



Test Report

No.: SHHG1510041938MD

Date: NOV. 17, 2015

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

The following sample(s) was/were submitted and identified by the client as:

Sample Description : NITRILE GLOVE(NO-STERILE, AMBIDEXTROUS,POWDER FREE)
Style/ Item No. : XS,S,M,L,XL
Country of Origin : CHINA
Sample Receiving Date : NOV. 02, 2015
Testing Period : NOV. 02, 2015 TO NOV. 17, 2015
Test Performed : SELECTED TEST(S) AS REQUESTED BY APPLICANT
Test Requested : 1. BS EN 455-1: 2000 MEDICAL GLOVES FOR SINGLE USE –
PART 1: REQUIREMENTS AND TESTING FOR FREEDOM FROM HOLES
2. BS EN 455-2: 2015 MEDICAL GLOVES FOR SINGLE USE –
PART 2: REQUIREMENTS AND TESTING FOR PHYSICAL PROPERTIE
3. POWDER & LABELLING (BS 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. BS 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 : M
 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 | Pass | # 1 |

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

Number of test sample : 91 Pieces
 Type : examination/procedure gloves
 The manufacturing batch code : /
 Size : XS, S, M, L, XL
 Defects observed before testing : No defects
 Test Result : Pass

| Clause | Test Items | Result | Note |
|--------|------------|--------|------|
| 4 | Dimensions | Pass | #2 |
| 5 | Strength | Pass | #3 |



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3. BS 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 | #4 |
| 4.6 | Labelling | N/C | #6 |

Note:

1. See result 1.
2. See result 2.
3. See result 3.
4. Test according to EN ISO 21171-2006.
5. The powder of sample was 0.58mg<2mg.
6. N/C means not conducted as per client's request.



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Test results:

1. Watertightness test for detection of holes

Sample Quantity: 200

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

2. Dimensions

Sample Quantity: 65pcs

| Size | XS | | | | | | | | | | | | |
|------------|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|
| Length(mm) | 244 | 243 | 242 | 242 | 243 | 242 | 241 | 242 | 241 | 242 | 241 | 242 | 241 |
| Width(mm) | 80 | 79 | 80 | 80 | 79 | 80 | 80 | 79 | 79 | 80 | 79 | 78 | 79 |

Median value:

Length (mm): 242mm
Width (mm): 79mm

| Size | S | | | | | | | | | | | | |
|------------|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|
| Length(mm) | 245 | 245 | 244 | 245 | 246 | 244 | 244 | 245 | 245 | 243 | 244 | 245 | 244 |
| Width(mm) | 86 | 87 | 85 | 86 | 85 | 86 | 86 | 87 | 85 | 86 | 86 | 85 | 87 |

Median value:

Length (mm): 245mm
Width (mm): 86mm

| Size | M | | | | | | | | | | | | |
|------------|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|
| Length(mm) | 250 | 249 | 250 | 251 | 249 | 249 | 250 | 249 | 250 | 250 | 248 | 249 | 250 |
| Width(mm) | 98 | 97 | 98 | 98 | 98 | 97 | 96 | 97 | 98 | 98 | 97 | 97 | 98 |

Median value:

Length (mm): 250mm
Width (mm): 98mm

| Size | L | | | | | | | | | | | | |
|------------|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|
| Length(mm) | 252 | 251 | 252 | 250 | 252 | 251 | 252 | 250 | 251 | 250 | 251 | 252 | 250 |
| Width(mm) | 106 | 107 | 105 | 105 | 106 | 107 | 106 | 107 | 107 | 106 | 105 | 105 | 107 |

Median value:

Length (mm): 251mm
Width (mm): 106mm



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| Size | XL | | | | | | | | | | | | |
|------------|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|
| Length(mm) | 244 | 245 | 244 | 243 | 245 | 244 | 246 | 245 | 246 | 246 | 247 | 245 | 244 |
| Width(mm) | 111 | 110 | 111 | 110 | 110 | 112 | 112 | 110 | 111 | 110 | 111 | 110 | 110 |

Median value:

Length (mm): 245mm

Width (mm): 110mm

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 |

Table 2 Dimensions for examination/procedure glove

| 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 |

3. Strength

Sample Quantity: 26pcs

| Size | M | | | | | | | | | | | | |
|---|------|------|------|------|------|------|------|------|------|------|------|------|------|
| Force at break(N) | 6.52 | 7.20 | 7.88 | 7.12 | 7.17 | 7.95 | 7.96 | 7.27 | 7.48 | 7.02 | 7.57 | 7.82 | 6.92 |
| Force at break after challenge testing(N) | 8.68 | 7.82 | 7.40 | 7.46 | 7.50 | 8.13 | 8.02 | 7.52 | 8.17 | 7.74 | 7.57 | 7.17 | 8.01 |

Median value:

Force at break during shelf life (N): 7.27

Force at break after challenge testing (N): 7.74



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Requirements: see table 3

Table 3 — Median values of force at break

| | Force at break in Newton | | |
|--|-----------------------------|------------------------------|-------|
| | Surgical gloves | Examination/procedure gloves | |
| | a) | 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:

- As per client's declare, these gloves (five size: XS, S, M, L, XL) only size different, the material is the same, and only the gloves of size M were tested to Watertightness test for detection of holes and Strength.



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Sample Photo:

Received sample (XS)



Received sample (S)



Received sample (M)



Received sample (L)



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Received sample (XL)



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