Guantes de Nitrilo

Roentgen

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MODO DE USO:

Cómo ponerse los guantes:

1. Seleccione los guantes del tamaño adecuado y verifique el período de validez.
2. Quítese las joyas y cualquier artículo alrededor de las manos y lávese o desinfecte antes de usar guantes.
3. Con su mano no dominante, levante el guante pellizcando el interior y el exterior del puño.

Tenga cuidado de tocar la menor parte posible de la parte exterior de los guantes. Deje que el guante cuelgue con los dedos apuntando hacia abajo. Desliza con cuidado tu mano dominante en el guante. No ajuste la posición del guante en su mano hasta que el otro guante esté puesto.

4. Asegúrese de que no haya rasgaduras ni rasgaduras en los guantes. Si ve alguno, quítese los guantes y comience de nuevo.

Cómo quitarse los guantes:

1. Apriete el puño de los guantes con los dedos enguantados y despegue hacia abajo desde la muñeca, girando el guante al revés.
2. Sostenga el guante de adentro hacia afuera con la mano enguantada y, con la mano sin guante, deslice el dedo / separe la muñeca del guante restante, teniendo cuidado de no tocar la parte exterior del guante.
3. Nuevamente, pele hacia abajo, alejándose de la muñeca, volviendo el guante al revés.
4. Continúe tirando del guante hacia abajo y sobre el guante de adentro hacia afuera que sostiene en su mano enguantada.
5. Esto asegurará que ambos guantes estén al revés, un guante envuelto dentro del otro, sin contaminantes en las manos desnudas.

Show Room México

Importaciones Dentales Roentgen SA de CV
Camino San Juan de Aragón 856-D, Col. Casas Alemán,
CP 07580 CDMX México
Tels. (55) ***5748-4995***, ***5737-0075*** y ***5767-9365***

US Corporate Offices

Roentgen Dental Supplies LLC
7950 NW 53rd Street, Suite 337, Miami FL 33166
Phone (305) ***749-9799*** Fax (866) ***480-9591***

www.tudepositodental.com *deposito.dental.roentgen* *ventas@tudepositodental.com* *55 3269 8800*

Reporte de Calidad

Guantes de Nitrilo Roentgen

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Número de Revisión
HSA/QR9.28c/10

Propiedades físicas

Superficie	La apariencia de los guantes de nitrilo debe ser limpia y bien formada, y la superficie no debe estar dañada ni manchada.	Conforme	Calificado
Tamaño básico	Después de usar los guantes de nitrilo, debe cubrir las manos del usuario.	Conforme	Calificado
	Longitud del guante de nitrilo: 235 mm	Conforme	Calificado
	Ancho del guante de nitrilo: 112 mm	Conforme	Calificado
	Grosor del guante de nitrilo: 0,117 mm	Conforme	Calificado
Composición y peso gramo	Los guantes de nitrilo deben estar hechos de 95 % de látex de nitrilo, 3,4 % de óxido de zinc, 1,6 % de ácido esteárico.	Conforme	Calificado
	Los guantes de nitrilo deben ser impermeables y sin agujeros.	Conforme	Calificado
	El peso de los guantes de nitrilo está de acuerdo con GB 10213-2006	Conforme	Calificado
Guantes de nitrilo Resistencia a la rotura	Los guantes de nitrilo deben usarse con facilidad.	Conforme	Calificado
	La resistencia a la rotura de cada guante no debe ser inferior a 7,0 N antes y después del envejecimiento	Conforme	Calificado
	El alargamiento de cada guante no debe ser inferior al 500 % antes del envejecimiento	Conforme	Calificado
	El alargamiento de cada guante no debe ser inferior al 400% después del envejecimiento	Conforme	Calificado

Propiedades biológicas

Indicadores microbiológicos (no esterilizante)	Total bacterial colonies ≤ 200 cfu/g.		≤200 ufc/g	Calificado
	Las bacterias coliformes no se pueden detectar.		No detectado	Calificado
	Bacterias piógenas patógenas	No se debe detectar Pseudomonas aeruginosa.	No detectado	Calificado
		No se debe detectar Staphylococcus aureus.	No detectado	Calificado
		No se detectarán cocos hemolíticos.	No detectado	Calificado
	Colonias fúngicas totales≤100ufc/g.		≤100 ufc/g	Calificado
Conclusión	Calificado (Sello)			

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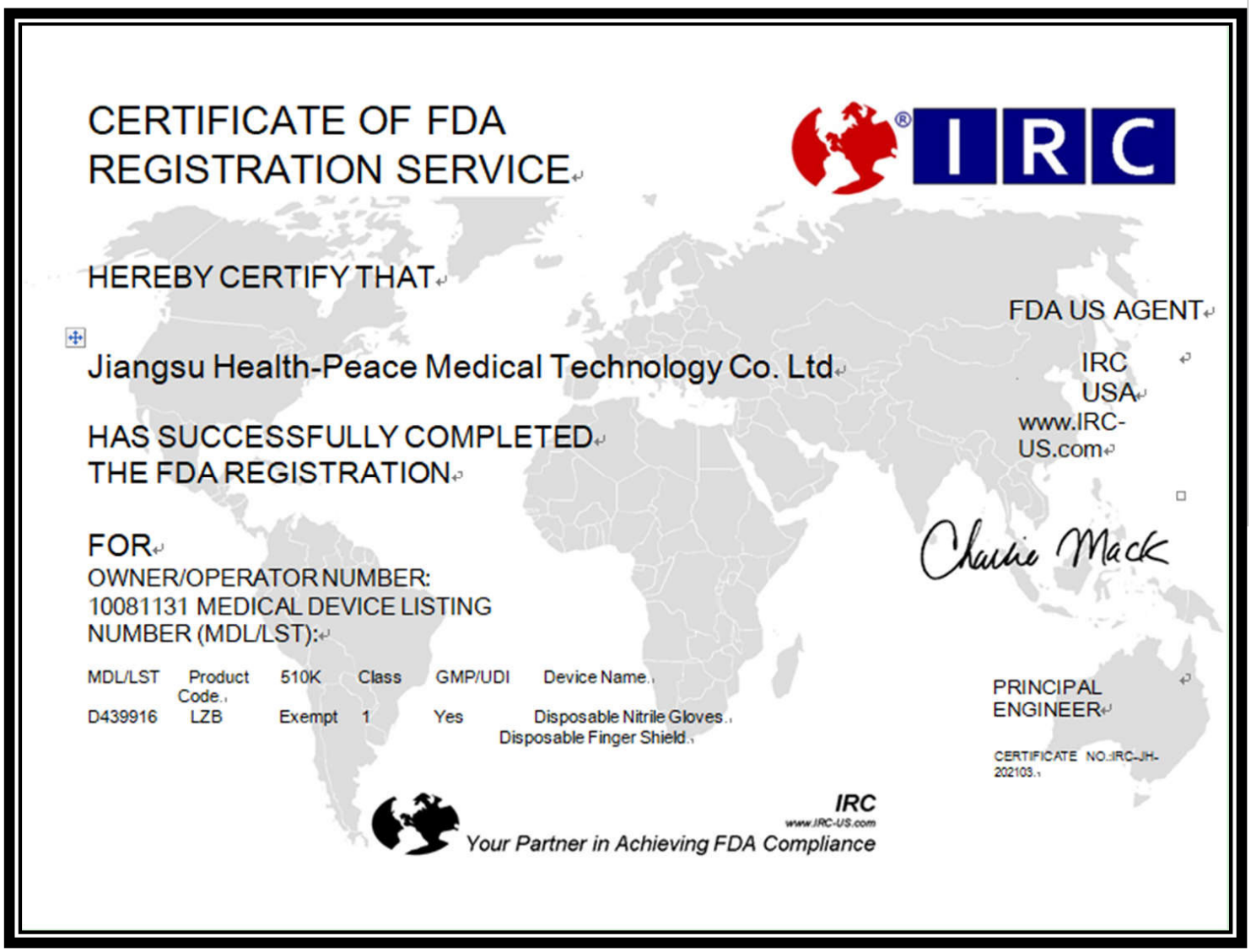

CERTIFICATE OF FDA REGISTRATION SERVICE

IRC

HEREBY CERTIFY THAT

Jiangsu Health-Peace Medical Technology Co. Ltd

HAS SUCCESSFULLY COMPLETED THE FDA REGISTRATION

FOR

OWNER/OPERATOR NUMBER:
10081131 MEDICAL DEVICE LISTING NUMBER (MDL/LST):

MDL/LST	Product Code.	510K	Class	GMP/UDI	Device Name.
D439916	LZB	Exempt	1	Yes	Disposable Nitrile Gloves. Disposable Finger Shield.

FDA US AGENT

IRC
USA
www.IRC-US.com

Charlie Mack

PRINCIPAL ENGINEER

CERTIFICATE NO.:IRC-JH-202103.

IRC
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Your Partner in Achieving FDA Compliance

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KAICHENG CERTIFICATION

Certificate of Registration

Jiangsu Health-Peace Medical Technology Co., Ltd.

ABN: 91320412MA24YLW51T

Registered address:Building 2, No.9, Zijin Road, Zhangpu Town, Kunshang

Production / Business address:No.9, Zijin Road, Zhangpu Town, Kunshan City, Jiangsu Province

Quality Management System

which complies with the requirements of:

GB/T 19001-2016/ISO 9001:2015

The registration covers The sales and production(Except qualification license) of Disposable Nitrile CHeck Gloves（Non-sterilization）

Original Certification: 2021-04-12
Issue/Revised Date: 2021-04-12
Registration No:KC104G7003Q
Expiry Date: 2024-04-11

The certified organization must regularly receive supervision and audit and passed the examination and approval.This certificate will continue to be valid. The qualified label attached to the certificate indicates that the audit has been approved.
Kaicheng Certification Company(CNCA-R-2016-215,Address: Room 602, No. 7, Lane 313, Ningguo Road,Yangpu District, Shanghai) issued this certificate according to the rules of CNCA and the rules of certification of Shanghai Certification Company
The certificate can bo vertified on CNCA's web site at www.cnca.gov.cn.
Certificate valid status can query at www. shkcrz. com

KAICHENG CERTIFICATION
上海开成认证
SHKC

signer:

Shanghai Kaicheng Certification Co., Ltd.

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U.S. FOOD & DRUG ADMINISTRATION

August 17, 2021

Jiangsu Health-Peace Medical Technology Co. Ltd
% Johnson Lui
Consultant
CNMED Consultant
31 Archer St
Upper MT Gravatt, QLD 4122
Australia

Re: K211708
Trade/Device Name: Disposable Medical Nitrile Gloves
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA
Dated: July 30, 2021
Received: August 3, 2021

Dear Johnson Lui:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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AKRON RUBBER DEVELOPMENT LABORATORY, INC.

Testing. Development. Problem Solving.

August 25, 2021

▪TEST REPORT▪

PN 160628

PHARMACEUTICAL SERVICES

Prepared For:

Jiangsu Health-Peace Medical Technology Co., Ltd.
Dongan Youdian Street, Huangli Town, Wujin, Changzhou, Jiangsu
Changzhou, China

Prepared By: Tiffany Heller
Manager, Pharmaceutical Services

Approved By: Ana C Barbur, M.S.
Vice President, Analytical & Chemical Services

Rev 101218

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ZERTIFIKAT ■ CERTIFICATE ■ СЕРТИФИКАТ ■ CERTIFICADO ■ CERTIFICAT

RIOMAVIX

CERTIFICATE OF NOTIFICATION

This is to certify that, according to the Regulation (EU) 2017/745, Riomavix S.L. performed all notification duties and responsibilities as the European Authorized Representative:

MANUFACTURER: Jiangsu Health-Peace Medical Technology Co.,Ltd

ADDRESS: Donga Youdian Street,Huangli Town Wujin,Changzhou,Jiangsu

The manufacturer has provided Riomavix S.L. with all the appropriate declaration according to the European Council Regulation (EU) 2017/745 including the EC Declaration of Conformity confirming that its medical device, as stipulated here below, is fulfilling the essential requirements of the European Council Regulation (EU) 2017/745.

Devices: Disposable Medical PVC gloves(non-sterile)

Classification: I

Where the manufacturer affix the CE mark to the device listed they must ensure that all the essential requirements of European Council Regulation (EU) 2017/745 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/549/2021

Executive Director

Issue date: 19/MAR/2021
Cert. No.: R20210310-3

CE

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

Certificaciones:

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ZERTIFIKAT ■ CERTIFICATE ■ СЕРТИФИКАТ ■ CERTIFICADO ■ CERTIFICAT

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ADDRESS: Donga Youdian Street,Huangli Town Wujin,Changzhou,Jiangsu

The manufacturer has provided Riomavix S.L. with all the appropriate declaration according to the European Council Regulation (EU) 2017/745 including the EC Declaration of Conformity confirming that its medical device, as stipulated here below, is fulfilling the essential requirements of the European Council Regulation (EU) 2017/745.

Devices: Disposable Medical Nitrile gloves(non-sterile)

Classification: I

Where the manufacturer affix the CE mark to the device listed they must ensure that all the essential requirements of European Council Regulation (EU) 2017/745 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/548/2021

Executive Director

Issue date: 19/MAR/2021
Cert. No.: R20210310-2

CE

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