DISPOSITIF MEDICAL DE CLASSE 1

Dossier de Conformité

Masque Chirurgical Type IIR

Réf. interne : LM2504

Fiche Produit

Masque Chirurgical Type IIR

Référence : LM2504

Norme : EN14683+AC:2019 IIR, relative au règlement (EU) 2017/745/UE

PRÉSENTATION DU PRODUIT

Masques chirurgicaux Type IIR à usage unique, non stériles

Masque destiné à empêcher les germes présents dans les voies respiratoires de sortir et de contaminer l'entourage. Permet de limiter la transmission des virus aéroportés par les personnes infectées. Ce masque est résistant à la projection pour réduire l'exposition potentielle du porteur au sang et aux liquides corporels. Ce masque est adapté au milieu hospitalier, pour un usage médical.

CONFORMITÉ DU PRODUIT

Masques conformes aux dispositions réglementaires suivantes :

- Norme harmonisée **EN 14683+AC : 2019 (Type IIR)** qui évalue l'efficacité du matériau filtrant dans le sens de l'expiration.
- Règlement UE **2017/745/UE**.
- Marquage **CE**.

CARACTÉRISTIQUES TECHNIQUES

Masques non stériles à USAGE UNIQUE

Efficacité de filtration bactérienne : BFE >= 98 %

Réspirabilité : < 60 pa/cm2

Bioburden : < 30 Cfu/G

Couches : 3

Durée de vie : 5 ans

Utilisation unique : efficace 4h

Dimensions du masque : 9.5 x 17.5cm

COMPOSITION DU MASQUE

- 35% couche de PP non-tissé,
- 30% couche de PP non-tissé soufflé par fusion,
- 35% couche de PP non-tissé.
- Une barette nasale pour une meilleure étanchéité
- Une couche interne et externe ultra déperlante
- Avec élastiques
- Sans latex

INSTRUCTIONS D'UTILISATION

- Tirez et déployez le masque à deux mains pour vous assurer que le pince-nez est vers le haut.
- Tenez le masque sur le visage et tirez la bande élastique jusqu'aux oreilles.
- Appuyez sur le clip du nez pour épouser la forme du nez.
- Durée de vie : 4h. Ne pas réutiliser.

PRÉCAUTIONS D'EMPLOIS

LIMITES D'UTILISATION : Dispositif à usage unique. Utiliser 2 à 3 masques par jour par personne.

STOCKAGE : Les masques ont une durée de conservation limitée et doivent être stockés dans un endroit à l'abri de la lumière et de l'humidité entre 10 et 25°C.

AVERTISSEMENT : Il est essentiel que le masque soit enlevé en dernier, après tout autre matériel de protection (gants, surblouse, lunettes de protection) afin de limiter au maximum tout risque de contamination. Les mains doivent impérativement être désinfectées après le retrait du masque.

DÉCLARATION DE CONFORMITÉ CE DU FABRICANT

ANNEXE 1

CE

DECLARATION OF CONFORMITY

Regarding Medical Device Regulation (EU) 2017/745

CE

Manufacturer: Sunsmed Protective Products Ltd

Address: No.18,Industrial Park, Maozui Town, XiantaoCity, 433000, Hubei Province, China

EC Representative: SUNGO Europe B.V

Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Product Name: Disposable Medical Face Mask

Model: 17.5*9.5cm

SRN: / **Basic UDI-DI:** /

Classification: Class I

Rule: Rule 1, Annex VIII, Regulation (EU) 2017/745

Conformity Assessment Procedure: Annex II+III of Regulation (EU) 2017/745

We herewith declare that the above-mentioned products meet the requirements of Medical Device Regulation (EU) 2017/745 and the following harmonized standards

EN ISO 14971: 2012
EN ISO 15223-1: 2016
EN 1041: 2008+A1:2013
ISO 10993-1: 2018
EN ISO 10993-5: 2009
EN ISO 10993-10: 2013
EN 14683:2019+AC:2019

Signature

Name / Position: 孙娜/General Manager

Date: 2021/11/13

Place: Xian tao / China

On behalf of SUNGO Europe office, I confirmed [illegible] QA/QEP of the company who issue this document.

Sungo

Authorized Signature

CE

DÉCLARATION DE CONFORMITÉ DE L'IMPORTATEUR/ DISTRIBUTEUR

L'importateur et distributeur soussigné :

JSE GROUPE 29 AVENUE ANATOLE FRANCE, 94220 CHARENTON-LE-PONT, FRANCE

déclare que le produit :

- Dénomination du produit : MASQUE CHIRURGICAL TYPE IIR
- Référence interne du produit : LM2504 / LM2504-XS

est conforme aux dispositions réglementaires définies par le Règlement Européen et les normes harmonisées. Conformément au règlement UE 2017/745/UE, JSE GROUPE déclare avoir à sa disposition l'ensemble de la documentation technique incluant la déclaration CE de conformité et les rapports de test, et les tiens à disposition des autorités nationales pour une durée d'au moins cinq ans.

Les rapports d'essais du laboratoire Nelson Labs purchase order SHLAB2003160001A effectués par le fabricant Sunsmed Protective Product Ltd. démontrent la conformité du masque LM2504/ LM2504-XS à la norme européenne harmonisée EN14683+AC:2019 en type IIR sur les annexes B,C et D rapport d'essais 1277685-S01 ainsi que la résistance aux projections suivant la norme ISO22609 : 2004 rapport d'essai 1277684-S01.

Dans le cadre d'un autocontrôle, JSE Groupe a également fait réaliser des rapports d'essais auprès du laboratoire SGS en date du 27/08/2020. Ces rapports de test n°SL52035285180501TX démontrent également la conformité du masque LM2504/ LM2504-XS à la norme européenne harmonisée EN14683+AC:2019 en type IIR.

Le produit est également conforme aux normes suivantes :

- EN ISO 10993-1 :2009 (Biocompatibilité des dispositifs médicaux)
- EN ISO 14971 :2019 (gestion des risques des dispositifs médicaux)
- EN ISO 10993-10 : 2013 (essais irritations et de sensibilisation cutanée)
- EN ISO 15223-1 :2017 (Marquages des dispositifs médicaux)
- EN 1041 :2008+A1 :2013 (Informations des dispositifs)
- EN ISO 10993-5 :2010 (cytotoxicité in vitro)

La référence décrite est fabriquée par le fabricant :

SUNSMED PROTECTIVE PRODUCTS LTD NO.18, INDUSTRIAL PARK, MAOUZUI TOWN, XIANTAO CITY, HUBEI PROVINCE, CHINA

et représenté par le mandataire européen :

SUNGO EUROPE B.V. OLYMPISCH STADION 24, 1076DE AMSTERDAM, NETHERLANDS

Fait à Paris, le 30/01/2021

L'importateur / distributeur :

Nom et qualité du signataire :
Simon MECHALY
Président

Signature :

Nelson Labs.
A Sotera Health company

Sponsor:
Joyce Lee
Sunsmed Protective Products Ltd.
Industrial Park, Maozui Town
Xiantao City
Hubei Province, 433000
CHINA

Bacterial Filtration Efficiency (BFE) and Differential Pressure (Delta P) Final Report

Test Article:	Surgical Face Mask
Purchase Order:	SHLAB2003160001A
Study Number:	1277685-S01
Study Received Date:	16 Mar 2020
Testing Facility:	Nelson Laboratories, LLC 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A.
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0004 Rev 18
Deviation(s):	None

Summary: The BFE test is performed to determine the filtration efficiency of test articles by comparing the bacterial control counts upstream of the test article to the bacterial counts downstream. A suspension of *Staphylococcus aureus* was aerosolized using a nebulizer and delivered to the test article at a constant flow rate and fixed air pressure. The challenge delivery was maintained at 1.7 - 3.0 x 10^3 colony forming units (CFU) with a mean particle size (MPS) of 3.0 ± 0.3 µm. The aerosols were drawn through a six-stage, viable particle, Andersen sampler for collection. This test method complies with ASTM F2101-19 and EN 14683:2019, Annex B.

The Delta P test is performed to determine the breathability of test articles by measuring the differential air pressure on either side of the test article using a manometer, at a constant flow rate. The Delta P test complies with EN 14683:2019, Annex C and ASTM F2100-19.

All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Test Side:	Inside
BFE Test Area:	~40 cm^2
BFE Flow Rate:	28.3 Liters per minute (L/min)
Delta P Flow Rate:	8 Liters per minute (L/min)
Conditioning Parameters:	85 ± 5% relative humidity (RH) and 21 ± 5°C for a minimum of 4 hours
Test Article Dimensions:	~175 mm x ~150 mm
Positive Control Average:	2.0 x 10^3 CFU
Negative Monitor Count:	<1 CFU
MPS:	3.2 µm

Study Director James W. Luskin

23 MAR 2020
Study Completion Date

1277685-S01

Results:

Test Article Number	Percent BFE (%)
1	99.8
2	>99.9
3	>99.9[a]
4	99.9
5	>99.9

[a] There were no detected colonies on any of the Andersen sampler plates for this test article.

Test Article Number	Delta P ($mm\ H_2O/cm^2$)	Delta P (Pa/cm^2)
1	3.8	37.5
2	4.0	39.5
3	4.1	40.0
4	4.2	40.9
5	4.1	40.2

The filtration efficiency percentages were calculated using the following equation:

$$\%\ BFE = \frac{C - T}{C}\ x\ 100$$

C = Positive control average
T = Plate count total recovered downstream of the test article
Note: The plate count total is available upon request

Nelson Labs.
A Sotera Health company

Sponsor:
Joyce Lee
Sunsmed Protective Products Ltd.
Industrial Park, Maozui Town,
Xiantao City, 433000
Hubei Province,
CHINA

Synthetic Blood Penetration Resistance Final Report

Test Article:	Surgical Face Mask
Purchase Order:	SHLAB2003160001A
Study Number:	1277684-S01
Study Received Date:	16 Mar 2020
Testing Facility:	Nelson Laboratories, LLC 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A.
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0012 Rev 09
Deviation(s):	None

Summary: This procedure was performed to evaluate surgical facemasks and other types of protective clothing materials designed to protect against fluid penetration. The purpose of this procedure is to simulate an arterial spray and evaluate the effectiveness of the test article in protecting the user from possible exposure to blood and other body fluids. The distance from the target area surface to the tip of the cannula is 30.5 cm. A test volume of 2 mL of synthetic blood was employed using the targeting plate method.

This test method was designed to comply with ASTM F1862 and ISO 22609 (as referenced in EN 14683:2019 and AS4381:2015) with the following exception: ISO 22609 requires testing to be performed in an environment with a temperature of 21 ± 5°C and a relative humidity of 85 ± 10%. Instead, testing was performed at ambient conditions within one minute of removal from the environmental chamber held at those parameters.

All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Number of Test Articles Tested:	32
Number of Test Articles Passed:	29
Test Side:	Outside
Pre-Conditioning:	Minimum of 4 hours at 21 ± 5°C and 85 ± 5% relative humidity (RH)
Test Conditions:	22°C and 22% RH

Study Director James W. Luskin Study Completion Date 23 Mar 2020

1277684-S01

Results: Per ASTM F1862 and ISO 22609, an acceptable quality limit of 4.0% is met for a normal single sampling plan when ≥29 of 32 test articles show passing results.

Test Pressure: 160 mmHg (21.3 kPa)

Test Article Number	Synthetic Blood Penetration
1-8, 10-13, 15-27, 29-32	None Seen
9, 14, 28	Yes

Nelson Labs
A Sotera Health company

Sponsor:
Joyce Lee
Sunsmed Protective Products Ltd.
Idustrial Park, Maozui Town
Xiantao City, 433000
Hubei Province
CHINA

Microbial Cleanliness (Bioburden) of Medical Masks Final Report

Test Article:	Surgical Face Mask
Purchase Order:	SHLAB2003160001A
Study Number:	1277683-S01
Study Received Date:	16 Mar 2020
Testing Facility:	Nelson Laboratories, LLC 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A.
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0036 Rev 15 Customer Specification Sheet (CSS) Number: 202001516 Rev 01
Deviation(s):	None

Summary: The testing was conducted in accordance with EN 14683:2019, with the exception of approximate volumes of eluent used when performing the extraction procedure and a temperature range of 30-35°C used for aerobic incubation.

When bioburden results are calculated using a software program, manual calculations may differ slightly due to rounding. The counts determined on products are colony forming units and may not always reflect individual microorganisms. The sponsor performs any statistical analysis and determines the acceptable limits. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Results:

Unit Number	Weight (g)	Aerobic	Fungal	Total Bioburden (CFU/mask)	Total Bioburden (CFU/g)
1	3.2	45	<3	48.2	15.1
2	3.0	54	6	60.0	20.0
3	2.9	17	<3	19.6	6.8
4	2.9	32	<3	35.2	12.1
5	2.7	74	3	76.8	28.4
Recovery Efficiency			37.6%		

< = No Organisms Detected
Note: The results are reported as colony forming units (CFU) per mask.

Robert Putnam electronically approved
Study Director Robert Putnam

01 Apr 2020 20:19 (+00:00)
Study Completion Date and Time

Method Suitability:

Organism	Percentage
Bacillus atrophaeus	79%

Test Method Acceptance Criteria: If applicable, anaerobic controls are acceptable for the bioburden test results. The number of masks to be tested shall be a minimum of 5 or more to meet an acceptable quality level of 4%. The bioburden of the medical mask shall be < 30 CFU/g tested.

Procedure:

Positive Controls/Monitors:	*Bacillus atrophaeus*
Extract Fluid:	Peptone Tween®
Extract Fluid Volume:	150 mL
Extract Method:	Orbital Shaking for 15 minutes at 250 rpm
Plating Method:	Membrane Filtration
Agar Medium:	Tryptic Soy Agar Potato Dextrose Agar
Recovery Efficiency:	Exhaustive Rinse Method
Aerobic Bacteria:	Plates were incubated 3 - 7 days at 30-35°C, then enumerated.
Fungal:	Plates were incubated 5 - 7 days at 20-25°C, then enumerated.

Nelson Labs
A Sotera Health company

Sponsor:
Joyce Lee
Sunsmed Protective Products Ltd.
Idustrial Park, Maozui Town
Xiantao City, 433000
Hubei Province
CHINA

12 May 2020

Dear Joyce,

This letter is to summarize the Surgical Face Mask results gathered from Microbial Cleanliness (Bioburden) testing performed under Nelson Laboratories (NL) study #1277683-S01, Splash Resistance testing performed under study #1277684-S01, and Bacterial Filtration Efficiency (BFE) and Differential Pressure (Delta P) testing performed under study #1277685-S01

All testing was conducted in accordance with EN 14683:2019. The following performance requirements for medical face masks under this standard are as follows:

Test	Type I	Type II	Type IIR
BFE (%)	≥ 95	≥ 98	≥ 98
Delta P (Pa/cm²)	< 40	< 40	< 60
Splash resistance pressure (kPa)	Not required	Not required	≥ 16,0 (120 mmHg)
Microbial Cleanliness (CFU/g)	≤ 30	≤ 30	≤ 30

Note: This table is meant to aid the sponsor in interpreting results. Further interpretation of the data is the responsibility of the sponsor and no conclusion can be made by NLI.

JJH /for — 15 May 2020

Study Director — Janelle R. Bentz, M.S. — Date

Results:

BFE and Delta P:

Study #1277685-S01:

Test Article Number	Percent BFE (%)
1	99.8
2	>99.9
3	>99.9[a]
4	99.9
5	>99.9

[a] There were no detected colonies on any of the Andersen sampler plates for this test article.

Test Article Number	Delta P (mm H_2O/cm^2)	Delta P (Pa/cm^2)
1	3.8	37.5
2	4.0	39.5
3	4.1	40.0
4	4.2	40.9
5	4.1	40.2

Test Article Dimensions:	~175 mm x ~150 mm
Positive Control Average:	2.0×10^3 CFU
Negative Monitor Count:	<1 CFU
MPS:	3.2 µm

Microbial Cleanliness (Bioburden): When bioburden results are calculated using a software program, manual calculations may differ slightly due to rounding.

Study #1277683-S01:

Unit Number	Weight (g)	Aerobic	Fungal	Total Bioburden (CFU/mask)	Total Bioburden (CFU/g)
1	3.2	45	<3	48.2	15.1
2	3.0	54	6	60.0	20.0
3	2.9	17	<3	19.6	6.8
4	2.9	32	<3	35.2	12.1
5	2.7	74	3	76.8	28.4

< = No Organisms Detected

Note: The results are reported as colony forming units (CFU) per mask.

Splash Resistance:
Study #1277684-S01:

Test Pressure: 160 mmHg (21.3 kPa)

Test Article Number	Synthetic Blood Penetration
1-8, 10-13, 15-27, 29-32	None Seen
9, 14, 28	Yes

Please let me know if you have any questions. I can be reached at (801) 290-7569 or jbentz@nelsonlabs.com. Thank you for testing with Nelson Laboratories, LLC.

SGS

ilac-MRA CNAS 中国认可 国际互认 检测 TESTING CNAS L0599

Test Report **SL52035285180501TX** **Date:August 27,2020**

JSE SOURCING
29 AVENUE ANATOLE FRANCE 94220 CHARENTON LE PONT FRANCE

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

Sample Description	:	(A)Surgical mask EN14683:2019 IIR
Buyer	:	JSE SOURCING
Brand	:	JSE MEDICAL
Composition	:	(A)nonwoven fabric+Melt-blown fabric+nonwoven fabric
Sample Color	:	(A)Blue
Style No.	:	LM2504 / LM2504-XS
Lot No.	:	LTLM250410082020
Test Performed	:	Selected test(s) as requested by applicant
Sample Receiving Date	:	Aug 06, 2020
Testing Period	:	Aug 06, 2020 - Aug 27, 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)

Dongjing Liu / Hailian Xuan (Authorized Signatory)

3rd Building,No.889,Yishan Road,Xuhui District,Shanghai,China 200233 t (86-21) 61402666 f (86-21) 64958763 www.sgsgroup.com.cn
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Test Result

EN 14683:2019+AC:2019 Medical Face Masks-Requirements and Test Methods

Clause 5.2 Performance Requirement

Clause 5.2.2 Bacterial Filtration Efficiency (BFE)
(EN 14683:2019+AC:2019 Annex B)

Sample: A

Test Side	:	Inside
Test Area	:	Approximately 60 cm^2
Flow Rate	:	28.3 L/min
Pre-Conditioning	:	Minimum of 4 hours at 21±5°C and 85±5% R.H.
Dimensions of test specimen	:	~176mm x 155mm
Positive Control Average	:	1969.5 CFU
Negative Monitor Count	:	< 1 CFU
Mean Particle Size	:	3.0 ±0.3μm
Test bacteria	:	Staphylococcus aureus ATCC 6538

Test Item	Specimen No.	Result
Bacterial Filtration Efficiency (BFE)	1	99.9%
	2	99.9%
	3	99.9%
	4	99.9%
	5	99.9%

Remark:

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

The number of specimens that shall be tested is minimum 5, but can be greater and shall be increased if necessary to allow for an AQL(Acceptable Quality Level) of 4%.

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Clause 5.2.3 Breathability
(EN 14683 :2019+AC:2019 Annex C)

Sample: A
Test Side : Randomly test in different location (1 around and 4 away from the centric point) on each of the 5 masks
Pre-Conditioning : Minimum of 4 hours at 21±5°C and 85±5% R.H.
Test Area : 4.9 cm^2
Flow Rate : 8 l/min

Specimen No.	Test Area No.	Different Pressure for each tested area (Pa/cm^2)	The average value for each test specimen (Pa/cm^2)
1	1-1	56.9	56
	1-2	53.0	
	1-3	54.2	
	1-4	58.5	
	1-5	57.6	
2	2-1	56.9	57
	2-2	55.2	
	2-3	58.1	
	2-4	56.8	
	2-5	59.7	
3	3-1	51.9	55
	3-2	53.3	
	3-3	55.7	
	3-4	59.6	
	3-5	56.3	
4	4-1	58.9	57
	4-2	59.6	
	4-3	52.6	
	4-4	59.3	
	4-5	56.8	
5	5-1	59.2	58
	5-2	54.4	
	5-3	59.8	
	5-4	59.2	
	5-5	57.6	

Remark:
1) Performance Requirement: Type I<40 Pa/cm^2, Type II<40 Pa/cm^2, Type IIR<60 Pa/cm^2
2) The number of specimens that shall be tested is minimum 5, but can be greater and shall be increased if necessary to allow for an AQL(Acceptable Quality Level) of 4%.

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Clause 5.2.4 Splash Resistance
(ISO 22609 :2004)

Sample: A
Test Blood Pressure : 16.0kPa
Pre-Conditioning : Minimum of 4 hours at 21±5°C and 85±5% R.H.
Distance of the mask to the tip of cannula : 300±10mm

Test Specimen#	Penetration on inside surface	Conclusion	Test Specimen#	Penetration on inside surface	Conclusion
1	None Seen	Pass	17	None Seen	Pass
2	None Seen	Pass	18	None Seen	Pass
3	None Seen	Pass	19	None Seen	Pass
4	None Seen	Pass	20	None Seen	Pass
5	None Seen	Pass	21	None Seen	Pass
6	None Seen	Pass	22	None Seen	Pass
7	None Seen	Pass	23	None Seen	Pass
8	None Seen	Pass	24	None Seen	Pass
9	None Seen	Pass	25	None Seen	Pass
10	None Seen	Pass	26	None Seen	Pass
11	None Seen	Pass	27	None Seen	Pass
12	None Seen	Pass	28	None Seen	Pass
13	None Seen	Pass	29	None Seen	Pass
14	None Seen	Pass	30	None Seen	Pass
15	None Seen	Pass	31	None Seen	Pass
16	None Seen	Pass	32	None Seen	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) Test was conducted within 60s after removal from conditioning chamber.
3) 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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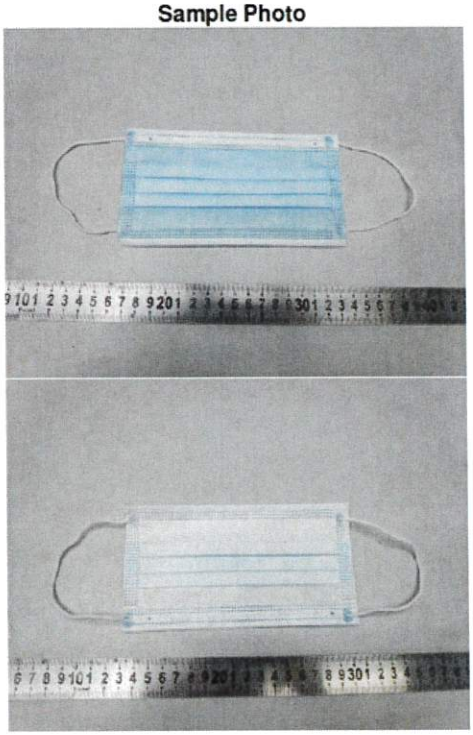
Clause 5.2.5 Microbial Cleanliness
(EN 14683:2019+AC:2019 Annex D and EN ISO 11737-1:2018)

Sample: A

Test Specimen#	Mask Weight(g)	Total Bioburden, (CFU/mask)	Total Bioburden, (CFU/g)
1#	2.76	78	28.26
2#	2.74	66	24.09
3#	2.76	36	13.04
4#	2.77	63	22.74
5#	2.79	12	4.30

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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中国认可
国际互认
检测
TESTING
CNAS L13034

In Vitro Cytotoxicity Test

MTT Method

Final Report

Verification

Report Number:	CSTBB20080331
Article Name:	Surgical face mask
Method Standard:	ISO 10993-5：2009

Sponsor

Sunsmed Protective Products Ltd.

Industrial park,Maozui Town,Xinatao City,433000,Hubei

Test Facility

CCIC Huatongwei international inspection (Suzhou) Co., Ltd

Room 101, Building G, Ruoshui Road 388, Suzhou, Jiangsu, China

CONTENTS

Notices

1. Please apply for rechecking within 15 days of receiving the report if there is any objection.
2. Any erasure or without special 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 report is only responsible for the test results of the tested samples.
5. The report shall not be reproduced except in full without the written approval of the company.

Abstract

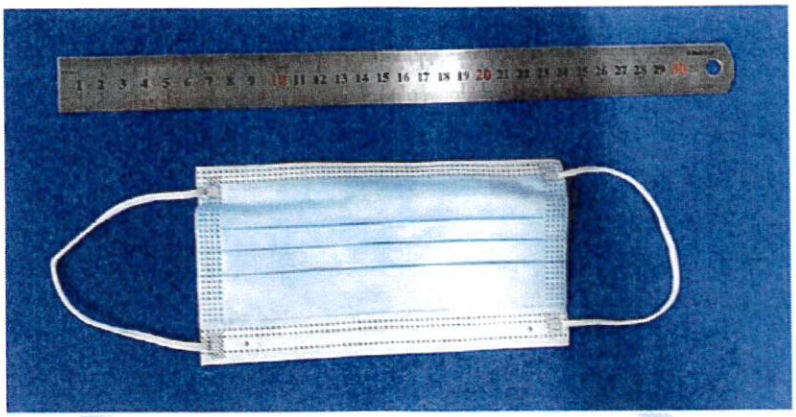
In this study, mammalian L-929 cells were cultured in vitro according to ISO 10993-5:2009 to test the potential cytotoxicity of the test article.

The test articles and the control material were separately placed in MEM medium containing 10% fetal bovine serum, and extracted in a 37 °C incubator for 24 hours. After the end of the extraction, the cell culture medium in the 96-well plate (10^4 cells/well) cultured for 24 hours was removed and replaced with the corresponding extract, cultured in 37 °C, 5% CO_2, >90% humidity for 24 hours. After the culture, the morphology and cell lysis of the cells were observed under the microscope, and the cytotoxicity of the test samples was determined by MTT assay.

The results showed that the cells in the blank control group and the negative control group (high density polyethylene) were well-formed throughout the experiment and showed no cytotoxic reaction. A severe cytotoxic response was shown in the positive control group (ZDEC). The 100% concentration of the test extract retained a normal appearance after 24 hours of incubation, and the cell viability was 87.8%. The data of each group met the acceptance criteria, and the results of this test were valid.

Based on the above results, it can be concluded that under the experimental conditions, the test article Surgical face mask have no potential toxicity to L-929 in the MTT method.

Study Verification and Signature



Protocol Number	SST2008011805BB
Protocol Effective Date	2020-08-12
Technical Initiation Date	2020-08-17
Technical Completion Date	2020-08-19
Final Report Completion Date	2020-10-13

Personnel — Betty — 2020-10-13 Date Completed

Approved — Study Director — 2020-10-14 Date Completed

Supervisory — Test Facility Manager — 2020-10-14 Date Completed

CCIC Huatongwei international inspection (Suzhou) Co., Ltd.

Quality Assurance Statement and GLP Statement

Quality Assurance Statement

The Quality Assurance Unit conducted inspections on the following dates. The findings were reported to the Study Director and to the HTW's Management.

The final report was reviewed to assure that the report accurately describes the methods and standard operating procedures. The reported results accurately reflect the raw data of the nonclinical study conducted per the protocol.

Phase Inspected	Date	Study Director	Management
Experiment	2020-08-17	2020-08-17	2020-08-17
Raw Data	2020-08-19	2020-08-19	2020-08-19
Final Report	2020-10-13	2020-10-13	2020-10-13

The findings of these inspections have been reported to Management and the Study Director.

Hui Jiang
Quality Assurance

2020-10-13
Date

GLP Statement

This study was conducted in compliance with current U.S. Food and Drug Administration regulations set forth in 21 CFR, Part 58.

The sections of the regulations not performed by or under the direction of HTW, exempt from this Good Laboratory Practice Statement, included characterization and stability of the test article and its mixture with carriers, 21 CFR, Part 58.105 and 58.113.

Study Director

2020-10-13
Date

1.0 Purpose

The purpose of the test is to determine the potential cytotoxicity toxicity of a mammalian cell culture (mouse fibroblast L-929 cells) in response to the test article.

2.0 Reference

Biological evaluation of medical devices-Part 5: Tests for In Vitro Cytotoxicity (ISO 10993-5: 2009)

Biological evaluation of medical devices-Part 12: Sample preparation and reference materials (ISO 10993-12: 2012)

3.0 Test and control articles

Groups	Test article	Negative Control Article	Positive Control Article	Blank Control
Name	Surgical face mask	High Density Polyethylene Film	ZDEC	MEM medium, with addition 10% FBS
Manufacture	Sunsmed Protective Products Ltd.	Hatano Research Institute. FDSC	Sigma-Aldrich.	Hyclone
Size	17.5x9.5cm	3 cm×10 cm (5 sheets)	25 g	500 ml
Model	S-203	/	/	/
Lot Batch#	20200610	C-161	BCBQ6847V	AF29479404
Test Article Material	Nonwoven fabric and Melt-blown fabric	/	/	/
Physical State	Solid	Solid	Solid	Liquid
Color	Blue	White	White	Pink
Packaging Material	Paper box	/	/	/
Sterilized or Not	No	No	No	Yes
Concentration	/	/	0.1%	/
Total Surface or weight	Not provided	/	/	/
Storage Condition	Room Tep.	Room Tep.	Room Tep.	4°C
Note: The information about the test article was supplied by the sponsor wherever applicable.				

4.0 Identification and justification of test system

L-929 mouse fibroblast cells obtained from American Type Culture Collection (ATCC).

L-929 cells have been used for cytotoxicity studies because they demonstrate sensitivity to extractable cytotoxic articles. Also, the test article is extracted and administered in vitro to mouse fibroblast L929 cells through a solvent compatible with the test system, which is the optimal route of administration available in this test system as recommended in ISO 10993-5.

5.0 Equipment and reagents

5.1 Instruments

Vertical pressure steam sterilizer (SHB026), CO_2 Incubator (SHB002), Steel Straight Scale (SHB076), Electronic Balance (SHB016), Clean bench (SHB014), Multiskan Spectrum Microplate Spectrophotometer (SHB003), Bench type low speed centrifuge (SHB022), Inverted microscope (SHB005)

5.2 Reagents

MEM (Hyclone, AF29479404), FBS (Clark, JC65941), Penicillin-Streptomycin (Gibco, 2145469), Tryps in (Gibco, 2085461), PBS (Hyclone, AE27749269), MTT (3-(4,5-Dimethylthiazol-2-yl)-2,5-diphenyletrazoliu m bromide) (Sigma, MKBG2038V), Isopropyl alcohol (Macklin, C10954717)

6.0 Experiment design and dose

6.1 Sample preparation

According to the table below, aseptic extraction of the test article sealed and incubated in MEM medium (10% FBS) at 37 °C, 5% CO_2 and 60 rpm for 24 hours.

Groups	Sampling		Sterilization	Aseptic Extraction In Inert Container				Final Extract
	Sampling Manner	Actually sampling	Method	Ratio	Extracts	Condition	pH	Clear or Not
Test article	Whole	570.0 cm^2	EO	6 cm^2: 1 ml	95.0 ml	37 °C 24 h	7.4	Clear
Negative Control	Random	60.0 cm^2	UV	3 cm^2: 1 ml	20.0 ml	37 °C 24 h	7.4	Clear
Positive Control	Random	0.02 g	Filter	0.1 g: 100 ml	20.0 ml	37 °C 24 h	7.4	Clear
Blank Control	/	/	/	/	20.0 ml	37 °C 24 h	7.4	Clear

The changes of the leaching solution was observed after extraction. No particulates or color changes were observed in pre- and post-extraction, and immediately be used in the follow-up experiment. The color and pH of the extraction solution did not change before and after use, and the pH value was 7.4 after leaching.

6.2 Test method

Aseptic procedures were used for handling cell cultures. L-929 cells were cultured in MEM medium (10% FBS, 1% Penicillin-Streptomycin solution) at 37 °C in a humidified atmosphere of 5% CO_2, then digested by 0.25% trypsin containing EDTA to get single cell suspension. 1×10^5 cells/ml suspension were obtained by centrifuging (1000 rpm, 5 min) and re-dispersing in MEM medium.

The suspended cells were dispensed at 100 µl per well in 96-well plate, and cultured in cell incubator (5% CO_2, 37 °C, >90% humidity). Cell morphology was evaluated to verify that the monolayer was satisfactory.

After the cells grew to about 70% and form a monolayer, original culture medium was discarded. The 96-well plates were then treated with 100 µl of extract of test article (100%、75%、50%、25%), control article, negative article and positive article respectively. The 96-well plate was incubated at 37 °C in cell incubator of 5% CO_2 for 24 h. Six replicates of each test were tested.

After incubation, observe the cell morphology first and then discard the culture medium. Add 50 µl MTT (1mg/ml) to each well and then incubated at 37 °C in a humidified atmosphere of 5% CO_2 for 2 hours. The liquid in each well was tipped out and 100 µl Isopropyl alcohol was added to each well to suspend the cell layer.

Evaluate the suspension above with a dual-wavelength spectrophotometer with the measurement wavelength at 570 nm.

7.0 Statistical method

Mean±standard deviation ($\bar{x} \pm s$)

The cell cytotoxicity ratio = OD_{570} of test (or positive or negative) article group/ OD_{570} of blank control group×100%.

8.0 Evaluation criteria

8.1 The 50% extract of the test article should have at least the same or a higher viability than the 100% extract. Otherwise the test should be repeated.

8.2 The lower the Viab.% value, the higher the cytotoxic potential of the test article is.

8.3 If viability is reduced to < 70% of the blank, it has a cytotoxic potential.

8.4 The Viab.% of the 100% extract of the test article is the final result.

9.0 Results of the test

9.1 Results of the cell morphology

Table 1 Observation of the cell morphology

Group	Before inoculation	Before treated with extract	24 h after treatment
Blank control	Discrete intracytoplasmatic granules, no cell lysis, no reduction of cell growth.	Discrete intracytoplasmatic granules, no cell lysis, no reduction of cell growth.	Discrete intracytoplasmatic granules, no cell lysis, no reduction of cell growth.
Negative control			Discrete intracytoplasmatic granules, no cell lysis, no reduction of cell growth.
Positive control			Nearly complete or complete destruction of the cell layers.
100% Test article extract			The cells showed a round shape and a change in cell morphology occasionally, and there were particles in the cytoplasm, occasionally cell lysis and slight growth inhibition.
75% Test article extract			Discrete intracytoplasmatic granules, no cell lysis, no reduction of cell growth.
50% Test article extract			Discrete intracytoplasmatic granules, no cell lysis, no reduction of cell growth.
25% Test article extract			Discrete intracytoplasmatic granules, no cell lysis, no reduction of cell growth.

9.2 Results of the cell vitality

Table2 Results of the cell vitality

Group	OD value								Viab. (%)
	1	2	3	4	5	6	$\bar{x}$	s	
Blank control	0.614	0.630	0.630	0.633	0.618	0.616	0.623	0.008	100.0
Negative control	0.602	0.602	0.607	0.607	0.616	0.609	0.607	0.005	97.4
Positive control	0.054	0.054	0.051	0.058	0.057	0.059	0.056	0.003	8.9
100% test article extract	0.556	0.549	0.547	0.545	0.543	0.542	0.547	0.005	87.8
75% test article extract	0.589	0.581	0.580	0.588	0.582	0.587	0.585	0.004	93.8
50% test article extract	0.609	0.610	0.593	0.593	0.590	0.589	0.597	0.009	95.8
25% test article extract	0.592	0.589	0.600	0.612	0.596	0.606	0.599	0.009	96.1

10.0 Conclusion

Under the conditions of this study, the test article have no potential toxicity to L-929 cells.

11.0 Compliance

US FDA Good Laboratory Practice Regulations 21 CFR 58, effective June 20, 1979, as amended 52 FR 33780, Sept. 4, 1987, and subsequent amendments

Standard operating procedure of CCIC Huatongwei international inspection (Suzhou) Co., Ltd.

12.0 Record

All raw data pertaining to this study and a copy of the final report are to be stored in the designated archive files at Huatongwei.

13.0 Confidentiality Agreement

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

中国认可
国际互认
检测
TESTING
CNAS L13034

Skin Sensitization Test

Guinea Pig Maximization

Final Report

Verification

Report Number: CSTBB20080601

Article Name: Surgical face mask

Method Standard: ISO 10993-10: 2010

Sponsor	Test Facility
Sunsmed Protective Products Ltd.	CCIC Huatongwei international inspection (Suzhou) Co., Ltd
Industrial park,Maozui Town,Xinatao City,433000,Hubei	Room 101, Building G, Ruoshui Road 388, Suzhou, Jiangsu, China

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Notices

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2. Any erasure or without special 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 report is only responsible for the test results of the tested samples.
5. The report shall not be reproduced except in full without the written approval of the company.

Abstract

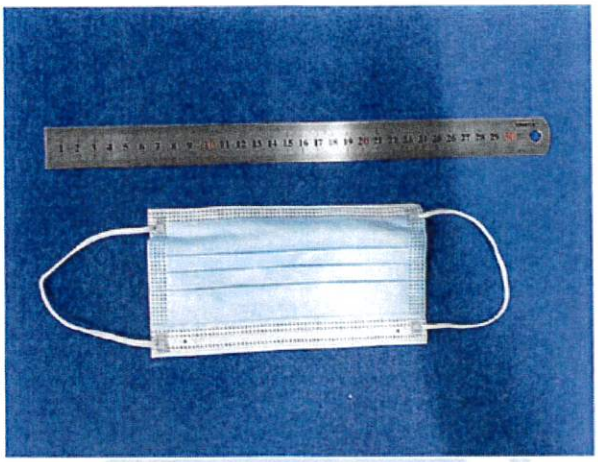
In this study, we took guinea pigs to observe the skin sensitization of the test article according to ISO 10993-10: 2010.

The test article were extracted in Constant Temperature Vibrator at 50 °C, 60 rpm for 72 h by 0.9 % Sodium Chloride Injection and Sesame Oil. Mix 50:50 (by volume) stable emulsion of Freund's complete adjuvant with selected solvent. Intradermal induction and topical induction were operated in the clipped intrascapular region of each animal. After the topical induction phase was completed on day 14, all test and control animals were challenged with the test sample. The erythema and edema of the challenge site were observed to test the sensitization response of the test article. According to the Magnusson and Kligman scales, the response to erythema and edema at each application site of the skin was described and scored 24 hours and 48 hours after the challenge phase.

The results showed that the guinea pigs in the negative control group (0.9 % Sodium Chloride Injection, Sesame Oil) retained a normal appearance throughout the test and showed no skin irritants. A severe skin reactions for erythema and oedema were shown in the positive control group (DNCB). While in test article group, the response of skin on testing side did not exceed that on the control side. The skin reactions for erythema and oedema were not observed in test article group. The data of each group met the acceptance criteria, and the results of this test were considered valid.

Based on the above results, it can be concluded that under the experimental conditions, the test article has no potential skin sensitization on guinea pigs in the extraction method.

Study Verification and Signature



Protocol Number	SST2008011806BB
Protocol Effective Date	2020-08-12
Technical Initiation Date	2020-08-14
Technical Completion Date	2020-09-11
Final Report Completion Date	2020-10-13

Personnel Betty — 2020-10-13 Date Completed

Approved — Study Director — 2020-10-13 Date Completed

Supervisory — Test Facility Manager — Date Completed

CCIC Huatongwei international inspection (Suzhou) Co., Ltd.

Quality Assurance Statement and GLP Statement

Quality Assurance Statement

The Quality Assurance Unit conducted inspections on the following dates. The findings were reported to the Study Director and to the HTW's Management.

The final report was reviewed to assure that the report accurately describes the methods and standard operating procedures. The reported results accurately reflect the raw data of the nonclinical study conducted per the protocol.

Phase Inspected	Date	Study Director	Management
Experiment	2020-08-14	2020-08-14	2020-08-14
Raw Data	2020-09-11	2020-09-11	2020-09-11
Final Report	2020-10-13	2020-10-13	2020-10-13

The findings of these inspections have been reported to Management and the Study Director.

Hui Tang
Quality Assurance

2020-10-13
Date

GLP Statement

This study was conducted in compliance with current U.S. Food and Drug Administration regulations set forth in 21 CFR, Part 58.

The sections of the regulations not performed by or under the direction of HTW, exempt from this Good Laboratory Practice Statement, included characterization and stability of the test article and its mixture with carriers, 21 CFR, Part 58.105 and 58.113.

Study Director

2020-10-13
Date

1.0 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.

2.0 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)

3.0 Test and control articles

Groups	Test article	Negative Control Article(Polar)	Negative Control Article(Non-Polar)	Positive Control
Name	Surgical face mask	Sodium Chloride Injection (SC)	Sesame Oil (SO)	2, 4-Dinitrochlorobenzene (DNCB)
Manufacture	Sunsmed Protective Products Ltd.	Shijiazhuang No.4 Pharmaceutical	Ji'an Lv yuan natural flavor oil refinery, Qingyuan District	TOKYO CHEMICAL INDUSTRY CO., LTD
Size	17.5x9.5cm	500 ml	5L	25 g
Model	S-203	/	/	/
Lot Batch#	20200610	1912121907	20200528	H2UKD-DM
Test Article Material	Nonwoven fabric and Melt-blown fabric	/	/	/
Physical State	Solid	Liquid	Liquid	Solid
Color	Blue	Colorless	Light yellow	Light yellow
Package material	Paper box	/	/	/
Sterilized or Not	No	/	/	/
Concentration	/	0.9 %	/	Induction Concentration: 0.5 % Challenge Concentration: 0.1 % Dissolved in ethanol
Total Surface/Weight	Not provided	/	/	/

Storage Condition	Room Tep.	Room Tep.	Room Tep.	Room Tep.
The information about the test article was supplied by the sponsor wherever applicable.				

4.0 Identification of test system

4.1 Test animal

Species: Hartley Guinea Pig (Cavia Porcellus)

Number: 30 (20 Test +10 Control)

Sex: 15 ♀, 15 ♂

Initial body weight: 300.0~500.0 g

Health status: Healthy, not previously used in other experimental procedures. Female animals were nul liparous and not pregnant.

Animal identification: Ear tag

Cages: Plastic cage

Acclimation Period: 7 days under the same conditions as for the actual test

4.2 Justification of test system

The albino guinea pig has been used historically for sensitization studies (Magnusson and Kligman, 1 970). The guinea pig is believed to be the most sensitive animal model for this type of study. DNCB is the positive control article recommended in the test instructions. To ensure the sensitivity of the experime ntal system, the positive control article should be verified every three months.

5.0 Animal Management

Animal purchase: Wuxi hengtai experimental animal breeding co. LTD SCXK (SU) 2020-0003

Bedding: Corncob Jiangsu Xietong Pharmaceutical Bio-engineering Co., Ltd.

Feed: Guinea pigs were fed with full-price pellets Jiangsu Xietong Pharmaceutical Bio-engineering 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.

6.0 Equipment and reagents

6.1 Instruments

Constant Temperature Vibrator (SHB007, calibration data: 2020/3/16), Autoclave (SHB026, calibration data: 2020/3/16), Electronic scale (SHB017, calibration data: 2020/3/16)

6.2 Reagents

Freund's adjuvant Complete liquid (SIGMA, Lot No: SLBR3877V), Sodium dodecyl sulfate (SDS SIGMA, Lot No: SLBL2304V)

7.0 Experiment design

7.1 Sample preparation

The extracts of test article will be prepared according to the following steps:

Aseptic Sampling			Extraction in sterile vessels				
Sampling Manner	Actually sampling	Ratio	Reagent		Temperature	Time	pH
Whole	570.0 cm^2	6 cm^2: 1 ml	SC	95.0 ml	50 °C	72 h	5.5
	570.0 cm^2		SO	95.0 ml			/

Both inducements and excitations were prepared by the number of times. The state of the leaching solution did not change visually after the leaching was advanced. After extraction, the samples were stored at room temperature for no more than 24 h. The extraction solution is clear, and the pH value has not been adjusted, filtered, centrifuged, diluted and other processes. The control solution was prepared under the same conditions.

7.2 Test method

7.2.1 Intradermal induction phaseI

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.

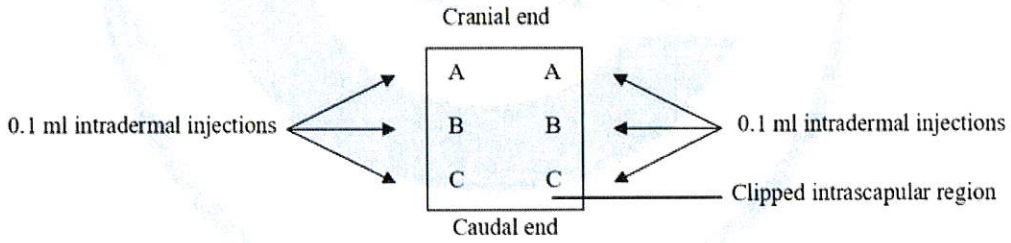


Figure 1 Location of intradermal injection sites

7.2.2 Topical induction phaseII

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 test article extract by topical application to the intrascapular region of each animal, using a patch of area approximately 8 cm^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.

7.2.3 Challenge phase

At 14d after completion of the topical induction phase, challenge all test and control animals with the test

sample. Absorbent gauzes (2.5 cmx2.5 cm) were soaked respectively with test article and control article. 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.

8.0 The results observed

The day after challenge exposure, the patch will be removed and the area cleaned gently with gauze if necessary. The site will be wiped gently with a 0.9 % saline soaked gauze sponge prior to each scoring period. The challenge sites will be observed for signs of irritation and sensitization reaction, as indicated by erythema and edema. If necessary, the fur will be shaved or clipped in advance for the convenience of dermal score.

Daily challenge observation scores will be recorded approximately 24, and 48 hours after patch removal in accordance with the following classification system for skin reactions:

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

9.0 Evaluation criteria

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.

10.0 Results of the test

All animals were survived and no abnormal signs were observed during the study.Individual results of dermal scoring for the challenge appear in Table 2.

11.0 Conclusion

The test article showed no evidence of causing delayed dermal contact sensitization in the guinea pig. Results and conclusions apply only to the test article tested. Any extrapolation of these data to other articles is the sponsor's responsibility.

12.0 Compliance

US FDA Good Laboratory Practice Regulations 21 CFR 58, effective June 20, 1979, as amended 52 FR 33780, Sept. 4, 1987, and subsequent amendments

Standard operating procedure of CCIC Huatongwei international inspection (Suzhou) Co., Ltd.

13.0 Record

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

14.0 Confidentiality Agreement

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

Table 2 Guinea pig Sensitization Dermal Reactions

Group		No.	Pretest weight(g)	Finished weight (g)	The Challenge patch was removed 24h later		The Challenge patch was removed 48h later		Positive rate
					Erythema	Swelling	Erythema	Swelling	
SC	Test	1	310.9	363.0	0	0	0	0	0%
		2	307.9	383.0	0	0	0	0	
		3	311.5	350.8	0	0	0	0	
		4	311.6	372.9	0	0	0	0	
		5	308.9	352.9	0	0	0	0	
		6	309.7	371.6	0	0	0	0	
		7	312.1	382.8	0	0	0	0	
		8	304.0	360.7	0	0	0	0	
		9	306.2	377.5	0	0	0	0	
		10	303.8	351.8	0	0	0	0	
	Control	11	302.6	362.8	0	0	0	0	—
		12	310.9	354.8	0	0	0	0	
		13	303.5	365.8	0	0	0	0	
		14	303.6	360.6	0	0	0	0	
		15	305.8	375.1	0	0	0	0	
SO	Test	16	307.6	377.2	0	0	0	0	0%
		17	302.8	365.9	0	0	0	0	
		18	316.8	359.5	0	0	0	0	
		19	307.7	368.7	0	0	0	0	
		20	315.9	360.5	0	0	0	0	
		21	318.8	360.7	0	0	0	0	
		22	317.9	374.6	0	0	0	0	
		23	306.7	381.2	0	0	0	0	
		24	314.3	367.7	0	0	0	0	
		25	306.2	365.3	0	0	0	0	
	Control	26	307.8	355.6	0	0	0	0	—
		27	306.8	366.2	0	0	0	0	
		28	302.5	381.0	0	0	0	0	
		29	317.8	365.0	0	0	0	0	
		30	303.4	352.5	0	0	0	0	

Table 3 Positive control

Group	No.	Pretest weight(g)	Finished weight (g)	The Challenge patch was removed 24 h later		The Challenge patch was removed 48 h later		Positive rate
				Erythem	Swelling	Erythema	Swelling	
Test	1	309.8	354.0	1	0	1	0	100%
	2	307.2	352.1	2	0	2	0	
	3	306.3	360.2	1	0	1	0	
	4	314.1	382.9	1	0	1	0	
	5	307.1	351.0	1	0	2	0	
	6	318.7	352.9	1	0	2	0	
	7	312.1	374.0	1	0	1	0	
	8	310.4	358.6	1	0	1	0	
	9	303.3	366.1	2	0	2	0	
	10	308.7	354.2	1	0	2	0	
Control	11	312.9	353.0	0	0	0	0	—
	12	307.7	359.0	0	0	0	0	
	13	303.7	353.7	0	0	0	0	
	14	307.9	372.3	0	0	0	0	
	15	310.8	380.9	0	0	0	0	

Note: The positive control was CSTBB20080001P1 (Finish date: 2020-09-11)

中国认可
国际互认
检测
TESTING
CNAS L13034

Skin Irritation Test

Extraction Method

Final Report

Verification

Report Number: CSTBB20080160

Article Name: Surgical face mask

Method Standard: ISO 10993-10: 2010

Sponsor	Test Facility
Sunsmed Protective Products Ltd.	CCIC Huatongwei international inspection (Suzhou) Co., Ltd
Industrial park,Maozui Town,Xinatao City,433000,Hubei	Room 101, Building G, Ruoshui Road 388, Suzhou, Jiangsu, China

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2. Any erasure or without special 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 report is only responsible for the test results of the tested samples.
5. The report shall not be reproduced except in full without the written approval of the company.

Abstract

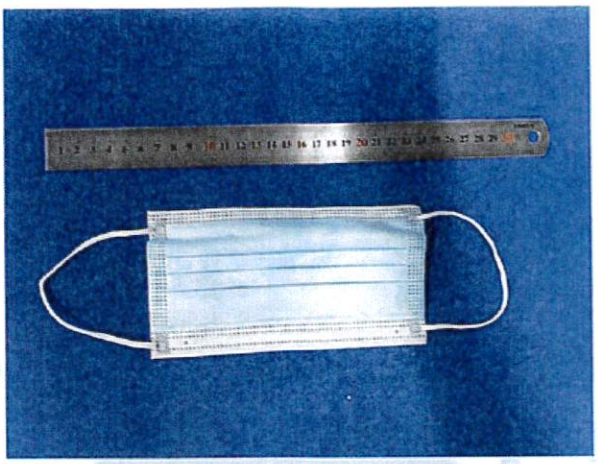
In this study, we took New Zealand white Rabbits to observe the skin irritation of the test article according to ISO10993-10:2010.

The test article were extracted in Constant Temperature Vibrator at 50 °C, 60 rpm for 72 h by 0.9 % Sodium Chloride Injection and Sesame Oil. Apply 0.5 ml extracts of test article or control to 2.5 cm×2.5 cm 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, and then wrap the application sites with a bandage for a minimum of 4 h. At the end of the contact time, remove the dressing. The describe and score the skin reaction for erythema and oedema 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.

The results showed that the rabbits in the negative control group (0.9 % Sodium Chloride Injection, Sesame Oil) retained a normal appearance throughout the test and showed no skin irritants. A severe skin reactions for erythema and oedema were shown in the positive control group (SDS). While in test article group, the response of skin on testing side did not exceed that on the control side. The skin reactions for erythema and oedema were not observed in test article group. The data of each group met the acceptance criteria, and the results of this test were considered valid.

Based on the above results, it can be concluded that under the experimental conditions, the test article has no potential skin irritation on rabbit in the extraction method.

Study Verification and Signature



Protocol Number	SST2008011804BB
Protocol Effective Date	2020-08-12
Technical Initiation Date	2020-08-14
Technical Completion Date	2020-08-21
Final Report Completion Date	2020-10-13

Personnel Betty 2020-10-13
Date Completed

Approved
Study Director 2020.10.13
Date Completed

Supervisory
Test Facility Manager 2020-10-13
Date Completed

CCIC Huatongwei international inspection (Suzhou) Co., Ltd.

Quality Assurance Statement and GLP Statement

Quality Assurance Statement

The Quality Assurance Unit conducted inspections on the following dates. The findings were reported to the Study Director and to the HTW's Management.

The final report was reviewed to assure that the report accurately describes the methods and standard operating procedures. The reported results accurately reflect the raw data of the nonclinical study conducted per the protocol.

Phase Inspected	Date	Study Director	Management
Experiment	2020-08-14	2020-08-14	2020-08-14
Raw Data	2020-08-21	2020-08-21	2020-08-21
Final Report	2020-10-13	2020-10-13	2020-10-13

The findings of these inspections have been reported to Management and the Study Director.

Hui Jiang
Quality Assurance

2020-10-13
Date

GLP Statement

This study was conducted in compliance with current U.S. Food and Drug Administration regulations set forth in 21 CFR, Part 58.

The sections of the regulations not performed by or under the direction of HTW, exempt from this Good Laboratory Practice Statement, included characterization and stability of the test article and its mixture with carriers, 21 CFR, Part 58.105 and 58.113.

Study Director

2020-10-13
Date

1.0 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.

2.0 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)

3.0 Test and control articles

Groups	Test article	Negative Control Article(Polar)	Negative Control Article(Non-Polar)	Positive Control
Name	Surgical face mask	Sodium Chloride Injection (SC)	Sesame Oil (SO)	10 % sodium dodecyl sulfate (SDS)
Manufacture	Sunsmed Protective Products Ltd.	Shijiazhuang No.4 Pharmaceutical	Lv yuan natural flavor oil refinery, Qingyuan District, Ji'an City	SIGMA
Size	17.5x9.5cm	500 ml	5L	25 g
Model	S-203	/	/	/
Lot Batch#	20200610	1912121907	20200528	SLBL2304V
Test Article Material	Nonwoven fabric and Melt-blown fabric	/	/	/
Physical State	Solid	Liquid	Liquid	Solid
Color	Blue	Colorless	Light yellow	Colorless
Packaging Material	Paper box	/	/	/
Sterilized or Not	No	/	/	/
Concentration	/	0.9 %	/	10 %
Total Surface	Not provided	/	/	/
Storage Condition	Room Tep.	Room Tep.	Room Tep.	Room Tep.
The information about the test article was supplied by the sponsor wherever applicable.				

4.0 Identification of test system

4.1 Test animal

Species: New Zealand white Rabbit

Number: 6

Sex: 3 ♀, 3 ♂

Weight: >2 kg

Health status: Healthy, not previously used in other experimental procedures. Female animals were nul liparous and not pregnant.

Animal identification: Ear tattoo

Cages: Stainless steel cage

Acclimation Period: 7 days under the same conditions as for the actual test

4.2 Justification of test system

The rabbit is specified as an appropriate animal model for evaluating potential skin irritants by the c urrent testing standards. Positive control 10% sodium dodecyl sulfate has been substantiated at HTW with this method.

5.0 Animal Managment

Animal purchase: Wuxi hengtai experimental animal breeding co., LTD SCXK (SU) 2020-0003

Bedding: /

Feed: Experimental rabbits were fed a maintenance diet

Water: Drinking water met the Standards for Drinking Water Quality GB 5749-2006

Animal room temperature: 18-26 °C

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

6.0 Equipment and reagents

6.1 Instruments

Constant Temperature Vibrator (SHB007, calibration data: 2020/3/16), Autoclave (SHB026, calibration data: 2020/3/16), Electronic scale (SHB017, calibration data: 2020/3/16)

7.0 Experiment design

7.1 Sample preparation

The extracts of test article will be prepared according to the following steps:

Aseptic Sampling			Extraction in sterile vessels				
Sampling Manner	Actually sampling	Ratio	Reagent		Temperature	Time	pH
Whole	570.0 cm^2	6 cm^2: 1 ml	SC	95.0 ml	50 °C	72 h	5.5
	570.0 cm^2		SO	95.0 ml			/

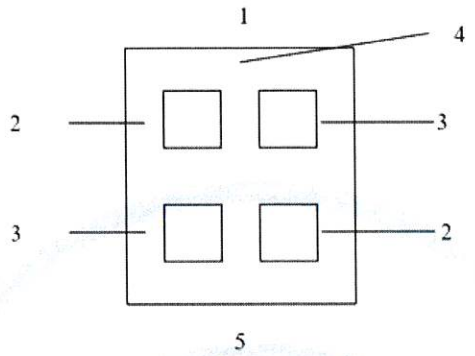
The state of the leaching solution did not change visually after the leaching was advanced. The extractions were clear, and the pH value has not been adjusted, filtered, centrifuged, diluted and other processes, before dosing stored at room temperature no more than 24 h. The control solution was prepared under the same conditions

7.2 Test method

Use the rabbits with healthy intact skin. Fur was generally clipped within 4-24 h 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 10×15 cm).

Apply 0.5 ml extract (s) of test article or control to 2.5 cm×2.5 cm 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.



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

Figure1 Location of skin application sites

8.0 The results observed

The 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

9.0 Evaluation criteria

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 was 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.

10.0 Results of the test

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.

11.0 Conclusion

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

12.0 Compliance

US FDA Good Laboratory Practice Regulations 21 CFR 58, effective June 20, 1979, as amended 52 FR 33780, Sept. 4, 1987, and subsequent amendments

Standard operating procedure of CCIC Huatongwei international inspection (Suzhou) Co., Ltd.

13.0 Record

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

14.0 Confidentiality Agreement

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

Table 2 Skin irritation response observation

Reagent	Rabbit No	Pretest weight (kg)	Finished weight (kg)	Group	Reaction	Interval (hours): score=left/right			
						1±0.1 h	24±2 h	48±2 h	72±2 h
SC	1	2.14	2.28	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	2.20	2.34	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	2.09	2.23	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			
SO	4	2.16	2.27	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
	5	2.10	2.24	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
	6	2.07	2.20	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	Reaction	Interval (hours): score=left site/right site			
			1±0.1 h	24±2 h	48±2 h	72±2 h
1	Positive control	Erythema	0/1	2/1	2/3	3/3
		Oedema	1/0	2/2	3/2	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	0/0	1/2	3/3	4/4
		Oedema	1/1	3/2	3/4	3/4
	Negative Control	Erythema	0/0	0/0	0/0	0/0
		Oedema	0/0	0/0	0/0	0/0
3	Positive control	Erythema	1/1	2/3	4/3	4/4
		Oedema	1/0	2/2	4/4	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			5.8			

Positive control performed once every six months see CSTBB20070001P3(Finish date: 2020-07-31)

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Sunsmed Protective Products Ltd.
No. 18, Industrial Park, Maozui Town
Xiantao City
433000 Hubei
P.R. 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 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:	2020-03-17
Certificate Registration No.:	SX 60147826 0001
An audit was performed. Report No.:	15095978 006
This Certificate is valid until:	2022-08-11

Certification Body

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

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

Date 2020-03-17

Fuxiu Sheng

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax +49 221 806-3935 e-mail:cert-validity@de.tuv.com http://www.tuv.com/safety

TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60147826 0001
Report No.: 15095978 006

Organization:
Sunsmed Protective Products Ltd.
No. 18, Industrial Park, Maozui Town
Xiantao City
433000 Hubei
P.R. China

Scope:

Products:

- Surgical Caps
- Non Woven Face Masks
- Surgical Gowns
- Isolation Gowns
- Coveralls
- Sleeve Protectors
- Shoe Covers
- Bed Protections
- PE Plastic Aprons
- Surgical Drapes
- Surgical Packs

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

Certification Body

TÜV Rheinland LGA Products GmbH
TÜVRheinland
Zertifizierungsstelle

Fuxiu Sheng

Date: 2020-03-17

Doc. No. SM-CE02-09 Effective date: 2017.09.12 Ver. A/0

Sunsmed Protective Product Ltd.

Clinical Evaluation

(Nonwoven Face Masks)

NO.:SM-CE02-09

Compiled by: Zeng panjun

Hospital: Xiantao hospital affiliated hospital

Date: 2017.09.06

1. members of the clinical evaluation team

No.	Name	Title	Education	Specialty	Remark
1	Sun Qinkun	General manager	Bachelor Degree	Secretarial	lead assessor
2	Sun Na	General Manager Assistant	Bachelor Degree	clinical medicine	vice- lead assessor
3	Zhao zhigang	Technical Manager	College degree	medicine	assessor
4	Li Haihong	Quality Manager	Senior degree	Materials Science	assessor
5	Bao Liuhui	Document Retrieval	Bachelor Degree	Nursing specialty	assessor

2. Purpose

According to the requirements of the appendix X of MDD 93/42/EEC, we compile this clinical data to certify that the products of our company fulfilled the requirements of the appendix 1. I.e. Non-woven Facemasks, must give a evidence of the clinical performance and safety is qualified, appropriate and adequate to conform with the pertinent essential requirements of the Directive, and risks and side effects is acceptable when weighed against the intended benefits of the device.

3. Intended uses of Facemasks and side effect

Product name: Non-woven Facemasks
Intended use: Made of non-woven fabrics. Cover the mouth or nose or facial position to protect the patients from infective agents from the noses and mouths of the staff and, in certain situations, additionally to protect the wearer against splashes of potentially contaminated liquids and particles, also can be used in other areas. Single-use.
Materials: Nonwoven
Validity: 3 years.

4. History of the product

Nonwoven face masks made from PP nonwovens and SMS composite nonwovens have been used in the operating rooms of major hospitals and clinics in developed countries such as the United States, Europe for many years. The surgical infection rate from 6.51% to 2.83%; and never reported by the use of the above materials into a nonwoven face mask that causes a user

or patient to die or cause a serious deterioration in their health status and a potential accident of death or health deterioration.

5. Comparison with other company

The device manufactured by our company share the same principle, intended use, main structure and components of most of already marketed Non-woven Facemasks manufactured by other companies, such as Xuzhou Vimed Nonwoven Co., Ltd., it holds CE certification certified CE by TUV.

Contrast Item	Certified products	Contrast product	Difference
Product name	Non Woven Facemask	Non Woven Facemask	accordance
Manufacturer	Sunsmed Protective Products Ltd.	Xuzhou Vimed Nonwoven Co., Ltd.	
Notify Body	TUV Rheinland (Shanghai) Co., Ltd.	TUV Rheinland (Shanghai) Co., Ltd.	accordance
Listing situation	2016.10	\	accordance
Working principle	The air containing the harmful substance is filtered through the filter material of the mask, and then is inhaled by the human body.	The air containing the harmful substance is filtered through the filter material of the mask, and then is inhaled by the human body.	accordance
Material	Non woven	Non woven	accordance
Structure composition	non-woven or w/filter paper	non-woven or w/filter paper	accordance
Main performance	BFE ≧ 95	BFE ≧ 95	accordance
sterile method	EO sterile	EO sterile	accordance
Intended use	Facemask is held away from nose & month for comfort and protection	Facemask is held away from nose & month for comfort and protection	accordance

6. History of the company

The company engaged in product production and business activities, give priority to the production of mature technology, quality and stability of the raw material suppliers, so that the market continue to develop, the rapid increase in the number of production. Since the establishment of the company, product sales gradually increased, exported to Europe and the United States, Southeast Asia, Africa and other countries and regions; a number of foreign

customers designated as fixed-point processing plant. 2003 as of the end of September, a total of 80,000 sales of nonwoven face mask, never received customers because of my company's products in the physical and chemical indicators and other aspects of unqualified complaints, no case led to the death of the user or the patient or a serious deterioration of their health And potential accidents of death or health deterioration.
Therefore, from the historical performance of product sales and third party on my company's production capacity, production environment and quality system recognition that: the production technology, environmental and quality system to ensure product safety, to achieve the intended use.

In our company's "product risk analysis report", from its raw materials, production processes and other possible risks are analyzed, and the possible risks to take effective control measures, so that the risk has been reduced to an acceptable Level, the report shows that the value of the use of the product is far greater than its risk,
In summary, my company's operating clothing its use value is far greater than its risk, can be used as a one-time medical equipment.

7. Distribution area and quantity

The Non-woven Facemasks are not distributed yet.

8. Feedback from customers

Customer feedback is delivered to our company in the post production phase, the corrective and preventive actions are taken to prevent the non-conformance from reoccurring. The Non-woven Facemasks is not distributed yet.

9. Clinical literature searches

9.1 Clinical literature searches plan

We mainly through the following ways to collect product-related clinical literature, including

European medicine database
Technical Committee of the EC Committee
Related hospital public information
Medical Industry Association Public Information

9.1.1 Device name/model:
Name: Non-woven Facemasks

9.1.2 Scope of the literature search:
Non-woven Facemasks,

9.1.3 Methods
(i) Date of search: Feb.12,2014-Sep.12,2015
(ii) Name of person(s) undertaking the literature search:

Name	Title	Responsibility
Bao Liuhui	Document Retrieval	Literature search
Li Haihong	Quality Manager	Evaluate the literature search results
Zhao Zhigang	Technical Manager	Approval of the literature search results

(iii) Period covered by search:
Feb.17,2012-Feb.20,2016

(iv) Literature sources used to identify data:
1) scientific databases –CNKI, MEDLINE, EMBASE, WANFANG DATA, VIP DATA.
2) specialised databases - MEDION
3) systematic review databases-Cochrane Collaboration
4) clinical trial registers - CENTRAL
5) adverse event report databases - MAUDE
6) customers feedback
7) other reference texts

(v) Database search details:
1) search terms (key words, indexing headings): Non-woven Facemasks, suture staple, circumcision operation.
2) medium used: On-line.

(vi) Selection criteria used to choose articles:
1) the article shall be focused on Non-woven Facemasks;
2) the Non-woven Facemasks involved in the articles shall focus on the same type of our products, or comparison between our types and other types;
3) the article is better to focus on products clinical evaluation, functional evaluation, characteristics influenced on product function, risk assessment and control;
4) the article resource shall be effective, valid, and it is better from professional institutes researches;
5) try to adopt the newest articles resources.

10. Conclusion

It can be concluded from above narration that the products with CE marking of this company, Non-woven Facemasks, can be safe, little risks and in accordance with requirements by used as medical device.

11. Post market clinical follow-up (PMCF)

Reference on MEDDEV 2.12-2, the company has built the post market clinical follow-up plan in order to recognize these infrequent complications or problems only apparent after widespread use, or these long-term performance issues.

11.1 Post market clinical follow-up plan

11.1.1 Device name/model:
Name: Non-woven Facemasks

11.1.2 Staff arrangement and periodity of PMCF
(i) Name of person(s) undertaking the PMCF:

Name	Title	Responsibility
All sales person		Collect all customers feedbacks and adverse events data
Bao Liuhui	Document Retrieval	Evaluate all possible recognized risks in production in all periods
Li Haihong	Quality Manager	Documentation, relevant products problems collection. Follow up of patients samples who are enrolled in the clinical trails.
Zhao Zhigang	Technical Manager	Approval of the PMCF plan and any found results or problems.

(ii) Period covered by PMCF:
Oct.28, 2014-Oct.27,2017
In order to recognize adequately these infrequent complications or problems only apparent after widespread use, and consider the 3 years validity of the product, we decide to apply PMCF in four years, and had began on Oct.28, 2014, and will be finished on Oct.27,2017.

11.1.3 What will be focused on PMCF
(i) PMCF should always be considered for devices where identification of possible emerging risks and the evaluation of long term safety and performance are critical. In identifying such emerging risk, the following criteria should be taken into account :

- **innovation**, when the design of the device, the material, the principles of operation, the technology, or the medical indication is new
- **severity** of the disease,
- **sensitive target population**
- **risky anatomical location**
- **well known risk** from the literature
- **well known risk** of similar marketed devices

- **Identification** of an acceptable risk during pre-CE clinical evaluation, which should be monitored in a longer term and/or through a larger population.
- **Obvious discrepancy** between the pre-market follow up timescales and the expected life of the product

(ii) following actions will be taken:
• All received complaints and adverse events data will be systematically reviewed, and all product related adverse events will be notified to the relevant Competent Authority (ies). This includes all sources of information known by the manufacturer, including published literature.
• Monitoring of postmarket performance will take into account relevant data publicly available with similar devices especially when the CE marking was based on equivalence.
• PMCF in the form of follow up of all or a justifiable subset of patients already enrolled in pre-marketing Clinical Investigations; or on specific sub-groups and/or prospective study or registry of a sample of products.

11.2 PMCF outputs

By far, according to customers feedback and PMCF of the company, no other risks, infrequent complications, problems are found. The Non-woven Facemasks is safe, satisfy its intended use and no side effects are found.

12. Clinical Risks

According to R&D, clinical literature research, and feedback of equivalent device, the Non-woven Facemasks will probably face clinical hazards during treatments.
For the clinical risk control, please see Risk Analysis Report (RS-203, A/0)

13. Listing clinical follow-up plan and re-evaluation cycle

Products listed, should continue to track, mainly consider the following aspects:
The results of the clinical investigation include identified incidents
Average life expectancy of the device
manufacturer's claim to the device (statement)
assertive equivalence of performance
new information
Clinical reevaluation cycle
Companies based on clinical follow-up summary and related circumstances to determine timing of clinical re-evaluation, usually not more than 5 years.

Doc. No. SM-CE02-05 Effective date: 2016.02.17 Ver. A/0

Risk Analysis Plan

Table of contents

1 Foreword

This report is to describe the risk control carried on the Non-woven Face masks manufactured by our company. All potential hazards and potential cause of each hazard have been determined in this report. Evaluations have been made on possible severity level may led by each hazard and probability of occurrence of each hazard. For unacceptable risks, necessary measures must be taken, and also evaluate the residual risk level after taking relevant measures.

By taking proper measures to reduce the risks which may lead to various kinds of potential hazards to the acceptable level, and also to reduce the total amount of every kind of hazards to the acceptable level.

2 Purpose

Aim of this risk control is to carry out determination on all risks that may be led by the Non-woven Face masks that have been put into production in our company, also to stipulate the necessary relative measures, in order to keep the risk level within an acceptable level. By taking risk control the company may take relative measures of continuously improving quality of the products, to meet customer stipulated or potential requirements constantly.

3 Application

This risk analysis is applied to Non-woven Face masks produced by the company.

4 Documents reference

4.1 Standards

EN ISO 10993-1:2009+ AC:2010	Biological evaluation of medical devices -- Part 1: Evaluation and testing
EN ISO 10993-5:2009	Biological evaluation of medical devices— Part 5: Tests for in vitro cytotoxicity
ISO 10993-10:2010	Biological Evaluation of Medical Device-Part 10:stimulation and allergic reaction
EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
EN ISO 10993-7:2008+ AC:2009	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
ISO 10993-10:2010	Biological Evaluation of Medical Device-Part 10:stimulation and allergic reaction
EN 14683:2005	Surgical masks - Requirements and test methods
EN ISO 22612:2005	Clothing for protection against infectious agents - Test method for resistance to dry microbial penetration

EN ISO 11607-1:2009	Packaging for terminally sterilized medical devices- Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2:2006	Packaging for terminally sterilized medical devices- Part 2: Validation requirements for forming, sealing and assembly process
EN ISO 11737-1:2006	Sterilization of medical devices- Microbiological methods-Part 1: Determination of a population of microorganisms on products
EN ISO 11737-2:2009	Sterilization of medical devices- Microbiological methods-Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
EN ISO 11737-1:2006	Sterilization of medical devices- Microbiological methods-Part 1: Determination of a population of microorganisms on products
EN 62366:2008	Medical devices - Application of usability engineering to medical devices
EN ISO 11135:2014	Sterilization Standard- ethylene oxide

4.2 Production specification

Please refer to production specification instruction.

5 Object of risk control

Intended use of the product

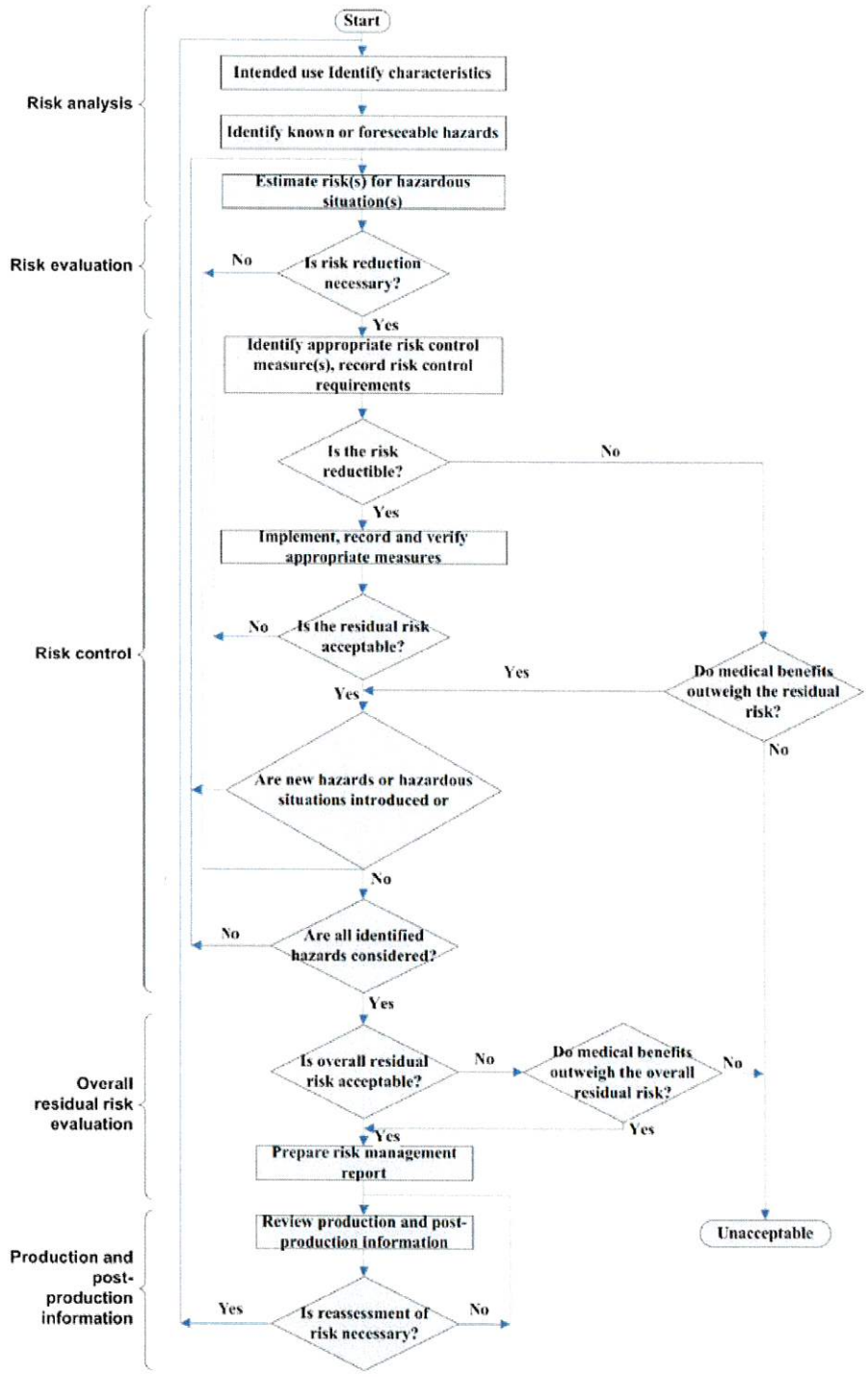
Non-woven Face masks is made of non-woven fabrics. Cover the mouth or nose or facial position to protect the patients from infective agents from the noses and mouths of the staff and, in certain situations, additionally to protect the wearer against splashes of potentially contaminated liquids and particles, also can be used in other areas. Single-use.

6 Members of the risk control group

Name	Title	Responsibility	Authority
Zhao Zhigang	Management Representative	General control of Risk management	Review, approve the risk management plan and risk management report.
Zhao Zhigang	Production manager	Risk management for product realization phase	Review and implement the risk management plan
Li Haihong	QC manager	Risk management for product realization phase	Review and implement the risk management plan
Sun Yali	Sales manager	Risk management for post-marketing surveillance phase	Review and implement the risk management plan
Bao Liuhui	Technician	Prepare the risk analysis report	/

7 Risk management process

Overview of the steps in the risk management process see the following flowchart:



8. Implementation of risk control process

8.1 Step1: Determination on known and foreseeable hazards

The hazard will be marked with "H....." in risk control form. (see the risk analysis report)

Information resources: the following information can be regarded as potential hazard list

- ·Available risk analysis report on homologous product
- ·Investigations on developer of the product
- ·Determinations made by medical experts
- ·Analysis medical devices report from foreign authorities
- ·Site documents, complains and accident records gained from homologous products which have been put into use.

8.1.1 Estimation on severity level of each hazard

Severity level of each hazard must be estimated and semi-quantitative judged (in the form of serious level) by the medical expert

Severity level	Code	Description
Negligible	S1	Inconvenience or temporary discomfort
Minor	S2	Results in temporary injury or impairment not requiring professional medical intervention
Serious	S3	Results in injury or impairment requiring professional medical intervention
Critical	S4	Results in permanent impairment of life-threatening injury
Catastrophic	S5	Results in patient death

8.1.2 Judgment of potential causes of each hazard

Members of the group shall at first find the potential causes directly base on their professional knowledge.

The founded hazard causes must be recorded in "Cause" column of risk control report, and mark with "C...". (see the risk analysis report)

8.1.3 Estimation on probability of occurrence of each cause

Occurrence probability of each potential cause must be estimated. In addition, the relative information resources are:

- Using experience of equivalent products (e.g. service statistic data)
- Customer complain
- Investigation on service life of self product
- Expert judgment

Such estimation carried out by relative personnel can be divided into following 5 categories:

Level	Code	Probability of occurrence
Improbable	P1	$<10^{-7}$
Remote	P2	10^{-5}~10^{-7}
Occasional	P3	10^{-4}~10^{-5}
Probable	P4	10^{-3}~10^{-4}
Frequent	P5	10^{-2}~10^{-3}

8.2 Step2: Risk estimation (before taking control measures)

Two risk factors were concluded in first hazard/cause item: hazard severity level and occurrence probability, relative risk. Three "risk area" can be defined according to advise of EN ISO14971:2012.

1. Not acceptable area: U
2. Wide acceptable area: A

8.3 Step3: Risk evaluation

Probability of occurrence	Severity level				
	Negligible (S1)	Minor (S2)	Serious (S3)	Critical (S4)	Catastrophic (S5)
Frequent (P5)	U	U	U	U	U
Probable (P4)	U	U	U	U	U
Occasional (P3)	A	A	U	U	U
Remote (P2)	A	A	A	U	U
Improbable (P1)	A	A	A	A	A

U: Unacceptable risk

A: Insignificant risk

All risks estimated for each hazard/cause must be recorded in column of risk control form in the form of risk range (U, A) categories, and noted separately whether control measures are available.

8.4 Step4: Taking risk control measures

If no control measures are available for estimated risks, it is unacceptable, then control measures must be taken for each hazard cause. If several control measures were designed at the same time, then the effect will be the result when all relative control measures are taken.

All the measures must be recorded in the column "relative measures" of risk control form, and marked with "M….". (see the risk analysis report)

8.5 Step5: Evaluation on residual risks

The severity level or occurrence probability will be decreased or both of the stated after taking control measures. Sometime it cannot be quantificationally

determined that in which level a group of relative control measures can decrease the risk factors (severity level or occurrence rate). The evaluation on residual risks is the summing-up of analysis of the group members based on their individual professional knowledge.
All changing of each category must be recorded in the column "residual risk" of risk control form. (see the risk analysis report)
The residual risk of each hazard/cause may base on the determined risk area (N/AC AC R) stipulated in the previous chapter.

8.6 Step6: Risk/benefit analysis
R does not means that the aim has been reached, it can be acceptable only when it is technically unpractical or the expense raised the further risk decrease measures is larger than the benefit it will bring, and also the benefit is larger than the risk. If R range is the result of risk decreasing, then an explanation must be made on why the further risk decreasing is unpractical.

8.7 Step7 Result of risk control
As showing in the risk control form (see the risk analysis report), the residual risks of each hazard/cause shall be reduced to acceptable or R range, total amount of residual individual risk shall also be regarded as acceptable.

8.8 Step8 Production and post-production information
Collect and review information about the medical device or similar devices in the production and post-production phases.

9. Conclusion on risk control
As displayed in risk analysis report (see appendix 4), there have carried out more detailed risk analysis and evaluation on all items that may occur hazard led by the Non-woven Facemasks through the above, and think all risks are under control and acceptable, also been verified by long term clinic use, the occurrence probability is extremely low, safety of the medical device has been adequately stipulated, summing up all the above, we think the risks are all under control and be acceptable. When new documents and data are used, the new round of risk analysis shall be carried out, for example, along with time passing, the risk may change and production process and product structure may be change accordingly. New risk may occurs or to be determined for the first time.

10. Appendix
-Risk analysis report (Appendix 4: RS- S203, A/0)