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

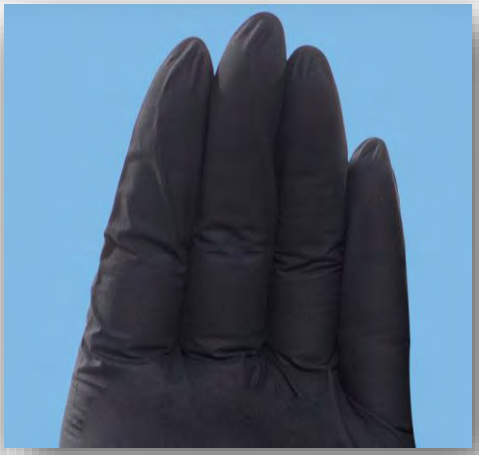
丁腈手套由人工合成的丁腈橡胶制成。相比较乳胶手套，丁腈手套具有更优越的抗穿刺能力、抗细菌渗透能力、抗化学性能力及持久穿戴力。可为使用者提供更安全的防护。目前丁腈手套被欧美各大实验室、研究所、医院、诊所、疗养院等医疗机构广泛使用，得到了用户的高度评价

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

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®

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

TÜVRheinland®
LGA
Precisely Right.

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

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, 052260 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 2020-04-10 until 2020-10-19.
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

2020-04-14

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

www.tuv.com

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

TÜVRheinland®
Precisely Right.

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
/07	JinZhou XinRui Plastic Products Co., Ltd. Unified Social Credit Code: 911301835795985148 Registration Address: South Tongda Rd., East Dist., Jinzhou City, 052260 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, 050000 Hebei, P. R. China Operation Address: same as above	Manufacture and Distribution of Patient Examination Gloves
/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

2020-04-14

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

第一类医疗器械备案凭证

石家庄鸿业塑胶制品有限公司：

根据相关法规要求，对你单位第一类医疗器械：一次性使用医用PVC/丁腈合成手套予以备案，备案号：冀石械备20200138号。

石家庄市市场监督管理局

（盖章）

日期：2020年05月15日

第一类医疗器械备案信息表

备案号： 冀石械备20200138号

备案人名称:	石家庄鸿业塑胶制品有限公司
备案人组织机构代码：	91130100752433415G
备案人注册地址：	河北省赞皇县东高工业区
生产地址:	河北省赞皇县东高工业区
代理人:	/
代理人注册地址:	/
产品名称:	一次性使用医用 PVC/丁腈合成手套
型号/规格:	产品分非消毒型和经环氧乙烷消毒型。按长度和掌宽分为ⅠXS、ⅠS、ⅠM、ⅠL、ⅠXL、ⅡXS、ⅡS、ⅡM、ⅡL、ⅡXL十种规格。
产品描述:	该产品以PVC粉、增塑剂、液体丁腈胶为主要原料，经过高温烘烤而成。因加入不同颜色的色母而分别呈蓝色、绿色、黑色、白色、黄色、紫色、粉色、红色、蓝紫色、自然色（自然色为产品的原色未加色母）。
预期用途:	用于防止医生与患者之间的交叉感染。
备注:	
备案单位和日期:	石家庄市市场监督管理局 备案日期：2020年05月15日
变更情况:	

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 17, 2013

Hongye Plastic Products Company, Limited
C/O Ms. Kathy Liu
Project Manager
Surprotect, Incorporated
3973 Schaefer Avenue
CHINO CA 91710

Re: K122408
Trade/Device Name: Powder Free Nitrile Examination Gloves (Black, White, Green)
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZA
Dated: November 26, 2012
Received: November 27, 2012

Dear Ms. 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Device
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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

Attachment A

INDICATION FOR USE

510 (k) NUMBER (IF KNOW): K122408
APPLICANT: Hongye Plastic Products Co., Ltd.
DEVICE NAME: Powder Free Nitrile Examination Gloves (Black, White, Green)

INDICATIONS FOR USE:

A patient examination glove is disposable non-sterile device intended for medical purpose that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

Prescription Use _____ AND/ OR Over-The-Counter-Use ___√___
(Part 21 CFR 801 Subpart D) (21CFR 801Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Elizabeth F. Claverie
2013.01.16 14:53:22 -05'00'

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K122408

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

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

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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