Test Report

No.: SHHL1811067691SD-01 Date: APR. 02, 2019 Page: 1 of 10

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THE TEST REPORT IS TO SUPERSEDE THE TEST REPORT No.: SHHL1811067691SD, DATE: MAR. 29, 2019, ORIGINAL REPORT SHALL BE INVALID.
THE TEST REPORT UPDATED PROTOCOL.

Sample Description	: NITRILE 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.

Melody Zhang
Authorized Signatory

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Test Conducted:

BS 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

REMARK: NA = Not Applicable NC = Not conducted as per client's request

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Test Result Page:

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

SUMMARY

The animal skin irritation test of the test article, Nitrile 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:	Nitrile 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 6cm^2:1 ml (Surface area of the test sample to volume of extraction

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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 ℃ 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 kg ~ 2.5 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

suspended cages identified by a card indicating the Identification No of the test article and first treatment date.

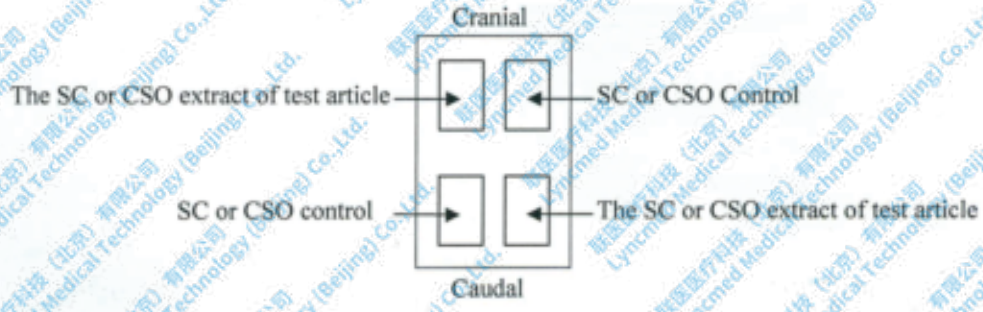
Environmental: The room temperature and humidity was monitored daily. The room temperature range was from 20℃ to 26℃. The room humidity range was from 50% to 70%.

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.

Reaction	Primary Irritation Score
Erythema and eschar formation	
No erythema	0
Very slight erythema (barely perceptible)	1
Well-defined erythema	2
Moderate erythema	3
Severe erythema (beet-redness) to eschar formation preventing grading of erythema	4
Oedema formation	
No oedema	0
Very slight oedema (barely perceptible)	1
Well-defined oedema (edges of area well-define by definite raising)	2
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

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.

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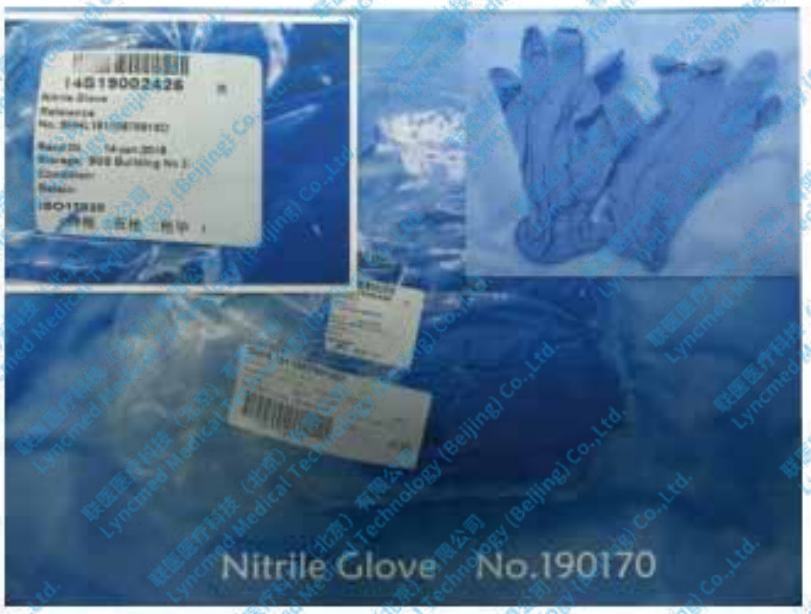
PHOTOGRAPH OF THE TEST ARTICLE



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

Clause	Test Items	Result	Note
4.4	Powder-free gloves	Pass	#1

Notes : #1 Test according to EN ISO 21171:2006, the average mass of powder per glove was 0.06mg.

Remark:

1. 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.
2. The declaration of conformity is only based on the actual value of laboratory activity, measurement uncertainty of the results not take into account.

Sample Photo:

SGS authenticate the photo on original report only

End of Report

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