SHAOXING YIBON MEDICAL CO., LTD
NO.347 YUEWANG ROAD, PAOJIANG INDUSTRIAL ZONE, SHAOXING, ZHEJIANG

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

Sample Description	:	(A)Face mask Product: Surgical face masks Lot No.: YB200004 Specification: 17.5X9.5CM-3P Method: EN 14683-2019
Sample Color	:	(A)yellow
Manufacturer	:	SHAOXING YIBON MEDICAL CO., LTD
Proposed Care Instruction	:	/
Test Performed	:	Selected test(s) as requested by applicant
Sample Receiving Date	:	May 11, 2020
Testing Period	:	May 11, 2020 - May 23, 2020
Test Result(s)	:	Unless otherwise stated the results shown in this test report refer only to the sample(s) tested, for further details, please refer to the following page(s).

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

Sara Guo (Account Executive)

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Test Result

Medical Face Masks-Requirements and Test Methods
(EN 14683:2019)

Clause 5.2.2 Bacterial filtration efficiency (BFE)*
(EN 14683 :2019 Annex B)

	1#	2#	3#	4#	5#
(BFE), %	99.5	99.8	99.7	99.7	99.6

Remark: Performance Requirement: Type I≥95%, Type II≥98%, Type IIR≥98%

* This test standard is not within the accredited scope in SGS Shanghai testing centre, it is carried out by PONY, its CMA certificate No. is 160920340809

Clause 5.2.3 Breathability (Differential Pressure)
(EN 14683 :2019 Annex C, Flow rate 8 l/min)

	1#	2#	3#	4#	5#
Differential pressure △P (Pa/cm^2)	39	36	34	35	33

Remark: Performance Requirement: Type I<40 Pa/cm^2, Type II<40 Pa/cm^2, Type IIR<60 Pa/cm^2

Clause 5.2.4 Splash Resistance
(ISO 22609 :2004, Pressure 16.0 kPa)

Penetration on inside surface							
1#	2#	3#	4#	5#	6#	7#	8#
Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
9#	10#	11#	12#	13#	14#	15#	16#
Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
17#	18#	19#	20#	21#	22#	23#	24#
Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
25#	26#	27#	28#	29#	30#	31#	32#
Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Number of Pass:			32				
Overall result:			Acceptable				

Remark:
1) Performance Requirement Type I: N/A, Type II: N/A, Type IIR: ≥16.0kPa
2) Distance of the medical face mask target area surface to the tip of cannula is 300±10mm.
3) Condition and Test temperature (21±5)° C, relative humidity (85±10)%
4) An acceptable quality limit of 4.0% is met for a single sampling plan when 29 or more of the 32 tested specimens show pass results

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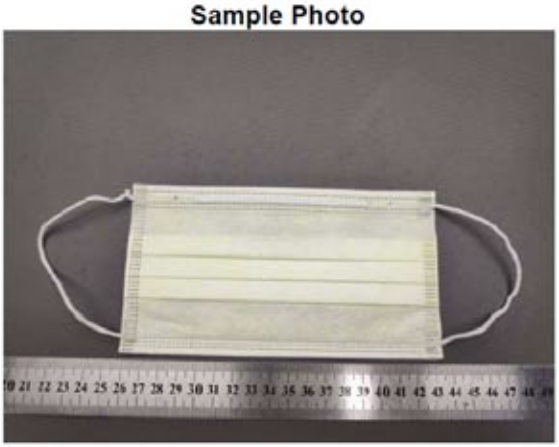
Clause 5.2.5 Microbial Cleanliness
(EN 14683: 2019 Annex D)

	1#	2#	3#	4#	5#
CFU/g	2	1	4	1	1

Remark: Performance Requirement: Type I≤30 CFU/g, Type II≤30 CFU/g, Type IIR≤30 CFU/g

Sample Photo



The statement of conformity in this test report is only based on measured values by the laboratory and does not take their uncertainties into consideration.

End of Report

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STUDY REPORT

Date : 2019-04-26
No. : DY19040122

TEST FACILITY

STC (Dongguan)
68 Fumin Nan Road, Dalang,
Dongguan, Guangdong,
China. (Zip code 523770)

SPONSOR

Shao Xing Yibon Medical Co.,Ltd
347 Yuewang Road, Paojiang,
ShaoXing,Zhejiang,
China

CONFIDENTIAL

STUDY TITLE

Cytotoxicity Test Elution Method of Surgical face mask using ISO 10993-5:2009 Test Methods Test on Extract, Minimal Essential Medium with 10% Fetal Bovine Serum Extract

TEST ARTICLE NAME

Surgical face mask

TEST ARTICLE IDENTIFICATION

CP-MD-0964

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STUDY REPORT

Date: 2019-04-26
No.: DY19040122

Summary

The test article, Surgical face mask, was evaluated for potential cytotoxic effects. This study was conducted following the guidelines of ISO 10993-5, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (2009). A single preparation of the test article was extracted in single strength Minimum Essential Medium at 37°C for 24 hours. The negative control, reagent control, and positive control extracts were similarly extracted. Triplicate monolayers of L-929 mouse fibroblast cells were dosed with each extract and incubated at 37℃ in the presence of 5% CO_2 for 24 hours. Following incubation, the monolayers were examined microscopically for abnormal cell morphology and cellular degeneration.

The test article extract showed occasional evidence of causing mid cell lysis or toxicity. The test article extracts meet the requirements of the test, the grade was not greater than 2 (Mild).

Authorized Signatory Approval: Tang

Jonathan Tang

STC (Dongguan) Company Limited

68 Fumin Nan Road, Dalang, Dongguan, China. (Zip Code : 523 770)
Tel : (86 769) 8111 9888 Fax : (86 769) 8111 6222 E-mail : dgstc@dgstc.org Homepage :www.dgstc.org

1. Introduction

1.1 Purpose

The purpose of this study was to determine the potential of a test article to cause cytotoxicity.

1.2 Testing Guidelines

This study was based on the requirements of the International Organization for Standardization ISO 10993-5, Biological evaluation of medical device – Part 5: Tests for in vitro cytotoxicity (2009).

1.3 Dates

Test Article Received:	2019.04.01
Cells Dosed:	2019.04.16
Observations Concluded:	2019.04.18

2. Identification of Test and Control Articles

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

Table 1: Test Article

Name:	Surgical face mask
Size:	17.5*9.5cm
Model:	Sterilization
Lot:	1805002
Strength, Purity and Composition:	The mask is composed of non-woven, melt-blown non-woven, mask belt and nose clip
Color:	White
Physical Description of the Test Article:	Solid
Storage Conditions:	Room Temperature
Manufacture date:	20180520
Expiration Date:	20210519

Table 2: Negative Control Article

Name:	High Density Polyethylene
Lot:	C-161
Source:	Hatano Research Institute, Food and Drug Safety Center
Component:	High Density Polyethylene Film

Table 3: Positive Control Article

Name:	ZDEC
Lot:	A-161K
Source: Component:	Hatano Research Institute, Food and Drug Safety Center 0.1% ZDEC Polyurethane Film

Table 4: Ancillary Materials

Growth Media:	Single strength Minimum Essential Medium supplemented with 10% fetal bovineserum, 1% antibiotics (100 U/mL penicillin, 100 µg/mL streptomycin)
Formulation:	44.5 mL MEM+ 5 mL FBS+0.5 mL antibiotics

Table 5: Extraction Vehicle

Name:	MEM

Table 6: Ragents

Name	Brand	Lot
MEM	GiBco	2046542
FBS	GiBco	42G3279K
Penicillin, Streptomycin	GiBco	2019315

3. Test System

3.1 Test System and Justification of Test System

Mammalian cell culture monolayer consisting of L-929 mouse fibroblast cells (ATCCN umber: CCL-1, Lot Number: 70001022) was used. In vitro mammalian cell culture studies have been used historically to evaluate cytotoxicity of biomaterials and medical devices.

3.2 Test System Management

L-929 mouse fibroblast cells were propagated and maintained in flasks containing IX MEM at 37°C with 5% carbon dioxide (CO_2). For this study, a 6-well plate was seeded with 4.5×10^5 cells/ well and incubated at 37°C (humidified) with 5% CO_2 to obtain semi-confluent monolayers of cells prior to use. Aseptic procedures were used in thehandling of the cell cultures following approved STC Standard Operating Procedures.

4. Method

4.1 Test and Control Article Preparation

The test articles were measured and calculated. The preparations of the test article and the negative control were subjected to the extraction conditions as described below. The extracts were continuously agitated during extraction. The MEM extraction method was conducted in the presence of serum to optimize extraction of both polar and non-polar components.

Table 7: Extraction

Article	Extraction Ratio	Article Amount	Volume of Vehicle	Extraction Condition
Test Article	0.1 g :1 mL	0.892 g	8.92 mL	37±1℃ for 24±2 h
Negative Control	3 cm^2:1 mL	18cm^2	6mL	37±1℃ for 24±2 h
Positive Control (ZDEC)	6 cm^2:1 mL	36 cm^2	6mL	37±1℃ for 24±2 h
Reagent Control	Not Applicable	Not Applicable	10 mL	37±1℃ for 24±2 h

The following table contains a description of the test and control article extracts before and after extraction.

Table 8: Condition of Extracts

Vehicle	Time Observed	Extract	Condition of Extracts		
			Color	Clarity	Particulates
MEM	Before Extraction	Test Article	Pink	Clear	None
		Negative Control	Pink	Clear	None
		Positive Control (ZDEC)	Pink	Clear	None
		Reagent Control	Pink	Clear	None
	After Extraction	Test Article	Pink	Clear	None
		Negative Control	Pink	Clear	None
		Positive Control (ZDEC)	Pink	Clear	None
		Reagent Control	Pink	Clear	None
	Prior to Use	Test Article	Pink	Clear	None
		Negative Control	Pink	Clear	None
		Positive Control (ZDEC)	Pink	Clear	None
		Reagent Control	Pink	Clear	None

There appeared to be no visible changes to the test article during the extraction process. The extracts were tested immediately following extraction. The extracts were not centrifuged, filtered, or otherwise altered prior to dosing.

4.2 Test Procedure

Triplicate culture wells were selected which contained a subconfluent cell monolayer. The growth medium contained in the triplicate cultures was replaced with 1.5 mL of the test extract in each well. Similarly, the growth medium in triplicate 6-wells plate was replaced with 1.5 mL of the reagent control, the negative control and the positive control extracts. The wells of each plate were labeled with the appropriate lab number or control and the replicate number. Each plate was labeled with the test code and the dosing date. The wells were incubated at 37°C in 5% CO_2 for 24 hours.

Following incubation, the cells were examined microscopically to evaluate cellular characteristics and percent lysis.

5. Evaluation and Statistical Analysis

Scoring forcytotoxicity will be based on the following criteria:

Table 9: Test Scoring

Grade	Reactivity	Conditions of all Cultures
0	None	Discrete intracytoplasmic granules, no cell lysis, no reduction of cell growth.
1	Slight	Not more than 20% of the cells are round, loosely attached and without intracytoplasmic granules, or show changes in morphology; occasional lysed cells are present; only slight growth inhibition observable.
2	Mild	Not more than 50% of the cells are round, devoid of intracytoplasmic granules; no extensive cell lysis; not more than 50% growth inhibition observable.
3	Moderate	Not more than 70% of the cell layers contain rounded cells or are lysed; cell layers not completely destroyed, but more than 50% growth inhibition observed.
4	Severe	Nearly complete or complete destruction of the cell layers.

For the test to be valid the reagent control and the negative control extracts must have had a reactivity of none (grade 0) and the positive control extract must have been a grade 3 or 4. Percent rounding and percent cells without intracytoplasmic granules are not evaluated in the event of 100% lysis. The test article extract met the requirements of the test if the biological response was less than or equal to grade 2 (mild). The test would have been repeated if the controls did not perform as anticipated.

All times and temperatures reported herein are approximate and are within ranges established by the external standards described in the References section of this report and/or STC standard operating procedures.

6. Results

All system suitability criteria were met, indicating a valid test assay.

Table 10 - Individual Test Data

Well	Conditions of all Cultures	Grade	Reactivity
Test (1)	Not more than 20% of the cells are round, loosely attached and without intracytoplasmic granules, or show changes in morphology; occasional lysed cells are present; only slight growth inhibition observable.	1	Slight
Test (2)	Not more than 20% of the cells are round, loosely attached and without intracytoplasmic granules, or show changes in morphology; occasional lysed cells are present; only slight growth inhibition observable.	1	Slight
Test (3)	Not more than 20% of the cells are round, loosely attached and without intracytoplasmic granules, or show changes in morphology; occasional lysed cells are present; only slight growth inhibition observable.	1	Slight
NegativeControl (1)	Discrete intracytoplasmic granules, no cell lysis, no reduction of cell growth.	0	None
NegativeControl (2)	Discrete intracytoplasmic granules, no cell lysis, no reduction of cell growth.	0	None
NegativeControl (3)	Discrete intracytoplasmic granules, no cell lysis, no reduction of cell growth.	0	None

PositiveControl (1)	Nearly complete or complete destruction of the cell layers.	4	Severe
PositiveControl (2)	Nearly complete or complete destruction of the cell layers.	4	Severe
PositiveControl (3)	Nearly complete or complete destruction of the cell layers.	4	Severe

Note: 1, 2, and 3 indicate duplication

7. Conclusion

The MEM test extract showed occasional mid lysed cells are present to L-929 mouse fibroblast cells. The test article extract met the requirements of the test since the grade was notgreater than 2(Mild).

Results and conclusions apply only to the test article tested. Any extrapolation of these data to other articles is the sponsor's responsibility.

8. Records

All raw data pertaining to this study and a copy of the final report are retained in designated STC archive files in accordance with STC SOPs.

9. ISO Compliance

All procedures were compliance to ISO 17025.

10. References

International Organization for Standardization (ISO) 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (2018).

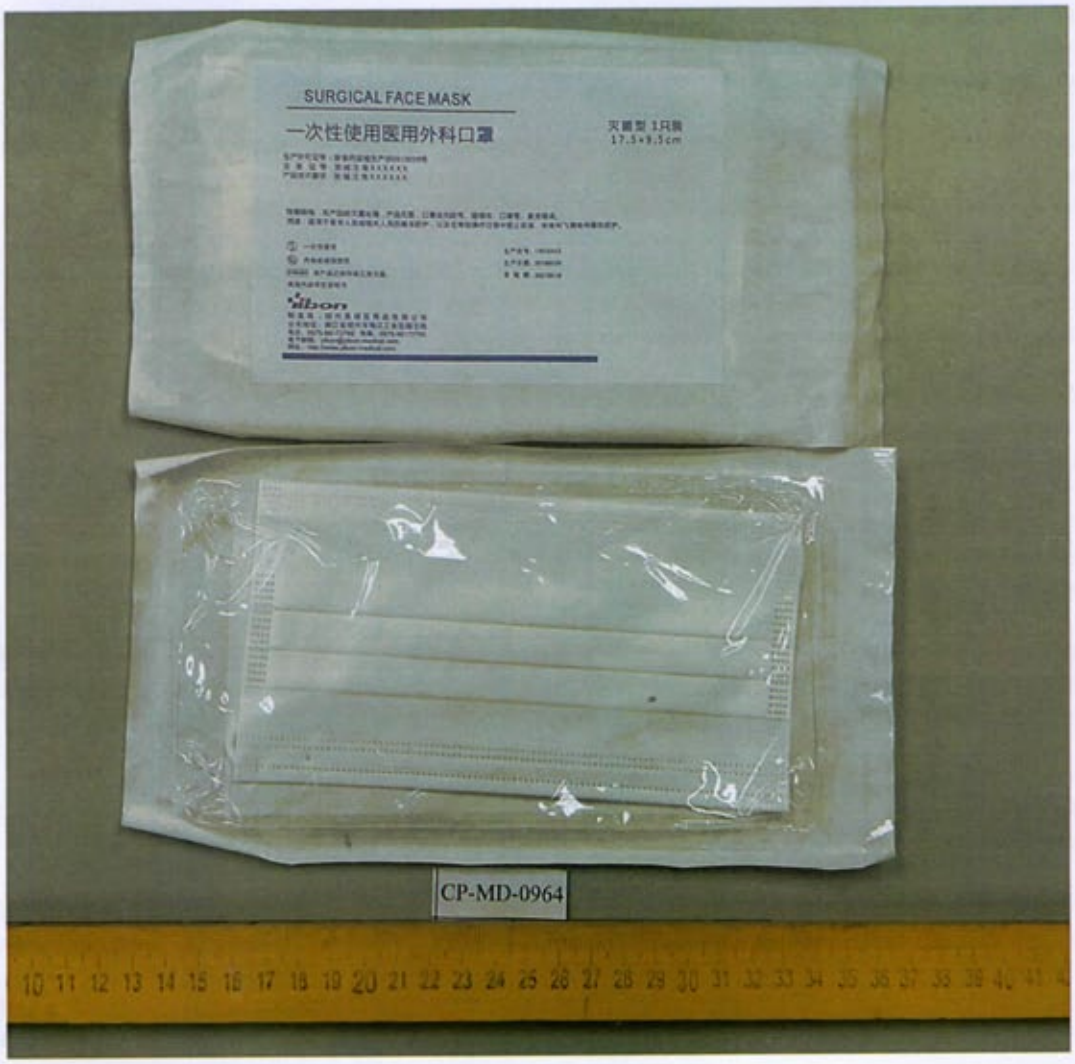
International Organization for Standardization (ISO) 10993-5, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (2009).

International Organization for Standardization (ISO) 10993-12, Biological evaluation of medical devices - Part 12: Sample preparation and reference materials (2012).

International Organization for Standardization (ISO) 17025, General requirements for the competence of testing and calibration laboratories (2017).

STUDY REPORT

Appendix 1 – Photograph(s) of Test Articles



***** ENDOF TEST REPORT *****

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TESTING
CNAS L2954

Sanitation & Environment Technology Institute, Soochow University, Final Report

Report Number: SDWH- M201900484-5(E)

Skin Irritation Test of
Surgical face mask
using ISO 10993-10:2010 Test Method
Sesame Oil Extract

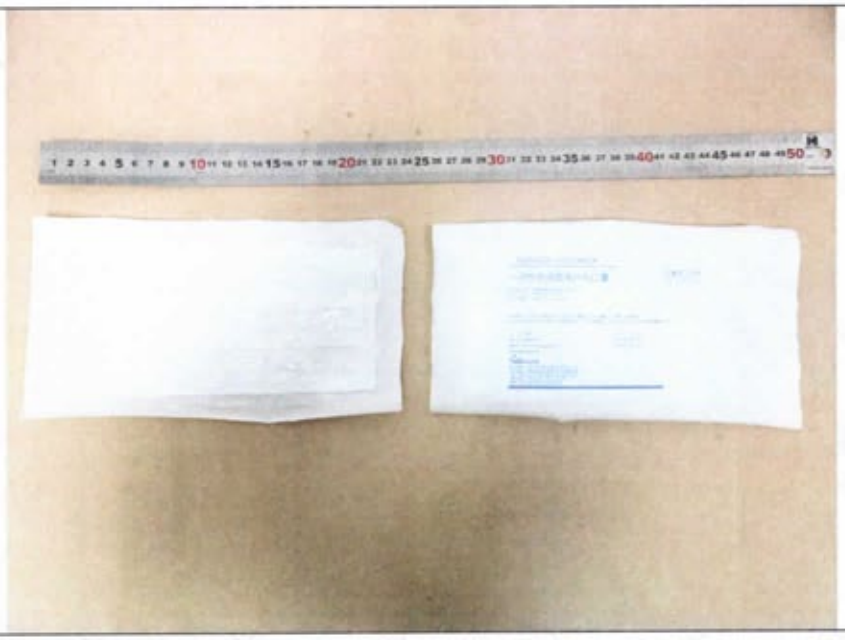
Sponsor
ShaoXing Yibon Medical Co.,Ltd
Yuewang Road,Paojiang,ShaoXing,Zhejiang,China
Manufacturer
ShaoXing Yibon Medical Co.,Ltd

CONTENTS

SUPPLEMENTARY EXPLANATION

1. Please apply for rechecking within 15 days of receiving the report if there are any objections.
2. Any erasure or without special inspection and testing seal renders the report null and void.
3. The report is only valid when signed by the persons who edited, checked and approved it.
4. The result relate only to the articles tested.
5. The report shall not be reproduced except in full without the written approval of the institute.

STUDY VERIFICATION AND SIGNATURE

Test Article	
Test Article Receipt:	2019-02-18
Protocol No:	SDWH-PROTOCOL-M201900484-5
Protocol Effective Date:	2019-03-01
Technical Initiation Date:	2019-03-01
Technical Completion Date:	2019-03-08
Final Report Completion Date:	2019-03-14

Edited by : Jang Tanan 2019-03-14
Date

Checked by : Dai Mingwei 2019-03-14
Study Director Date

Approved by : Wang Yi 2019-03-14
Authorized signatory Date

苏州大学卫生与环境技术研究所 检验检测专用章 (2)

Sanitation & Environment Technology Institute, Soochow University

1.0 Summary

The extract of test article Surgical face mask was evaluated for skin irritation. The test and control extracts were applied to the skin of rabbit, the skin responses on application sites were observed and recorded in (1±0.1) h, (24±2) h, (48±2) h and (72±2) h respectively after removal of the patches. According to what was observed, the skin reaction on test sites did not exceed that on the control sites. The primary irritation index for the test article was calculated to be 0.
The test result showed that the response of the test article extract was categorized as negligible under the test condition.

2.0 Purpose

To evaluate the potential skin irritation caused by test article contact with the skin surface of rabbits and extrapolating the results to humans, but it does not establish the actual risk of irritation.

3.0 Reference

Biological evaluation of medical devices-Part 10: Tests for irritation and skin sensitization (ISO 10993-10:2010)
Biological evaluation of medical devices-Part 12: Sample preparation and reference materials (ISO 10993-12:2012)
Biological evaluation of medical devices-Part 2: Animal welfare requirements (ISO 10993-2:2006)

4.0 Compliance

ISO/IEC 17025:2005 General requirements for the competence of testing and calibration laboratories (CNAS-CL01 Accreditation Criteria for the competence of testing and calibration laboratories)
China National Accreditation Service for Conformity Assessment
Laboratory Accreditation Certificate No.CNAS L2954
Accreditation Criteria for the competence of Inspection Body (Certification and Accreditation Administration of the People's Republic of China CMA 180015144061)

5.0 Identification of test and control articles

5.1 Test article

Name: Surgical face mask
Test article initial state: Sterilized, EO Sterilization
CAS Code: Not supplied by sponsor (N/S)
Model: Sterilization
Size: 17.5x9.5cm
Lot/ Batch: 1805002
Test Article Material: The mask is composed of non-woven , melt-blown nonwoven, mask belt and nose clip
Packaging Material: N/S
Physical State: Solid
Color: white
Density: N/S
Stability: N/S
Solubility: N/S
Storage Condition: Room Temperature
Intended Clinical Use: It is suitable for the basic protection of medical personnel or related personnel, as well as the protection of preventing the spread of blood, body fluids and spatters in the process of invasive operation.
The information about the test article was supplied by the sponsor wherever applicable.

5.2 Negative Control

Name: Sesame oil (SO)
Manufacturer: Ji'an luyuanxiangliao. Co., Ltd.
Size: 25kg
Lot/ Batch#: 20190220
Physical State: Oily liquid
Color: Pale yellow
Storage Condition: Room Temperature

5.3 Positive Control

Name: 20% sodium dodecyl sulfate
Manufacturer: Solarbio
Size: 500g
Lot/ Batch#: 530M031
Concentration: 20%
Solvent: Sesame Oil
Date prepared: 2018-12-25
Physical State: Suspension
Color: Yellow
Storage Condition: Room Temperature

6.0 Identification of test system

Species: New Zealand white Rabbit (single strain).
Number: 3
Sex: Female
Weigh: Initial body weight not less than 2kg
Health status: Healthy, not previously used in other experimental procedures, young adult, nulliparous and not pregnant.
Housing: Animals were housed in cages identified by a card indicating the lab number, test code and first treatment date.
Animal identification: Stain with picric acid
Cages: Stainless steel cage
Acclimation Period: 7 days under the same conditions as for the actual test

7.0 Animal Care and Maintenance

Animal purchase: Provided by Suzhou Experimental Animal Sci-tech Co., Ltd. <Permit Code: SCXK (SU) 2015-0007>
Bedding: NA
Feed: Rabbit Diet, Suzhou Experimental Animal Sci-tech Co., Ltd.
Water: Drinking water met the Standards for Drinking Water Quality GB 5749-2006
Animal room temperature: 18-26℃
Animal room relative humidity: 30%-70%
Lights: 12 hours light/dark cycle, full-spectrum lighting
Personnel: Associates involved were appropriately qualified and trained.
Selection: Only healthy, previously unused animals were selected.
There were no known contaminants present in the feed, water expected to interfere with the test data.

8.0 Justification of the test system

The rabbit is specified as an appropriate animal model for evaluating potential skin irritants by the current testing standards. Positive control 20% sodium dodecyl sulfate has been substantiated at

SDWH with this method.

9.0 Route of administration

The patches (about 2.5cm×2.5cm) which moistened by test article extract, and directly applying to the rabbit skin is considered to be the best mean of contact.

10.0 Experiment design

10.1 Sample and Control Preparation

See the table below for test article extract preparation.

Aseptic Sampling		Aseptic Agitation Extraction In Inert Container			Final Extract	
Sampling Manner	Actually sampling	Ratio	SO	Condition	pH	Clear or Not
Whole Surface area of one test article is 166.25cm². (Provided by sponsor)	Surface area 166.25cm²	6cm² : 1ml	27.7 ml	37℃, 72h	5.5	Clear

There was no change in the extraction solvent (pre- and post-extraction).

The extract was stored at 4℃ and tested within 24h after extraction without the process of pH value adjustment, filtering, centrifugation, dilution, etc.

The vehicle (without the test article) was similarly prepared to serve as the control.

10.2 Equipment

Horizontal Large Capacity Constant Temperature Vibrator (SDWH897), Calibration Expire (2019-05-15)

Autoclave (SDWH2097), Calibration Expire (2019-11-04)

Electronic Scale (SDWH442), Calibration Expire (2019-05-15)

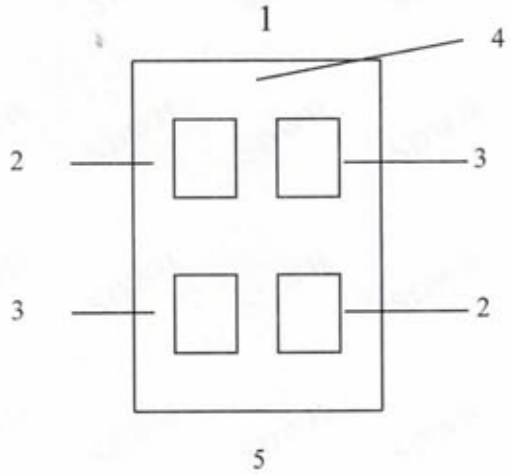
Steel Straight Scale (SDWH463), Calibration Expire (2019-08-22)

10.3 Reagents

Sesame oil (SO) (Ji'an luyuanxiangliao. Co. Ltd, Lot No: 20190220)

10.4 Experimental Procedure

Use the rabbits with healthy intact skin. Fur was generally clipped within 4-24h of testing on the backs of the rabbits, a sufficient distance on both sides of the spine for application and observation of all test sites (approximately 10×15cm).



1- Cranial end, 2- Test site, 3- Control site, 4- Clipped dorsal region, 5- Caudal end

Figure1 Location of skin application sites

Apply 0.5ml extract (s) of test article or control to 2.5cm×2.5cm absorbent gauze patches, and then apply the patch soaked with the extract of test article or control directly to the skin on each side of each rabbit as shown in Figure 1, and then wrap the application sites with a bandage (semi-occlusive or occlusive) for a minimum of 4h. At the end of the contact time, remove the dressing.

10.5 Observation of animal

Describe and score the skin reaction for erythema and oedema according to the scoring system given in Table 1 for each application site at each time interval. Record the appearance of each application site at (1±0.1) h, (24±2) h, (48±2) h and (72±2) h following removal of the patches.

Table 1 Classification System for Skin Reaction

Erythema and Eschar Formation:	Numerical Grading
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
Edema Formation:	
No edema	0
Very slight edema (barely perceptible)	1
Well-defined edema (edges of area well-defined by definite raising)	2
Moderate edema (raised approximately 1mm)	3
Severe edema (raised more than 1mm and extending beyond exposure area)	4
Maximal possible score for irritation	8
Irritation Response Categories in the Rabbit	
Response Category	Mean score
Negligible	0 to 0.4
Slight	0.5 to 1.9
Moderate	2 to 4.9
Severe	5 to 8

NOTE: Other adverse changes at the skin sites were recorded and are reported

10.6 Evaluation of results

Use only (24±2) h, (48±2) h and (72±2) h observations for calculation.

After the 72 h grading, all erythema grades plus oedema grades (24±2) h, (48±2) h and (72±2) h were totalled separately for each test sample and blank for each animal. The primary irritation score for an animal was calculated by dividing the sum of all the scores by 6 (two test/observation sites, three time points).

To obtain the primary irritation index for the test article, add all the primary irritation scores of the individual animals and divide by the number of animals.

When blank or negative control is used, calculate the primary irritation score for the controls and subtract that score from the score using the test material to obtain the primary irritation score.

10.7 Results

All animals were survived and no abnormal signs were observed during the study. According to what observed, the response of skin on testing side does not exceed that on the control side. Thus, the primary irritation index for the test article was calculated to be 0. See table 2.

10.8 Conclusion

The test result showed that the response of the test article extract was categorized as negligible under the test condition.

11.0 Record Storage

All raw data pertaining to this study and a copy of the final report are to be retained in designated SDWH archive.

12.0 Confidentiality Agreement

Statements of confidentiality were as agreed upon prior to study initiation.

13.0 Deviation statement

There were no deviations from the approved study protocol which were judged to have any impact on the validity of the data.

Table 2 Dermal Observations

Rabbit No	Group		Interval (hours): score=left site/right site			
			1±0.1	24±2	48±2	72±2
1	Test Article	Erythema	0/0	0/0	0/0	0/0
		Oedema	0/0	0/0	0/0	0/0
	Negative Control	Erythema	0/0	0/0	0/0	0/0
		Oedema	0/0	0/0	0/0	0/0
2	Test Article	Erythema	0/0	0/0	0/0	0/0
		Oedema	0/0	0/0	0/0	0/0
	Negative Control	Erythema	0/0	0/0	0/0	0/0
		Oedema	0/0	0/0	0/0	0/0
3	Test Article	Erythema	0/0	0/0	0/0	0/0
		Oedema	0/0	0/0	0/0	0/0
	Negative Control	Erythema	0/0	0/0	0/0	0/0
		Oedema	0/0	0/0	0/0	0/0
Primary irritation index			0			

Table 3 Positive control

Rabbit No	Group		Interval (hours): score=left site/right site			
			1±0.1	24±2	48±2	72±2
1	Positive control	Erythema	1/1	2/2	3/3	4/4
		Oedema	1/0	2/3	3/3	4/3
	Negative Control	Erythema	0/0	0/0	0/0	0/0
		Oedema	0/0	0/0	0/0	0/0
2	Positive control	Erythema	1/1	3/2	3/3	4/3
		Oedema	1/1	2/2	3/3	4/4
	Negative Control	Erythema	0/0	0/0	0/0	0/0
		Oedema	0/0	0/0	0/0	0/0
3	Positive control	Erythema	1/0	2/2	3/2	4/4
		Oedema	1/1	2/2	3/3	3/3
	Negative Control	Erythema	0/0	0/0	0/0	0/0
		Oedema	0/0	0/0	0/0	0/0
Primary irritation index			5.8			

Note: Positive control performed once every six months, see SDWH-M201804440-2(Completed Date: 2018-12-28).

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Sanitation & Environment Technology Institute, Soochow University, Final Report

Report Number: SDWH- M201900484-4(E)

Skin Irritation Test of
Surgical face mask
Using ISO 10993-10:2010 Test Method
0.9% Sodium Chloride Injection Extract

Sponsor
ShaoXing Yibon Medical Co.,Ltd
Yuewang Road,Paojiang,ShaoXing,Zhejiang,China
Manufacturer
ShaoXing Yibon Medical Co.,Ltd

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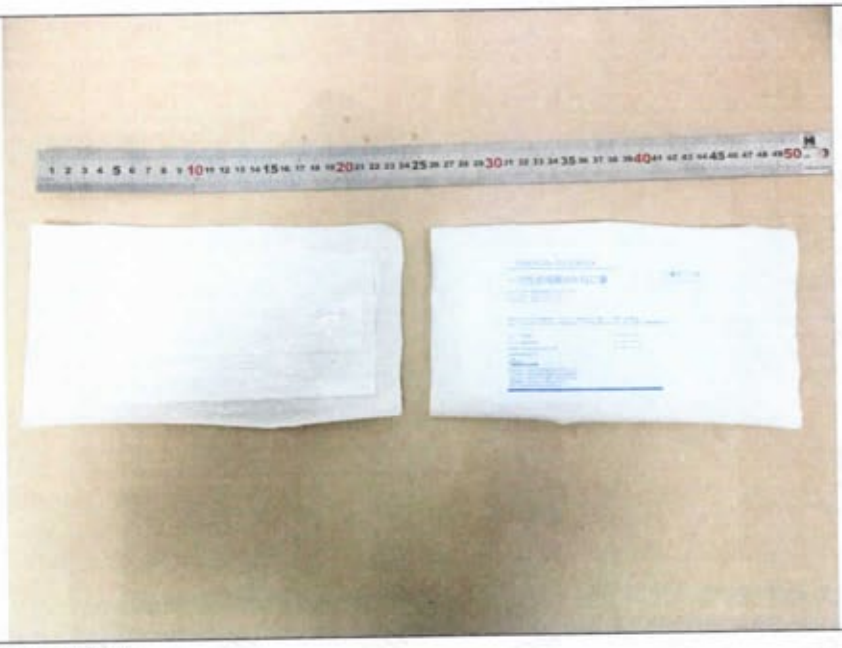
SUPPLEMENTARY EXPLANATION

1. Please apply for rechecking within 15 days of receiving the report if there are any objections.
2. Any erasure or without special inspection and testing seal renders the report null and void.
3. The report is only valid when signed by the persons who edited, checked and approved it.
4. The result relate only to the articles tested.
5. The report shall not be reproduced except in full without the written approval of the institute.

STUDY VERIFICATION AND SIGNATURE

Test Article	
Test Article Receipt:	2019-02-18
Protocol No:	SDWH-PROTOCOL-M201900484-4
Protocol Effective Date:	2019-03-01
Technical Initiation Date:	2019-03-01
Technical Completion Date:	2019-03-08
Final Report Completion Date:	2019-03-14

Edited by : Jiang Yuncun 2019-03-14
Date

Checked by : Study Director 2019-03-14
Date

苏州大学卫生与环境技术研究所 检验检测专用章 (2)

Approved by : Authorized signatory 2019-03-20
Date

Sanitation & Environment Technology Institute, Soochow University

1.0 Summary

The extract of test article Surgical face mask was evaluated for skin irritation. The test and control extracts were applied to the skin of rabbit, the skin responses on application sites were observed and recorded in (1±0.1) h, (24±2) h, (48±2) h and (72±2) h respectively after removal of the patches. According to what was observed, the skin reaction on test sites did not exceed that on the control sites. The primary irritation index for the test article was calculated to be 0.
The test result showed that the response of the test article extract was categorized as negligible under the test condition.

2.0 Purpose

To evaluate the potential skin irritation caused by test article contact with the skin surface of rabbits and extrapolating the results to humans, but it does not establish the actual risk of irritation.

3.0 Reference

Biological evaluation of medical devices-Part 10: Tests for irritation and skin sensitization (ISO 10993-10:2010)
Biological evaluation of medical devices-Part 12: Sample preparation and reference materials (ISO 10993-12:2012)
Biological evaluation of medical devices-Part 2: Animal welfare requirements (ISO 10993-2:2006)

4.0 Compliance

ISO/IEC 17025:2005 General requirements for the competence of testing and calibration laboratories (CNAS-CL01 Accreditation Criteria for the competence of testing and calibration laboratories)
China National Accreditation Service for Conformity Assessment
Laboratory Accreditation Certificate No.CNAS L2954
Accreditation Criteria for the competence of Inspection Body (Certification and Accreditation Administration of the People's Republic of China CMA 180015144061)

5.0 Identification of test and control articles

5.1 Test article

Name: Surgical face mask
Test article initial state:Sterilized, EO Sterilization
CAS Code: Not supplied by sponsor (N/S)
Model: Sterilization
Size: 17.5x9.5cm
Lot/ Batch: 1805002
Test Article Material: The mask is composed of non-woven , melt-blown nonwoven, mask belt and nose clip
Packaging Material: N/S
Physical State: Solid
Color: white
Density: N/S
Stability: N/S
Solubility: N/S
Storage Condition: Room Temperature
Intended Clinical Use: It is suitable for the basic protection of medical personnel or related personnel, as well as the protection of preventing the spread of blood, body fluids and spatters in the process of invasive operation.
The information about the test article was supplied by the sponsor wherever applicable.

5.2 Negative Control

Name: 0.9% sodium chloride injection (SC)
Manufacturer: Chenxin Pharmaceutical Co., Ltd.
Size: 500ml
Lot/ Batch#: 1810300722
Physical State: Liquid
Color: Colourless
Storage Condition: Room Temperature

5.3 Positive Control

Name: 20% sodium dodecyl sulfate
Manufacturer: Solarbio
Size: 500g
Lot/ Batch#: 530M031
Concentration: 20%
Solvent: 0.9% sodium chloride injection (SC)
Date prepared: 2018-12-25
Physical State: Liquid
Color: Colourless
Storage Condition: Room Temperature

6.0 Identification of test system

Species: New Zealand white Rabbit (single strain)
Number: 3
Sex: Female
Weight: Initial body weight not less than 2kg
Health status: Healthy, not previously used in other experimental procedures, young adult, nulliparous and not pregnant.
Housing: Animals were housed in cages identified by a card indicating the lab number, test code and first treatment date.
Animal identification: Stain with picric acid
Cages: Stainless steel cage
Acclimation Period: 7 days under the same conditions as for the actual test

7.0 Animal Care and Maintenance

Animal purchase: Provided by Suzhou Experimental Animal Sci-tech Co., Ltd. <Permit Code: SCXK (SU) 2015-0007>
Bedding: NA
Feed: Rabbit Diet, Suzhou Experimental Animal Sci-tech Co., Ltd.
Water: Drinking water met the Standards for Drinking Water Quality GB 5749-2006
Animal room temperature: 18-26℃
Animal room relative humidity: 30%-70%
Lights: 12 hours light/dark cycle, full-spectrum lighting
Personnel: Associates involved were appropriately qualified and trained.
Selection: Only healthy, previously unused animals were selected.
There were no known contaminants present in the feed, water expected to interfere with the test data.

8.0 Justification of the test system

The rabbit is specified as an appropriate animal model for evaluating potential skin irritants by the current testing standards. Positive control 20% sodium dodecyl sulfate has been substantiated at

SDWH with this method.

9.0 Route of administration

The patches (about 2.5cm×2.5cm) which moistened by test article extract, and directly applying to the rabbit skin is considered to be the best mean of contact.

10.0 Experiment design

10.1 Sample and Control Preparation

See the table below for test article extract preparation.

Aseptic Sampling		Aseptic Agitation Extraction In Inert Container			Final Extract	
Sampling Manner	Actually sampling	Ratio	SC	Condition	pH	Clear or Not
Whole Surface area of one test article is 166.25cm². (Provided by sponsor)	Surface area 166.25cm²	6cm² : 1ml	27.7ml	37℃, 72h	6.0	Clear

There was no change in the extraction solvent (pre- and post-extraction).

The extract was stored at 4℃ and tested within 24h after extraction without the process of pH value adjustment, filtering, centrifugation, dilution, etc.

The vehicle (without the test article) was similarly prepared to serve as the control.

10.2 Equipment

Horizontal Large Capacity Constant Temperature Vibrator (SDWH897), Calibration Expire (2019-05-15)

Autoclave (SDWH2097), Calibration Expire (2019-11-04)

Electronic Scale (SDWH442), Calibration Expire (2019-05-15)

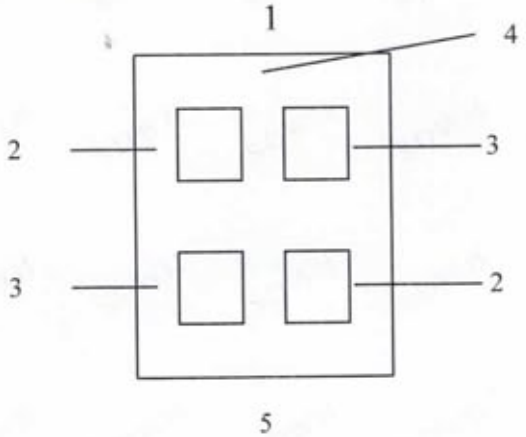
Steel Straight Scale (SDWH463), Calibration Expire (2019-08-22)

10.3 Reagents

0.9% sodium chloride injection (Chenxin Pharmaceutical Co., Ltd. Lot No: 1810300722)

10.4 Experimental Procedure

Use the rabbits with healthy intact skin. Fur was generally clipped within 4-24h of testing on the backs of the rabbits, a sufficient distance on both sides of the spine for application and observation of all test sites (approximately 10×15cm).



1- Cranial end, 2- Test site, 3- Control site, 4- Clipped dorsal region, 5- Caudal end

Figure1 Location of skin application sites

Apply 0.5ml extract (s) of test article or control to 2.5cm×2.5cm absorbent gauze patches, and then

apply the patch soaked with the extract of test article or control directly to the skin on each side of each rabbit as shown in Figure 1, and then wrap the application sites with a bandage (semi-occlusive or occlusive) for a minimum of 4h. At the end of the contact time, remove the dressing.

10.5 Observation of animal

Describe and score the skin reaction for erythema and oedema according to the scoring system given in Table 1 for each application site at each time interval. Record the appearance of each application site at (1±0.1) h, (24±2) h, (48±2) h and (72±2) h following removal of the patches.

Table 1 Classification System for Skin Reaction

Erythema and Eschar Formation:	Numerical Grading
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
Edema Formation:	
No edema	0
Very slight edema (barely perceptible)	1
Well-defined edema (edges of area well-defined by definite raising)	2
Moderate edema (raised approximately 1mm)	3
Severe edema (raised more than 1mm and extending beyond exposure area)	4
Maximal possible score for irritation	8
Irritation Response Categories in the Rabbit	
Response Category	Mean score
Negligible	0 to 0.4
Slight	0.5 to 1.9
Moderate	2 to 4.9
Severe	5 to 8

NOTE: Other adverse changes at the skin sites were recorded and are reported

10.6 Evaluation of results

Use only (24±2) h, (48±2) h and (72±2) h observations for calculation.

After the 72 h grading, all erythema grades plus oedema grades (24±2) h, (48±2) h and (72±2) h were totalled separately for each test article and blank for each animal. The primary irritation score for an animal was calculated by dividing the sum of all the scores by 6 (two test/observation sites, three time points).

To obtain the primary irritation index for the test article add all the primary irritation scores of the individual animals and divide by the number of animals.

When blank or negative control is used, calculate the primary irritation score for the controls and subtract that score from the score using the test material to obtain the primary irritation score.

10.7 Results

All animals were survived and no abnormal signs were observed during the study. According to what observed, the response of skin on testing side did not exceed that on the control side. Thus, the primary irritation index for the test article was calculated to be 0. See table 2.

10.8 Conclusion

The test result showed that the response of the test article extract was categorized as negligible under the test condition.

11.0 Record Storage

All raw data pertaining to this study and a copy of the final report are to be retained in designated SDWH archive.

12.0 Confidentiality Agreement

Statements of confidentiality were as agreed upon prior to study initiation.

13.0 Deviation statement

There were no deviations from the approved study protocol which were judged to have any impact on the validity of the data.

Table 2 Dermal Observations

Rabbit No	Group		Interval (hours): score=left site/right site			
			1±0.1	24±2	48±2	72±2
1	Test Article	Erythema	0/0	0/0	0/0	0/0
		Oedema	0/0	0/0	0/0	0/0
	Negative Control	Erythema	0/0	0/0	0/0	0/0
		Oedema	0/0	0/0	0/0	0/0
2	Test Article	Erythema	0/0	0/0	0/0	0/0
		Oedema	0/0	0/0	0/0	0/0
	Negative Control	Erythema	0/0	0/0	0/0	0/0
		Oedema	0/0	0/0	0/0	0/0
3	Test Article	Erythema	0/0	0/0	0/0	0/0
		Oedema	0/0	0/0	0/0	0/0
	Negative Control	Erythema	0/0	0/0	0/0	0/0
		Oedema	0/0	0/0	0/0	0/0
Primary irritation index			0			

Table 3 Positive control

Rabbit No	Group		Interval (hours): score=left site/right site			
			1±0.1	24±2	48±2	72±2
1	Positive control	Erythema	1/1	2/2	3/3	4/4
		Oedema	0/1	2/2	2/3	3/3
	Negative Control	Erythema	0/0	0/0	0/0	0/0
		Oedema	0/0	0/0	0/0	0/0
2	Positive control	Erythema	1/1	2/2	3/3	4/4
		Oedema	1/1	2/2	3/3	4/3
	Negative Control	Erythema	0/0	0/0	0/0	0/0
		Oedema	0/0	0/0	0/0	0/0
3	Positive control	Erythema	1/1	2/2	3/3	4/4
		Oedema	1/0	2/1	3/2	4/3
	Negative Control	Erythema	0/0	0/0	0/0	0/0
		Oedema	0/0	0/0	0/0	0/0
Primary irritation index			5.6			

Note: Positive control performed once every six months, see SDWH-M201804440-1(Completed Date: 2018-12-28).

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Sanitation & Environment Technology Institute, Soochow University, Final Report

Report Number: SDWH- M201900484-3(E)

Skin Sensitization Test of
Surgical face mask
Using ISO 10993-10:2010 Test Methods
Guinea Pig Maximization Test
Sesame oil Extract

Sponsor
ShaoXing Yibon Medical Co.,Ltd
Yuewang Road,Paojiang,ShaoXing,Zhejiang,China
Manufacturer
ShaoXing Yibon Medical Co.,Ltd

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SUPPLEMENTARY EXPLANATION

1. Please apply for rechecking within 15 days of receiving the report if there are any objections.
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4. The result relate only to the articles tested.
5. The report shall not be reproduced except in full without the written approval of the institute.

STUDY VERIFICATION AND SIGNATURE

Test Article	
Test Article Receipt:	2019-02-18
Protocol No:	SDWH-PROTOCOL-M201900484-3
Protocol Effective Date:	2019-03-01
Technical Initiation Date:	2019-03-01
Technical Completion Date:	2019- 03-28
Final Report Completion Date:	2019- 04-01

Edited by : _____ 2019-04-01
Date

Checked by : _____ 2019-04-01
Study Director Date

Approved by : _____ _____
Authorized signatory Date

Sanitation & Environment Technology Institute, Soochow University

1.0 Study Summary

The extract of the test article Surgical face mask (extraction in Sesame oil) was evaluated for its potential to induce skin sensitization in the Guinea Pig Maximization Test.
The test article extract was intradermally injected and applied topically for induction to ten guinea pigs. Five control animals were treated accordingly but with the solvent alone. The topical challenge with the test article extract elicited no skin reaction in the test and in the control animals. The skin sensitization rate was determined with 0%.
As defined by the scoring system of Magnusson and Kligman the test article extract showed no signification evidence of causing skin sensitization in the guinea pig under the conditions of this study.

2.0 Purpose

The test was designed to evaluate the potential of a test article to cause skin sensitization. The test is used as a procedure for screening of contact allergens in guinea pigs and extrapolating the results to humans, but it does not establish the actual risk of sensitization.

3.0 Reference

Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization (ISO 10993-10:2010)
Biological evaluation of medical devices-Part 12: Sample preparation and reference materials (ISO 10993-12:2012)
Biological evaluation of medical devices-Part 2: Animal welfare requirements (ISO 10993-2:2006)

4.0 Compliance

ISO/IEC 17025:2005 General requirements for the competence of testing and calibration laboratories (CNAS-CL01 Accreditation Criteria for the competence of testing and calibration laboratories)
China National Accreditation Service for Conformity Assessment
Laboratory Accreditation Certificate No. CNAS L2954
Accreditation Criteria for the competence of Inspection Body (Certification and Accreditation Admin istration of the People's Republic of China CMA 180015144061)

5.0 Identification of test and control articles

5.1 Test article
Test article name: Surgical face mask
Test article initial state:Sterilized, EO Sterilization
CAS Code: Not supplied by sponsor (N/S)

Model: Sterilization
Size: 17.5x9.5cm
Lot/ Batch: 1805002
Test Article Material: The mask is composed of non-woven , melt-blown nonwoven, mask belt and nose clip
Packaging Material: N/S
Physical State: Solid
Color: white
Density: N/S
Stability: N/S
Solubility: N/S
Storage Condition: Room Temperature
Intended Clinical Use: It is suitable for the basic protection of medical personnel or related personnel, as well as the protection of preventing the spread of blood, body fluids and spatters in the process of invasive operation
The information about the test article was supplied by the sponsor wherever applicable.

5.2 Control article

5.2.1 Negative Control
Article Name: Sesame oil (SO).
Manufacturer: Ji'an luyuanxiangliao. Co. Ltd
Size: 25kg
Lot/ Batch#: 20190220
Physical State: Oily liquid
Color: Pale yellow
Storage Condition: Room Temperature

5.2.2Positive Control
Article Name: 2, 4-Dinitrochlorobenzene (DNCB)
Manufacturer: Xiya Reagent^{R}
Size: 100g
Lot/ Batch#: W5656
Induction Concentration: 0.5%
Challenge Concentration: 0.1%
Solvent: Sesame oil
Date prepared: 2018-12-17
Physical State: Liquid
Color: light yellow
Storage Condition: Room Temperature

6.0 Identification of test system

Species: Hartley Guinea Pig (Cavia Porcellus)
Number: 15 (10 Test +5 Negative Control)
Sex: males

Initial body weight: 300～500g
Health status: Healthy, not previously used in other experimental procedures
Housing: Animals were housed in groups in cages identified by a card indicating the lab number, test code and first treatment date, etc
Animal identification: Stain with picric acid
Cages: Plastic cage
Acclimation Period: 7 days under the same conditions as for the actual test

7.0 Animal Care and Maintenance

Animal purchase: Suzhou Experimental Animal Sci-tech Co., Ltd. <Permit Code: SCXK (SU) 2015-0007>
Bedding: Corncob, Suzhou shuangshi laboratory animal feed science Co.,Ltd
Feed: Guinea Pig Diet, Suzhou Experimental Animal Sci-tech Co., Ltd.
Water: Drinking water met the Standards for Drinking Water Quality GB 5749-2006
Animal room temperature: 18-26℃
Animal room relative humidity: 30%-70%
Lights: 12 hours light/dark cycle, full-spectrum lighting
Personnel: Associates involved were appropriately qualified and trained
Selection: Only healthy, previously unused animals were selected
There were no known contaminants present in the feed, water, or bedding expected to interfere with the test data

8.0 Justification of the test system

The albino guinea pig has been used historically for sensitization studies (Magnusson and Kligman, 1970). The guinea pig is believed to be the most sensitive animal model for this type of study .The susceptibility of the guinea pig to a known sensitizing agent, 2, 4-Dinitrochlorobenzene (DNCB) has been substantiated at SDWH.

9.0 Route of administration

The test article was extracted and administered in vivo through a medium compatible with the test system. Dermal application corresponds to the likely route of human exposure.

10.0 Experiment design

10.1 Sample and Control Preparation

Intradermal induction phase Ⅰ:

Aseptic Sampling	Aseptic Agitation Extraction In Inert Container	Final Extract

Sampling Manner	Actually sampling	Ratio	sesame oil	Condition	pH	Clear or Not
Whole Surface area of one test article is 166.25cm². (Provided by sponsor)	Surface area 166.25cm²	6cm² : 1ml	27.7ml	37℃, 72h	5.5	Clear

Topical induction phase II :

Aseptic Sampling		Aseptic Agitation Extraction In Inert Container			Final Extract	
Sampling Manner	Actually sampling	Ratio	sesame oil	Condition	pH	Clear or Not
Whole Surface area of one test article is 166.25cm². (Provided by sponsor)	Surface area 166.25cm²	6cm² : 1ml	27.7ml	37℃, 72h	5.5	Clear

Challenge phase:

Aseptic Sampling		Aseptic Agitation Extraction In Inert Container			Final Extract	
Sampling Manner	Actually sampling	Ratio	sesame oil	Condition	pH	Clear or Not
Whole Surface area of one test article is 166.25cm². (Provided by sponsor)	Surface area 166.25cm²	6cm² : 1ml	27.7ml	37℃, 72h	5.5	Clear

There is no change in the extraction solvent (pre- and post-extraction). The extract was stored at 4℃ and tested within 24h after extraction without the process of pH value adjustment, filtering, centrifugation, dilution, etc.

The vehicle (without the test article) was similarly prepared to serve as the control.

10.2 Equipment

Horizontal Large Capacity Constant Temperature Vibrator (SDWH897), Calibration Expire (2019-05-15)

Autoclave (SDWH2097), Calibration Expire (2019-11-04)

Steel Straight Scale (SDWH463) ,Calibration Expire（2019-08-22）

Electronic scale (SDWH442) ,Calibration Expire（2019-05-15）

10.3 Reagents

Freund's Adjuvant,Complete liquid

Manufacturer: SIGMA

Lot No: SLBX3240

Sodium dodecyl sulfate (SDS)

Manufacturer: Sinopharm Chemical ReagentCo., Ltd
Lot No: F20090922
Concentration: 10%
Solvent: Distilled water
Date prepared: 2019-01-07

10.4 Intradermal induction phase Ⅰ

A pair of 0.1ml intradermal injections was made for each of the following, into each animal, at the injection sites (A, B and C) as shown in Figure 1 in the clipped intrascapular region.
Site A: A 50:50 (volume ratio) stable emulsion of Freund's complete adjuvant mixed with the chosen solvent.
Site B: The test sample (undiluted extract); the control animals were injected with the solvent alone.
Site C: The test sample at the concentration used at site B, emulsified in a 50:50 volume ratio stable emulsion of Freund's complete adjuvant and the solvent (50%); the control animals were injected with an emulsion of the blank liquid with adjuvant.

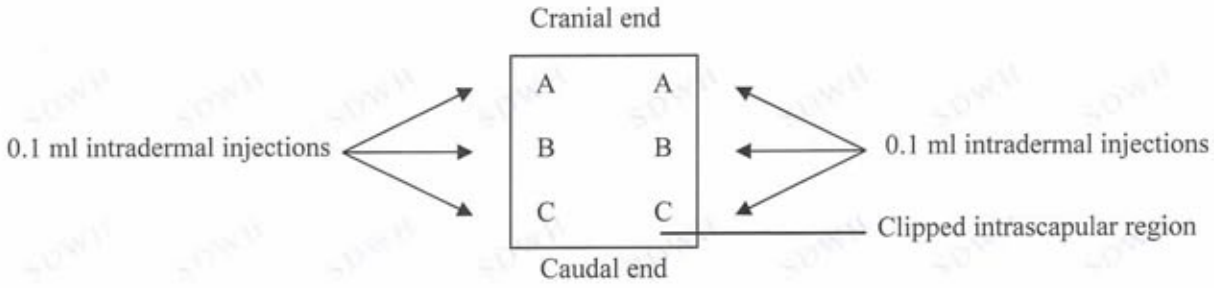

Figure 1 Location of intradermal injection sites

10.5 Topical induction phase Ⅱ

The maximum concentration that can be achieved in Intradermal induction phase Ⅰ did not produce irritation, animals are pretreated with 10% sodium dodecyl sulfate 24(±2) hours before the topical induction application.
At 7 d after completion of the intradermal induction phase, administer 0.5ml test article extract by topical application to the intrascapular region of each animal, using a patch of area approximately 8cm^2 (absorbent gauze), so as to cover the intradermal injection sites. Secure the patches with an occlusive dressing. Remove the dressings and patches after (48±2) h.
Treat the control animals similarly, using the blank liquid alone.

10.6 Challenge phase

At 14 d after completion of the topical induction phase, challenge all test and control animals with the test sample. Absorbent gauzes (2.5cmx2.5cm) were soaked respectively with 0.5ml test article and 0.5ml control aritcle. Apply the test article extract and control article topically to two sites that were not treated during the induction stage.Secure with an occlusive dressing. Remove the dressings and patches after (24±2) h.

10.7 Observation of animal

Observe the appearance of the challenge skin sites of the test and control animals (24±2) h and (48±2) h after removal of the dressings. Full-spectrum lighting was used to visualize the skin reactions. Describe and grade the skin reactions for erythema and oedema according to the Magnusson and Kligman grading given in Table 1 for each challenge site and at each time interval.

10.8 Evaluation of results

Magnusson and Kligman grades of 1 or greater in the test group generally indicate sensitization, provided grades of less than 1 are seen in control animals.
If grades of 1 or greater are noted in control animals, then the reactions of test animals which exceed the most severe reaction in control animals are presumed to be due to sensitization.
If the response is equivocal, rechallenge is recommended to confirm the results from the first challenge.
The outcome of the test is presented as the frequency of positive challenge results in test and control animals.

Table 1 Magnusson and Kligman scale

Patch test reaction	Grading scale
No visible change	0
Discrete or patchy erythema	1
Moderate and confluent erythema	2
Intense erythema and/or swelling	3

10.9 Results

Individual results of dermal scoring for the challenge appear in Table 2.

10.10 Conclusion

Under the conditions of this study, the test article Surgical face mask extract showed no significant evidence of causing skin sensitization in the guinea pig.

11.0 Record Storage

All raw data pertaining to this study and a copy of the final report are to be retained in designated SDWH archive.

12.0 Confidentiality Agreement

Statements of confidentiality were as agreed upon prior to study initiation.

13.0 Deviation statement

There were no deviations from the approved study protocol which were judged to have any impact on the validity of the data.

Table 2 Guinea pig Sensitization Dermal Reactions

Group	Animal Number	24±2h before phase II patch application		24±2 h following Challenge phase		48±2 h following Challenge phase		Positive rate after challenge phase
		Left	Right	Test sites	Control sites	Test sites	Control sites	
Test Group	1	0	0	0	0	0	0	0%
	2	0	0	0	0	0	0	
	3	0	0	0	0	0	0	
	4	0	0	0	0	0	0	
	5	0	0	0	0	0	0	
	6	0	0	0	0	0	0	
	7	0	0	0	0	0	0	
	8	0	0	0	0	0	0	
	9	0	0	0	0	0	0	
	10	0	0	0	0	0	0	
Negative control	11	0	0	0	0	0	0	—
	12	0	0	0	0	0	0	
	13	0	0	0	0	0	0	
	14	0	0	0	0	0	0	
	15	0	0	0	0	0	0	

Table 3 Weigh change and Clinical observation

Group	Animal Number	Weight (g)		Clinical observation except dermal reactions
		Before injection	After experiment	
Test Group	1	334	411	Normal
	2	337	415	Normal
	3	353	439	Normal
	4	357	445	Normal
	5	301	362	Normal
	6	318	387	Normal
	7	326	399	Normal
	8	313	379	Normal
	9	340	420	Normal
	10	323	396	Normal
Negative control	11	359	442	Normal
	12	322	395	Normal
	13	311	377	Normal
	14	319	389	Normal
	15	323	390	Normal

Table 4 Guinea pig Sensitization Dermal Reactions of Positive Group

Group	Animal Number	24±2h before phase II patch application		24±2 h following Challenge phase		48±2 h following Challenge phase		Positive rate after challenge phase
		Left	Right	Test sites	Control sites	Test sites	Control sites	
Positive Group	1	3	3	2	0	2	0	100%
	2	3	3	1	0	1	0	
	3	3	3	2	0	2	0	
	4	3	3	2	0	2	0	
	5	3	3	1	0	2	0	
Negative control	6	0	0	0	0	0	0	—
	7	0	0	0	0	0	0	
	8	0	0	0	0	0	0	
	9	0	0	0	0	0	0	
	10	0	0	0	0	0	0	

Note: The data of positive control come from SDWH- M201804434-2(Completed Date: 2019-01-10)

Table 5 Weigh change and Clinical observation of Positive Group

Group	Animal Number	Weight (g)		Clinical observation except dermal reactions
		Before injection	After experiment	
Positive Group	1	305	367	Normal
	2	310	374	Normal
	3	353	437	Normal
	4	301	362	Normal
	5	349	433	Normal
Negative control	6	357	444	Normal
	7	345	428	Normal
	8	343	424	Normal
	9	327	401	Normal
	10	357	442	Normal

Note: The data of positive control come from SDWH- M201804434-2(Completed Date: 2019-01-10)

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CNAS L2954

Sanitation & Environment Technology Institute, Soochow University, Final Report

Report Number: SDWH- M201900484-2(E)

Skin Sensitization Test of
Surgical face mask
Using ISO 10993-10:2010 Test Methods
Guinea Pig Maximization Test
0.9% Sodium Chloride Injection Extract

Sponsor
ShaoXing Yibon Medical Co.,Ltd
Yuewang Road,Paojiang,ShaoXing,Zhejiang,China
Manufacturer
ShaoXing Yibon Medical Co.,Ltd

CONTENTS

SUPPLEMENTARY EXPLANATION

1. Please apply for rechecking within 15 days of receiving the report if there are any objections.
2. Any erasure or without special inspection and testing seal renders the report null and void.
3. The report is only valid when signed by the persons who edited, checked and approved it.
4. The result relate only to the articles tested.
5. The report shall not be reproduced except in full without the written approval of the institute.

STUDY VERIFICATION AND SIGNATURE

Test Article	
Test Article Receipt:	2019-02-18
Protocol No:	SDWH-PROTOCOL-M201900484-2
Protocol Effective Date:	2019-03-01
Technical Initiation Date:	2019-03-01
Technical Completion Date:	2019-03-28
Final Report Completion Date:	2019-04-01

Edited by : _____ 2019-04-01
Date

Checked by : Zhang Yan 2019.04.01
Study Director Date

Approved by : _____ 2019.4.8
Authorized signatory Date

Sanitation & Environment Technology Institute, Soochow University

1.0 Study Summary

The extract of the test article Surgical face mask (extraction in 0.9% Sodium Chloride for Injection) was evaluated for its potential to induce skin sensitization in the Guinea Pig Maximization Test.
The test article extract was intradermally injected and applied topically for induction to ten guinea pigs. Five control animals were treated accordingly but with the solvent alone. The topical challenge with the test article extract elicited no skin reaction in the test and in the control animals. The skin sensitization rate was determined with 0%.
As defined by the scoring system of Magnusson and Kligman the test article extract showed no signification evidence of causing skin sensitization in the guinea pig under the conditions of this study.

2.0 Purpose

The test was designed to evaluate the potential of a test article to cause skin sensitization. The test is used as a procedure for screening of contact allergens in guinea pigs and extrapolating the results to humans, but it does not establish the actual risk of sensitization.

3.0 Reference

Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization (ISO 10993-10:2010)
Biological evaluation of medical devices-Part 12: Sample preparation and reference materials (ISO 10993-12:2012)
Biological evaluation of medical devices-Part 2: Animal welfare requirements (ISO 10993-2:2006)

4.0 Compliance

ISO/IEC 17025:2005 General requirements for the competence of testing and calibration laboratories (CNAS-CL01 Accreditation Criteria for the competence of testing and calibration laboratories)
China National Accreditation Service for Conformity Assessment
Laboratory Accreditation Certificate No. CNAS L2954
Accreditation Criteria for the competence of Inspection Body (Certification and Accreditation Admin istration of the People's Republic of China CMA 180015144061)

5.0 Identification of test and control articles

5.1 Test article

Test article name: Surgical face mask
Test article initial state:Sterilized, EO Sterilization
CAS Code: Not supplied by sponsor (N/S)

Model: Sterilization
Size: 17.5x9.5cm
Lot/ Batch: 1805002
Test Article Material: The mask is composed of non-woven , melt-blown nonwoven, mask belt and nose clip
Packaging Material: N/S
Physical State: Solid
Color: white
Density: N/S
Stability: N/S
Solubility: N/S
Storage Condition: Room Temperature
Intended Clinical Use: It is suitable for the basic protection of medical personnel or related personnel, as well as the protection of preventing the spread of blood, body fluids and spatters in the process of invasive operation
The information about the test article was supplied by the sponsor wherever applicable.

5.2 Control article

5.2.1Negative Control
Article Name: 0.9% Sodium Chloride Injection (SC)
Manufacturer: Chenxin Pharmaceutical Co., Ltd.
Size: 500ml
Lot/ Batch#: 1810300722
Physical State: Liquid
Color: Colorless
Storage Condition: Room Temperature

5.2.2Positive Control
Article Name: 2, 4-Dinitrochlorobenzene (DNCB)
Manufacturer: Xiya Reagent®
Size: 100g
Lot/ Batch#: W5656
Induction Concentration: 0.5%
Challenge Concentration: 0.1%
Solvent: 0.9% Sodium Chloride Injection
Date prepared: 2018-12-17
Physical State: Liquid
Color: light yellow
Storage Condition: Room Temperature

6.0 Identification of test system

Species: Hartley Guinea Pig (Cavia Porcellus)
Number: 15 (10 Test +5 Negative Control)
Sex: males

Initial body weight: 300～500g
Health status: Healthy, not previously used in other experimental procedures
Housing: Animals were housed in groups in cages identified by a card indicating the lab number, test code and first treatment date, etc
Animal identification: Stain with picric acid
Cages: Plastic cage
Acclimation Period: 7 days under the same conditions as for the actual test

7.0 Animal Care and Maintenance

Animal purchase: Suzhou Experimental Animal Sci-tech Co., Ltd. <Permit Code: SCXK (SU) 2015-0007>
Bedding: Corncob, Suzhou shuangshi laboratory animal feed science Co.,Ltd
Feed: Guinea Pig Diet, Suzhou Experimental Animal Sci-tech Co., Ltd.
Water: Drinking water met the Standards for Drinking Water Quality GB 5749-2006
Animal room temperature: 18-26℃
Animal room relative humidity: 30%-70%
Lights: 12 hours light/dark cycle, full-spectrum lighting
Personnel: Associates involved were appropriately qualified and trained
Selection: Only healthy, previously unused animals were selected
There were no known contaminants present in the feed, water, or bedding expected to interfere with the test data

8.0 Justification of the test system

The albino guinea pig has been used historically for sensitization studies (Magnusson and Kligman, 1970). The guinea pig is believed to be the most sensitive animal model for this type of study .The susceptibility of the guinea pig to a known sensitizing agent, 2, 4-Dinitrochlorobenzene (DNCB) has been substantiated at SDWH.

9.0 Route of administration

The test article was extracted and administered in vivo through a medium compatible with the test system. Dermal application corresponds to the likely route of human exposure.

10.0 Experiment design

10.1 Sample and Control Preparation

Intradermal induction phase Ⅰ:

Aseptic Sampling	Aseptic Agitation Extraction In Inert Container	Final Extract

Sampling Manner	Actually sampling	Ratio	SC	Condition	pH	Clear or Not
Whole Surface area of one test article is 166.25cm². (Provided by sponsor)	Surface area 166.25cm²	6cm² : 1ml	27.7ml	37℃, 72h	6.0	Clear

Topical induction phase Ⅱ :

Aseptic Sampling		Aseptic Agitation Extraction In Inert Container			Final Extract	
Sampling Manner	Actually sampling	Ratio	SC	Condition	pH	Clear or Not
Whole Surface area of one test article is 166.25cm². (Provided by sponsor)	Surface area 166.25cm²	6cm² : 1ml	27.7ml	37℃, 72h	6.0	Clear

Challenge phase:

Aseptic Sampling		Aseptic Agitation Extraction In Inert Container			Final Extract	
Sampling Manner	Actually sampling	Ratio	SC	Condition	pH	Clear or Not
Whole Surface area of one test article is 166.25cm². (Provided by sponsor)	Surface area 166.25cm²	6cm² : 1ml	27.7ml	37℃, 72h	6.0	Clear

There is no change in the extraction solvent (pre- and post-extraction). The extract was stored at 4℃ and tested within 24h after extraction without the process of pH value adjustment, filtering, centrifugation, dilution, etc.

The vehicle (without the test article) was similarly prepared to serve as the control.

10.2 Equipment

Horizontal Large Capacity Constant Temperature Vibrator (SDWH897), Calibration Expire (2019-05-15)

Autoclave (SDWH2097), Calibration Expire (2019-11-04)

Steel Straight Scale (SDWH463) ,Calibration Expire（2019-08-22）

Electronic scale (SDWH442) ,Calibration Expire（2019-05-15）

10.3 Reagents

Freund's Adjuvant,Complete liquid

Manufacturer: SIGMA

Lot No: SLBX3240

Sodium dodecyl sulfate (SDS)

Manufacturer: Sinopharm Chemical ReagentCo., Ltd
Lot No: F20090922
Concentration: 10%
Solvent: Distilled water
Date prepared: 2019-01-07

10.4 Intradermal induction phase Ⅰ

A pair of 0.1ml intradermal injections was made for each of the following, into each animal, at the injection sites (A, B and C) as shown in Figure 1 in the clipped intrascapular region.
Site A: A 50:50 (volume ratio) stable emulsion of Freund's complete adjuvant mixed with the chosen solvent.
Site B: The test sample (undiluted extract); the control animals were injected with the solvent alone.
Site C: The test sample at the concentration used at site B, emulsified in a 50:50 volume ratio stable emulsion of Freund's complete adjuvant and the solvent (50%); the control animals were injected with an emulsion of the blank liquid with adjuvant.

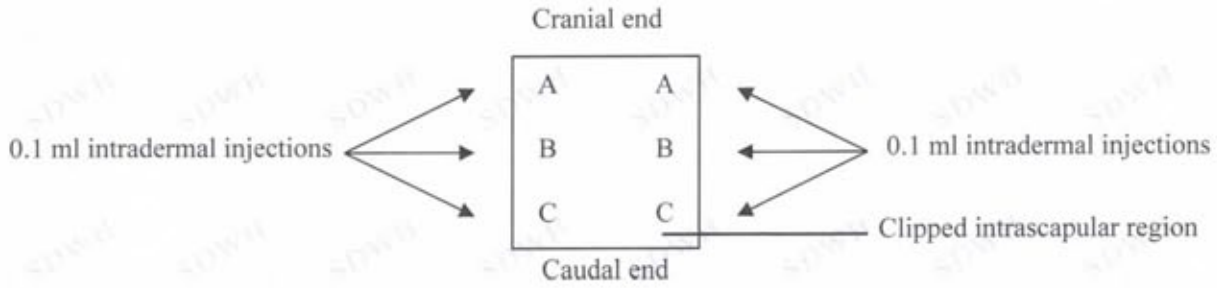

Figure 1 Location of intradermal injection sites

10.5 Topical induction phase Ⅱ

The maximum concentration that can be achieved in Intradermal induction phase Ⅰ did not produce irritation, animals are pretreated with 10% sodium dodecyl sulfate 24(±2) hours before the topical induction application.
At 7 d after completion of the intradermal induction phase, administer 0.5ml test article extract by topical application to the intrascapular region of each animal, using a patch of area approximately 8cm^2 (absorbent gauze), so as to cover the intradermal injection sites. Secure the patches with an occlusive dressing. Remove the dressings and patches after (48±2) h.
Treat the control animals similarly, using the blank liquid alone.

10.6 Challenge phase

At 14 d after completion of the topical induction phase, challenge all test and control animals with the test sample. Absorbent gauzes (2.5cmx2.5cm) were soaked respectively with 0.5ml test article and 0.5ml control aritcle. Apply the test article extract and control article topically to two sites that were not treated during the induction stage.Secure with an occlusive dressing. Remove the dressings and patches after (24±2) h.

10.7 Observation of animal

Observe the appearance of the challenge skin sites of the test and control animals (24±2) h and (48±2) h after removal of the dressings. Full-spectrum lighting was used to visualize the skin reactions. Describe and grade the skin reactions for erythema and oedema according to the Magnusson and Kligman grading given in Table 1 for each challenge site and at each time interval.

10.8 Evaluation of results

Magnusson and Kligman grades of 1 or greater in the test group generally indicate sensitization, provided grades of less than 1 are seen in control animals.
If grades of 1 or greater are noted in control animals, then the reactions of test animals which exceed the most severe reaction in control animals are presumed to be due to sensitization.
If the response is equivocal, rechallenge is recommended to confirm the results from the first challenge.
The outcome of the test is presented as the frequency of positive challenge results in test and control animals.

Table 1 Magnusson and Kligman scale

Patch test reaction	Grading scale
No visible change	0
Discrete or patchy erythema	1
Moderate and confluent erythema	2
Intense erythema and/or swelling	3

10.9 Results

Individual results of dermal scoring for the challenge appear in Table 2.

10.10 Conclusion

Under the conditions of this study, the test article Surgical face mask extract showed no significant evidence of causing skin sensitization in the guinea pig.

11.0 Record Storage

All raw data pertaining to this study and a copy of the final report are to be retained in designated SDWH archive.

12.0 Confidentiality Agreement

Statements of confidentiality were as agreed upon prior to study initiation.

13.0 Deviation statement

There were no deviations from the approved study protocol which were judged to have any impact on the validity of the data.

Table 2 Guinea pig Sensitization Dermal Reactions

Group	Animal Number	24±2h before phase II patch application		24±2 h following Challenge phase		48±2 h following Challenge phase		Positive rate after challenge phase
		Left	Right	Test sites	Control sites	Test sites	Control sites	
Test Group	1	0	0	0	0	0	0	0%
	2	0	0	0	0	0	0	
	3	0	0	0	0	0	0	
	4	0	0	0	0	0	0	
	5	0	0	0	0	0	0	
	6	0	0	0	0	0	0	
	7	0	0	0	0	0	0	
	8	0	0	0	0	0	0	
	9	0	0	0	0	0	0	
	10	0	0	0	0	0	0	
Negative control	11	0	0	0	0	0	0	—
	12	0	0	0	0	0	0	
	13	0	0	0	0	0	0	
	14	0	0	0	0	0	0	
	15	0	0	0	0	0	0	

Table 3 Weigh change and Clinical observation

Group	Animal Number	Weight (g)		Clinical observation except dermal reactions
		Before injection	After experiment	
Test Group	1	349	433	Normal
	2	355	442	Normal
	3	337	415	Normal
	4	322	393	Normal
	5	307	370	Normal
	6	356	445	Normal
	7	305	372	Normal
	8	317	386	Normal
	9	313	379	Normal
	10	327	400	Normal
Negative control	11	358	447	Normal
	12	354	442	Normal
	13	325	399	Normal
	14	346	429	Normal
	15	339	418	Normal

Table 4 Guinea pig Sensitization Dermal Reactions of Positive Group

Group	Animal Number	24±2h before phase II patch application		24±2 h following Challenge phase		48±2 h following Challenge phase		Positive rate after challenge phase
		Left	Right	Test sites	Control sites	Test sites	Control sites	
Positive Group	1	3	3	1	0	2	0	100%
	2	3	3	2	0	2	0	
	3	3	3	2	0	1	0	
	4	3	3	1	0	1	0	
	5	3	3	2	0	1	0	
Negative control	6	0	0	0	0	0	0	—
	7	0	0	0	0	0	0	
	8	0	0	0	0	0	0	
	9	0	0	0	0	0	0	
	10	0	0	0	0	0	0	

Note: The data of positive control come from SDWH-M201804434-1 (Completed Date: 2019-01-10)

Table 5 Weigh change and Clinical observation of Positive Group

Group	Animal Number	Weight (g)		Clinical observation except dermal reactions
		Before injection	After experiment	
Positive Group	1	355	440	Normal
	2	322	391	Normal
	3	354	441	Normal
	4	317	385	Normal
	5	308	370	Normal
Negative control	6	358	444	Normal
	7	332	408	Normal
	8	356	444	Normal
	9	346	429	Normal
	10	329	402	Normal

Note: The data of positive control come from SDWH-M201804434-1 (Completed Date: 2019-01-10)

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2020-06-16

To Whom It May Concern

This is to confirm that Re-certification Audit for ISO 13485, Surveillance Audit for MDD was carried out on behalf of TÜV Rheinland LGA Products GmbH Certification Body as follows:

Applicant: **Shaoxing Yibon Medical Co., Ltd.**
Address: **No. 341 Yuewang Road, Paojiang Industrial Zone, Shaoxing, Zhejiang 312000, China**

Scope: **Manufacture and Distribution of Medical Dressings, Sterile Catheterization Sets, Sterile Dialysis Sets, Plastic and Metal Surgical Instruments, Sterile Suture Removal Sets, Sterile Staple Removal Sets, Medical Bowl Sets, Disinfection Sets, Sterile Dressing Sets, Infusion Dressing Sets, Surgical Dressing Sets**

Standards: **EN ISO 13485:2016**

Date: 2020-05-06~09
Report No.: 15068619 013

The corrective action proposed by the company are acceptable, therefore the auditors will recommend that TÜV Rheinland LGA Products GmbH Certification Body Certificate for a Quality Management System should be issued.

Yours sincerely,
TÜV RHEINLAND (SHANGHAI) Co., Ltd.

Ella Feng

Ms. Ella FENG
Lead Auditor
Medical Services

TÜV Rheinland
(Shanghai) Co., Ltd.

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Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Shaoxing Yibon Medical Co., Ltd.
No. 341 Yuewang Road
Paojiang Industrial Zone
Shaoxing
312000 Zhejiang
China

has established and applies a quality management system for medical devices for the following scope:

Manufacture and Distribution of Medical Devices

(see attachment for products and additional site included)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:	2017-06-29
Certificate Registration No.:	SX 60120554 0001
An audit was performed. Report No.:	15068619 004
This Certificate is valid until:	2020-06-16

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH
TÜVRheinland
Zertifizierungsstelle

Date 2017-06-29

X. Ren

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
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Doc. 1/1, Rev.0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60120554 0001
Report No.: 15068619 004

Organization:
Shaoxing Yibon Medical Co., Ltd.
No. 341 Yuewang Road
Paojiang Industrial Zone
Shaoxing
312000 Zhejiang
China

Scope:

Products:

Medical Dressings, Catheterization Sets, Dialysis Sets, Plastic Surgical Instruments, Suture Remover Sets, Staple Remover Sets, Medical Bowl Sets, Disinfection Sets

Site included:

No. 347 Yuewang Road, Paojiang Industrial Zone, Shaoxing, Zhejiang 312000, China

Manufacture of the a.m. Products

Certification Body

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Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

X. Ren

Date: 2017-06-29