

## 资质荣誉 Certificates



石家庄鸿锐集团在管理、生产过程和质量控制上严格遵循美国FDA的QSR要求及ISO9001、ISO13485的标准，以确保我们的产品符合甚至优于ASTM和其他相关国家的标准。

我集团通过ISO9001质量管理认证，PVC和Nitrile手套荣获美国FDA 510K证书、欧盟CE证书，通过了EN374测试和欧洲食品安全接触测试，Nitrile手套还通过CHEMO测试。



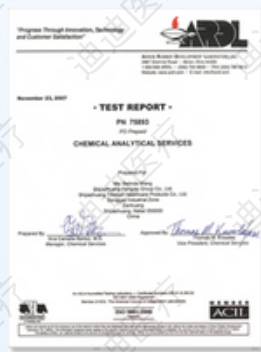
ISO质量管理认证



欧盟CE认证



SGS无尘检验报告



美国CHEMO认证



美国FDA 510K证书

## 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<br>230mm for size M-XL minimum | S-2, AQL4.0              | XS: 230-238mm<br>S: 234-242mm<br>M: 230-242mm<br>L: 238-244mm<br>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       |
| <b>Tensile Strength (Mpa)</b>  |  |                          |   |            |
| Before aging                   | 14Mpa minimum                                      | S-2, AQL4.0              | 15.7-19.9Mpa  | Pass       |
| After aging                    | 14Mpa minimum                                      |                          | 15.2-18.6Mpa  | Pass       |
| <b>Ultimate Elongation (%)</b> |  |                          |   |            |
| 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.

## 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  |

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|                      |                      |                              |       |        |      |      |      |      |      |      |      |      |      |      |      |      |      |
|----------------------|----------------------|------------------------------|-------|--------|------|------|------|------|------|------|------|------|------|------|------|------|------|
| 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   | 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 | 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 | 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 | 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 | 0.05 | 0.06 |      |
| 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 | 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  |      |

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**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<br>(V=Visual Defect, I=Immediate Leak, 2= Two Minute Leak) |   |   |  |   | Cumulative # Defects/<br>Cumulative # Gloves tested |
|-----------------------|--|---|---|--|---|---|
| Round #<br>1          | Gloves #<br>        | Gloves #<br>   | Gloves #<br>   | Gloves #<br>   | Gloves #<br>   | 0/125   |
| Round #<br>/          | Gloves #<br>        | Gloves #<br>   | Gloves #<br>   | Gloves #<br>   | Gloves #<br>   | /   |
| Round #<br>/          | Gloves #<br>       | Gloves #<br>  | Gloves #<br>  | Gloves #<br>  | Gloves #<br>  | /   |
| Round #<br>/          | Gloves #<br>      | Gloves #<br> | Gloves #<br> | Gloves #<br> | Gloves #<br> | /   |
| Round #<br>/          | Gloves #<br>      | Gloves #<br> | Gloves #<br> | Gloves #<br> | Gloves #<br> | /   |
| Round #<br>/          | Gloves #<br>      | Gloves #<br> | Gloves #<br> | Gloves #<br> | Gloves #<br> | /   |

**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

## **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





## 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

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# 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

# 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 amidextrous) |
| NPF2002-S  |  |
| NPF2003-M  |  |
| NPF2004-L  |  |
| NPF2005-XL |  |

**Classification:**

**Sizes:**

| Sizes |    | EN ISO 374-1:2016 TYPE B              | Level | EN 374-4:2013 | Degradation % |
|-------|----|---------------------------------------|-------|---------------|---------------|
| 6     | XS | 40% Sodium hydroxide                  | 6     |               | -16.0         |
| 7     | S  | 30% Hydrogen peroxide                 | 3     |               | 26.8          |
| 8     | M  | 37% Formaldehyde                      | 4     |               | 34.0          |
| 9     | L  |                                       |       |               |               |
| 10    | XL | 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:

Date first issued: 10/08/2018

Date of issue: 15/07/2019



Anita Brennan



Geoff Graham

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.