

Test Report No.: SHHL1811067692SD-01 Date: APR. 02, 2019 Page: 1 of 10

LYNCMED MEDICAL TECHNOLOGY (BEIJING) CO., LTD
ROOM 119, FLOOR 1, GUOTOUSHANGKE BUILDING NO. 1111, SOUTH HUIHE ROAD
CHAOYANG DISTRICT, CHINA

THE TEST REPORT IS TO SUPERSEDE THE TEST REPORT No.: SHHL1811067690SD, DATE: MAR. 29, 2019, ORIGINAL REPORT SHALL BE INVALID. THE TEST REPORT UPDATED PROTOCOL.

Sample Description : LATEX GLOVE

Style No. : M

Sample Receiving Date : NOV. 27, 2018

Testing Period : NOV. 27, 2018 TO APR. 02, 2019

Test Performed : SELECTED TEST(S) AS REQUESTED BY APPLICANT
Test Requested : SELECTED TEST(S) AS REQUESTED BY APPLICANT
Test Result(s) : FOR FURTHER DETAILS, PLEASE REFER TO THE

FOLLOWING PAGE(S)

Conclusion : FOR FURTHER DETAILS, PLEASE REFER TO THE

FOLLOWING PAGE(S)

Signed for and on behalf of SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd.



Digitally signed by Gutan Ghenadie Date: 2022.09.21 23:43:40 EEST Reason: MoldSign Signature Location: Moldova



Melody Zhang Authorized Signatory



Unless otherwise agreed in writing, this document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at http://www.sgs.com/en/Terms-and-Conditions.aspx.and, for electronic format documents at http://www.sgs.com/en/Terms-and-Conditions.ferms-a-Document.aspx. Attention is grawn to the limitation of leading to the second of the seco



Test Report No.: SHHL1811067692SD-01 Date: APR. 02, 2019 Page: 2 of 10

Test Conducted:

BS EN 455-3	S EN 455-3:2015 Medical glove for single use-part 3: Requirements and testing for biological evaluation				
Clause	Test Category	TEST RESULT			
4.1	General – sensitization (Maximization method)	PASS (SEE RESULT PAGE			
4.3	Endotoxins	PASS (SEE RESULT PAGE			
4.4	Powder	PASS (SEE RESULT PAGE			
4.5	Protein, Total leachable	NA			
4.6	Labelling	NC			



Unless otherwise agreed in writing, this document is issued by the Company subject to its General Conditions of Service printe vorteral available on request or accessible at http://www.ags.com/en/Terms-and-Conditions.ags.and, for electronic format documents subject to Terms and Conditions for Electronic Documents at <a href="http://www.ags.com/en/Terms-and-Conditions/Terms-e-Document.ags.attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of lient's instructions. If any. The Company's sole responsibility is to its Client and this document does not exonerate parties to ransaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduces except in full, without prior written approval of the Company. Any unauthorized alteration, forgery or falsification of the content of appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law. Unless otherwise stated thresults shown in this test report refer only to the sample(s) tested and such sample(s) are retained for 30 days only the surface of the subject of the such as the surface of the surface of the development of the surface of the s



Test Report No.: SHHL1811067692SD-01 Date: APR. 02, 2019 Page: 3 of 10

Test Result Page:

Attachment 1: Test for irritation (Animal skin irritation test)

SUMMARY

The animal skin irritation test of the test article, Latex Glove, was conducted to assess the potential of the material to produce irritation. This study was conducted based on the requirements of the International Organization for Standardization ISO 10993-10: 2010: Biological Evaluation of Medical Devices - Part 10: Tests for irritation and skin sensitization. ISO 10993-12: 2012: Biological evaluation of medical devices Part 12: Sample preparation and reference materials.

The test article was extracted in 0.9% sodium chloride injection (SC) and cotton seed oil (CSO). Each extract and corresponding reagent control was contacted on animal skin directly. Observations for erythema and edema were conducted at 24, 48 and 72 hours after contact.

Under the conditions of this study, there was no evidence of significant irritation from the test article to rabbits. The response category for the extracts of the test article was negligible.

MATERIALS

The test article provided by the sponsor was identified and handled as follows:

Test Article: Latex Glove Sterilization Status: Non-sterile

Storage Conditions: Room temperature

Extraction Vehicle: 0.9% sodium chloride injection (SC)

Cotton seed oil (CSO)

Test Article Preparation: According the requirement of the sponsor, the test

articles were sterilized by ethylene oxide two weeks

before the treatment.

Based on the ISO 10993-12:2012, the ratio of 6cm²:1 ml (Surface area of the test sample to volume of extraction



Unless otherwise agreed in writing, this document is issued by the Company subject to its General Conditions of Service prints vertical, available on request or accessible at http://www.sgs.com/en/Terms-and-Conditions.aspx and, for electronic format documents the conditions of the

4[®] Building, No.889, Yishan Road, Xuhui District Shanghai, China 200233

t (86) 400 960 9661

f (86–21) 6115 6899

www.sgsgroup.com.cn e sas.china@sas.com



Test Report No.: SHHL1811067692SD-01 Date: APR. 02, 2019 Page: 4 of 10

vehicle), 90cm² of the test articles were covered with 15ml of extraction vehicle under aseptic conditions for preparing the SC and CSO test extract at 37 °C for 72h

respectively. The extracts were used after extraction.

Reagent Control: The extraction vehicles (without test article) were

similarly prepared to serve as the reagent control.

Condition of extracts: All the extract of the test and controls were clear.

In addition, according ISO 10993-10 requirement, 10% Sodium Dodecyl Sulfate as a positive control was used previously for another study (2018.12.24~2018.12.28). Complete data is traceable in laboratory records.

METHODS

Test System:

Species: Rabbit

Strain: New Zealand White

Source: SHANGHAI SONGLIAN LAB ANIMAL-FIELD

Sex: Male

Body weight range: $2.4 \text{ kg} \sim 2.6 \text{ kg}$ Age: Young adult

Number of animals: Six

Animal Management:

Husbandry: Conditions conformed to "Laboratory animal-

Requirements of environment and housing facilities".

Food: Diet was provided from Shanghai Pu Lu Teng Biological

Technology Co., Ltd.

Housing: Healthy animals were acclimatized to the laboratory

conditions for 7 days before the treatment, and then

they were individually housed in stainless steel



Unless otherwise agreed in writing, this document is issued by the Company subject to its General Conditions of Service prints vertical, available on request or accessible at http://www.sgs.com/en/Terms-and-Conditions.aspx and, for electronic format documents the conditions of the

4th Building, No.889, Yishan Road, Xuhui District Shanghai, China 200233

t (86) 400 960 9661

f (86–21) 6115 6899

www.sgsgroup.com.cn



Test Report No.: SHHL1811067692SD-01 Date: APR. 02, 2019 Page: 5 of 10

suspended cages identified by a card indicating the

Identification No of the test article and first treatment

date.

Environmental: The room temperature and humidity was monitored daily.

The room temperature range was from 20°C to 26°C. The

room humidity range was from 50% to 70%.

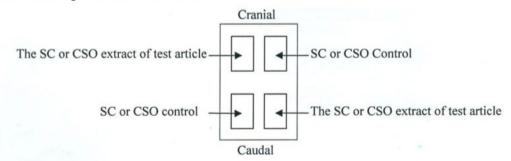
Personnel Associates involved were appropriately qualified and

trained.

Selection: Only healthy, previously unused rabbits were selected.

Experimental Procedure:

On the day before the test, the rabbits were closely clipped the fur on the backs of the animals, and both sides of the spinal for application and observation of all test sites, approximately 10 cm x15 cm. A 25 mm×25 mm section of absorbent gauze patch was saturated with freshly prepared the extract, and then was applied to the test sites. The extract of test article and the reagent control were directly applied to the region as illustrated below:



The application sites were covered with a gauze patch and then the application sites were wrapped with a semi-occlusive bandage for 24 h. At the end of the contact time, the dressings were removed. A natural lighting was used to visualize the skin reactions. The skin reactions for erythema and oedema were described and scored at 1, 24, 48 and 72 hours.

The tissue reaction for erythema and oedema were graded according to the classification system given below for each site and at each time observed, and the results were recorded.



Unless otherwise agreed in writing, this document is issued by the Company subject to its General Conditions of Service printer overleaf, available on request or accessible at http://www.ags.com/en/Terms-and-Conditions.ags, and, for electronic format documents subject to Terms and Conditions for Electronic Documents at http://www.ags.com/en/Terms-and-Conditions/Terms-a-Document.ags.attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits or Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced except in full, without prior written approval of the Company. Any unauthorized alteration, foregry or flaisfication of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law. Unless otherwise stated the results shown in this test report refer only to the sample(s) tested and such sample(s) are retained for 30 days only only to the sample(s) tested and such sample(s) are retained for 30 days only.

4^b Building, No.889, Yishan Road, Xuhui District Shanghai, China 200233 中国・ト海・徐江区宣山路889号4号様 邮第: 200233

t (86) 400 960 9661

1 (86-21) 6115 689

www.sgsgroup.com.cn e sgs.china@sgs.com



Test Report No.: SHHL1811067692SD-01 Date: APR. 02, 2019

Reaction	Primary Irritation		
neaction	Score		
Erythema and eschar formation	00010		
No erythema			
Very slight erythema (barely perceptible)			
Well-defined erythema			
Moderate erythema			
Severe erythema (beet-redness) to eschar formation preventing grading of erythema			
Oedema formation			
No oedema			
Very slight oedema (barely perceptible)			
Well-defined oedema (edges of area well-define by definite raising)			
Moderate oedema (raised approximately 1 mm)	3		
Severe oedema (raised more than 1mm and extending beyond exposure area)	4		

Only the 24, 48 and 72hours observations were used for calculation. For each animal, the score both erythema and oedema at each time point were added together separately for each test article and the negative control. The primary irritation score for an animal was calculated by dividing the sum of all the scores by 6 (2 test sites x 3 time points). All the primary irritation scores of individual animals were added and divided by the number of animals, and then the primary irritation scores for each test article were obtained. A similar calculation was made with the negative control. The primary irritation index was obtained by subtracting the score of the negative control from the test article score and the response categories were given as below:

Mean score	Response category	
0 to 0.4	Negligible	
0.5 to 1.9	Slight	
2 to 4.9	Moderate	
5 to 8	Severe	



Unless otherwise agreed in writing, this document is issued by the Company subject to its General Conditions of Service printer overleaf, available on request or accessible at http://www.ags.com/en/Terms-and-Conditions.ags, and, for electronic format documents subject to Terms and Conditions for Electronic Documents at http://www.ags.com/en/Terms-and-Conditions/Terms-a-Document.ags.attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits or Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced except in full, without prior written approval of the Company. Any unauthorized alteration, foregry or flaisfication of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law. Unless otherwise stated the results shown in this test report refer only to the sample(s) tested and such sample(s) are retained for 30 days only only to the sample(s) tested and such sample(s) are retained for 30 days only.

4th Building, No.889, Yishan Road, Xuhui District Shanghai, China 200233 中国·上海·徐汇区宜山路889号4号楼 邮编: 200233

t (86) 400 960 9661 t (86) 400 960 9661

f (86-21) 6115 6899 f (86-21) 6115 6899 www.sgsgroup.com.cn e sgs.china@sgs.com

Page: 6 of 10



Test Report No.: SHHL1811067692SD-01 Date: APR. 02, 2019 Page: 7 of 10

RESULTS

All animals appeared clinically normal throughout the study. All sites of the test extract and the reagent control appeared normal following removal the patches; the score of the test extract and the reagent control all were 0.

The Primary Irritation Index (PII) of the test article was all 0.0.

CONCLUSION

Under the conditions of this study, there was no evidence of significant irritation from the test article to rabbits. The response category for the extracts of the test article was negligible.



Unless otherwise agreed in writing, this document is issued by the Company subject to its General Conditions of Service printe vorteral available on request or accessible at http://www.ags.com/en/Terms-and-Conditions.ags.and, for electronic format documents subject to Terms and Conditions for Electronic Documents at <a href="http://www.ags.com/en/Terms-and-Conditions/Terms-e-Document.ags.attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of lient's instructions. If any. The Company's sole responsibility is to its Client and this document does not exonerate parties to ransaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduces except in full, without prior written approval of the Company. Any unauthorized alteration, forgery or falsification of the content of appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law. Unless otherwise stated thresults shown in this test report refer only to the sample(s) tested and such sample(s) are retained for 30 days only the surface of the subject of the such as the surface of the surface of the development of the surface of the s



Test Report

No.: SHHL1811067692SD-01

Date: APR. 02, 2019

Page: 8 of 10

PHOTOGRAPH OF THE TEST ARTICLE





Unless otherwise agreed in writing, this document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at http://www.sgs.com/en/Terms-and-Conditions.aspx and, for electronic format documents, subject to Terms and Conditions for Electronic Documents at http://www.sgs.com/en/Terms-and-Conditions/Terms-e-Document.aspx. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced except in full, without prior written approval of the Company. Any unauthorized alteration, foregrey or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law. Unless otherwise stated the results shown in this test report refer only to the sample(s) tested and such sample(s) are retained for 30 days only.

Attention: To check the authenticity of testing (inspection report & certificate, please contact us at telephone: (86-75) 8307 1443,



Test Report No.: SHHL1811067692SD-01 Date: APR. 02, 2019 Page: 9 of 10

The following test was performed by SGS other internal laboratory

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

ClauseTest ItemsResultNote4.4Powder-free glovesPass# 1

Notes : #1 Test according to EN ISO 21171:2006, the average mass of powder per glove was 0.7mg.

Remark:

- Since the data and / or information above division line of front page is provided by the applicant, the relevant results or conclusions of this report are only made for these data and / or information, SGS is not responsible for the authenticity, integrity and results of the data and information and / or the validity of the conclusion. Testing results only apply to the sample as received.
- The declaration of conformity is only based on the actual value of laboratory activity, measurement uncertainty of the results not take into account.



Unless otherwise agreed in writing, this document is issued by the Company subject to its General Conditions of Service printer overleaf, available on request or accessible at http://www.sgs.com/en/Terms-and-Conditions.aspx.and, for electronic format documents with the conditions of the conditions o

4" Building, No.889, Yishan Road, Xuhui District Shanghai, China 200233
中国・上海・公丁区宮山路889号4号楼 帆線・200233

t (86) 400 960 9661

f (86-21) 6115 689

www.sgsgroup.com.cn e sgs.china@sgs.com



Test Report

No.: SHHL1811067692SD-01

Date: APR. 02, 2019

Page: 10 of 10

Sample Photo:



SGS authenticate the photo on original report only

End of Report



Unless otherwise agreed in writing, this document is issued by the Company subject to its General Conditions of Service printer overleaf, available on request or accessible at http://www.ags.com/en/Terms-and-Conditions.ags, and, for electronic format documents subject to Terms and Conditions for Electronic Documents at http://www.ags.com/en/Terms-and-Conditions/Terms-a-Document.ags.attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits or Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced except in full, without prior written approval of the Company. Any unauthorized alteration, foregry or flaisfication of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law. Unless otherwise stated the results shown in this test report refer only to the sample(s) tested and such sample(s) are retained for 30 days only only to the sample(s) tested and such sample(s) are retained for 30 days only.

4" Building, No.889, Yishan Road, Xuhui District Shanghai, China 200233 中国・上海・徐汇区宜山路889号4号楼 邮编: 200233 t (86) 400 960 9661 t (86) 400 960 9661 f (86-21) 6115 6899 f (86-21) 6115 6899

www.sgsgroup.com.cn e sgs.china@sgs.com