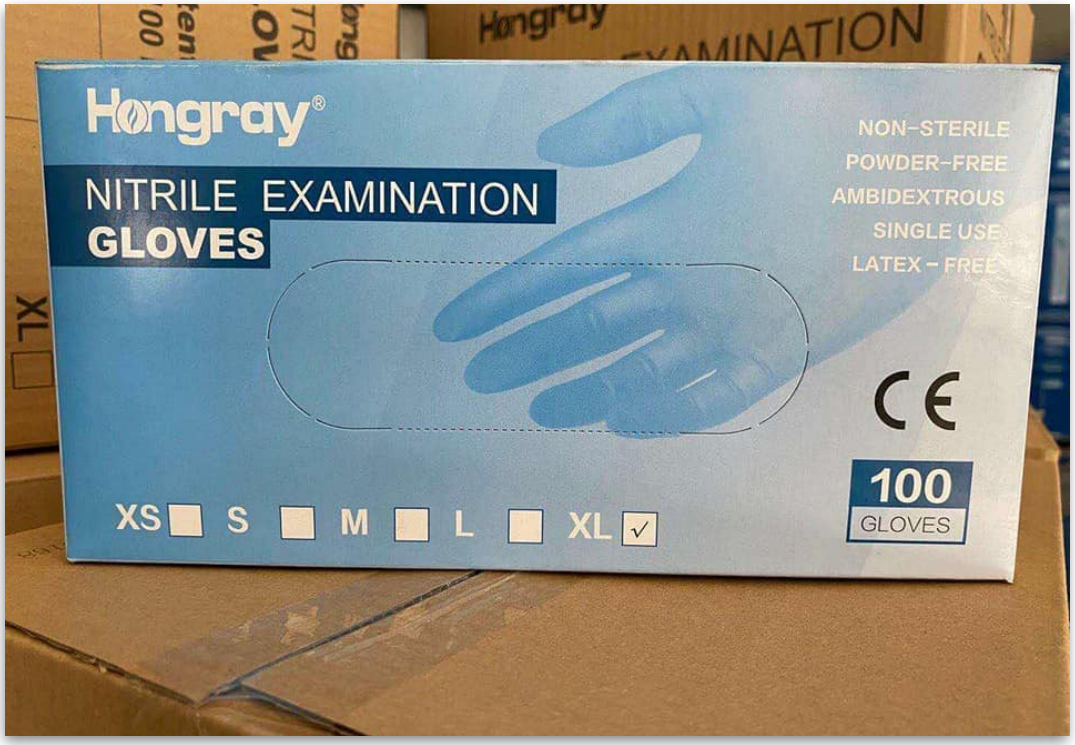
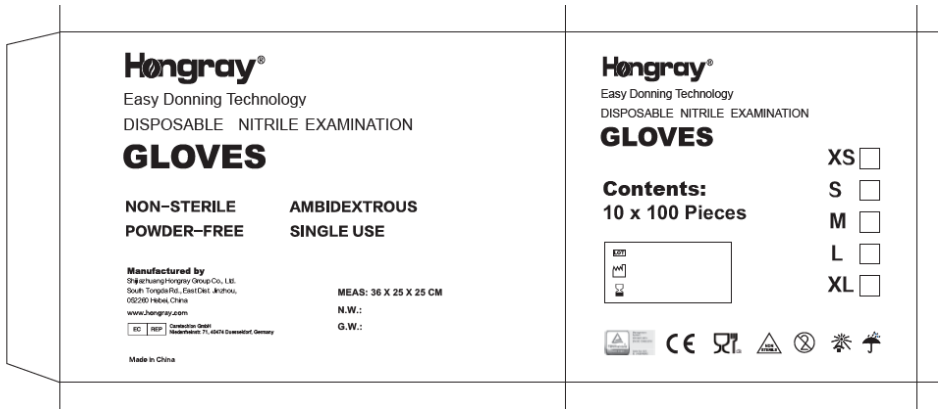
NITRILE EXAMINATION GLOVES

Clear Labels with Sizing for Ease of Identification





Hongray

NITRILE EXAMINATION GLOVES

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: Wupan

Date: March 03, 2020

Regulatory Authority

CERTIFICATE of Conformity

TÜV

Registration No.: AK 60003547 0001

Report No.: 21100703 003

Holder: Shijiazhuang Hongray Group
Syntex Healthcare Products
Co., Ltd. Hebei Province
No. 1 Fanjiazhuang Industrial Zone
Xinji City, 052360
China

Product: Schutzhandschuhe
Protective Gloves

Identification: medical gloves for single use
Nitrile gloves, blue sizes S, M and L

Tested acc. to: EN 455-1:2000
EN 455-2:2000
EN 455-3:1999

The certificate of conformity refers to the above mentioned product. This is to certify that the specimen is in conformity with the assessment requirement mentioned above. This certificate does not imply assessment of the production of the product and does not permit the use of a TÜV Rheinland mark of conformity.

Certification Body

Cologne, 25.10.2002

Dipl.-Ing. H.-J. Krüger

TÜV Rheinland Product Safety GmbH - Am Grauen Stein - D-51105 Köln

NITRILE EXAMINATION GLOVES

SGS

VERIFICATION OF EN 455 CONDITIONAL COMPLIANCE

No.:	SHHG1510041938MDC
Product Name:	NITRILE GLOVE(NO-STERILE, AMBIDEXTROUS,POWDER FREE)
Style No:	XS, S, M, L, XL
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:	BS EN455-1:2000 MEDICAL GLOVES FOR SINGLE USE-PART1:REQUIREMENTS AND TESTING FOR FREEDOM FROM HOLES BS EN455-2:2015 MEDICAL GLOVES FOR SINGLE USE-PART2:REQUIREMENTS AND TESTING FOR PHYSICAL PROPERTIE BS EN455-3:2015 MEDICAL GLOVES FOR SINGLE USE-PART 3: REQUIREMENTS AND TESTING FOR BIOLOGICAL EVALUATION (CLAUSE4.4&4.6 POWDER&LABELLING)
as shown in the Test Report Number(s):	SHHG1510041938MD

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.

Vincent Feng
CTS/HEC Hardgoods Regional Technical Manager
SGS-CSTC Standards Technical Services Co., Ltd.

December 11, 2015

SGSPAPER 16317741

中华人民共和国
PEOPLE'S REPUBLIC OF CHINA
医疗器械产品出口销售证明
CERTIFICATE FOR EXPORTATION OF MEDICAL PRODUCTS

证书编号：冀石药监械出 20200026
Certificate NO.: Certificate of medical device exports made in shijiazhuang issued by Hebei Drug Supervision Administration No. 20200026

产品名称：详见附表
Product(s): **Details as per attached list.**

规格型号：详见附表
Model: **Details as per attached list.**

产品注册或备案凭证号：详见附表
Registration certificate(s): **Details as per attached list.**

生产企业：石家庄鸿欣橡胶制品有限公司
Manufacturer: Shijiazhuang Syntex Rubber Products Co., Ltd.

生产企业住所：河北省辛集市范家庄村西 307 国道路南
Address of manufacturer: South 307 National Road, Fanjiazhuang, Xinji, Hebei Province

生产许可或备案凭证号：冀辛食药监械生产备 20180002 号
Manufacturing License(s): Medical device on file under xinji Food and Drug Supervision Administration,Hebei Province No.20180002

兹证明上述产品已准许在中国生产和销售。 This is to certify that the above products have been registered to be manufactured and sold in China.

证明有效日期至： 2022 年 03 月 28 日
This certification valid until: Mar.28,2022

备注：无
Remark: nothing

2020 年 03 月 29 日
（出具单位盖章）

NITRILE EXAMINATION GLOVES

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

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:	Description:
NPF2001-XS	Disposable nitrile glove (blue beaded ambidextrous)
NPF2002-S	
NPF2003-M	
NPF2004-L	
NPF2005-XL	

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

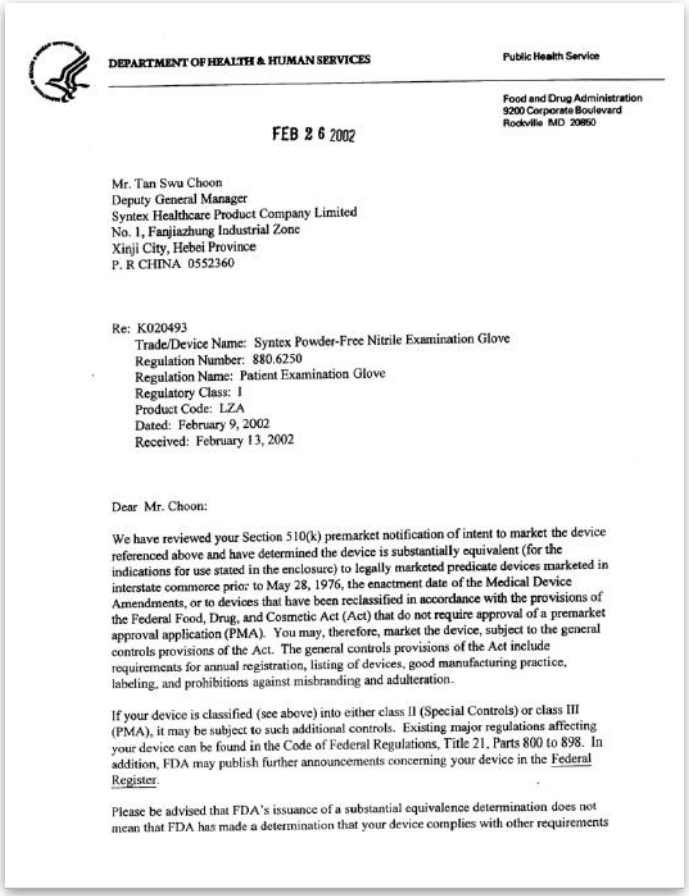
Date first issued: 10/08/2018
Date of issue: 15/07/2019 **Expiry date: 10/08/2023**

Page 1 of 2

SATRA Technology Europe Limited, Bracetown Business Park, Clonee, D15YN2P, Republic of Ireland.

NITRILE EXAMINATION GLOVES

510(k) # K02493



DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 6 2002

Mr. Tan Swu Choon
Deputy General Manager
Syntex Healthcare Product Company Limited
No. 1, Fanjiazhung Industrial Zone
Xinji City, Hebei Province
P. R CHINA 0552360

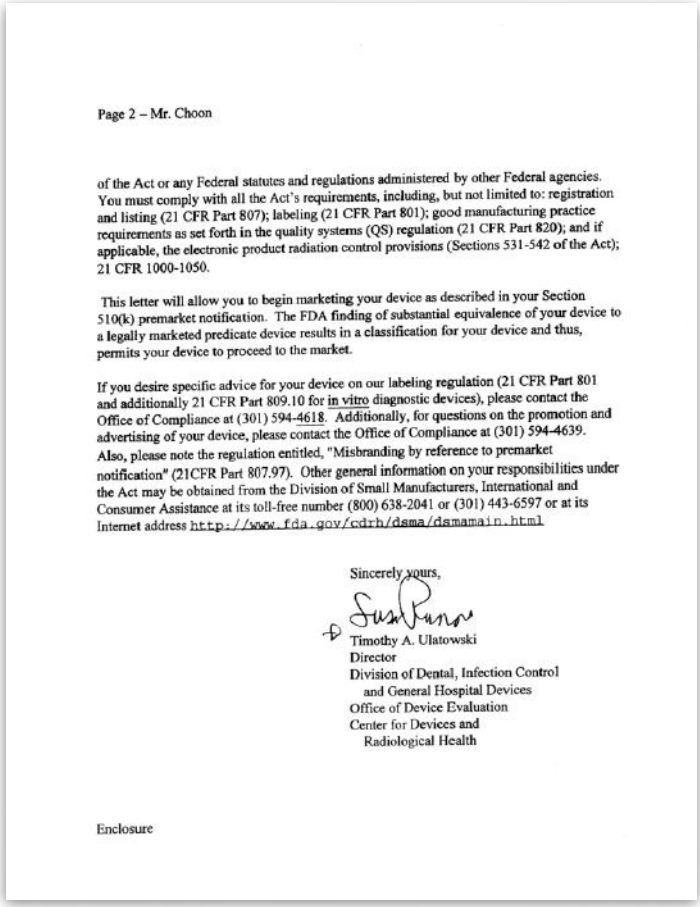
Re: K020493
Trade/Device Name: Syntex Powder-Free Nitrile Examination Glove
Regulation Number: 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZA
Dated: February 9, 2002
Received: February 13, 2002

Dear Mr. Choon:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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



Page 2 – Mr. Choon

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); 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.

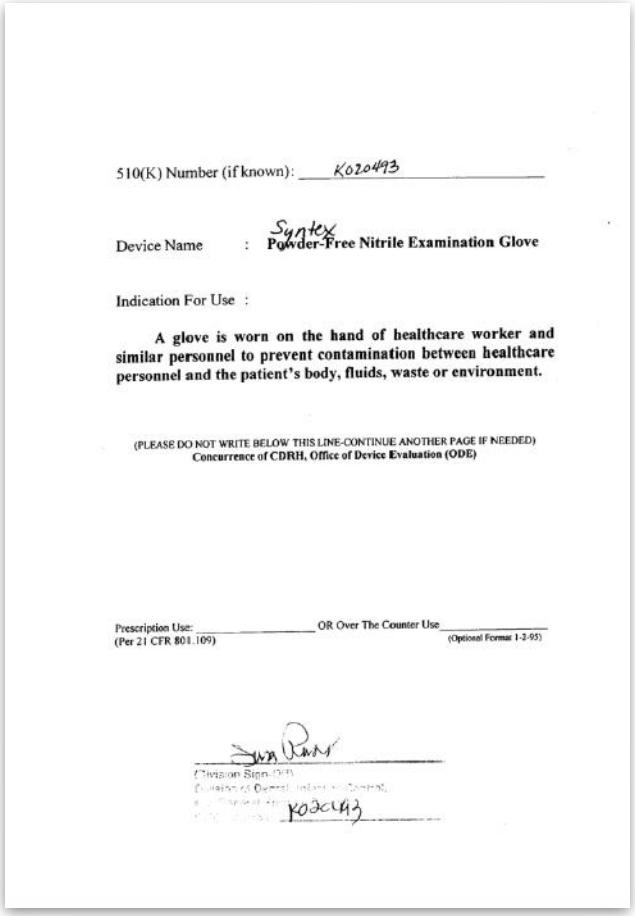
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure



510(K) Number (if known): K020493

Device Name : Syntex Powder-Free Nitrile Examination Glove

Indication For Use :

A glove is worn on the hand of healthcare worker and similar personnel to prevent contamination between healthcare personnel and the patient's body, fluids, waste or environment.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: _____ OR Over The Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-95)

Division Sign-Off
K020493

NITRILE EXAMINATION GLOVES

Nitrile Gloves.

100% Latex Free, No allergy.

More exceeding feature of puncture-resistance, anti-bacteria's penetration, chemical-proof.

Durable & Flexible, Surface-textured, Soft feeling, Comfortable donning.

Tapered cuff is easy for donning and operating.

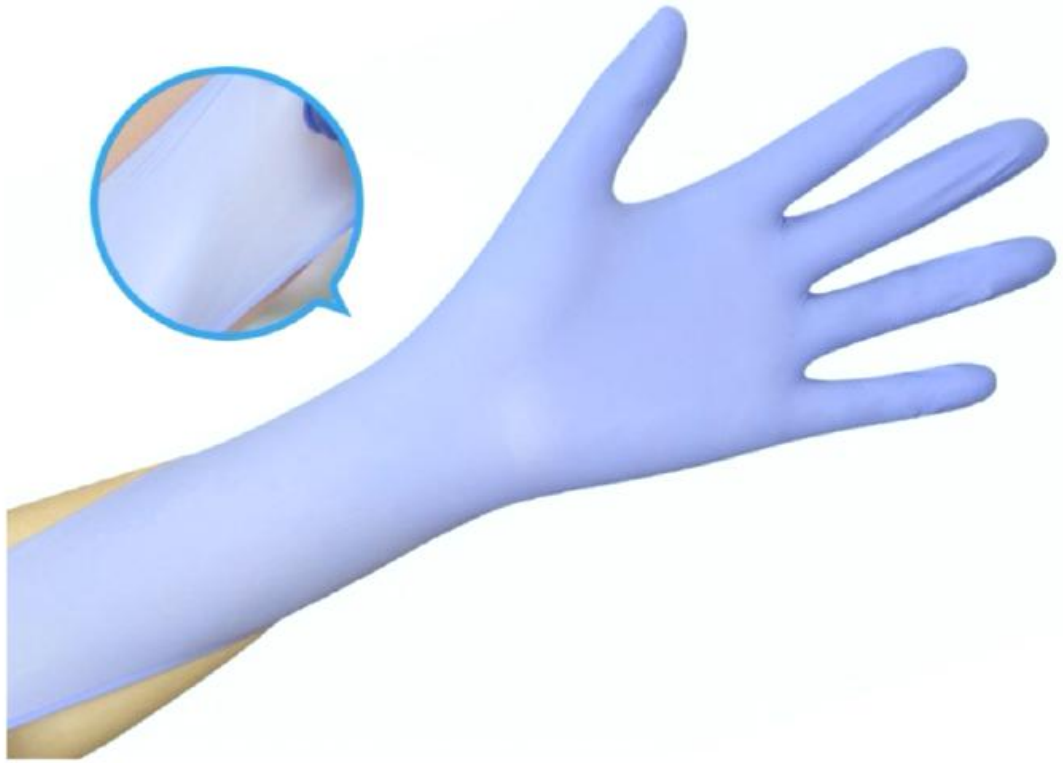
CE Certification, FDA 510K Listing.

Hongray

NITRILE EXAMINATION GLOVES

SPECS

- 100% Latex Free
- Highly Elastic and Super Soft
- Rolled Rim to facilitate easy Donning.
- Designed to give a natural rubber-like feel.
- Textured in finger tips for enhanced grip.
- Fluid Resistant: Yes
- Puncture resistant, protein and powder-free nitrile.



Quality standards

- Complies with EN 455 and EN 374
- Complies with ASTM D6319 (USA Related Product)

Tensile	Tensile strength (MPA) Before aging: 18Mpa min After aging: 20Mpa min Elongation at break (%) Before aging: 600% min After aging: 500% min	Tensile strength (MPA) Before aging: 14Mpa min After aging: 14Mpa min Elongation at break (%) Before aging: 500% min After aging: 400% min
Powder Content	2 mg/glove maximum	
Protein Content	Free Protein	

Hongray

NITRILE EXAMINATION GLOVES

Hongray

Technical Specifications

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