

Test Report

No.: QDHL1810022710MD

Date: OCT.30,2018

Page: 1 of 5

LYNCMED MEDICAL TECHNICAL(BEIJING)CO., LTD
ROOM 119, NO.1111, SOUTH HUIHE ROAD, CHAOYANG DISTRICT, BEIJING

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

Sample Description : NITRILE GLOVE
SGS Ref. No. : SHHL1810057370MD
Sample Receiving Date : OCT.16,2018
Testing Period : OCT.16,2018 TO OCT.30,2018
Test Performed : SELECTED TEST(S) AS REQUESTED BY APPLICANT
Test Requested : EN 455-2-2015 MEDICAL GLOVES FOR SINGLE USE –
PART 2: REQUIREMENTS AND TESTING FOR PHYSICAL
PROPERTIES
Test Result(s) : PLEASE REFER TO THE FOLLOWING PAGE(S)
Conclusion : THE SUBMITTED SAMPLE MET THE TEST REQUIREMENT.

SGS-CSTC Standards Technical Services (Qingdao) Co., Ltd.
Approved by:



Zhou Xinkuan, SK
Lab Manager



SGS-CSTC Standards Technical Services (Qingdao) Co., Ltd.
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Test Conducted:

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

| | | |
|---------------------------------|---|---|
| Number of test sample | : | 39 Pieces |
| The type of gloves | : | examination/procedure gloves b) |
| Manufacturing batch code | : | / |
| Size | : | Surgical gloves: / Examination/procedure gloves: M |
| Defects observed before testing | : | No defects |

| Clause | Test Items | Result | Note |
|--------|--|--------|------|
| 4 | Dimensions | --- | --- |
| 4.2 | Length | Pass | # 1 |
| 4.3 | Width | Pass | # 1 |
| 5 | Strength | --- | --- |
| 5.2 | Force at break | Pass | # 2 |
| 5.3 | Force at break after challenge testing | Pass | # 2 |

Notes : #1 See result 1
#2 See result 2



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Test Report

No.: QDHL1810022710MD

Date: OCT.30,2018

Page: 3 of 5

Test Result:

1. Dimensions

Sample Quantity: 13pcs

| Size | M | | | | | | | | | | | | |
|------------|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|
| Length(mm) | 242 | 243 | 234 | 244 | 245 | 240 | 239 | 243 | 243 | 243 | 240 | 248 | 238 |
| Width(mm) | 96 | 95 | 96 | 95 | 95 | 95 | 95 | 96 | 98 | 95 | 95 | 96 | 96 |

Median value:

Length (mm): 243

Width (mm): 95

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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2. Strength

Sample Quantity: 26pcs

| Size | M | | | | | | | | | | | | |
|---|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|
| Force at break(N) | 5.0 | 5.0 | 6.6 | 6.6 | 5.8 | 5.2 | 6.6 | 6.2 | 5.2 | 6.1 | 6.6 | 6.4 | 6.9 |
| Force at break after challenge testing(N) | 7.8 | 8.2 | 6.0 | 8.3 | 9.7 | 6.9 | 8.6 | 6.3 | 8.5 | 8.0 | 8.5 | 7.3 | 8.3 |

Median value:

Force at break during shelf life (N): 6.2

Force at break after challenge testing (N): 8.2

Requirements: see table 3

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).



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Sample Photo:

Received sample



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End of Report



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