WEHERE
MEDICAL

DISPOSABLE GLOVES

Hangzhou Wehere Medical Technology Co.,Ltd



RM#902,Block A1,Canal Vanke Center,Gongshu District,Hangzhou,310015,China
www.weheremedical.com
www.weheremed.com

DISPOSABLE VINYL GLOVES



- Compliant with food handling requirements
- No latex protein to cause allergy
- DOP or DEHP free
- Made from premium quality PVC
- Higher tensile strength and more tactile sens tivity



SPECIFICATIONS

Sizes	S / M / L / XL	Powder Content	Powder- Free
Glove Length (±10mm)	245	Palm Thickness (±0.2mm)	0.07
Color	Clear, Blue	Tensile Strength(Mpa)	Min.12 before and after aging
Sterile	No	Pinholes(Inspection Level)	AQL 2.5
Elongation(%)	Min. 320	Surface	Smooth
Shelf Life	5 years	Certifications	EN374/EN420

Packing: 100pcs/box, 10boxes/ctn Box Sizes: 240*120*60mm Carton Sizes: 315*258*245mm

WEHERE MEDICAL

DISPOSABLE VINYL EXAM GLOVES



- No latex protein to cause allergy
- DOP or DEHP free
- Made from premium quality PVC
- Higher tensile strength and more tactile sensitivity
- Suitable for medical, healthcare and other industries



SPECIFICATIONS

Sizes	S / M / L / XL	Powder Content	Powder- Free
Glove Length (±10mm)	245	Palm Thickness (±0.2mm)	0.08
Color	Clear	Tensile Strength(Mpa)	Min.12 before and after aging
Sterile	No	Pinholes(Inspection Level)	AQL 1.5
Elongation(%)	Min. 320	Surface	Smooth
Shelf Life	5 years	Certifications	EN455/FDA510K

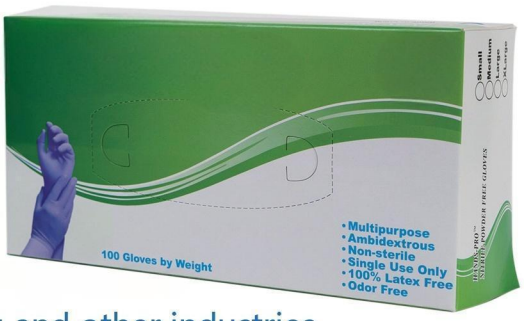
Packing: 100pcs/box, 10boxes/ctn Box Sizes: 240*120*60mm Carton Sizes: 315*258*245mm

WEHERE MEDICAL

DISPOSABLE NITRILE GLOVES



- Compliant with food handling requirements
- Excellent softness and wearing fitness
- Finger textured for a reliable , consistent grip
- Beaded cuff ensures easy donning and prevents roll down
- Latex-free, powder-free and odor-free
- Suitable for electronics, catering, food processing and other industries



SPECIFICATIONS

Sizes	S / M / L / XL	**Powder Content**	Powder- Free
Glove Length (±10mm)	240	**Palm Thickness (±0.2mm)**	0.07
Color	Bule,Black, White	**Tensile Strength(Mpa)**	Min.14 before and after aging
Sterile	No	**Pinholes(Inspection Level)**	AQL 2.5
Elongation(%)	Min. 500	**Surface**	Finger texture
Shelf Life	3 years	**Certifications**	EN374/EN420

Packing: 100pcs/box, 10boxes/ctn Box Sizes: 240*120*60mm Carton Sizes: 315*258*245mm

WEHERE MEDICAL

DISPOSABLE NITRILE EXAM GLOVES



- No latex protein to cause allergy
- Excellent softness and wearing fitness
- Finger textured for a reliable , consistent grip
- Beaded cuff ensures easy donning and prevents roll down
- Suitable for medical , healthcare and other industries.



SPECIFICATIONS

Sizes	S / M / L / XL	**Powder Content**	Powder- Free
Glove Length (±10mm)	240	**Palm Thickness (±0.2mm)**	0.07
Color	Blue,White, Blue-purple	**Tensile Strength(Mpa)**	Min.14 before and after aging
Sterile	No	**Pinholes(Inspection Level)**	AQL 1.5
Elongation(%)	Min. 500	**Surface**	Finger texture
Shelf Life	3 years	**Certifications**	EN455/FDA510(K)

Packing: 100pcs/box, 10boxes/ctn Box Sizes: 240*120*60mm Carton Sizes: 315*258*245mm

WEHERE MEDICAL

DISPOSABLE LATEX GLOVES



- Made from premium natural latex, low level of extractable proteins and chemical residue
- Excellent softness, tactile sensitivity and wearing fitness
- Beaded cuff for easy donning and prevention of roll back
- Textured for improved grip



SPECIFICATIONS

Sizes	S / M / L / XL	**Powder Content**	Powder- Free
Glove Length (±10mm)	245	**Palm Thickness (±0.2mm)**	0.08
Color	White	**Tensile Strength(Mpa)**	Min.16 before aging and Min.14 after aging
Sterile	No	**Pinholes(Inspection Level)**	AQL 1.5
Elongation(%)	Min. 650	**Surface**	Finger texture
Shelf Life	3 years	**Certifications**	EN455

Packing: 100pcs/box, 10boxes/ctn Box Sizes: 240*120*60mm Carton Sizes: 315*258*245mm

WEHERE MEDICAL

DISPOSABLE SNYMAX VINYL EXAM GLOVES



- Easier donning than standard vinyl gloves
- Competitive price performance
- PU coating with no protein, limiting allergy risk
- Increased protection, resisting acid , alkali and oil



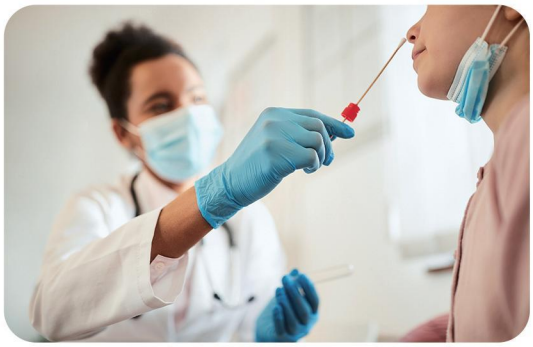
SPECIFICATIONS

Sizes	S / M / L / XL	**Powder Content**	Powder- Free
Glove Length (±10mm)	245	**Palm Thickness (±0.2mm)**	0.08
Color	Yellow, White	**Tensile Strength(Mpa)**	Min.14 before and after aging
Sterile	No	**Pinholes(Inspection Level)**	AQL 1.5
Elongation(%)	Min. 350	**Surface**	Smooth
Shelf Life	5 years	**Certifications**	EN455/EN374/EN420

Packing: 100pcs/box, 10boxes/ctn Box Sizes: 240*120*60mm Carton Sizes: 315*258*245mm

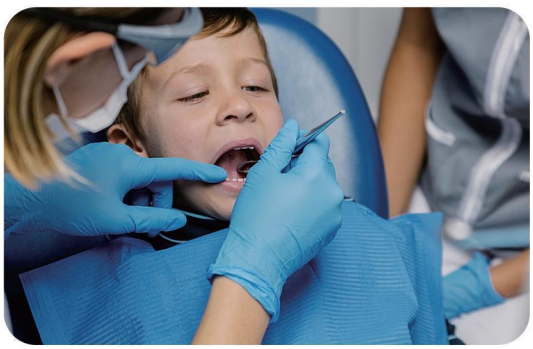
WEHERE MEDICAL

APPLICATION







WEHERE MEDICAL

CERTIFICATES



POSI

CERTIFICATE

This is to certify that the Quality Management System of

JiangXi Handspro Products Solutions Co., Ltd.

Business License Number: 91360426MA361UFL2T
Registered Address: Chuangye Avenue Fenglin New District, De'an County, JiuJiang City, JiangXi Province, 330400 P.R.China
Audit Address: Chuangye Avenue Fenglin New District, De'an County, JiuJiang City, JiangXi Province, 330400 P.R.China

applicable to

Production and Sales of Non-sterile Vinyl Examination Gloves, Latex Examination Gloves and Nitrile Examination Gloves (export only)

has been assessed and registered by POSI against the provisions of

ISO13485:2016

This registration is subject to the company maintaining a quality management system, to the above standard, which will be monitored by POSI.
Please consult the website: www.posicert.com
The certificate information is also available on the CNCA official website: http://cx.cnca.cn.

General Manager

Certificate Registration No: 381210113R0S
Initial issue date: 2021.08.06 Issue date: 2022.10.14 Valid until: 2024.08.05

Shanghai POSI Certification Co., Ltd.
Room 1301-C-7, No.1500, Century Avenue, Pudong New Area, Shanghai ,China.Email:info@posicert.com

ISO13485



POSI

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This is to certify that the Quality Management System of

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Registered Address: Chuangye Avenue Fenglin New District, De'an County, JiuJiang City, JiangXi Province, 330400 P.R.China
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applicable to

Production and Sales of Non-sterile Vinyl Examination Gloves, Latex Examination Gloves and Nitrile Examination Gloves (export only)

has been assessed and registered by POSI against the provisions of

GB/T19001-2016 idt ISO9001:2015

This registration is subject to the company maintaining a quality management system, to the above standard, which will be monitored by POSI.
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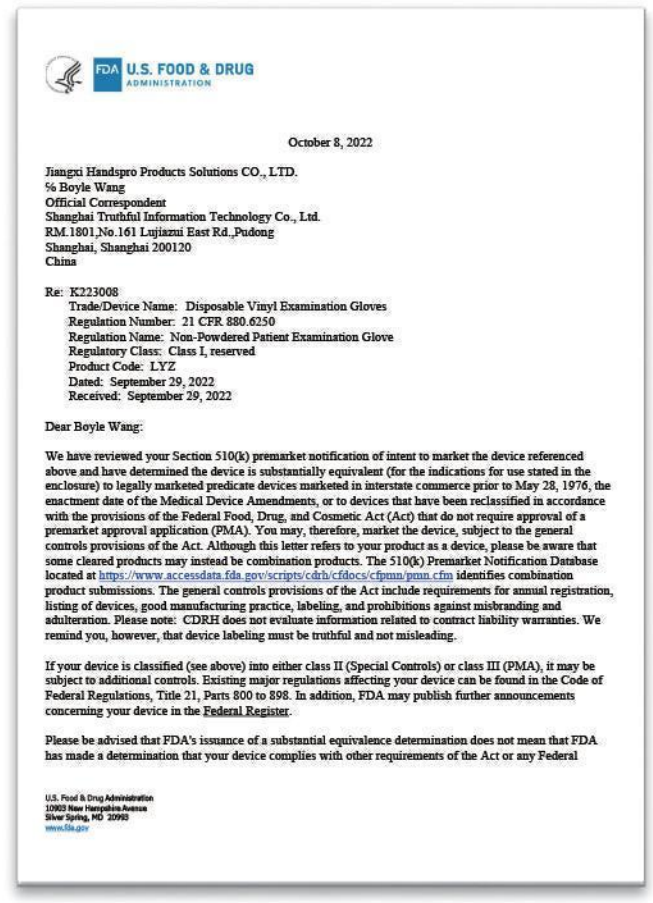
中国认可 国际互认 管理体系 MANAGEMENT SYSTEM CNAS C219-M

General Manager

Certificate Registration No: 38121Q0230R0S
Initial issue date: 2021.08.06 Issue date: 2022.10.14 Valid until: 2024.08.05

Shanghai POSI Certification Co., Ltd.
Room 1301-C-7, No.1500, Century Avenue, Pudong New Area, Shanghai ,China.Email:info@posicert.com

ISO9001



U.S. FOOD & DRUG ADMINISTRATION

October 8, 2022

Jiangxi Handspro Products Solutions CO., LTD.
℅ Boyle Wang
Official Correspondent
Shanghai Truthful Information Technology Co., Ltd
RM.1801,No.161 Lujiazui East Rd.,Pudong
Shanghai, Shanghai 200120
China

Re: K223008
Trade/Device Name: Disposable Vinyl Examination Gloves
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LYZ
Dated: September 29, 2022
Received: September 29, 2022

Dear Boyle Wang:

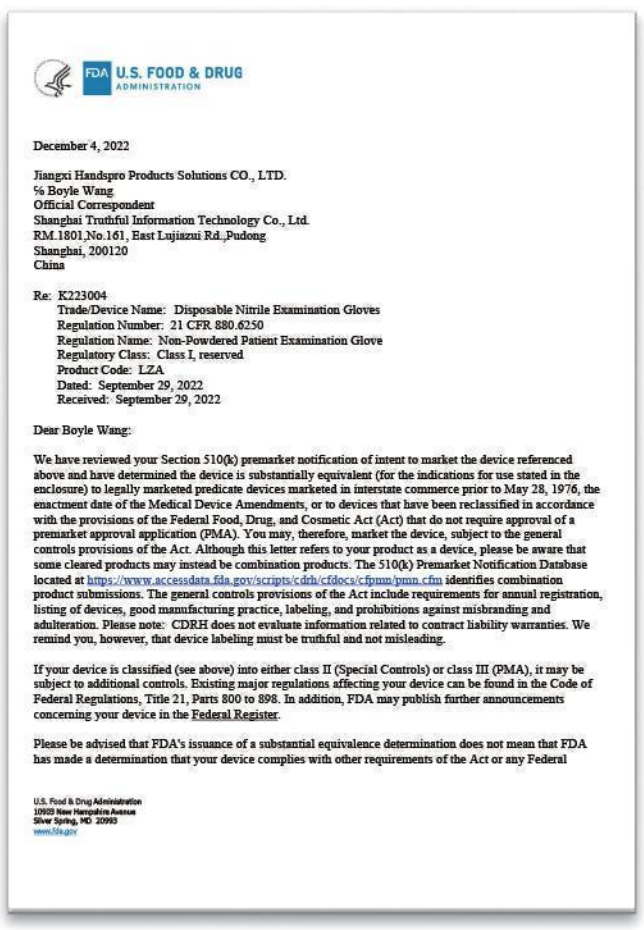
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

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

FDA-VINYL



U.S. FOOD & DRUG ADMINISTRATION

December 4, 2022

Jiangxi Handspro Products Solutions CO., LTD.
℅ Boyle Wang
Official Correspondent
Shanghai Truthful Information Technology Co., Ltd.
RM.1801,No.161, East Lujiazui Rd.,Pudong
Shanghai, 200120
China

Re: K223004
Trade/Device Name: Disposable Nitrile Examination Gloves
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA
Dated: September 29, 2022
Received: September 29, 2022

Dear Boyle Wang:

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.

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

FDA-NITRILE



SATRA TECHNOLOGY

Issued to: Jiangxi Handspro Products Solutions Co., Ltd. Chuangye Road, Fenglin Industrial Zone of De'an Jiujiang Jiangxi China

Notified Body: 2777 SATRA customer number: P22244

EU Type-Examination Certificate

Certificate number: 2777/23160-01/E00-00

This EU Type-Examination Certificate covers the following product group(s) supported by testing to the relevant standards/technical specifications and examination of the technical file documentation. It has been issued Under Module B of Regulation 2016/425 on personal protective equipment. This product group has been shown to satisfy the applicable essential health and safety requirements as a Category III product.

Product reference: HPVN00
Description: Disposable vinyl gloves, powder-free; Colour: Clear; Thickness: ≥0.05mm

Sizes: S:6, M:7, L:8, XL:9

Classification: EN ISO 374-1:2016+A1:2018 Type B	Level	EN ISO 374-4:2019 Degradation %
40% Sodium Hydroxide (K)	6	2.1
30% Hydrogen Peroxide (P)	6	-0.5
37% Formaldehyde (T)	5	2.1

EN ISO 374-5:2016	Level
Protection against Bacteria and Fungi	Pass
Protection against Viruses	Pass

Standards/Technical specifications applied:
EN ISO 21420:2020; EN ISO 374-1:2016+A1:2018; EN ISO 374-5:2016

Technical reports/Approval documents:
SATRA: CHM0339655 2243 1, CHM0339655 2243 2, CHT0338227/2239, CHM0300881/2031/LH, CHT0301009/2032

Signed on behalf of SATRA: Geoff Graham

Date first issued: 14/12/2022
Date of issue: 14/12/2022
Expiry date: 14/12/2027

Page 1 of 2

EU Type-VINYL



SATRA TECHNOLOGY

Issued to: Jiangxi Handspro Products Solutions Co., Ltd. Chuangye Road, Fenglin Industrial Zone of De'an Jiujiang Jiangxi China

Notified Body: 2777 SATRA customer number: P22244

EU Type-Examination Certificate

Certificate number: 2777/23401-01/E00-00

This EU Type-Examination Certificate covers the following product group(s) supported by testing to the relevant standards/technical specifications and examination of the technical file documentation. It has been issued Under Module B of Regulation 2016/425 on personal protective equipment. This product group has been shown to satisfy the applicable essential health and safety requirements as a Category III product.

Product reference: HPNT00
Description: Disposable nitrile gloves, powder free; Colour: Blue

Sizes: 6-9 (S-XL)

Classification: EN ISO 374-1:2016+A1:2018/Type B	Level	EN ISO 374-4:2019 Degradation %
(K) Sodium hydroxide 40%	6	-5.7
(P) Hydrogen peroxide 30%	4	46.8
(T) Formaldehyde 37%	3	48.3

EN ISO 374-5:2016	
Protection against Bacterial and Fungi	Pass
Protection against Viruses	Pass

Standards/Technical specifications applied:
EN ISO 21420:2020; EN ISO 374-1:2016+A1:2018; EN ISO 374-5:2016

Technical reports/Approval documents:
SATRA: CHT0338228/2239; CHM0339653/2243/JL/A; CHM0339653/2243/JL/B; CHM0340959 2247 1

Signed on behalf of SATRA: Geoff Graham

Date first issued: 16/01/2023
Date of issue: 16/01/2023
Expiry date: 16/01/2028

Page 1 of 2

EU Type-NITRILE



DECLARATION OF CONFORMITY
ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative
SUNGO Europe B.V.
Olympisch Stadion 24, 1076DE
Amsterdam, Netherlands
SRN: NL-AR-000000247

Manufacturer
Name: JIANGXI HANDSPRO PRODUCTS SOLUTIONS CO.,LTD
Address: Chuangye Avenue Fenglin New District, De'an County,JiuJing City, JiangXi Province, 330400 P.R.China

Conformity Assessment
Conformity Assessment Procedure
Annex II+III of Regulation (EU) 2017/745

Product Information
Name : Vinyl Examination Gloves
Model : XS S M L XL
GMDN : 60857
Basic UDI-DI : /
Classification: Class I

Applicable Standards
EN ISO 14971:2019
EN ISO 15223-1:2016
EN 1041:2008+A1:2013
ISO 10993-1:2018 EN ISO 10993-5:2009
EN ISO 10993-10:2013 EN 455-1: 2020
EN 455-2: 2015 EN 455-3: 2015

Remark
The declaration of conformity is valid in connection with the release technical document CE- MDR - HK-03-02.
All the supporting documentation is retained at the premises of the manufacturer.
The Declaration of Conformity is exclusively under the sole responsibility of the manufacturer.

Declaration
We herewith declare that the above-mentioned products meet the requirements of Medical Device Regulation (EU) 2017/745 and the applicable standards above.

Signature: Date:
Position:GM Place:

Sungo
Authorized Signature (S)

CE



KINGDOM OF SAUDI ARABIA / المملكة العربية السعودية
Saudi Food & Drug Authority / الهيئة العامة للغذاء والدواء
Operations Sector / قطاع العمليات

VISION 2030 رؤية

Executive Department of registration and licensing / الإدارة التنفيذية للتسجيل والتراخيص

رخصة ممثل قانوني
Authorised Representative License

Issuing Authority: Saudi Food And drug Authority. / جهة الاصدار: الهيئة العامة للغذاء والدواء

Enabling Legislation: Medical Device Interim Regulation supported by Implementing Rule MDS-IR5 on Licensing of Authorised Representatives. / المرجع القانوني: لائحة رقابة الأجهزة والمنتجات الطبية والقواعد الإجرائية (IR5-MDS) الخاصة بترخيص الممثل القانوني.

Licensed Activity: acting on behalf of the MANUFACTURER for the medical device within the KSA according to the AR agreement with the exception to the paragraph pertaining additional tasks and Provisions. / نشاط المنشأة: التمثيل القانوني للمصنع داخل المملكة العربية السعودية وفقاً لاتفاقية التمثيل القانوني فيما عدا المادة الخاصة بالمهام والأحكام الاضافية الاختيارية.

أصدرت رخصة ممثل قانوني لـ شركه مستودع الصفا للأدويه المحدوده

An Authorised Representative license has been issued to: Al Safa Warehouse For Pharmaceuticals Company Ltd

License Number: ARL-2021-MD-1248 / رقم الرخصة بالنظام

MANUFACTURER: Jiangxi Handspro Products Solution CO., LTD / المصنع

Account number for AR: C-1384 / رقم الحساب للممثل القانوني

Issuing date/ Expiry date: 06/7/2021 - 05/7/2023 / تاريخ الاصدار / تاريخ الانتهاء

Issuance Type: New / نوع الاصدار: جديد

Device category(ies): 1. Single-use Devices / أصناف الأجهزة والمنتجات الطبية

Establishments Licensing Department Manager / مدير إدارة ترخيص المنشآت

أ. بدر بن فهد العقيل

Page 1 of 1

SFDA-SAUDI ARABIA



ДЕПАРТАМЕНТ ЛЕКАРСТВЕННЫХ СРЕДСТВ И МЕДИЦИНСКИХ ИЗДЕЛИЙ ПРИ МИНИСТЕРСТВЕ ЗДРАВООХРАНЕНИЯ КЫРГЫЗСКОЙ РЕСПУБЛИКИ

РЕГИСТРАЦИОННОЕ УДОСТОВЕРЕНИЕ
МИ-KG-1566
В соответствии с №224 от 22.11.2021 г

настоящее регистрационное удостоверение выдано:
JIANGXI HANDSPRO PRODUCTS SOLUTIONS CO., LTD, Китай, Chuangye Avenue Fenglin New District, Dean County, JiuJiang City, JiangXi Province, 330400

JIANGXI HANDSPRO PRODUCTS SOLUTIONS CO., LTD, Китай, Chuangye Avenue Fenglin New District, Dean County, JiuJiang City, JiangXi Province, 330400

ОсОО «BMG Pharm» (БиЭмДжи Фарм), Кыргызская Республика, г. Бишкек, ул. Матыева д. №89

в том, что Виниловые медицинские смотровые перчатки, размеры S, M, L.

класс потенциального риска применения медицинского изделия: 1

вид медицинского изделия в соответствии с Глобальной номенклатурой медицинских изделий: Перчатки смотровые/процедурные виниловые, неопудренные зарегистрировано и разрешено к выпуску в обращение на территории Кыргызской Республики.

Перечень комплектующих, принадлежностей и расходных материалов к модификации медицинского изделия приведен в приложении к настоящему регистрационному удостоверению на - л.

Приложение является неотъемлемой частью настоящего регистрационного удостоверения.

Срок действия регистрационного удостоверения: бессрочно

Дата регистрации: «22» ноября 2021 г.

Дата внесения изменений: «___» ________20__ г.

Директор Кагазднев Н.М.

М.П

0001986

Registration Certificate-Kazakhstan

OUR ADVANTAGE

Trusted Supplier

- Direct Manufacturer with competitive price
- Stable quality with ISO13485 & ISO9001 and FDA&CE certification
- Timely Delivery
- High-Quality service with professional team

Make your living healthier and make your life safer



WEHERE MEDICAL