



No.: QDHL1806013404MD

Date: JUL.09,2018

Page: 1 of 4

LYNCMED MEDICAL TECHNOLOGY (BEIJING) CO.,LTD.
NO.1111, SOUTH HUIHE ROAD, CHAOYANG DISTRICT, BEIJING, CHINA 100020

The following samples were submitted and identified by/on behalf of the client as:

Name of Product/Item

PVC EXAMINATION GLOVES

Country of Origin

CHINA

Sample Receiving Date

JUN.21,2018

Testing Period

JUN.21,2018 TO JUL.09,2018

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

(EXCEPT FOR CLAUSE 7 LABELLING)

Test Result(s)

FOR FURTHER DETAILS, 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



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No.: QDHL1806013404MD

Date: JUL.09,2018

Page: 2 of 4

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 c)
Manufacturing batch code	:	1
Size	:	Examination/procedure gloves: M
Defects observed before testing	1	No defects
Test Result	:	Pass

Clause	Test Items		Result	Note
4	Dimensions		Pass	# 1
5	Strength		Pass	#2
7	Labeling		N/C	# 3

Notes

#1 See result 1

#2 See result 2

#3 N/C means not conducted as per client's request.

Test Result:

1. Dimensions

Sample Quantity: 13 Pieces

Size							M				li la		
Length(mm)	245	245	248	244	245	249	244	245	248	244	250	244	244
Width(mm)	96	98	97	97	96	98	96	98	97	96	96	98	97

Median value:

Length (mm): 245 Width (mm): 97



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No.: QDHL1806013404MD

Date: JUL.09,2018

Page: 3 of 4

Requirements: see table 1&2

Table 1 Dimensions for surgical gloves

Size	Median length	Median width				
	in mm	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		≤80		
Small		80±10		
Medium	≥240	95±10		
Large		110±10		
Extra Large		≥110		

2. Strength

Sample Quantity: 26 Pieces

Size							M						
Force at break(N)	3.6	4.0	4.6	4.3	4.2	3.7	4.4	4.5	4.6	4.7	4.4	3.8	4.4
Force at break after challenge testing(N)	4.7	4.5	4.3	4.7	4.8	5.0	4.3	4.7	3.4	3.6	4.2	5.4	4.8

Median value:

Force at break (N): 4.4

Force at break after challenge testing (N): 4.7



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No.: QDHL1806013404MD

Date: JUL.09,2018

Page: 4 of 4

Requirements: see table 3

Table 3 — Median values of force at break

		Force at break in Newton	= -	
	i. Surgical gloves a)	Examination/procedure glob) 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	

- Requirements for all surgical gloves.
- Requirements for all examination gloves, except gloves made from thermoplastic materials (e.g. polyvinylchloride, polyethylene)..
- Requirements for gloves made from thermoplastic materials (e.g. polyvinylchloride, polyethylene).

Sample Photo:

Received sample

SGS authenticate the photo on original report only

End of Report

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