Rapid Test Kit

Classification: Others

IVD Devices: Novel coronavirus (SARS-CoV-2) nucleic acid detection kit (LFD method)

Classification: Others

Where the manufacturer affix the CE mark to the device listed they must ensure that all the essential requirements of European Council Directive 98/79/EC are met.

The notification of abovementioned device has been completed by the European Authorized Representative in Spain. The Spain Competent Authority is notified of the manufacture's device and has allocated registration. The registration number is RPS/1858/2020.

Executive Director

RIOMAVIX R RIOMAVIX RIOMAVIX

Issue date: 03 Aug. 2020
Cert. No.: R2020080302

CE

Riomavix S.L.
Calle de Almansa 55, 1D, Madrid 28039 Spain

Confirmation of performance	Klus Apotheke KlusLab

SARS-CoV-2-Antigen Test

With this we would like to confirm, that we have tested and used the above-mentioned chromatographic immunoassay tests (lateral flow immunoassay) with excellent performance, reliability and functionality. The tests are single-use, easy to perform and may be accomplished within a 12-15min timeframe. The tests can detect qualitatively antigens from SARS-CoV-2 swapped from the nasopharynx region of a patient. This might help to identify individuals infected by SARS-CoV-2 in a rapid manner. The test is intended for professional use in a laboratory and Point-of-care environment.

Used batch number:	**X20200601**
Expiry date:	**May 31st, 2021**

MANUFACTURER

Shanghai Liangrun Biomedicine Technology Co., Ltd.
Level 4, Building 1, N° 271 Gang'ao Road, Pilot Free Trade Zone
200131 Shanghai
China

CE MARKING AND REPRESENTATIVE

Riomavix S.L.
Calle de Almansa, 55, 1D
E-28039 Madrid
Spain

This certificate has been issued on behalf of the manufacturer from:

SITE OF CERTIFICATION

Klus-Apotheke AG
Hegibachstr. 102
8032 Zürich
Switzerland
+41 44 381 70 30
☒ GMP Authorisation: 511561-102633629

QUALITY CONTROL

KlusLab
Witikonerstrasse 15
8032 Zürich
Switzerland
+41 44 430 00 28
☒ GMP Authorisation: 511561-102633629

Dr. Johannes Fröhlich
Responsible Person

Zürich, 14/10/2020 J. Fröhlich

Statement of Compliance

This is to state that Technical Documentation (LR-CE-01, Rev A) for Product(s)

Diagnostic Kit for the Quantitative Determination of Human Cysteine Proteinase Inhibitor CST4（ELISA）

(Class: others according to Annex II of the Directive 98/79/EC)

Manufactured by

Shanghai Liang Run Biomedicine Technology Co., Ltd.

Level 4, Building 1, No. 271, Gang'ao Road, Pilot Free Trade Zone, 200131, Shanghai, P.R. China

Has been assessed as meeting the Essential Requirements and relevant provisions of EC Directive 98/79/EEC for in Vitro Diagnostic Medical Device

For SGS-CSTC Standards Technical Services Co., Ltd.
System & Services Certification Division

Reference No: CN/SZH9148
Valid from Nov. 2015 to Nov. 2020
Issue1. Certificate since Nov. 2015

CE

SGS-CSTC Standards Technical Services Co., Ltd. Shanghai Branch

SGS Bldg. 11/F, Building B, No. 900, Yishan Road, Xuhui District, Shanghai, China

SGS

GP4753 Issue 2

SGS

Statement of Compliance

This is to state that Technical Documentation (LR-CE-01, Rev A) for Product(s)

Diagnostic Kit for the Quantitative Determination of Human Cysteine Proteinase Inhibitor CST4（ELISA）

(Class: others according to Annex II of the Directive 98/79/EC)

Manufactured by

Shanghai Liang Run Biomedicine Technology Co., Ltd.

Level 4, Building 1, No. 271, Gang'ao Road, Pilot Free Trade Zone, 200131, Shanghai, P.R. China

Has been assessed as meeting the Essential Requirements and relevant provisions of EC Directive 98/79/EEC for in Vitro Diagnostic Medical Device

For SGS-CSTC Standards Technical Services Co., Ltd.
System & Services Certification Division

Reference No: CN/SZH9148
Valid from Nov. 2015 to Nov. 2020
Issue1, Certificate since Nov. 2015

CE

SGS-CSTC Standards Technical Services Co., Ltd. Shanghai Branch

SGS Bldg. 11/F, Building B, No. 900, Yishan Road, Xuhui District, Shanghai, China

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Shanghai Liang Run Biomedicine Technology Co., Ltd.
Level 4, Building 1
No. 271 Gang'ao Road
Pilot Free Trade Zone
200131 Shanghai
China

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

Design and Development, Manufacture and Distribution of in-vitro diagnostic kits used in the detection of tumor biomarkers with ELISA methods

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:	2019-01-02
Certificate Registration No.:	SX 60128512 0001
An audit was performed. Report No.:	15079254 004
This Certificate is valid until:	2021-04-22

Certification Body

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

Date 2019-01-02

Herbert Zhong

TÜV Rheinland LGA Products GmbH
TÜVRheinland
Zertifizierungsstelle

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
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TÜV Rheinland LGA Products GmbH · 90431 Nürnberg

Shanghai Liang Run Biomedicine
Technology Co., Ltd.
Level 4, Building 1
No. 271 Gang'ao Road
Pilot Free Trade Zone
200131 SHANGHAI
CHINA

Contact

Tel. +49 911 655-5225
Mail service@de.tuv.com

Date January 02, 2019

Application for : **QMS**
Certificate No. : SX 60128512 Sheet 0001
Device : Only for QM-System audit
Test requirement : EN ISO 13485:2016

Dear Madame or Sir,

Enclosed please find the new certificate No. SX 60128512 0001 replacing the previous certificate.

With effective date of the new certificate, the previous certificate (number see new certificate) becomes invalid.

Kind regards

Certification body

Herbert Zhong

Test sample: no, documentation available

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LGA Products GmbH

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