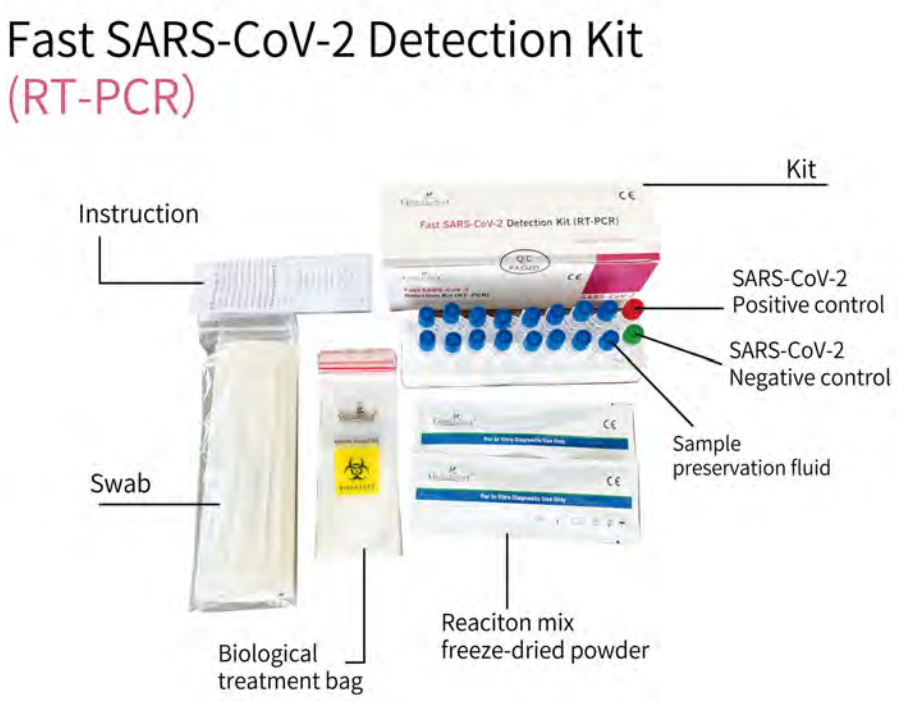
ALPERA

ALPERA GmbH
HermannßPfordte
Gasse 12
3400 Weidling
Austria
Email: office@alpera.at
Web: www.Alpera.at

MAVERICK qPCR Maschine SARS-CoV-2 Test (RT-PCR) Präsentation

Schnelles SARS-CoV-2 Detektionskit (RT-PCR)



Produktparameter:

16 Tests / Box
32 Tests / Box
48 Tests / Box
96 Tests / Box

Verwendungszweck:

Das schnelle SARS-CoV-2 Detection Kit (RT-PCR) ist ein Echtzeit-RT-PCR-Assay für den qualitativen Nachweis von Nukleinsäure aus dem SARS-CoV-2-Virus in nasopharyngealen und vorderen Nasenabstrichproben, die von Personen erhalten wurden, die von ihrem Gesundheitsdienstleister auf COVID-19 verdächtigt wurden.

Das Prinzip der Inspektion:

Dieses Produkt wird durch hocheffiziente Nukleinsäuren freigesetzt und mittels Sondenfluoreszenz-RT-PCR auf Nukleinsäuren getestet. Die Ähnlichkeiten und Unterschiede zwischen den Genen RdRp und N zwischen den Stämmen von Coronaviren zu vergleichen und spezifische Primersonden zu entwerfen. Gleichzeitig wird die humane RNaseP-Gensequenz als Vorlage verwendet, um die Primersonde als internen Kontrollindex zu entwerfen. Darunter die neuartige Coronavirus-SARS-CoV-2-spezifische Sonde RdRp-Gen und das N-Gen markER FAM-Fluoreszenz, intern kontrollierter Genmarker VIC-Fluoreszenz.

Schnelles SARS-CoV-2 Detektionskit (RT-PCR)

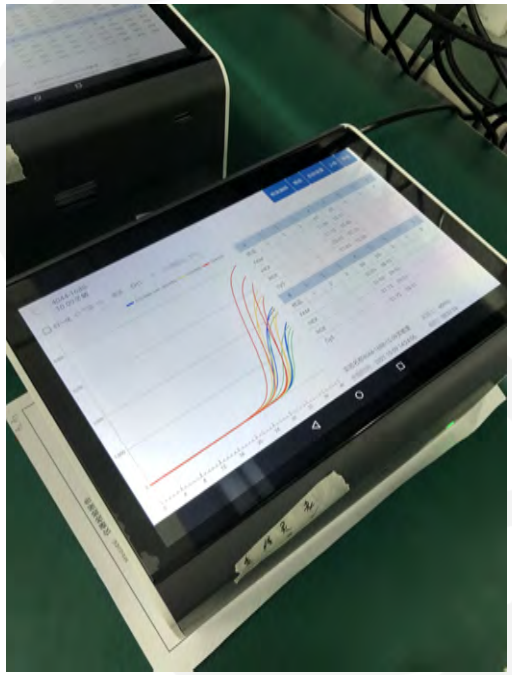
>>Versuchsergebnis:

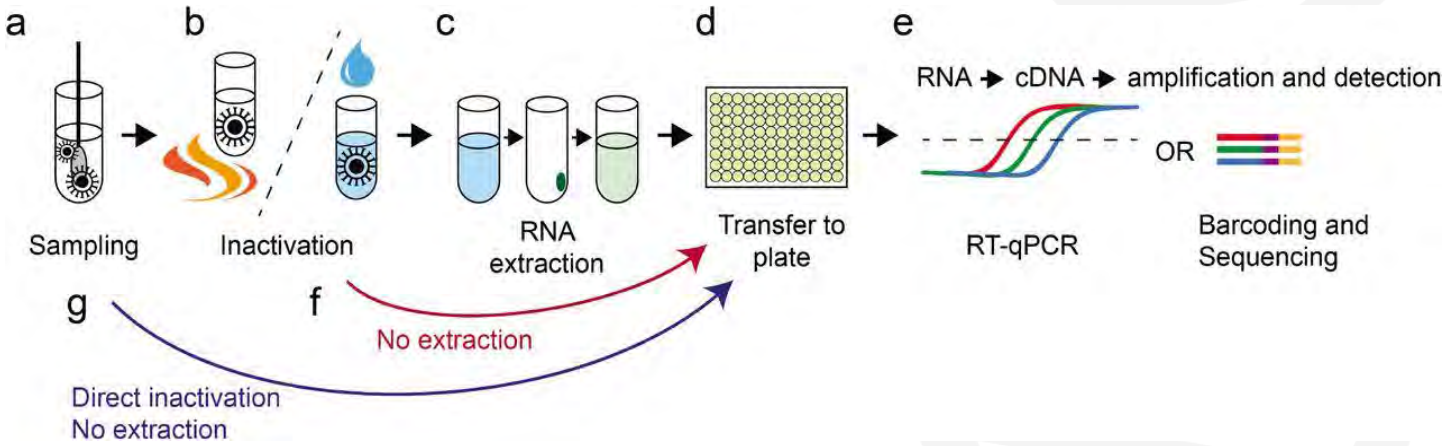
	Ct value		Result Analysis
	FAM	HEX	
1#	>38	>38	SARS-CoV-2 negative
2#	≤38	≤38	SARS-CoV-2 positive
3#	≤38	>38	Re-test: If Channel FAM is still ≤ 38, report as SARS-CoV-2 positive.
4#	>38	≤38	Re-test: If Channel HEX/VIC/JOE is still ≤38, report as SARS-CoV-2 positive.

>>Produkteigenschaften:

Bequem Transport	Gefriergetrockneter Regent für einfacheren Transport ohne Kühlkette (2 - 8 C)
Einfach zu bedienen	Einfache Bedienung mit extraktionsfreien Testverfahren
Schnelles Ergebnis	Testergebnis generiert in 40 Minuten
Genau	Erkennungsgrenze: 1000 Kopien/mlEmpfindlichkeit (PPA): 100% Spezifität (NPA): 100% Gesamtprozentuale Vereinbarung (OPA):100%

>> Das PCR-Instrument und die Schritte:





Zertifizierung

- CE Zertifizierung
- ISO Zertifizierung
- CE. Konformitätserklärung
- CE Zertifikat des Instruments und Prüfbericht

CE certification

CIBG
Ministerie van Volksgezondheid, Welzijn en Sport

Formatec:

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

Datum: 25 oktober 2021
Betreft: aanmelding In-vitro diagnostica

Geachte heer Wei,

Op 14 oktober 2021 ontving ik uw notificatie krachtens artikel 4, eerste lid van het Nederlandse Besluit in-vitro diagnostica (BIVD) om onder de bedrijfsnaam Zhejiang Jilong Biotechnology 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 IgM/IgG Rapid Test,
COVID-19 Antigen Rapid Test,
COVID-19 Antigen Rapid Test (Sputum),
COVID-19 Neutralizing Antibody Rapid Test,
COVID-19 Nucleic Acid Detection Kit (LAMP),
Fast SARS-CoV-2 Detection Kit (RT-PCR)
(geen merknaam) (NL-CA002-2021-62717)

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).

Notificatie van in-vitro diagnostische medische hulpmiddelen impliceert dat de fabrikant, Zhejiang Jilong Biotechnology 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.

Let op:
de notificatie van uw IVD Klasse other product vervalt per 26 mei 2022.
Valt uw IVD product onder een hogere risicoklasse (lijst A, B of zelftesten)? Dan mag uw product tot en met uiterlijk 25 mei 2025 op de markt blijven als IVD product.

De Staatssecretaris van Volksgezondheid, Welzijn en Sport,
namens deze,

Afdelingshoofd
Farmatec

Dr. M.J. van de Velde

CIBG
Ministerie van Volksgezondheid, Welzijn en Sport

NOTIS

Lotus NL B.V. | Log out

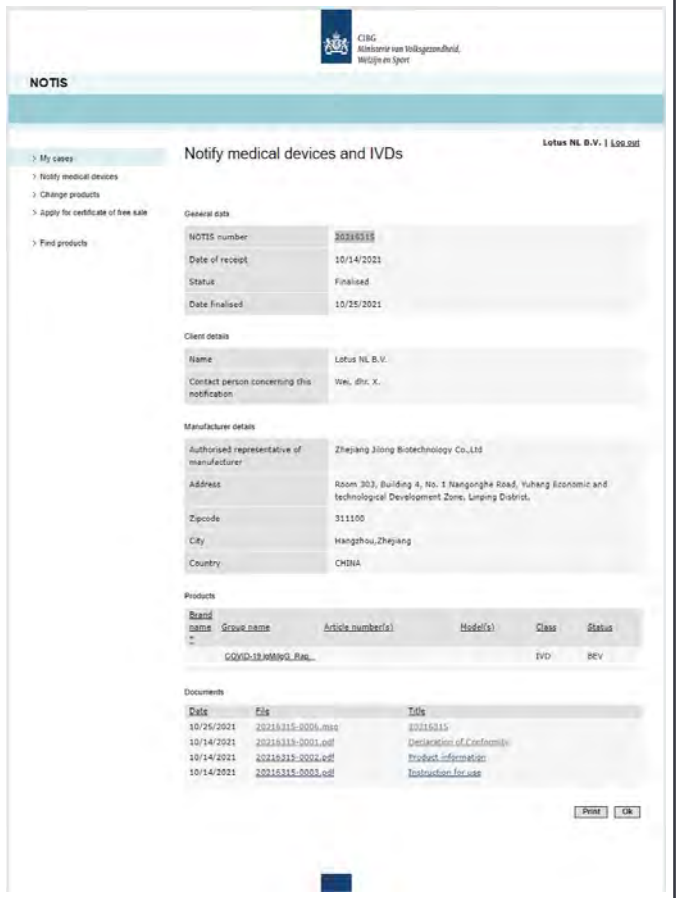
- My cases
- Notify medical devices
- Change products
- Apply for certificate of free sale
- Find products

Notify medical devices and IVDs

Product

Status	BEV - Notification confirmed
Brand name	
Alternative brand name	
Group name	COVID-19 IgM/IgG Rapid Test, COVID-19 Antigen Rapid Test, COVID-19 Antigen Rapid Test (Sputum), COVID-19 Neutralizing Antibody Rapid Test, COVID-19 Nucleic Acid Detection Kit (LAMP), Fast SARS-CoV-2 Detection Kit (RT-PCR)
Article number(s)	
Model(s)	
Class	IVDD Other in-vitro medical devices
Notified body	
Classification rule	
Type	CE-markering
Category/Categories	06 - In vitro diagnostic devices
GMDN Code	
Other nomenclature	NA
Brief description (in English)	A rapid test for the qualitative detection of IgG and IgM antibodies to COVID-19 in human whole blood ,serum or plasma specimens,A Kit test for the quantitative detection of COVID-19 antigen in human whole blood , Nasopharyngeal secretions ,or bronchoalveolar lavage fluid(BALF) specimens,This kit is used for in-vitro semi-quantitative determination of novel coronavirus neutralizing antibodies in human serum, plasma,venous whole blood or peripheral whole blood. The LAMP Test kit is used for the rapid, qualitative detection of the Nucleic Acid from SARS-CoV-2 in human Saliva in vitro for Home-test. Results are for the identification of SARS-CoV-2 N genes.This product is released by high-efficency nucleic acids and is tested for nucleic acids using probe fluorescent RT-PCR.
Brief description (in Dutch)	Een snelle test voor de kwalitatieve detectie van IgG- en IgM-antilichamen tegen COVID-19 in menselijk vol|bloed, serum of plasmamonsters Een kittest voor de kwantitatieve detectie van COVID-19-antigeen in menselijk vol|bloed, nasofaryngeale secreties of bronchoalveolaire spoelvloeistof (BALF) monsters. Deze kit wordt gebruikt voor in vitro sem-kwantitatieve bepaling van nieuwe coronavirusneutraliserende antilichamen in menselijk serum, plasma, veneus vol|bloed of perifeer vol|bloed. De LAMP-testkit wordt gebruikt voor de snelle, kwalitatieve detectie van het nucleinezuur van SARS-CoV-2 in menselijk speeksel in vitro voor Home-test. De resultaten zijn voor de identificatie van SARS-CoV-2 N-genen. Dit product wordt afgegeven door zeer efficiënte nucleinezuren en is getest op nucleinezuren met behulp van probe-fluorescerende RT-PCR.
New product	Yes
CE mark valid through	
Name of manufacturer	Zhejiang Jilong Biotechnology Co.,Ltd

Print Ok



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	20216315
Date of receipt	10/14/2021
Status	Finalised
Date finalised	10/25/2021

Client details

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

Manufacturer details

Authorised representative of manufacturer	Zhejiang Jilong Biotechnology Co.,Ltd
Address	Room 303, Building 4, No. 1 Nangonghe Road, Yuhang Economic and technological Development Zone, Linping District,
Zipcode	311100
City	Hangzhou,Zhejiang
Country	CHINA

Products

Brand name	Group name	Article number(s)	Model(s)	Class	Status
	COVID-19 IgM/IgG Rap			IVD	BEV

Documents

Date	File	Title
10/25/2021	20216315-0006.msg	20216315
10/14/2021	20216315-0001.pdf	Declaration of Conformity
10/14/2021	20216315-0002.pdf	Product information
10/14/2021	20216315-0003.pdf	Instruction for use

Print Ok

CE certification

RIOMAVIX

NOTIFICATION OF REGISTRATION

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: Zhejiang Jilong Biotechnology Co., Ltd.

ADDRESS: Room 303, Building 4, No.1 Nangonghe Road, Yuhang Economic and technological Development Zone, Linping District, 311100 Hangzhou, Zhejiang 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:

COVID-19 Antigen Rapid Test (one step Saliva)

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 notifed of the manufacture's device and has allocated registration. The registration number is RPS/2687/2021

Executive Director

Issue date: 24/Dec/2021
Cert. No.: R20211224-1

RIOMA

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

RIOMAVIX

NOTIFICATION OF REGISTRATION

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: Zhejiang Jilong Biotechnology Co., Ltd.

ADDRESS: Room 303, Building 4, No.1 Nangonghe Road, Yuhang Economic and technological Development Zone, Linping District, 311100 Hangzhou, Zhejiang 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:

Disposable Virus Sampling Kit

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 notifed of the manufacture's device and has allocated registration. The registration number is RPS/2688/2021

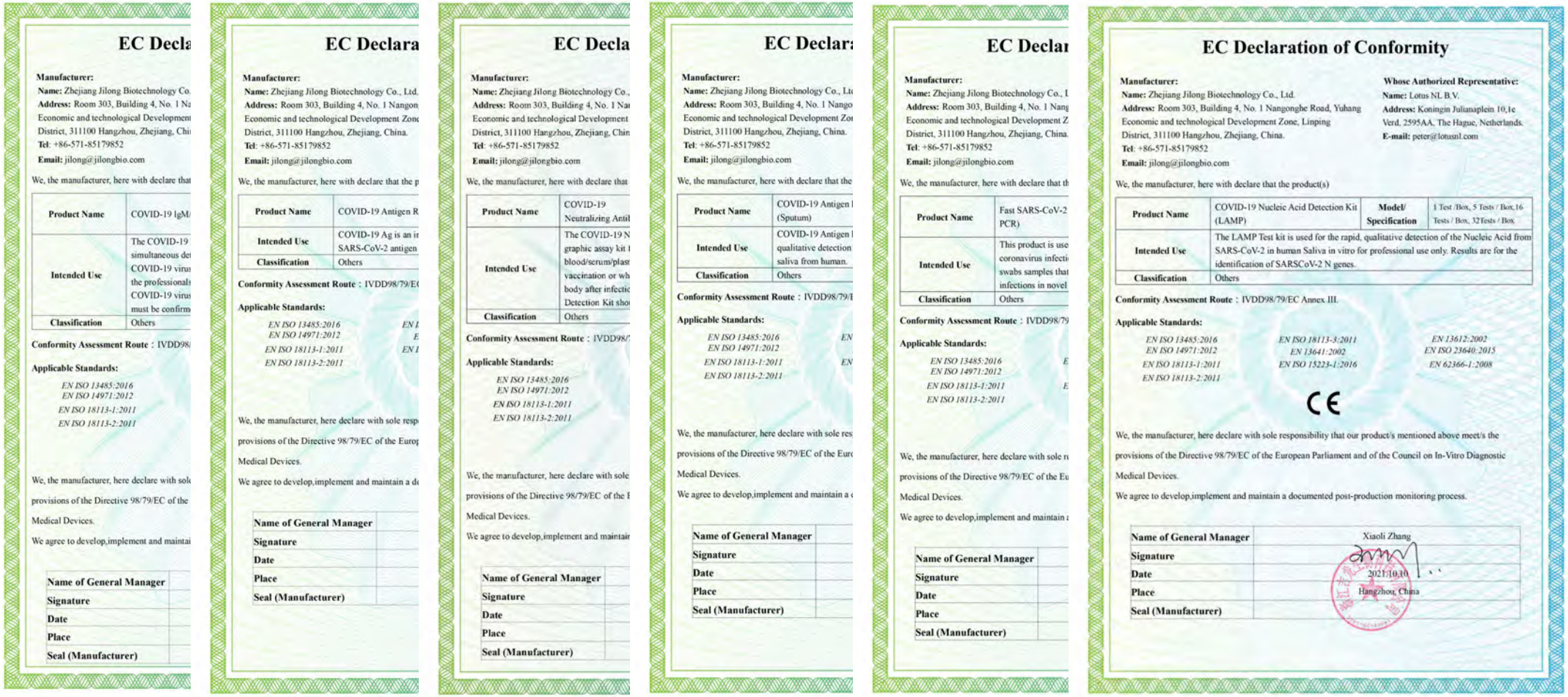
Executive Director

Issue date: 24/Dec/2021
Cert. No.: R20211224-2

RIOMA

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

CE. Declaration of Conformity



EC Declaration of Conformity

Manufacturer:
Name: Zhejiang Jilong Biotechnology Co., Ltd.
Address: Room 303, Building 4, No. 1 Nangonghe Road, Yuhang Economic and technological Development Zone, Linping District, 311100 Hangzhou, Zhejiang, China.
Tel: +86-571-85179852
Email: jilong@jilongbio.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	COVID-19 Nucleic Acid Detection Kit (LAMP)	**Model/ Specification**	1 Test /Box, 5 Tests / Box,16 Tests / Box, 32Tests / Box
Intended Use	The LAMP Test kit is used for the rapid, qualitative detection of the Nucleic Acid from SARS-CoV-2 in human Saliva in vitro for professional use only. Results are for the identification of SARSCoV-2 N genes.		
Classification	Others		

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

Applicable Standards:

EN ISO 13485:2016
EN ISO 14971:2012
EN ISO 18113-1:2011
EN ISO 18113-2:2011
EN ISO 18113-3:2011
EN 13641:2002
EN ISO 15223-1:2016
EN 13612:2002
EN ISO 23640:2015
EN 62366-1:2008

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	Xiaoli Zhang
Signature	
Date	2021.10.10
Place	Hangzhou, China
Seal (Manufacturer)	

CE. Declaration of Conformity

CE Declaration of Conformity CE

Manufacturer:	Zhejiang Jilong Biotechnology Co., Ltd. Room 303, Building 4, No. 1 Nangonghe Road, Yuhang Economic and technological Development Zone, Linping District, 311100 Hangzhou,Zhejiang, China. E-mail: jilong@jilongbio.com
Whose Single Authorized EU-Representative:	Riomavix S.L. Add.: Calle de Almansa 55, 1D, Madrid 28039 Spain E-mail: leis@riomavix.com
Product Name:	COVID-19 Antigen Rapid Test (One Step Saliva)

Classification : **Others of ANNEX II of IVDD**

Conformity Assessment Route: **Annex III**

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

General applicable directives:
In Vitro Diagnostic Medical Devices DIRECTIVE 98/79/EC

Harmonized standards:
EN ISO 13485:2016,EN ISO 15223-1:2016, ISO 14971:2019, EN 13641: 2002, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN 13612: 2002, EN ISO 23640:2015

Signature:
Name: Xiaoli Zhang
Title: General manager
Place/Date: China,2021-12-31

EC Declaration of Conformity **No.JL-DoC-002,A/0**
Page 1/1

CE EC Declaration of Conformity CE

Manufacturer:	Zhejiang Jilong Biotechnology Co., Ltd. Room 303, Building 4, No. 1 Nangonghe Road, Yuhang Economic and technological Development Zone, Linping District, 311100 Hangzhou,Zhejiang, China. E-mail: jilong@jilongbio.com
Whose Single Authorized EU-Representative:	Riomavix S.L. Add.: Calle de Almansa 55, 1D, Madrid 28039 Spain E-mail: leis@riomavix.com
Product Name:	Disposable Virus Sampling Kit

Classification : **Others of ANNEX II of IVDD**

Conformity Assessment Route: **Annex III**

We herewith under our sole responsibility declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

General applicable directives:
In Vitro Diagnostic Medical Devices DIRECTIVE 98/79/EC

Harmonized standards:
EN ISO 13485:2016,EN ISO 15223-1:2016, ISO 14971:2019, EN 13641: 2002, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN 13612: 2002, EN ISO 23640:2015

Signature:
Name: Xiaoli Zhang
Title: General manager
Place/Date: China, Dec.31,2021

EC Declaration of Conformity **No. JL-DoC-001,A/0**
Page 1/1

ISO **9001 &** ISO 13485

QUALITY MANAGEMENT SYSTEM CERTIFICATE

CERTIFICATE: ZWJM21Q10274R0S

Hereby Certify

Zhejiang Jilong Biotechnology Co., Ltd.

Uniform Social Credit Code: 91330110MA28TGPD59

Registration Address: Room 303, Building 4, No. 1 Nangonghe Road, Yuhang Economic and technological Development Zone, Linping District, 311100 Hangzhou , Zhejiang China.

Audit Address: Building 4, No. 1 Nangonghe Road, Yuhang Economic and technological Development Zone, Linping District, 311100 Hangzhou , Zhejiang China.

QMS conforms to:

GB/T19001-2016/ISO9001:2015

Scope of Certificate:

Design,development,production and sales of Novel Coronavirus Testing Kit(Novel Coronavirus antigen and related antibody testing kit by lateral flow assay,Novel Coronavirus nucleic acid detection kit by RT-PCR, and Novel Coronavirus nucleic acid detection kit by LAMP) (export only)

Issue Certificate Date: 2021-11-05 Registration Expiration Date:2024-11-04

Before the expiration date 2022-11-02, should have supervision or new certification audit.

Failed to pass the audit, this certificate is invalid.

This certificate information can be checked at official website of CNCA(http:// www.cnca.gov.cn)

Issued by:

Jiangsu Zhongwang Jiamei Certification Center Co., Ltd.

Room 522, Building 5, 2588 Wuzhong Avenue, Wuzhong Economic Development Zone, Suzhou, Jiangsu, China

www.jszwjm.com

MEDICAL DEVICE QUALITY MANAGEMENT SYSTEM CERTIFICATE

CERTIFICATE: ZWJM21Q10273R0S

Hereby Certify

Zhejiang Jilong Biotechnology Co., Ltd.

Uniform Social Credit Code: 91330110MA28TGPD59

Registration Address: Room 303, Building 4, No. 1 Nangonghe Road, Yuhang Economic and technological Development Zone, Linping District, 311100 Hangzhou , Zhejiang China.

Audit Address: Building 4, No. 1 Nangonghe Road, Yuhang Economic and technological Development Zone, Linping District, 311100 Hangzhou , Zhejiang China.

Medical Device QMS conforms to:

ISO13485:2016

Scope of Certificate:

Design,development,production and sales of Novel Coronavirus Testing Kit(Novel Coronavirus antigen and related antibody testing kit by lateral flow assay,Novel Coronavirus nucleic acid detection kit by RT-PCR, and Novel Coronavirus nucleic acid detection kit by LAMP) (export only)

Issue Certificate Date: 2021-11-05 Registration Expiration Date:2024-11-04

Before the expiration date 2022-11-02, should have supervision or new certification audit.

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Issued by:

Jiangsu Zhongwang Jiamei Certification Center Co., Ltd.

Room 522, Building 5, 2588 Wuzhong Avenue, Wuzhong Economic Development Zone, Suzhou, Jiangsu, China

www.jszwjm.com

Micro Dry Bath Constant Temperature Heater CE and Test Report

HUAXUN detection

Report No.: HX211003016475
Page : 1 of 38

LVD Test Report

Application No.	:	HX211003016475
Applicant	:	Zhejiang Jilong Biotechnology Co., Ltd
Equipment Under Test (EUT)		
EUT Name	:	Micro Dry Bath Constant Temperature Heater
Model No.	:	YQ-5001-32
Serial No.	:	See Page 2
Trademark	:	Globalselect
Receipt Date	:	2021-10-28
Test Date	:	2021-10-28 to 2021-11-05
Issue Date	:	2021-11-05
Standards	:	EN 60335-1: 2012 + A14: 2019
Conclusions	:	Complied

This report shows that the product technically complies with the Council LVD Directive 2014/35/EU requirements.

Test/Witness Engineer : Tidy Zhang

Approved & Authorized : Anthony Wang

CE

This test report is valid for above tested sample only and shall not be reproduced in part without written approval of the laboratory.

HUAXUN detection

CERTIFICATE OF CONFORMITY

No.	:	HX211003016474
Applicant	:	ZHEJIANG JILONG BIOTECHNOLOGY CO., LTD
Address	:	Room 303, Building 4, No. 1 Nangonghe Road, Yuhang Economic and technological Development Zone, Linping District, 311100 Hangzhou , Zhejiang China.
Manufacturer	:	ZHEJIANG JILONG BIOTECHNOLOGY CO., LTD
Address	:	Room 303, Building 4, No. 1 Nangonghe Road, Yuhang Economic and technological Development Zone, Linping District, 311100 Hangzhou , Zhejiang China.
Product	:	Micro Dry Bath Constant Temperature Heater
Model(s)	:	YQ-5001-32, YQ-5001-1,YQ-5001-4, YQ-5001-16, YQ-5001-96
Trademark	:	Globalselect
Test Standard(s)	:	EN IEC 55014-1: 2021; EN IEC 61000-3-2: 2019/A1: 2021; EN 61000-3-3:2013/A1:2019; EN IEC 55014-2: 2021.

The EUT described above has been tested by us with the listed standards and found in compliance with the Council EMC Directive 2014/30/EU. It is possible to use CE marking to demonstrate the compliance with the EMC Directive.

The certificate applies to the tested sample above mentioned only and shall not imply an assessment of the whole production. It is only valid in connection with the test report number: HX211003016474.

CE

Tidy Zhang

Nov. 05, 2021

HUAXUN detection

Report No.: HX211003016474
Page : 1 of 46

EMC Test Report

Application No.	:	HX211003016474
Applicant	:	Zhejiang Jilong Biotechnology Co., Ltd
Equipment Under Test (EUT)		
EUT Name	:	Micro Dry Bath Constant Temperature Heater
Model No.	:	YQ-5001-32
Serial No.	:	See Page 4
Trademark	:	Globalselect
Receipt Date	:	2021-10-28
Test Date	:	2021-10-28 to 2021-11-05
Issue Date	:	2021-11-05
Standards	:	EN IEC 55014-1: 2021; EN IEC 61000-3-2: 2019/A1: 2021; EN 61000-3-3:2013/A1:2019; EN IEC 55014-2: 2021.
Conclusions	:	PASS

In the configuration tested, the EUT complied with the standards specified above. The EUT technically complies with the 2014/30/EU directive requirements.

Test/Witness Engineer : Tidy Zhang

Approved & Authorized : Anthony Wang

CE

This report details the results of the testing carried out on one sample. The results contained in this test report do not relate to other samples of the same product. The manufacturer should ensure that all products in series production are in conformity with the product sample detailed in the report.

HUAXUN detection

CERTIFICATE OF CONFORMITY

No.	:	HX211003016475
Applicant	:	ZHEJIANG JILONG BIOTECHNOLOGY CO., LTD
Address	:	Room 303, Building 4, No. 1 Nangonghe Road, Yuhang Economic and technological Development Zone, Linping District, 311100 Hangzhou , Zhejiang China.
Manufacturer	:	ZHEJIANG JILONG BIOTECHNOLOGY CO., LTD
Address	:	Room 303, Building 4, No. 1 Nangonghe Road, Yuhang Economic and technological Development Zone, Linping District, 311100 Hangzhou , Zhejiang China.
Product	:	Micro Dry Bath Constant Temperature Heater
Model(s)	:	YQ-5001-32, YQ-5001-1,YQ-5001-4, YQ-5001-16, YQ-5001-96
Trademark	:	Globalselect
Test Standard(s)	:	EN 60335-1: 2012 + A14: 2019.

The EUT described above has been tested by us with the listed standards and found in compliance with the Council LVD Directive 2014/35/EU, It is possible to use CE marking to demonstrate the compliance with the LVD Directives.

The certificate applies to the tested sample above mentioned only and shall not imply an assessment of the whole production. It is only valid in connection with the test report number: HX211003016475.

CE

Tidy Zhang

Nov. 05, 2021

Global Distribution

China

Italy

The UK

Spain

India

New Zealand

Hungary

Indonesia

Egypt

Poland

Bulgaria

Belgium

Austria

Pakistan

Ethiopia

The United Arab Emirates

Malaysia

France

Kazakhstan

Czech Republic

Romania

The Netherlands

Germany

The Philippines

Turkey

Venezuela

Japan

Saudi Arabia

Thailand

Slovenia

Salvador

Sudan


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Global select®
ALPERA GmbH
HermannßPfordte
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