HONGRAY NITRILE GLOVES

MARCH, 2021

NITRILE EXAMINATION GLOVES

Powder Free / Latex Free - FDA 510K

DESCRIPTION

Hongray nitrile gloves are made of synthetic nitrile rubber. Comparing with latex gloves, they have **exceeding features of puncture-resistance, anti-bacterial penetration, chemical-proof and long duration**, providing better protection for users. Currently, the nitrile gloves have been widely used in all major laboratories, research agents, hospitals, clinics, dentists and medical institutions.

- Personal Protection
- Hospital / Dental
- Laboratory / Pharmacy
- Food Contact
- Cleaning
- Beauty / Body Art

FEATURES

Material	Nitrile
Type	Medical Examination
Sterile	No
Powder Free	Yes
Latex Free	Yes
Beaded Cuff	Yes
Ambidextrous	Yes
Colour	Blue
Outer Surface	Finger Textured
Length	230mm
Weight (M)	3.5kg ± 0.2g
Single Wall	Yes
Thickness - Palm	0.08 ± 0.03
Thickness - Fingers	0.10 ± 0.03
Sizes	S | M | L | XL

STANDARDS & ACCREDITATIONS

FDA 510k number k182600
ASTM D6319, ASTM 6978 (Chemo Rated)
EN 455/1/2/3
CE
ISO 9001, ISO 13485

PACKAGING

Box Size	100 Pcs / Box
Case Size	10 Boxes / Case (0.58 kg)

MANUFACTURING

Brand	Hongray
Manufactured	China

鸿锐集团Hongray®

专注手套生产20多年Dedicated to the glove industry for more than 20 years

丁腈手套
NITRILE GLOVES

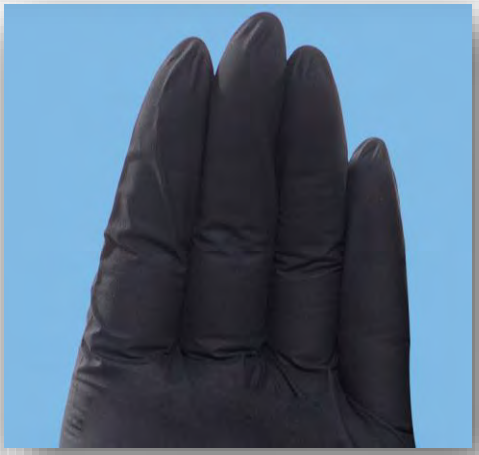
丁腈手套由人工合成的丁腈橡胶制成。相比较乳胶手套，丁腈手套具有更优越的抗穿刺能力、抗细菌渗透能力、抗化学性能力及持久穿戴力。可为使用者提供更安全的防护。目前丁腈手套被欧美各大实验室、研究所、医院、诊所、疗养院等医疗机构广泛使用，得到了用户的高度评价

Nitrile glove is the latest generation of gloves; it's made of synthetic nitrile rubber. Comparing with latex gloves, it has exceeding feature of puncture-resistance, anti-bacteria's penetration, chemical-proof and long duration, providing better protection for users. Currently, the nitrile gloves have been widely used in all major laboratories, research agents, hospitals, clinics, sanitariums and medical institutions, and gained high praises by users.

产品介绍
PRODUCT DESCRIPTION

- 丁腈 普通手套
- Nitrile gloves
- 100%丁腈橡胶，不会产生乳胶对人体的皮肤过敏问题。
- 100% Latex Free, No allergy.
- 更优越的抗穿刺能力、抗细菌渗透能力、抗化学性能力。
- More exceeding feature of puncture-resistance, anti-bacteria’s penetration, chemical-proof.
- 穿戴持久，表面麻面，操作更灵活。柔软，穿戴舒适。
- Durable & Flexible, Surface-textured, Soft feeling, Comfortable donning.
- 锥形袖口更便于穿戴、操作。
- Tapered cuff is easy for donning and operating.
- 无毒、无害、无味。精选配方、工艺先进、手感柔软、舒适防滑、操作灵活。
- Nontoxic, Harmless and Odorless. Choiceness Formula, Advanced Technology, Soft Feel, Comfortable, Skid Resistance and Flexible.
- 适用于医疗检查、牙科、急救、护理等多方面。
- The products are widely used in fields of medical examination, dentistry, first-aid, healthcare, etc.
- 防护性能、物理性能好，优于乳胶手套。
- Better protection and physical property, better than latex gloves.
- 无粉手套采用特殊的无粉工艺，防护更周到。
- Powder free gloves adopt special production technology, offering better protection.
- 本品为一次性使用手套。
- The products are disposable gloves.
- 包装方式：按客户需求
- Packing: According to customers’ requirements
- 品种：无粉、白色、兰色
- Types: Powder Free, White and Blue.
- 型号：XS号 S号 M号 L号 XL号
- Size: XS, S, M, L, XL

产品图片
PRODUCT Pictures



资质证书目录
Qualification Certificate List

- 1、医疗器械质量管理体系EN ISO13485证书、ISO9001质量管理体系证书
- Medical Device Quality Management System EN ISO 13485 Certificate,ISO 9001 Quality Management System Certificate
- 2、国内第一类医疗器械备案凭证
- China Medical Device Filing Certificate for Class I
- 3、FDA注册信息
- FDA Registration Information
- 4、性能测试报告
- PerformanceTest Report
- 5、欧盟医疗器械CE证书（DOC、技术文件评审报告）
- EUMedical DeviceCE Certificate (DOC, Technical Documentation ReviewReport
- 6、产品规格单(EU)
- Product Specification(EU)
- 7、EN455测试报告
- EN455 test report
- 8、包装标签(EU)
- Package Labeling (EU)

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Shijiazhuang Hongray Group Co., Ltd.
South Tongda Rd., East Dist.
Jinzhou
052260 Hebei
P.R. China

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

Manufacture and Distribution of Patient Examination Gloves

(see attachment for sites included)

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:	2020-04-16
Certificate Registration No.:	SX 60148697 0001
An audit was performed. Report No.:	16801058 009
This Certificate is valid until:	2020-10-25

Certification Body

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

Date 2020-04-16

Jing Zhang

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail:cert-validity@de.tuv.com http://www.tuv.com/safety

TÜVRheinland®

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60148697 0001
Report No.: 16801058 009

Organization:
Shijiazhuang Hongray Group Co., Ltd.
South Tongda Rd., East Dist.
Jinzhou
052260 Hebei
P.R. China

Scope:

Sites included:

Shijiazhuang Jiahe Plastic Glove Co., Ltd
Western Jiafeng Road, Mining Area, Shijiazhuang,
050100, Hebei, China

Manufacture of Patient Examination Gloves

Ever Light Plastic Products Co., Ltd.
Donggao Industrial Zone, Zanhuang, Shijiazhuang,
050000, Hebei, China

Manufacture of Patient Examination Gloves

Better Care Plastic Technology Co., Ltd.
Fuqian Xi Road, West district of Shenze Industrial Base,
Shenze County, 050000, Hebei,China

Manufacture of Patient Examination Gloves

Certification Body

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

Date: 2020-04-16

Jing Zhang

TÜVRheinland®

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60148697 0001
Report No.: 16801058 009

Organization:
Shijiazhuang Hongray
Group Co., Ltd.
South Tongda Rd., East Dist.
Jinzhou
052260 Hebei
P.R. China

Scope:

Sites included:

Shijiazhuang Jiahe Plastic Glove Co., Ltd
Western Jiafeng Road, Mining Area, Shijiazhuang,
050100, Hebei, China

Manufacture of Patient Examination Gloves

Ever Light Plastic Products Co., Ltd.
Donggao Industrial Zone, Zanhuang, Shijiazhuang,
050000, Hebei, China

Manufacture of Patient Examination Gloves

Better Care Plastic Technology Co., Ltd.
Fuqian Xi Road, West district of Shenze Industrial Base,
Shenze County, 050000, Hebei,China

Manufacture of Patient Examination Gloves

Certification Body

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

TÜV Rheinland LGA Products GmbH
TÜVRheinland
Notifizierungsstelle

Date: 2020-04-16

Jing Zhang

TÜVRheinland®

Doc. 3/3, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60148697 0001
Report No.: 16801058 009

Organization:
Shijiazhuang Hongray
Group Co., Ltd.
South Tongda Rd., East Dist.
Jinzhou
052260 Hebei
P.R. China

Scope:

Sites included:

Hong Di Plastic Products Co., Ltd.
Donggao Industrial Zone, Zanhuang, 050000, Hebei, China

Manufacture of Patient Examination Gloves

Shanxi Hongjin Plastic Technology Co., LTD
Coal Bed Gas Industrial Zone, Qu'e Town, Daning County,
Linfen City, 042300,Shanxi,China

Manufacture of Patient Examination Gloves

Certification Body

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

TÜV Rheinland LGA Products GmbH Akkreditierungsstelle

Date: 2020-04-16

Jing Zhang

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Business Stream Products
Certification Department

TÜV Rheinland LGA Products GmbH · 90431 Nürnberg

Shijiazhuang Hongray
Group Co., Ltd.
South Tongda Rd., East Dist.
Jinzhou
052260 HEBEI
P.R. CHINA

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

Date April 16, 2020

Application for : **QMS**
Certificate No. : SX 60148697 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 60148697 0001
replacing the previous certificate.

Kind regards

Certification body

Jing Zhang

Test sample: no, documentation available

TÜV Rheinland
LGA Products GmbH

Tillystraße 2
90431 Nürnberg

Tel. +49 911 655-5225
Fax +49 911 655-5226
Mail service@de.tuv.com
Web www.tuv.com/safety

Annex to certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1732303**

No.	Location	Scope
/01	Shijiazhuang Hongray Group Co., Ltd. Unified Social Credit Code: 91130100728799919R Registration Address: South Tongda Rd., East Dist., Jinzhou City, 052260 Hebei, P. R. China Operation Address: same as above	Distribution of Patient Examination Gloves
/02	Syntex Healthcare Products Co., Ltd. Unified Social Credit Code: 91130181734364356G Registration Address: Southern No. 307 National Highway Rd., Western Fanjiazhuang Village, Xinji City, 052360 Hebei, P. R. China Operation Address: same as above	Manufacture and Distribution of Patient Examination Gloves
/03	Grand Work Plastic Products Co., Ltd. Unified Social Credit Code: 91130100752433415G Registration Address: Donggao Industrial Zone, Zanhuang, 050000 Hebei, P. R. China Operation Address: same as above	Manufacture and Distribution of Patient Examination Gloves

Annex to certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1732303**

/06	Shijiazhuang Jiahe Plastic Glove Co., Ltd. Unified Social Credit Code: 91130107563240147C Registration Address: Northern Jiandi Village, Western Jiafeng Road, Mining Area, Shijiazhuang City, 050100 Hebei, P. R. China Operation Address: same as above	Manufacture and Distribution of Patient Examination Gloves
/08	Purtech Cleanroom Products Co., Ltd. Unified Social Credit Code: 91130181777701957N Registration Address: Fanjiazhuang Industrial Zone, Xinji City, 052360 Hebei, P. R. China Operation Address: same as above	Manufacture and Distribution of Patient Examination Gloves
/09	Ever Light Plastic Products Co., Ltd. Unified Social Credit Code: 91130100784064765D Registration Address: Donggao Industrial Zone, Zanhuang, 050000 Hebei, P. R. China Operation Address: same as above	Manufacture and Distribution of Patient Examination Gloves

Annex to certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1732303**

/10	Better Care Plastic Technology Co., Ltd. Unified Social Credit Code: 911301286920575093 Registration Address: Shenze Industrial Base (Fuqian Xi Road), Shenze County, 050000 Hebei, P. R. China Operation Address: same as above	Manufacture and Distribution of Patient Examination Gloves
/11	Shijiazhuang Hongzan Plastic Technology Co., Ltd. Unified Social Credit Code: 91130129567387090Y Registration Address: Donggao Industrial Zone, Zanhuang, Shijiazhuang City, 050000 Hebei, P. R. China Operation Address: same as above	Manufacture and Distribution of Patient Examination Gloves

Annex to certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1732303**

/12	Shanxi Hongjin Plastic Technology Co., Ltd. Unified Social Credit Code: 91141030MA0HDY6R5D Registration Address: Coal Bed Gas Industrial Zone, Qu'e Town, Daning County, Linfen City, 042300 Shanxi, P. R. China Operation Address: same as above	Manufacture and Distribution of Patient Examination Gloves

2020-08-18

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Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1732303**

Certificate Holder: **Shijiazhuang Hongray Group Co., Ltd.**
Unified Social Credit Code: 91130100728799919R
Registration Address: South Tongda Rd., East Dist.,
Jinzhou City, 52260 Hebei, P. R. China
Operation Address: same as above

including the locations according to annex

Scope: Manufacture and Distribution of Patient Examination Gloves

Proof has been furnished by means of an audit that the requirements of ISO 9001:2015 are met.

Validity: The certificate is valid from 2020-10-20 until 2023-04-19.
It remains valid subject to satisfactory surveillance audits.
First certification 2017

This certificate information can be searched on CNCA official website http://www.cnca.gov.cn

2020-08-18

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Certificate

Standard	**ISO 9001:2015**
Certificate Registr. No.	**01 100 1732303/01**

Organization: **Shijiazhuang Hongray Group Co., Ltd.**
South Tongda Rd., East Dist., Jinzhou City,
052260 Hebei, P. R. China

Site: c/o **Shijiazhuang Hongray Group Co., Ltd.**
Unified Social Credit Code: 91130100728799919R
Registration Address: South Tongda Rd., East Dist.,
Jinzhou City, 052260 Hebei, P. R. China
Operation Address: same as above

Scope: Distribution of Patient Examination Gloves

Proof has been furnished by means of an audit that the requirements of ISO 9001:2015 are met.

Validity: The certificate is valid in conjunction with the main certificate 01 100 1732303 from 2020-10-20 until 2023-04-19.
It remains valid subject to satisfactory surveillance audits.

This certificate information can be searched on CNCA official website http://www.cnca.gov.cn

2020-08-18

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Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1732303/02**

Organization: **Shijiazhuang Hongray Group Co., Ltd.**
South Tongda Rd., East Dist., Jinzhou City,
052260 Hebei, P. R. China

Site: c/o **Syntex Healthcare Products Co., Ltd.**
Unified Social Credit Code: 91130181734364356G
Registration Address: Southern No. 307 National Highway Rd.,
Western Fanjiazhuang Village, Xinji City,
052360 Hebei, P. R. China
Operation Address: same as above

Scope: Manufacture and Distribution of Patient Examination Gloves

Proof has been furnished by means of an audit that the requirements of ISO 9001:2015 are met.

Validity: The certificate is valid in conjunction with the main certificate 01 100 1732303 from 2020-10-20 until 2023-04-19.
It remains valid subject to satisfactory surveillance audits.

This certificate information can be searched on CNCA official website http://www.cnca.gov.cn

2020-08-18

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Certificate

Standard	**ISO 9001:2015**
Certificate Registr. No.	**01 100 1732303/03**

Organization: **Shijiazhuang Hongray Group Co., Ltd.**
South Tongda Rd., East Dist., Jinzhou City,
052260 Hebei, P. R. China

Site: c/o **Grand Work Plastic Products Co., Ltd.**
Unified Social Credit Code: 91130100752433415G
Registration Address: Donggao Industrial Zone,
Zanhuang, 050000 Hebei, P. R. China
Operation Address: same as above

Scope: Manufacture and Distribution of Patient Examination Gloves

Proof has been furnished by means of an audit that the requirements of ISO 9001:2015 are met.

Validity: The certificate is valid in conjunction with the main certificate 01 100 1732303 from 2020-10-20 until 2023-04-19.
It remains valid subject to satisfactory surveillance audits.

This certificate information can be searched on CNCA official website http://www.cnca.gov.cn

2020-08-18

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Certificate

Standard	**ISO 9001:2015**
Certificate Registr. No.	**01 100 1732303/06**

Organization: **Shijiazhuang Hongray Group Co., Ltd.**
South Tongda Rd., East Dist., Jinzhou City,
052260 Hebei, P. R. China

Site: c/o **Shijiazhuang Jiahe Plastic Glove Co., Ltd.**
Unified Social Credit Code: 91130107563240147C
Registration Address: Northern Jiandi Village,
Western Jiafeng Road, Mining Area, Shijiazhuang City,
050100 Hebei, P. R. China
Operation Address: same as above

Scope: Manufacture and Distribution of Patient Examination Gloves

Proof has been furnished by means of an audit that the requirements of ISO 9001:2015 are met.

Validity: The certificate is valid in conjunction with the main certificate 01 100 1732303 from 2020-10-20 until 2023-04-19.
It remains valid subject to satisfactory surveillance audits.

This certificate information can be searched on CNCA official website http://www.cnca.gov.cn

2020-08-18

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Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1732303/08**

Organization: **Shijiazhuang Hongray Group Co., Ltd.**
South Tongda Rd., East Dist., Jinzhou City,
052260 Hebei, P. R. China

Site: c/o **Purtech Cleanroom Products Co., Ltd.**
Unified Social Credit Code: 91130181777701957N
Registration Address: Fanjiazhuang Industrial Zone,
Xinji City, 052360 Hebei, P. R. China
Operation Address: same as above

Scope: Manufacture and Distribution of Patient Examination Gloves

Proof has been furnished by means of an audit that the requirements of ISO 9001:2015 are met.

Validity: The certificate is valid in conjunction with the main certificate 01 100 1732303 from 2020-10-20 until 2023-04-19.
It remains valid subject to satisfactory surveillance audits.

This certificate information can be searched on CNCA official website http://www.cnca.gov.cn

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Certificate

Standard	**ISO 9001:2015**
Certificate Registr. No.	**01 100 1732303/09**

Organization:

Shijiazhuang Hongray Group Co., Ltd.
South Tongda Rd., East Dist., Jinzhou City,
052260 Hebei, P. R. China

Site:

c/o **Ever Light Plastic Products Co., Ltd.**
Unified Social Credit Code: 91130100784064765D
Registration Address: Donggao Industrial Zone, Zanhuang,
050000 Hebei, P. R. China
Operation Address: same as above

Scope:

Manufacture and Distribution of Patient Examination Gloves

Proof has been furnished by means of an audit that the requirements of ISO 9001:2015 are met.

Validity:

The certificate is valid in conjunction with the main certificate 01 100 1732303 from 2020-10-20 until 2023-04-19.
It remains valid subject to satisfactory surveillance audits.

This certificate information can be searched on CNCA official website http://www.cnca.gov.cn

2020-08-18

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Certificate

Standard	**ISO 9001:2015**
Certificate Registr. No.	**01 100 1732303/10**

Organization:

Shijiazhuang Hongray Group Co., Ltd.
South Tongda Rd., East Dist., Jinzhou City,
052260 Hebei, P. R. China

Site:

c/o **Better Care Plastic Technology Co., Ltd.**
Unified Social Credit Code: 911301286920575093
Registration Address: Shenze Industrial Base (Fuqian Xi Road),
Shenze County, 050000 Hebei, P. R. China
Operation Address: same as above

Scope:

Manufacture and Distribution of Patient Examination Gloves

Proof has been furnished by means of an audit that the requirements of ISO 9001:2015 are met.

Validity:

The certificate is valid in conjunction with the main certificate 01 100 1732303 from 2020-10-20 until 2023-04-19.
It remains valid subject to satisfactory surveillance audits.

This certificate information can be searched on CNCA official website http://www.cnca.gov.cn

2020-08-18

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Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1732303/11**

Organization: **Shijiazhuang Hongray Group Co., Ltd.**
South Tongda Rd., East Dist., Jinzhou City,
052260 Hebei, P. R. China

Site: c/o **Shijiazhuang Hongzan Plastic Technology Co., Ltd.**
Unified Social Credit Code: 91130129567387090Y
Registration Address: Donggao Industrial Zone, Zanhuang,
Shijiazhuang City, 050000 Hebei, P. R. China
Operation Address: same as above

Scope: Manufacture and Distribution of Patient Examination Gloves

Proof has been furnished by means of an audit that the requirements of ISO 9001:2015 are met.

Validity: The certificate is valid in conjunction with the main certificate 01 100 1732303 from 2020-10-20 until 2023-04-19.
It remains valid subject to satisfactory surveillance audits.

This certificate information can be searched on CNCA official website http://www.cnca.gov.cn

2020-08-18

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Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1732303/12**

Organization: **Shijiazhuang Hongray Group Co., Ltd.**
South Tongda Rd., East Dist., Jinzhou City,
052260 Hebei, P. R. China

Site: c/o **Shanxi Hongjin Plastic Technology Co., Ltd.**
Unified Social Credit Code: 91141030MA0HDY6R5D
Registration Address: Coal Bed Gas Industrial Zone,
Qu'e Town, Daning County, Linfen City,
042300 Shanxi, P. R. China
Operation Address: same as above

Scope: Manufacture and Distribution of Patient Examination Gloves

Proof has been furnished by means of an audit that the requirements of ISO 9001:2015 are met.

Validity: The certificate is valid in conjunction with the main certificate 01 100 1732303 from 2020-10-20 until 2023-04-19.
It remains valid subject to satisfactory surveillance audits.

This certificate information can be searched on CNCA official website http://www.cnca.gov.cn

2020-08-18

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

www.tuv.com

DAkkS Deutsche Akkreditierungsstelle D-ZM-16031-01-00

TÜVRheinland®
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November 30, 2018

Better Care Plastic Technology Co., Ltd
℅ Kathy Liu
Project Manager
Hongray USA Medical Products Inc
3973 Schaefer Avenue, Chino, CA 91810, USA

Re: K182600
Trade/Device Name: Powder Free Nitrile Examination Glove, Tested for Use with Chemotherapy Drugs (Blue)
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I
Product Code: LZA, LZC
Dated: September 16, 2018
Received: September 21, 2018

Dear Kathy Liu:

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

statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Clarence W. Murray Iii III -S

For Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182600

Device Name
Powder Free Nitrile Examination Gloves, Tested for Use with Chemotherapy Drugs (Blue)

Indications for Use *(Describe)*
Powder Free Nitrile Examination Gloves, Tested for Use with Chemotherapy Drugs (Blue) is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.
Gloves have been tested for use with chemotherapy drugs using ASTM D6978 and will be labeled with a statement of compliance and a summary of the testing results.
Chemotherapy Drug Permeation
The following chemicals have been tested with these gloves:

Chemotherapy Drug	Minimum Breakthrough Detection Time (Minutes)
Carmustine(BCNU) (3.3 mg/ml)	11.0
Cisplatin (1mg/ml)	>240
Cyclophosphamide (20mg/ml)	>240
Dacarbazine (DTIC) (10mg/ml)	>240
Doxorubicin Hydrochloride (2mg/ml)	>240
Etoposide (Toposar) (20mg/ml)	>240
Fluorouracil (50mg/ml)	>240
Methotrexate (25mg/ml)	>240
Paclitaxel (Taxol) (6mg/ml)	>240
Thiotepa (THT) (10mg/ml)	28.8
Bleomycin (15.0mg/ml)	>240
Busulfan (6.0mg/ml)	>240
Carboplatin, (10.0mg/ml)	>240
Chloroquine, (50.0mg/ml)	>240
Cyclosporin, (100.0mg/ml)	>240
Cytarabine, (100.0mg/ml)	>240
Daunorubicin, (5.0mg/ml)	>240
Docetaxel, (10.0mg/ml)	>240
Epirubicin (Ellence), (2.0mg/ml)	>240
Fludarabine, (25.0mg/ml)	>240
Gemcitabine (Gemzar) (38.0mg/ml)	>240
Idarubicin, (1.0mg/ml)	>240
Ifosfamide, (50.0mg/ml)	>240
Irinotecan, (20.0mg/ml)	>240
Mechlorethamine HCI, (1.0mg/ml)	>240
Melphalan, (5.0mg/ml)	>240
Mitomycin C, (0.5mg/ml)	>240
Mitoxantrone, (2.0mg/ml)	>240
Oxaliplatin, (2.0mg/ml)	>240
Paraplatin, (10.0mg/ml)	>240
Retrovir, (10.0mg/ml)	>240
Rituximab, (10.0mg/ml)	>240
Topotecan HCL, (1.0mg/ml)	>240
Trisonex, (1.0mg/ml)	>240
Velcade (Bortezomib), (1.0mg/ml)	>240
Vincristine, (1.0mg/ml)	>240

* Please note that the following drugs have extremely low permeation times:
Carmustine: 11.0 minutes and Thiotepa: 28.8 minutes

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Better Care Plastic Technology Co., Ltd

Fuqian Xi Road, West district of Shenze Industrial Base, Shenze County,
Hebei Province, CHINA 050000

510(K) SUMMARY

The assigned 510(K) numbers: K182600
Date Prepared: November 18, 2018

1. Owner's Identification:

Mrs. Zhu Chunyan
Better Care Plastic Technology Co., Ltd.
Fuqian Xi Road, West district of Shenze Industrial Base, Shenze County, Hebei Province, CHINA 050000
Tel:86-311-66179653
Fax: 86-311-66179653

Contact: Ms. Kathy Liu, Project Manager or Ms Monica Yu
Hongray USA Medical Products Inc.
Address: 3973 Schaefer Avenue, Chino, CA 91810, USA
Tel:909-590-1611
Fax: 909-673-8347

2. Name of the Device:

Trade / Product Name: Powder Free Nitrile Examination Gloves, Tested for Use with Chemotherapy Drugs (Blue)
Common Name: Exam Gloves
Classification Name: Non-powdered patient Examination
Classification Regulation: 21 CFR 880.6250
Product Code: LZA, LZC
Classification Panel: General Hospital
Device Class: Class I

3. Predicate Device Information:

Central Medicare Sdn. Bhd.
Blue Non Sterile Powder Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs (K173942)

4. Device Description:

Powder Free Nitrile Examination Gloves, Tested for Use with Chemotherapy Drugs (Blue) are Class I Patient Examination Gloves and Specialty Chemotherapy Gloves. They are ambidextrous and come in different sizes—Extra Small, Small, Medium, Large and Extra Large.
Gloves meet the specification of ASTM D6319-10(2015) and have been tested for resistance to permeation by chemotherapy drugs as per ASTM D6978-05(2013).

510(K) SUMMARY

5. Indications for Use:

Powder Free Nitrile Examination Gloves, Tested for Use with Chemotherapy Drugs (Blue) is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.
Gloves have been tested for use with chemotherapy drugs using ASTM D6978-05(2013) and will be labeled with a statement of compliance and a summary of the testing results.
Chemotherapy Drug Permeation

The following chemicals have been tested with these gloves:

Chemotherapy Drug	Minimum Breakthrough Detection Time (Minutes)
Carmustine(BCNU) (3.3 mg/ml)	11.0
Cisplatin (1mg/ml)	>240
Cyclophosphamide (20mg/ml)	>240
Dacarbazine (DTIC) (10mg/ml)	>240
Doxorubicin Hydrochloride (2mg/ml)	>240
Etoposide (Toposar) (20mg/ml)	>240
Fluorouracil (50mg/ml)	>240
Methotrexate (25mg/ml)	>240
Paclitaxel (Taxol) (6mg/ml)	>240
Thiotepa (THT) (10mg/ml)	28.8
Bleomycin (15.0mg/ml)	>240
Busulfan (6.0mg/ml)	>240
Carboplatin, (10.0mg/ml)	>240
Chloroquine, (50.0mg/ml)	>240
Cyclosporin, (100.0mg/ml)	>240
Cytarabine, (100.0mg/ml)	>240
Daunorubicin, (5.0mg/ml)	>240
Docetaxel, (10.0mg/ml)	>240
Epirubicin (Ellence), (2.0mg/ml)	>240
Fludarabine, (25.0mg/ml)	>240
Gemcitabine (Gemzar) (38.0mg/ml)	>240
Idarubicin, (1.0mg/ml)	>240
Ifosfamide, (50.0mg/ml)	>240
Irinotecan, (20.0mg/ml)	>240
Mechlorethamine HCI, (1.0mg/ml)	>240
Melphalan, (5.0mg/ml)	>240

Mitomycin C, (0.5mg/ml)	>240
Mitoxantrone, (2.0mg/ml)	>240
Oxaliplatin, (2.0mg/ml)	>240
Paraplatin, (10.0mg/ml)	>240
Retrovir, (10.0mg/ml)	>240
Rituximab, (10.0mg/ml)	>240
Topotecan HCL, (1.0mg/ml)	>240
Trisonex, (1.0mg/ml)	>240
Velcade (Bortezomib), (1.0mg/ml)	>240
Vincristine, (1.0mg/ml)	>240

* Please note that the following drugs have extremely low permeation times: Carmustine: 11.0 minutes and Thiotepa: 28.8 minutes

6. Technological Characteristic Comparison Table:

The proposed device will be known as Powder Free Nitrile Examination Gloves, Tested for Use with Chemotherapy Drugs (Blue).

The following tables are summaries of the technological characteristics, biocompatibility and testing for use with chemotherapy drugs of the proposed and predicate devices.

General Comparison Table:

	Proposed Device K182600	Predicate Device K173942	Comparison
Trade Name	Powder Free Nitrile Examination Gloves, Tested for Use with Chemotherapy Drugs (Blue)	Blue Non Sterile Powder Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs	Similar
Product Code	LZA, LZC	LZA, LZC	Same
Regulation Number	21 CFR 880.6250	21 CFR 880.6250	Same
Class	I	I	Same

510(K) SUMMARY

Indications for Use	Powder Free Nitrile Examination Gloves, Tested for Use with Chemotherapy Drugs (Blue) is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.	Blue Non Sterile Powder Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs is a disposable device intended for medical purposes that is worn on the examiner's hands to prevent contamination between patient and examiner.	Same
Powder or Powder Free	Powder Free	Powder Free	Same
Design Feature	Ambidextrous	Ambidextrous	Same
Color	Blue	Blue	Similar
Labeling Informati on	Single-use indication, powder free, device name, glove size, quantity, Nitrile Examination Gloves, Non Sterile	Single-use indication, powder free, device name, glove size, quantity, Nitrile Examination Gloves, Non Sterile	Same
Chemotherapy Drug Permeation Claim	See below comparison table	See below comparison table	

Dimensions and Performance Comparison Table:

Technological Characteristics	Proposed Device K182600	Predicate Device K173942	Comparison
Length	Minimum 230mm	Minimum 230mm	Same
Palm Width (size) (mm)			
XS	70±10	70±10	Same
S	80±10	80±10	Same
M	95±10	95±10	Same

510(K) SUMMARY

L	110±10	110±10	Same
XL	120±10	120±10	Same
Thickness(mm)			
Finger	Minimum 0.05	0.10±0.03	Similar
Palm	Minimum 0.05	0.08±0.03	Similar
Tensile Strength, Before Aging	14MPa, min	14MPa, min	Same
Ultimate Elongation, Before Aging	500%, min	500%, min	Same
Tensile Strength, After Accelerated Aging	14MPa, min	14MPa, min	Same
Ultimate Elongation, After Accelerated Aging	400%, min	400%, min	Same
Freedom from holes	In accordance with ASTM D 5151-06, following ASTM D6319-10, G-1, AQL 2.5	In accordance with ASTM D 5151-06, following ASTM D6319-10, G-1, AQL 2.5	Same
Powder-Content	≤ 2 mg per glove	≤ 2 mg per glove	Similar
10993-10:2010 Skin Irritation Study	Under the conditions of the study, not an irritant	Under the conditions of the study, not an irritant	Same
10993-10:2010 Maximization Sensitization Study	Under the conditions of the study, not a sensitizer	Under the conditions of the study, not a sensitizer	Same
10993-5:2009 Cytotoxicity Test		Under the conditions of this study, not a cytotoxic potential	

Chemotherapy Permeation Comparison:

Tested Chemotherapy Drug and Concentration	Minimum BDT (Minutes)		Comparison
	Proposed Device K182600	Predicate Device K173942	
Carmustine(BCNU) (3.3 mg/ml)	11.0	12.4	Similar
Cisplatin (1mg/ml)	>240	>240	Same
Cyclophosphamide (20mg/ml)	>240	>240	Same
Dacarbazine (DTIC)	>240	>240	Same

510(K) SUMMARY

(10mg/ml)			
Doxorubicin Hydrochloride (2mg/ml)	>240	>240	Same
Etoposide (Toposar) (20mg/ml)	>240	>240	Same
Fluorouracil (50mg/ml)	>240	>240	Same
Methotrexate (25mg/ml)	>240	>240	Same
Paclitaxel (Taxol) (6mg/ml)	>240	>240	Same
Thiotepa (THT) (10mg/ml)	28.8	24.4	Similar
Bleomycin (15.0mg/ml)	>240	>240	Same
Busulfan (6.0mg/ml)	>240	>240	Same
Carboplatin, (10.0mg/ml)	>240	>240	Same
Chloroquine, (50.0mg/ml)	>240	>240	Same
Cyclosporin, (100.0mg/ml)	>240	>240	Same
Cytarabine, (100.0mg/ml)	>240	>240	Same
Daunorubicin, (5.0mg/ml)	>240	>240	Same
Docetaxel, (10.0mg/ml)	>240	>240	Same
Epirubicin (Ellence), (2.0mg/ml)	>240	>240	Same
Fludarabine, (25.0mg/ml)	>240	>240	Same
Gemcitabine (Gemzar) (38.0mg/ml)	>240	>240	Same
Idarubicin, (1.0mg/ml)	>240	>240	Same
Ifosfamide, (50.0mg/ml)	>240	>240	Same
Irinotecan, (20.0mg/ml)	>240	>240	Same
Mechlorethamine HCI, (1.0mg/ml)	>240	>240	Same
Melphalan, (5.0mg/ml)	>240	>240	Same
Mitomycin C, (0.5mg/ml)	>240	>240	Same
Mitoxantrone, (2.0mg/ml)	>240	>240	Same
Oxaliplatin, (2.0mg/ml)	>240	>240	Same
Paraplatin, (10.0mg/ml)	>240	>240	Same
Retrovir, (10.0mg/ml)	>240	>240	Same
Rituximab, (10.0mg/ml)	>240	>240	Same
Topotecan HCL, (1.0mg/ml)	>240	>240	Same
Trisonex, (1.0mg/ml)	>240	>240	Same
Velcade (Bortezomib), (1.0mg/ml)	>240	>240	Same
Vincristine, (1.0mg/ml)	>240	>240	Same

510(K) SUMMARY

7. Summary Non-Clinical Testing

Non-clinical tests were conducted to verify that the proposed device met all design specifications. The test results demonstrated that the proposed device complies with the following standards:

- ISO 10993-10:2010 Biological Evaluation of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization.
- ISO 10993-5:2009 Biological Evaluation of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity
- ASTM D6124-06 (Reapproved 2017), Standard Test Method for Residual Powder on Medical Gloves
- ASTM D5151-06 (Reapproved 2015), Standard Test Method for Detection of Holes in Medical Gloves.
- ASTM D6319-10(Reapproved 2015), Standard Specification for Nitrile Examination Gloves For Medical Application.
- ASTM D6978-05 (Reapproved 2013), Assessment of Reissuance of Medical Gloves to Permeation by Chemotherapy Drugs.

8. Summary of Clinical Testing

N/A

9. Conclusion:

The conclusions drawn from the nonclinical tests demonstrate that the proposed device is as safe, as effective, and performs as well as or better than the legally marketed predicated device.

September 14, 2018

· TEST REPORT ·

PN 143533

CHEMICAL ANALYTICAL SERVICES

Prepared For:

Renmin
Better Care Plastic Technology Co., Ltd.
Fuqian Xi Road,
West District of Shenze Industrial Base,
Shenze County,
Hebei Province,
China 050000

Prepared By: _____
Tiffany L Heller
Manager, Pharmaceutical Services

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

ACCREDITED
A Testing Lab
*Certificate Numbers 255.01 & 255.02

An A2LA Accredited Testing Laboratory — Certificate Numbers 255.01 & 255.02
ISO 9001:2008 Registered

ISO 9001:2008
Registered

September 14, 2018

Renmin
Better Care Plastic Technology Co., Ltd.

SUBJECT: Permeation testing per ASTM D6978 on one glove sample submitted by the above company.

RECEIVED: Sixty (60) blue gloves identified as; Powder Free Nitrile Examination Glove, Tested for Use with Chemotherapy Drugs (Blue); Size Medium; Lot# 1805C4A3-PF.

TEST CHEMICALS:

Table 1. List of the Testing Drugs and their Sources

TESTING CHEMOTHERAPY DRUGS	DRUG SOURCE
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	Sigma Aldrich; Lot # 018M4057V; Exp. 04/2019
Cisplatin, 1 mg/ml (1,000 ppm)	WG Critical Care; Lot# 7LO4842; Expiration 04/2019
Cyclophosphamide (Cytoxan), 20 mg/ml, (20,000 ppm)	Sandoz Inc.; Lot# 17101325; Expiration 10/12/2019
Dacarbazine (DTIC), 10 mg/ml, (10,000 ppm)	Teva; Lot# 31322092B; Expiration 11/2019
Doxorubicin Hydrochloride, 2 mg/ml (2,000 ppm)	Actavis Pharma; Lot# 7LJ5121; Expiration 07/2019
Etoposide (Toposar), 20 mg/ml (20,000 ppm)	Accord; Lot# X02633; Expiration 01/2020
Fluorouracil, 50 mg/ml, (50,000 ppm)	Sigma Aldrich; Lot# MKCD1558; Expiration 09/2019
Methotrexate, 25 mg/ml (25,000 ppm)	Hospira; Lot# E124437AA; Expiration 07/2019
Paclitaxel (Taxol), 6 mg/ml (6,000 ppm)	Hospira; Lot# E036865AA; Expiration 09/2018
Thiotepa (THT), 10 mg/ml (10,000 ppm)	USP; Lot # R046R0; Exp. 05/2019
Bleomycin, 15.0 mg/ml (15,000 ppm)	USP; Lot# L1L527; Expiration 12/2018
Busulfan, 6.0 mg/ml (6,000 ppm)	Sigma; CAS# 55-98-1; Lot# BCBS8240V
Carboplatin, 10.0 mg/ml (10,000 ppm)	Teva; Lot# 17I110A; Expiration 09/2019
Chloroquine, 50.0 mg/ml (50,000 ppm)	USP; Lot# F1L501; Expiration 08/2019
Cyclosporin A, 100.0 mg/ml (100,000 ppm)	USP; Lot# J0M382; Expiration 08/2019
Cytarabine, 100.0 mg/ml (100,000 ppm)	USP; Lot# R046F0; Expiration 04/2019
Daunorubicin, 5.0 mg/ml (5,000 ppm)	Sigma Aldrich; Lot# 125M4750V; Expiration 03/2019
Docetaxel, 10.0 mg/ml (10,000 ppm)	LC Labs; Lot# BDC-117; Expiration 01/2025
Epirubicin (Ellence), 2.0 mg/ml (2,000 ppm)	LC Labs; Lot# EPR-101; Expiration 12/2018
Fludarabine, 25.0 mg/ml (25,000 ppm)	USP; Lot# H1K220; Expiration 12/2019
Gemcitabine (Gemzar), 38.0 mg/ml (38,000 ppm)	LC Labs; Lot# GMC-105; Expiration 1/6/2025
Idarubicin, 1.0 mg/ml (1,000 ppm)	Sigma Aldrich, Lot# R080E0; Expiration 12/2019
Ifosfamide, 50.0 mg/ml (50,000 ppm)	West-Ward; Lot# BH0007; Expiration 11/2018
Irinotecan, 20.0 mg/ml (20,000 ppm)	LC Labs; Lot# RCN-105; Expiration 03/2024
Mechlorethamine HCl, 1.0 mg/ml (1,000ppm)	Sigma Aldrich; Lot# MKBW4481V; Expiration 03/2019
Melphalan, 5 mg/ml (5,000 ppm)	Sigma Aldrich; Lot# 072M4056V; Expiration 12/2018
Mitomycin C, 0.5 mg/ml (500 ppm)	Sigma Aldrich; Lot# MKBT1043V; Expiration 02/2019
Mitoxantrone, 2.0 mg/ml (2,000 ppm)	Sigma Aldrich; Lot# MKBR2210V; Expiration 02/2019
Oxaliplatin, 2.0 mg/ml (2,000 ppm)	LC Labs; Lot# XAP-111; 12/2019
Paraplatin, 10 mg/ml (10,000 ppm)	Teva; Lot# 17I110A; Expiration 09/2019
Retrovir, 10 mg/ml (10,000 ppm)	USP; Lot# R052L0; Expiration 12/2018
Rituximab, 10 mg/ml (10,000 ppm)	Hetero Oncology; Lot# RB1710A; Expiration 12/2019
Topotecan HCl, 1 mg/ml (1,000 ppm)	USP; Lot# R007C0; Expiration 12/2018
Trisonex, 1 mg/ml (1,000 ppm)	Sigma Aldrich; Lot# BCBQ8570V; Expiration 12/2018
Velcade (Bortezomib), 1 mg/ml (1,000 ppm)	LC Labs; Lot# BBZ-116; Expiration 4/2025
Vincristine, 1.0 mg/ml (1,000 mg/ml)	Hospira; Lot# E047139AAI Expiration 04/2019

COLLECTION MEDIA:

Table 2. Collection Media for Test Chemicals

TEST DRUG AND CONCENTRATION	COLLECTION MEDIUM
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	10% Ethanol Aqueous Solution
Cisplatin, 1 mg/ml (1,000 ppm)	Distilled Water
Cyclophosphamide (Cytoxan), 20 mg/ml, (20,000 ppm)	Distilled Water
Dacarbazine (DTIC), 10 mg/ml, (10,000 ppm)	Distilled Water
Doxorubicin Hydrochloride, 2 mg/ml (2,000 ppm)	Distilled Water
Etoposide (Toposar), 20 mg/ml (20,000 ppm)	Distilled Water
Fluorouracil, 50 mg/ml, (50,000 ppm)	9.20 pH Sodium Hydroxide Solution
Methotrexate, 25 mg/ml (25,000 ppm)	Distilled Water
Paclitaxel (Taxol), 6 mg/ml (6,000 ppm)	30% Methanol Aqueous Solution
Thiotepa (THT), 10 mg/ml (10,000 ppm)	Distilled Water
Bleomycin, 15.0 mg/ml (15,000 ppm)	Distilled Water
Busulfan, 6.0 mg/ml (6,000 ppm)	Distilled Water
Carboplatin, 10.0 mg/ml (10,000 ppm)	Distilled Water
Chloroquine, 50.0 mg/ml (50,000 ppm)	Distilled Water
Cyclosporin, 100.0 mg/ml (100,000 ppm)	Distilled Water
Cytarabine, 100.0 mg/ml (100,000 ppm)	Distilled Water
Daunorubicin, 5.0 mg/ml (5,000 ppm)	Distilled Water
Docetaxel, 10.0 mg/ml (10,000 ppm)	Distilled Water
Epirubicin (Ellence), 2.0 mg/ml (2,000 ppm)	Distilled Water
Fludarabine, 25.0 mg/ml (25,000 ppm)	Distilled Water
Gemcitabine (Gemzar), 38.0 mg/ml (38,000 ppm)	Distilled Water
Idarubicin, 1.0 mg/ml (1,000 ppm)	Distilled Water
Ifosfamide, 50.0 mg/ml (50,000 ppm)	Distilled Water
Irinotecan, 20.0 mg/ml (20,000 ppm)	Distilled Water
Mechlorethamine HCl, 1.0 mg/ml (1,000ppm)	Distilled Water
Melphalan, 5 mg/ml (5,000 ppm)	Distilled Water
Mitomycin C, 0.5 mg/ml (500 ppm)	Distilled Water
Mitoxantrone, 2.0 mg/ml (2,000 ppm)	Distilled Water
Oxaliplatin, 2.0 mg/ml (2,000 ppm)	Distilled Water
Paraplatin, 10 mg/ml (10,000 ppm)	Distilled Water
Retrovir, 10 mg/ml (10,000 ppm)	Distilled Water
Rituximab, 10 mg/ml (10,000 ppm)	Distilled Water
Topotecan HCl, 1 mg/ml (1,000 ppm)	Distilled Water
Trisonex, 1 mg/ml (1,000 ppm)	Distilled Water
Velcade (Bortezomib), 1 mg/ml (1,000 ppm)	Distilled Water
Vincristine, 1.0 mg/ml (1,000 mg/ml)	Distilled Water

TESTING CONDITIONS:

Standard Test Method Used:	ASTM D 6978
Deviation from Standard Test Method:	Used 1" Permeation Cell
Analytical Method:	UV/VIS Spectrometry
Testing Temperature:	35.0°C ± 2.0
Collection System:	Closed Loop
Specimen Area Exposed:	5.067 cm2
Selected Data Points:	25/test
Number of Specimens Tested:	3/test
Location Sampled From:	Cuff area

DETECTION METHOD OF CHEMICAL PERMEATION:

UV/VIS ABSORPTION SPECTROMETRY:

Instrument: Perkin Elmer UV/VIS Spectrometer Lambda 25

UV/VIS Absorption Spectrometry was used to measure the absorbance of test chemicals, which permeated through the specimens into the collection medium. The collection medium was circulated in a closed loop at 11 ml/minute of flow rate through the testing period. Data collection was performed according to the programmed schedule by means of UV Winlab software from the Perkin Elmer Corporation. The list of the characteristic wavelengths is shown below.

Table 3. Characteristic Wavelengths used in UV/VIS Absorption Spectrometry

TESTING DRUG	WAVELENGTH (nm)
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	229
Cisplatin, 1 mg/ml (1,000 ppm)	199
Cyclophosphamide (Cytoxan), 20 mg/ml, (20,000 ppm)	200
Dacarbazine (DTIC), 10 mg/ml, (10,000 ppm)	320
Doxorubicin Hydrochloride, 2 mg/ml (2,000 ppm)	232
Etoposide (Toposar), 20 mg/ml (20,000 ppm)	205
Fluorouracil, 50 mg/ml, (50,000 ppm)	269
Methotrexate, 25 mg/ml (25,000 ppm)	303
Paclitaxel (Taxol), 6 mg/ml (6,000 ppm)	231
Thiotepa (THT), 10 mg/ml (10,000 ppm)	199
Bleomycin, 15.0 mg/ml (15,000 ppm)	290
Busulfan, 6.0 mg/ml (6,000 ppm)	197
Carboplatin, 10.0 mg/ml (10,000 ppm)	192
Chloroquine, 50.0 mg/ml (50,000 ppm)	220
Cyclosporin, 100.0 mg/ml (100,000 ppm)	199
Cytarabine, 100.0 mg/ml (100,000 ppm)	272
Daunorubicin, 5.0 mg/ml (5,000 ppm)	269
Docetaxel, 10.0 mg/ml (10,000 ppm)	231
Epirubicin (Ellence), 2.0 mg/ml (2,000 ppm)	233 & 253
Fludarabine, 25.0 mg/ml (25,000 ppm)	261
Gemcitabine (Gemzar), 38.0 mg/ml (38,000 ppm)	202
Idarubicin, 1.0 mg/ml (1,000 ppm)	257
Ifosfamide, 50.0 mg/ml (50,000 ppm)	200
Irinotecan, 20.0 mg/ml (20,000 ppm)	200
Mechlorethamine HCl, 1.0 mg/ml (1,000ppm)	194
Melphalan, 5 mg/ml (5,000 ppm)	260
Mitomycin C, 0.5 mg/ml (500 ppm)	217
Mitoxantrone, 2.0 mg/ml (2,000 ppm)	242
Oxaliplatin, 2.0 mg/ml (2,000 ppm)	199
Paraplatin, 10 mg/ml (10,000 ppm)	192
Retrovir, 10 mg/ml (10,000 ppm)	266
Rituximab, 10 mg/ml (10,000 ppm)	192
Topotecan HCl, 1 mg/ml (1,000 ppm)	254
Trisonex, 1 mg/ml (1,000 ppm)	197
Velcade (Bortezomib), 1 mg/ml (1,000 ppm)	206
Vincristine, 1.0 mg/ml (1,000 mg/ml)	220

SAMPLE CHARACTERISTICS:

Table 4. Cuff thickness characteristics for the tested: Powder Free Nitrile Examination Glove, Tested for Use with Chemotherapy Drugs (Blue); Size Medium; Lot# 1805C4A3-PF.

Testing Drug	Thickness (mm)			Average (mm)	Weight/Unit Area (g/m^2)
	Sample 1	Sample 2	Sample 3		
Carmustine (BCNU)	0.054	0.053	0.053	0.054	51.0
Cisplatin	0.052	0.051	0.053	0.052	
Cyclophosphamide	0.051	0.053	0.054	0.053	
Dacarbazine (DTIC)	0.053	0.052	0.056	0.054	
Doxorubicin Hydrochloride	0.051	0.052	0.057	0.053	
Etoposide (Toposar)	0.051	0.053	0.055	0.053	
Fluorouracil	0.057	0.056	0.055	0.056	
Methotrexate	0.052	0.056	0.051	0.053	
Paclitaxel (Taxol)	0.051	0.057	0.053	0.054	
Thiotepa (THT)	0.050	0.055	0.051	0.052	
Bleomycin	0.048	0.047	0.045	0.047	48.9
Busulfan	0.052	0.044	0.046	0.047	
Carboplatin	0.047	0.047	0.045	0.046	
Chloroquine	0.048	0.047	0.045	0.047	
Cyclosporin	0.047	0.044	0.045	0.045	
Cytarabine	0.048	0.048	0.047	0.047	
Daunorubicin	0.046	0.046	0.044	0.046	
Docetaxel	0.045	0.045	0.045	0.045	
Epirubicin (Ellence)	0.045	0.046	0.046	0.045	
Fludarabine	0.048	0.045	0.046	0.046	
Gemcitabine (Gemzar)	0.047	0.047	0.047	0.047	
Idarubicin	0.047	0.046	0.045	0.046	
Ifosfamide	0.046	0.047	0.047	0.047	
Irinotecan	0.047	0.046	0.045	0.046	
Mechlorethamine HCl	0.046	0.046	0.044	0.045	
Melphalan	0.049	0.047	0.047	0.048	
Mitomycin C	0.048	0.046	0.047	0.047	
Mitoxantrone	0.048	0.046	0.045	0.046	
Oxaliplatin	0.045	0.044	0.045	0.045	
Paraplatin	0.043	0.043	0.045	0.043	
Retrovir	0.045	0.045	0.049	0.046	
Rituximab	0.046	0.045	0.047	0.046	
Topotecan HCl	0.043	0.047	0.045	0.045	
Trisonex	0.045	0.048	0.045	0.046	
Velcade (Bortezomib)	0.045	0.044	0.046	0.045	
Vincristine	0.045	0.044	0.044	0.044	

RESULTS:

Table 5. Permeation Test Results on Testing of: Powder Free Nitrile Examination Glove, Tested for Use with Chemotherapy Drugs (Blue); Size Medium; Lot# 1805C4A3-PF.

TEST CHEMOTHERAPY DRUGS	MINIMUM BREAKTHROUGH DETECTION TIME (Specimen 1/2/3) (Minutes)	STEADY STATE PERM. RATE (Specimen 1/2/3) (µg/cm²/minute)	OTHER OBSERVATIONS
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	11.0 (14.4,11.4,11.0)	0.4 (0.4,0.4,0.3)	Moderate swelling and slight degradation
Cisplatin, 1 mg/ml (1,000 ppm)	>240	N/A	Slight swelling and no degradation
Cyclophosphamide (Cytoxan), 20 mg/ml, (20,000 ppm)	>240	N/A	Slight swelling and no degradation
Dacarbazine (DTIC), 10 mg/ml, (10,000 ppm)	>240	N/A	Slight swelling and no degradation
Doxorubicin Hydrochloride, 2 mg/ml (2,000 ppm)	>240	N/A	Slight swelling and no degradation
Etoposide (Toposar), 20 mg/ml (20,000 ppm)	>240	N/A	Moderate swelling and slight degradation
Fluorouracil, 50 mg/ml, (50,000 ppm)	>240	N/A	Slight swelling and no degradation
Methotrexate, 25 mg/ml (25,000 ppm)	>240	N/A	Slight Swelling and no degradation
Paclitaxel (Taxol), 6 mg/ml (6,000 ppm)	>240	N/A	Moderate swelling and slight degradation
Thiotepa (THT), 10 mg/ml (10,000 ppm)	28.8 (38.6,28.8,32.7)	1.6 (1.6,1.4,1.9)	Slight swelling and no degradation
Bleomycin, 15.0 mg/ml (15,000 ppm)	>240	N/A	Slight swelling and no degradation
Busulfan, 6.0 mg/ml (6,000 ppm)	>240	N/A	Slight swelling and no degradation
Carboplatin, 10.0 mg/ml (10,000 ppm)	>240	N/A	Slight swelling and no degradation
Chloroquine, 50.0 mg/ml (50,000 ppm)	>240	N/A	Slight swelling and no degradation
Cyclosporin, 100.0 mg/ml (100,000 ppm)	>240	N/A	Slight swelling and no degradation
Cytarabine, 100.0 mg/ml (100,000 ppm)	>240	N/A	Moderate swelling and slight degradation
Daunorubicin, 5.0 mg/ml (5,000 ppm)	>240	N/A	Slight swelling and no degradation
Docetaxel, 10.0 mg/ml (10,000 ppm)	>240	N/A	Slight swelling and no degradation
Epirubicin (Ellence), 2.0 mg/ml (2,000 ppm)	>240	N/A	Slight swelling and no degradation
Fludarabine, 25.0 mg/ml (25,000 ppm)	>240	N/A	Slight swelling and no degradation

RESULTS cont.:

Table 5. Permeation Test Results on Testing of: Powder Free Nitrile Examination Glove, Tested for Use with Chemotherapy Drugs (Blue); Size Medium; Lot# 1805C4A3-PF.

TEST CHEMOTHERAPY DRUGS	MINIMUM BREAKTHROUGH DETECTION TIME (Specimen 1/2/3) (Minutes)	STEADY STATE PERM. RATE (Specimen 1/2/3) (µg/cm²/minute)	OTHER OBSERVATIONS
Gemcitabine (Gemzar), 38.0 mg/ml (38,000 ppm)	>240	N/A	Slight swelling and no degradation
Idarubicin, 1.0 mg/ml (1,000 ppm)	>240	N/A	Slight swelling and no degradation
Ifosfamide, 50.0 mg/ml (50,000 ppm)	>240	N/A	Slight Swelling and no degradation
Irinotecan, 20.0 mg/ml (20,000 ppm)	>240	N/A	Slight swelling and no degradation
Mechlorethamine HCl, 1.0 mg/ml (1,000ppm)	>240	N/A	Slight swelling and no degradation
Melphalan, 5.0 mg/ml (5,000 ppm)	>240	N/A	Slight swelling and no degradation
Mitomycin C, 0.5 mg/ml (500 ppm)	>240	N/A	Slight swelling and no degradation
Mitoxantrone, 2.0 mg/ml (2,000 ppm)	>240	N/A	Slight swelling and no degradation
Oxaliplatin, 2.0 mg/ml (2,000 ppm)	>240	N/A	Slight swelling and no degradation
Paraplatin, 10.0 mg/ml (10,000 ppm)	>240	N/A	Slight swelling and no degradation
Retrovir, 10.0 mg/ml (10,000 ppm)	>240	N/A	Slight swelling and no degradation
Rituximab, 10.0 mg/ml (10,000 ppm)	>240	N/A	Slight swelling and no degradation
Topotecan HCl, 1.0 mg/ml (1,000 ppm)	>240	N/A	Slight swelling and no degradation
Trisonex, 1.0 mg/ml (1,000 ppm)	>240	N/A	Slight swelling and no degradation
Velcade (Bortezomib), 1.0 mg/ml (1,000 ppm)	>240	N/A	Slight swelling and no degradation
Vincristine, 1.0 mg/ml (1,000 mg/ml)	>240	N/A	Slight swelling and no degradation

Tiffany L. Heller
Manager
Pharmaceutical Services
AKRON RUBBER DEVELOPMENT LABORATORY, INC.

Ana C. Barbur se

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

Shijiazhuang Hongray Group Co., Ltd.
South Tongda Rd., East Dist. Jinzhou City,Hebei , 052260,China

Performance Testing

The Standards used for production of Powder Free Nitrile Examination Gloves (Blue) are mainly based on ASTM D6319-19. In accordance with physical requirements established by ASTM standard, the following are the physical requirements and dimensional testing results:

Technological Characteristics	Standard/Test/FDA Guidance	Inspection Level and AQL	Result Summary	Conclusion
Length (mm)	220mm for size XS-S 230mm for size M-XL minimum	S-2, AQL4.0	XS: 230-238mm S: 234-242mm M: 230-242mm L: 238-244mm XL：232-241 mm	Pass
Width (mm)	XS:70±10	S-2, AQL4.0	77-78mm	Pass
	S: 80±10		86-88 mm	
	M: 95±10		96 -98mm	
	L: 110±10		108-110 mm	
	XL: 120±10		116-117 mm	
Palm Thickness (mm)	0.05mm minimum	S-2, AQL4.0	0.05-0.06mm	Pass
Finger Thickness (mm)	0.05mm minimum	S-2, AQL4.0	0.06-0.07mm	Pass
Tensile Strength (Mpa)				
Before aging	14Mpa minimum	S-2, AQL4.0	15.7-19.9Mpa	Pass
After aging	14Mpa minimum		15.2-18.6Mpa	Pass
Ultimate Elongation (%)				
Before aging	500% minimum	S-2, AQL4.0	500-550%	Pass
After aging	400% minimum		430-530%	Pass
Freedom from holes	AQL 2.5	G-I, AQL2.5	0/125, meet AQL2.5 requirements	Pass
Residual Powder	Not more than 2mg per glove	N=5	0.58mg	Pass

The detailed testing report of the gloves is attached herein.

Shijiazhuang Hongray Group Co., Ltd.
South Tongda Rd., East Dist. Jinzhou City,Hebei , 052260,China

PHYSICAL&PINHOLE TESTING

Testing requested:
For compliance with ASTM D6319-19 Standard Specification for Nitrile Examination Gloves, testing items are as follows:
1. Physical Dimensions and Physical Property;
2. Pinhole

Testing Methods:
As specified in ASTM D6319-19, ASTM D5151-19 and FDA 1000ml Water Leak Test (21 CFR 800.20).
1. Testing results for Physical Dimensions and Physical Property (13 pieces for each size are tested):

Size	Item		Std	1	2	3	4	5	6	7	8	9	10	11	12	13
XS	Length (mm) (min)		220	230	234	237	238	234	236	231	236	235	239	237	235	230
	Width (mm)		70±10	77	77	78	77	77	78	78	77	77	78	77	78	77
	Thickness (mm) (min)	Finger	0.05	0.06	0.06	0.06	0.07	0.06	0.07	0.06	0.07	0.06	0.07	0.06	0.07	0.06
		Palm	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.06	0.05	0.05	0.05	0.06	0.05
	Before aging	Tensile Strength (Mpa) (min)	14	16.8	17.9	16.8	15.9	16.7	17.8	16.8	16.9	17.5	18.4	18.6	18.9	20
		Elongation (%) (min)	500	530	520	510	530	510	530	530	530	510	520	500	530	520
	After aging	Tensile Strength (Mpa) (min)	14	16.1	15.9	16.4	15.9	16.7	17.4	17.8	16.9	16.8	16.4	18.6	18.6	18.8
		Elongation (%) (min)	400	530	530	510	530	510	490	510	500	500	500	520	510	490
S	Length (mm) (min)		220	233	238	237	238	236	236	234	236	236	239	242	239	242
	Width (mm)		80±10	87	88	87	86	87	86	88	86	88	88	87	87	87
	Thickness (mm) (min)	Finger	0.05	0.07	0.06	0.06	0.07	0.06	0.07	0.06	0.07	0.06	0.07	0.06	0.07	0.06
		Palm	0.05	0.06	0.05	0.05	0.05	0.05	0.06	0.05	0.05	0.05	0.05	0.05	0.05	0.05
	Before aging	Tensile Strength (Mpa) (min)	14	17.0	16.1	16.4	15.9	16.6	18.1	17.4	17.6	17.0	18.4	17.6	18.4	18.0
		Elongation (%) (min)	500	510	520	550	540	510	530	530	540	510	500	540	520	510
	After aging	Tensile Strength (Mpa) (min)	14	15.7	15.9	16.4	17.0	16.7	17.4	17.5	16.9	16.8	16.4	18.6	18.6	19.0
		Elongation (%) (min)	400	480	480	520	430	510	500	410	500	520	500	420	500	530
M	Length (mm) (min)		230	240	238	242	238	236	238	236	240	230	239	242	242	242
	Width (mm)		95±10	97	97	96	98	96	97	98	96	98	97	97	97	97
	Thickness (mm) (min)	Finger	0.05	0.07	0.06	0.06	0.07	0.06	0.07	0.06	0.07	0.06	0.07	0.06	0.07	0.06
		Palm	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05
	Before aging	Tensile Strength (Mpa) (min)	14	16.2	15.9	16.4	15.9	16.7	18.1	17.8	16.9	17.9	18.4	18.6	18.6	19.9
		Elongation (%) (min)	500	530	520	550	500	510	500	550	510	520	520	530	500	540
	After aging	Tensile Strength (Mpa) (min)	14	16.4	15.8	16.4	16.2	16.7	17.4	17.5	16.9	16.8	17.0	17.6	18.6	18.4
		Elongation (%) (min)	400	500	480	510	500	510	490	510	500	490	450	520	530	500
L	Length (mm) (min)		230	240	238	242	238	238	240	238	240	238	239	244	242	240
	Width (mm)		110±10	109	110	110	110	109	109	109	109	109	109	108	110	109
	Thickness (mm) (min)	Finger	0.05	0.06	0.06	0.06	0.07	0.06	0.07	0.06	0.07	0.06	0.07	0.06	0.07	0.06
		Palm	0.05	0.05	0.05	0.05	0.05	0.05	0.06	0.05	0.05	0.05	0.05	0.05	0.06	0.05
	Before aging	Tensile Strength (Mpa) (min)	14	16.0	15.9	16.4	15.9	16.7	18.1	17.8	16.9	17.5	18.4	18.6	18.6	19.7
		Elongation (%) (min)	500	540	520	550	520	510	500	550	520	520	500	550	500	540
	After aging	Tensile Strength (Mpa) (min)	14	15.6	15.9	17.1	15.9	16.7	17.2	17.8	16.9	16.8	16.1	18.6	17.0	16.7
		Elongation (%) (min)	400	490	480	510	510	510	490	510	400	500	500	520	510	490
XL	Length (mm) (min)		230	241	238	232	238	236	240	238	240	238	239	240	236	240
	Width (mm)		120±10	117	117	116	116	116	116	116	116	116	116	116	116	116
	Thickness (mm) (min)	Finger	0.05	0.07	0.06	0.06	0.07	0.06	0.07	0.06	0.07	0.06	0.07	0.06	0.07	0.06
		Palm	0.05	0.05	0.06	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05
	Before aging	Tensile Strength (Mpa) (min)	14	16.0	15.9	16.2	15.2	16.7	17.1	17.0	16.9	17.5	17.6	18.6	18.1	18.0
		Elongation (%) (min)	500	550	520	520	500	510	500	520	500	520	500	550	530	520
	After aging	Tensile Strength (Mpa) (min)	14	15.7	14.9	16.4	16.9	16.7	17.4	17.8	16.9	16.8	16.4	18.6	17.6	19.0
		Elongation (%) (min)	400	450	480	510	450	510	490	520	500	500	490	520	510	460

Shijiazhuang Hongray Group Co., Ltd.

South Tongda Rd., East Dist. Jinzhou City,Hebei , 052260,China

2. Testing Results for pinhole testing: as per ASTM D5151-19 and FDA 1000ml Water Leak Test (21 CFR 800.20).

Testing Criteria						Testing Result	Conclusion
Lot size	Round	Sample size	Cumulative sample size	Accepted/ Rejected Criteria			
				Ac	Re		
35,000 and above	First	125	125	1	7	125 glove are sampled, 0 piece leak	Pass
	Second	125	250	4	10		
	Third	125	375	8	13		
	Fourth	125	500	12	17		
	Fifth	125	625	17	20		
	Sixth	125	750	21	23		
	Seventh	125	875	25	26		

Conclusion:

The samples for Powder Free Nitrile Examination Gloves, Tested for Use with Chemotherapy Drugs (Blue) complies with ASTM D6319-19 Standard Specification for Nitrile Examination Gloves.

Approved by : Zhun Chunyan Reviewed by: Xu Lihua Prepared by: Xing Lifang Zhang Hui

Shijiazhuang Hongray Group Co., Ltd.
South Tongda Rd., East Dist. Jinzhou City,Hebei , 052260,China

Pinhole Testing results and conclusion:

Sequential Sample Run	**Defects locations devoted by "O" and type (V=Visual Defect, I=Immediate Leak, 2= Two Minute Leak)**					**Cumulative # Defects/ Cumulative # Gloves tested**
Round # 1	Gloves #	Gloves #	Gloves #	Gloves #	Gloves #	**0/125**
Round # /	Gloves #	Gloves #	Gloves #	Gloves #	Gloves #	/
Round # /	Gloves #	Gloves #	Gloves #	Gloves #	Gloves #	/
Round # /	Gloves #	Gloves #	Gloves #	Gloves #	Gloves #	/
Round # /	Gloves #	Gloves #	Gloves #	Gloves #	Gloves #	/
Round # /	Gloves #	Gloves #	Gloves #	Gloves #	Gloves #	/

Conclusion: The pinhole testing for Powder Free Nitrile Examination Gloves (Blue) meet the requirements of FDA 1000ml Water Leak Test (21 CFR 800.20).

Approved by : Zhu Chunyan

Reviewed by: Xu Lihua

Prepared by: Xing Lifang Zhang Hui

Shijiazhuang Hongray Group Co., Ltd.
South Tongda Rd., East Dist. Jinzhou City,Hebei , 052260,China

Powder Testing

Testing requested:
For compliance with residual powder content defined in ASTM D6319-19 Standard Specification For Nitrile Examination Gloves.

Test Methods:
As specified in ASTM D6124-06（2017）Standard Test Method for Residual Powder on Medical Gloves

Testing results:

Size	XS	S	M	L	XL
Sample quantity	5	5	5	5	5
Average content (mg/glove)	0.55	0.56	0.59	0.60	0.61
Powder Content Criteria: Not more than 2mg/glove for powder free glove.					

Conclusion:
The samples for Powder Free Nitrile Examination Gloves, (Blue) comply with residual powder content requirements specified in ASTM D6319-19 Standard Specification for Nitrile Examination Gloves.

Approved by: Zhu Chunyan

Reviewed by: Xu Lihua

Prepared by: Xing Lifang Zhang Hui

SHIJIAZHUANG HONGRAY GROUP CO LTD

SOUTH TONGDA RD., EAST DIST. JINZHOU CITY, HEBEI, 052260, CHINA

DECLARATION OF CONFORMITY

We hereby declare that the Disposable Powder Free Nitrile Examination Gloves, manufactured by subsidiary companies under Shijiazhuang Hongray Group Co. Ltd. with the size of XS, S, M, L and XL meet the provisions of the Directive 93/42/EEC as amended by 2007/47/EEC.

Applied harmonized standards: EN455-1:2000, EN455-2:2015, EN ISO 14971:2012, EN ISO 13485:2016.

Conformity assessment procedure: Follow the procedure referred to in Annex VII of Medical Device Directive 93/42/EEC as amended by 2007/47/EEC.

Signature: Wumin 

Date: February 26, 2019

Title: QA Director of Hongray Group

Shijiazhuang Hongray Group Co., Ltd

SHIJIAZHUANG HONGRAY GROUP CO LTD

SOUTH TONGDA RD., EAST DIST. JINZHOU CITY, HEBEI, 052260, CHINA

DECLARATION OF CONFORMITY

We hereby declare that the Disposable Powder Free Nitrile Examination Gloves, manufactured by subsidiary companies under Shijiazhuang Hongray Group Co. Ltd. with the size of XS, S, M, L and XL meet the PPE Regulation (EU) 2016/425.

Applied harmonized standards: EN420:2003+A1:2009, EN ISO374-1:2016, EN 374-2:2014, EN 374-4:2013, EN ISO 374-5:2016.

Signature: Wumin 

Date: February 26, 2019

Title: QA Director of Hongray Group
Shijiazhuang Hongray Group Co., Ltd

SATRA TECHNOLOGY

Issued to:

Shijiazhuang Hongray Group Co., Ltd
South Tongda Road, East District
Jinzhou City
Hebei
052260
China

Notified Body: 2777

SATRA customer number: P1853

EU Type-Examination Certificate

Certificate number: 2777/11050-02/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:
Following the EU Type-Examination this product group has been shown to satisfy the applicable essential health and safety requirements of Annex II of the PPE Regulation (EU) 2016/425 as a Category III product.

Product reference:

NPF2001-XS
NPF2002-S
NPF2003-M
NPF2004-L
NPF2005-XL

Description:

Disposable nitrile glove (blue beaded ambidextrous)

Sizes:

6	XS
7	S
8	M
9	L
10	XL

Classification:

EN ISO 374-1:2016 TYPE B	Level	EN 374-4:2013 Degradation %
40% Sodium hydroxide	6	-16.0
30% Hydrogen peroxide	3	26.8
37% Formaldehyde	4	34.0

EN ISO 374-5:2016	Level
Protection against bacteria and fungi	Pass
Protection against virus	Pass

Standards/Technical specifications applied:
EN ISO 374-1:2016; EN 374-4: 2013; EN ISO 374-5:2016; EN 420: 2003+A1: 2009

Technical reports/Approval documents:
SATRA: CHT0271907/1823/SPT/Issue 3, CHT0271907/1823/JS/A, CHT0271907/1823/JS/B, CHT0271907/1823.
SGS: HL50134/2019

Signed on behalf of SATRA: Anita Brennan — Anita Brennan — Geoff Graham

Date first issued: 10/08/2018
Date of issue: 15/07/2019

Expiry date: 10/08/2023

TERMS AND CONDITIONS

The following conditions apply in addition to SATRA's standard terms and conditions of business and those given in the current certification agreement.

The certificate holder is licensed to mark the products detailed within this certificate in accordance with Annex V (Module B) of the Regulation (EU) 2016/425 of the European Parliament and of the council of 9th March 2016 on personal protective equipment once you have drawn up an EU declaration of product conformity.

Please note:

1. Where the product is classified as category III then CE Marking of production is reliant on current compliance with Regulation 2016/425 module C2 or Module D. (Except that specifically produced to fit an individual user).
2. Full details of the scope of the certification and product(s) certified are contained within the manufacturer's technical documentation.
3. Where a translation of this certificate exists, the English language version shall be considered as the authoritative text.
4. Certification is limited to production undertaken at the sites listed in the manufacturers technical documentation.
5. Ongoing manufactured product shall be consistent with the product(s) certified and listed on this certificate.
6. The Manufacturer shall inform SATRA of any changes to the certified product or technical documentation.
7. Where results obtained during type testing are within the budget of uncertainty when compared to the pass requirement, classification or performance level, then it is the responsibility of the manufacturer to ensure that the factory production control and manufacturing tolerances are such that the product placed on the market meets with the stated requirements, classifications or performance levels.
8. This certificate shall be kept together with the relevant technical documentation in a safe place by the client named on this certificate. Production of this certificate and other documentation may be required by a representative of the EC member state government.
9. This certificate relates only to the condition of the testable items at the time of the certification procedure and is subject to the expiry date shown.
10. SATRA reserves the right to withdraw this certificate if it is found that a condition of manufacture, design, materials or packaging have been changed and therefore no longer comply with the requirements of Regulation 2016/425.

VERIFICATION OF EN 455 CONDITIONAL COMPLIANCE

No.:	SHHL1602007536MD-01C
Product Name:	DISPOSABLE NITRILE GLOVE
Style No:	XS,S,M,L,XL,XXL
Applicant:	SHIJIAZHUANG HONGRAY GROUP CO.,LTD SOUTH TONGDA RD.,EAST DIST. JINZHOU CITY, HEBEI, 052260, CHINA
Manufacturer:	SHIJIAZHUANG HONGRAY GROUP CO.,LTD SOUTH TONGDA RD.,EAST DIST. JINZHOU CITY, HEBEI, 052260, CHINA

Sufficient samples of the product have been tested and found to be in conformity with

Test Standard:	EN455-1:2000 MEDICAL GLOVES FOR SINGLE USE- PART 1: REQUIREMENTS AND TESTING FOR FREEDOM FROM HOLES EN455-2:2015 MEDICAL GLOVES FOR SINGLE USE- PART 2: REQUIREMENTS AND TESTING FOR PHYSICAL PROPERTIE EN455-3:2015 MEDICAL GLOVES FOR SINGLE USE- PART 3: REQUIREMENTS AND TESTING FOR BIOLOGICAL EVALUATION CLAUSE 4.4 & 4.6
as shown in the Test Report Number(s):	SHHL1602007536MD-01

This verification is only valid for the equipment and configuration described, and in conjunction with the test data detailed. It contains the result of the single examination of the subject being in hand and does not represent any universally valid decision concerning the quality of any subject of the current production.

Donna Gu
CRS/Hardline SBU Section Head
SGS-CSTC Standards Technical Services Co., Ltd.

Apr 12, 2016

SGSPAPER
16598818

CE DECLARATION OF CONFORMITY

Manufacturer,

Name: Shijiazhuang Hongray Group Co. Ltd.,

Address: South Tongda Road, East district, Jinzhou City, Hebei, 052260, China,

Declares that the MDD described hereafter

Products name and Model:

Disposable Nitrile Examination Gloves

XS, S, M, L and XL

Meet the provisions of the Council Directive 93/42/EEC as amended by 2007/47/EEC and Provisions of the Regulation (EU) 2017/745 which apply to them.

Examination gloves are classified as Class I medical devices in accordance with the rules set out in Annex VIII.

Applied harmonized standards: EN455-1:2000, EN455-2:2015, EN455-3:2015, EN ISO 14971:2012, EN ISO 13485:2016.

Conformity assessment procedure: Annex VII of Medical Device Directive 93/42/EEC as amended by 2007/47/EEC and Article 52 in MDR 2017/745.

The CE declaration of conformity is issued under the sole responsibility of Shijiazhuang Hongray Group Co. Ltd.

The products can be placed the following CE mark.

CE

Signature: Wumin

Date: March 03, 2020

Regulatory Authority

SGS

Test Report

No.: SHHL1602007536MD-01 Date: APR. 06, 2016 Page: 1 of 8

SHIJIAZHUANG HONGRAY GROUP CO., LTD
SOUTH TONGDA RD., EAST DIST. JINZHOU CITY, HEBEI, 052260, CHINA

THE TEST REPORT IS TO SUPERSEDE THE TEST REPORT No.: SHHL1602007536MD DATE: MAR. 28, 2016
The following sample(s) was/were submitted and identified by the client as:

Sample Description	: DISPOSABLE NITRILE GLOVE
Style/ Item No.	: XS,S,M,L,XL,XXL
Country of Origin	: CHINA
Sample Receiving Date	: FEB. 29, 2016
Testing Period	: FEB. 29, 2016 TO MAR. 28, 2016
Test Performed	: SELECTED TEST(S) AS REQUESTED BY APPLICANT
Test Requested	: 1. EN 455-1:2000 MEDICAL GLOVES FOR SINGLE USE – PART 1: REQUIREMENTS AND TESTING FOR FREEDOM FROM HOLES 2. EN 455-2: 2015 MEDICAL GLOVES FOR SINGLE USE – PART 2: REQUIREMENTS AND TESTING FOR PHYSICAL PROPERTIE 3. EN 455-3: 2015 MEDICAL GLOVES FOR SINGLE USE— PART 3: REQUIREMENTS AND TESTING FOR BIOLOGICAL EVALUATION CLAUSE 4.4 & 4.6
Test Result(s)	: FOR FURTHER DETAILS, PLEASE REFER TO THE FOLLOWING PAGE(S)
Conclusion	: THE SUBMITTED SAMPLE MET THE TEST REQUIREMENT.

****

Signed for and on behalf of
SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd.

Vincent Feng
Technical Manager

4F, Building, No.889, Yishan Road, Xuhui District Shanghai, China 200233 t (86) 400 960 9661 f (86-21) 6115 6899 www.sgsgroup.com.cn
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Test Conducted:

1. EN 455-1:2000 Medical gloves for single use – part 1: Requirements and testing for freedom from holes

Number of test sample	:	200 Pieces
The type of gloves	:	examination/procedure gloves
Manufacturing batch code	:	/
Batch size	:	/
Sample size	:	XS, S, M, L, XL, XXL
Number of non-conforming gloves	:	None
Defects observed before testing	:	No defects
Test Result	:	Pass

Clause	Test Items	Result	Note
5	Watertightness test for detection of holes	---	---
5.1	Referee testing		# 1&2

2. EN 455-2: 2015 Medical gloves for single use – part 2: Requirements and testing for physical propertie

Number of test sample	:	104 Pieces
Type	:	examination/procedure gloves
The manufacturing batch code	:	/
Size	:	XS, S, M, L, XL, XXL
Defects observed before testing	:	No defects
Test Result	:	Pass

Clause	Test Items	Result	Note
4	Dimensions	Pass	#3
5	Strength	Pass	#1&4
7	Labeling	Pass	/

3. EN 455-3: 2015 Medical gloves for single use—Part 3: Requirements and testing for biological evaluation

Number of test sample	:	5 Pieces
Finishes of gloves	:	Powdered-free gloves other than surgeon's gloves
Defects observed before testing	:	No defects
Test Result	:	Pass

Clause	Test Items	Result	Note
4.4	Powder	Pass	#1, 5&6
4.6	Labeling	Pass	/

Note:
1. As per client's declare, these gloves (four size: XS, S, M, L, XL, XXL) only size different, the material is the same, and only the glove of size M was tested.
2. See result 1.
3. See result 2.
4. See result 3.
5. Test according to EN ISO 21171-2006.
6. The powder of sample was 0.3mg＜2mg.

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Test Results:

1. Watertightness test for detection of holes

Sample Quantity: 200pcs

AQL: 1.5 Accept: 7 Reject: 8 Found: 0

2. Dimensions

Sample Quantity: 78pcs

Size	XS												
Length(mm)	253	253	253	254	252	255	256	254	253	254	252	253	253
Width(mm)	79	78	79	77	78	77	78	77	78	79	78	79	78

Median value:

Length (mm): 253
Width (mm): 78

Size	S												
Length(mm)	245	244	242	243	244	246	245	244	245	246	244	243	243
Width(mm)	88	85	87	86	88	87	86	88	87	88	87	86	86

Median value:

Length (mm): 244
Width (mm): 87

Size	M												
Length(mm)	244	245	245	246	245	247	246	245	244	245	246	247	246
Width(mm)	96	95	97	96	95	97	96	96	95	96	97	96	97

Median value:

Length (mm): 245
Width (mm): 96

Size	L												
Length(mm)	243	242	241	242	243	242	242	242	242	243	241	242	243
Width(mm)	109	108	107	109	108	107	108	107	108	109	108	107	107

Median value:

Length (mm): 242
Width (mm): 108

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Size	XL												
Length(mm)	249	248	250	249	247	248	249	248	248	249	248	249	248
Width(mm)	114	113	114	115	113	114	115	115	114	115	116	114	115

Median value:

Length (mm): 248

Width (mm): 114

Size	XXL												
Length(mm)	245	246	244	244	245	246	245	246	246	245	245	244	243
Width(mm)	119	118	120	119	118	119	118	120	119	118	119	120	119

Median value:

Length (mm): 245

Width (mm): 119

Requirements: see table 1&2

Table 1 Dimensions for surgical gloves

Size	Median length in mm	Median width in mm
5	≥250	67±4
5.5	≥250	72±4
6	≥260	77±5
6.5	≥260	83±5
7	≥270	89±5
7.5	≥270	95±5
8	≥270	102±6
8.5	≥280	108±6
9	≥280	114±6
9.5	≥280	121±6

Table 2 Dimensions for examination/procedure gloves

Size	Median length in mm	Median width in mm
Extra small	≥240	≤80
Small		80±10
Medium		95±10
Large		110±10
Extra Large		≥110

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3. Strength

Sample Quantity: 26pcs

Size	M												
Force at break(N)	9.19	8.79	9.27	9.02	8.25	9.35	9.27	9.36	8.98	8.38	9.02	8.90	9.58
Force at break after challenge testing(N)	9.41	9.50	9.50	9.38	9.58	9.46	9.23	9.38	9.77	9.50	9.58	9.18	9.65

Median value:

Force at break during shelf life (N): 9.02

Force at break after challenge testing (N): 9.50

Table 3 — Median values of force at break

	Force at break in Newton		
	Surgical gloves a)	Examination/procedure gloves b)	c)
Throughout shelf life tested according to 5.2 and within 12 months of manufacture tested according to 5.3	≥ 9,0	≥ 6,0	≥ 3,6
a) Requirements for all surgical gloves.			
b) Requirements for all examination gloves, except gloves made from thermoplastic materials (e.g. polyvinylchloride, polyethylene)..			
c) Requirements for gloves made from thermoplastic materials (e.g. polyvinylchloride, polyethylene).			

Remark:

1. The sample selecting amount for Watertightness test for detection of holes is deviated to 200 pcs as accessed by SGS.

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Sample Photo:

Received sample (size XS)

Received sample (size S)

Received sample (size M)

Received sample (size L)

SGS 检测专用章 Testing Service
SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd. Testing Center Hardness
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Received sample (size XL)

Received sample (size XXL)

Label

SHIJIAZHUANG HONGRAY GROUP CO., LTD.

DISPOSABLE NITRILE GLOVE

SINGLE USE ONLY
POWDER-FREE
AMBIDEXTROUS
NON-STERILE

SIZE: MEDIUM

DISPOSABLE NITRILE GLOVE

SGS authenticate the photo on original report only

End of Report

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CMA
180015144123
有效期至2024年07月09日止

检 验 报 告

报告编号：2019-Q-0328

委 托 方：石家庄鸿锐集团有限公司

样品名称：一次性使用医用丁腈手套

型　　号：M

检验类别：委托检验

河北省医疗器械与药品包装材料检验研究院

河北省医疗器械与药品包装材料检验研究院

检 验 报 告 首 页

报告编号：2019-Q-0328　　首页 1 页 W 1 页 Z 1 页 共 3 页

样品名称	一次性使用医用丁腈手套 送样	样品编号	2019-Q-0328
商　　标	鸿锐	型号规格	M
委托方	石家庄鸿锐集团有限公司	检验类别	委托检验
委托方地址	河北省晋州市通达路东段路南	产品编号/批号	01D9ANF
生产单位	石家庄鸿锐集团有限公司	抽样单编号	/
受检单位	/	生产日期	/
抽样单位	/	样品数量	150 副
抽样地点	/	抽样基数	/
抽样日期	/	检验地点	本院试验室
收样日期	2019 年 04 月 12 日	检验日期	2019 年 04 月 16 日至 2019 年 05 月 29 日
检验项目	部分项目		
检验依据	GB 10213-2006《一次性使用医用橡胶检查手套》		
检验结论	所检项目符合 GB 10213-2006《一次性使用医用橡胶检查手套》标准要求。 （检验报告专用章或检验单位公章） 签发日期　2019 年 05 月 30 日		
备注	1）报告中“——”表示此项不适用，报告中“/”表示此项空白。		

批 准：　　审 核：

职 务：副院长

河北省医疗器械与药品包装材料检验所

检 验 报 告

报告编号：2019-Q-0328　　W　共1 页　第1 页

检验项目		标准条款号	标准要求	抽样方案 n/Ac	检验结果	不合格品数	单项判定
尺寸 mm	长度	6.1	≥230	13/1	235.0～240.5	0	符合
	宽度		95±5		94.0～95.0		
	单层厚度		0.08～2.00		0.080～0.140		
不透水性		6.2	不得有渗漏现象	200/10	均无渗漏	0	符合
扯断力 N	老化前	6.3	≥7.0	13/1	7.02～7.18	1	符合
	老化后				6.98、7.01～7.11		
断裂伸长率	老化前		≥500%	13/1	501.0%～538.1%	0	符合
	老化后		≥400%		401.9%～439.0%		

审 核：马宁　　检 验：刘育英

2020.03.30 Hongray 品牌 Nitrile 100/盒 M号 尺寸: 240(L)x120(W)x65(H)mm 印刷色: C M K