HYGISUN®

REF HS0402R

Medical Face Mask

Earloop. Blue

EN14683: 2019+AC: 2019 Type IIR


HYGISUN
Medical Face Mask (Non-Sterile)
50 PCS
HYGISUN
REF HS0402R
Medical Face Mask (Non-Sterile)
EARLOOP, BLUE
Gesichtsmaske, 3-lagig
LOT:20200815
MFG:20200815
EXP:20220815
50 PCS


Ear strap
on both ears
Press down
around nose
Pull down mask
to cover jaw
4 260676 530102

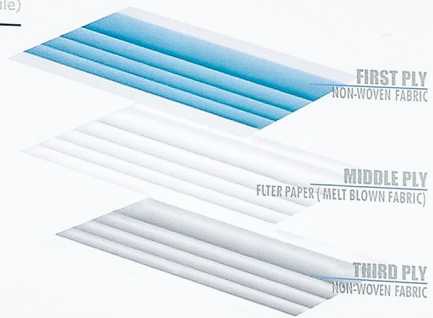
HYGISUN

Medical Face Mask (Non-Sterile)

REF HS0402R

EARLOOP, BLUE

Gesichtsmaske, 3-lagig



50 PCS

LATEX Latex Free

3-layer

2 Single Use


Sichuan Ai Doctor Medical Technology Co.,Ltd
333 Yongke Road,Yongsheng town,Wenjiang District,
Chengdu City,Sichuan Province, China
EC REP
SUNGO Europe B.V.
Olympisch Stadion 24, 1076DE Amsterdam,Netherlands
Storage method: Masks shall be stored in a clean,ventilated and dry warehouse.
Precautions： It is recommended to replace it every 2-4 hours, once it is contaminated, it should be replaced as soon as possible;
SIZE: 17X9.5CM
Made in China
EN 14683 Type II R
CE


BYCASUN
Medical Face Mask
50 pcs


HYGISUN
Medical Face Mask (Non-Sterile)
50 PCS
REF HS0402R
EARLOOP, BLUE
Gesichtsmaske, 3-lagig
LOT:20200815
MFG:20200815
EXP:20220815
50 PCS
产品合格证
QUALIFIED CERTIFICATE
QUALITY PASSED
检验 合格

取得国外标准认证或注册的医疗物资生产企业清单

Name List of Medical Devices and Supplies Companies with Certification/Authorization from other Countries

序号	生产企业	统一社会信用代码	国外注册认证情况
[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	四川艾医生医疗科技有限公司 Sichuan Ai Doctor Medical Technology Co.,Ltd.	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]

DECLARATION OF CONFORMITY

Regarding Medical Device Directive(93/42/EEC) including Directive 2007/47/EC

Manufacturer: . Sichuan Ai Doctor Medical Technology Co., Ltd

Address: No.333, Yongke Roade, Yongsheng Town, Chengdu Cross-strait Science and Technology Industrial Development Park, Wenjiang District, Chengdu, Sichuan, China

EC Representative: SUNGO Europe B.V.

Address: Olympisch Stadion 24, 1076DE Amsterdam,Netherlands

Product Name: Surgical mask (Non-sterile) HYGISUN®

Specification: Earloop Type 170*95MM

Classification: Class I (MDD, Annex IX), Rule 1(All non-invasive devices are in class I)

Conformity Assessment: Annex VII

CE

We confirm our product can meet the requirement of Medical Device Directive(93/42/EEC) and the following harmonized standards.

EN ISO 14971:2012

EN ISO 15223-1:2016

EN 1041:2013

EN ISO 10993-1:2009/AC:2010

EN ISO 10993-5:2009

EN ISO 10993-10:2013

EN 14683:2019

Title: CEO

Name: Yingbo Tang

Signature:

Date: 2020 年 6 月 3 日

On behalf of SUNGO Europe office, I confirmed we are EU REP of the company who issue this document.

Title: CEO

Name: Chen Lan

Signature:

Date: 2020 年 6 月 3 日

Authorized Signature(S)

CIBG
Ministerie van Volksgezondheid, Welzijn en Sport

> Retouradres Postbus 16114 2500 BC Den Haag

SUNGO Europe B.V.
T.a.v. de heer R. Luo
Olympisch Stadion 24
1076 DE Amsterdam

Farmatec

Bezoekadres:
Hoftoren
Rijnstraat 50
2515 XP Den Haag

T 070 340 6161

http://hulpmiddelen.farmatec.nl

Inlichtingen bij:
R.A.C. Ori

medische_hulpmiddelen@minvws.nl

Ons kenmerk:
CIBG-20202302

Bijlagen
-

Uw aanvraag
19 mei 2020

Correspondentie uitsluitend richten aan het retouradres met vermelding van de datum en het kenmerk van deze brief.

Datum: 29 mei 2020
Betreft: aanmelding medisch hulpmiddel klasse I

Geachte heer Luo,

Graag bevestig ik hierbij de ontvangst op 19 mei 2020 van de mededeling ex artikel 5 van het Besluit medische hulpmiddelen (BMH) dat bedrijf Sichuan Ai Doctor Medical Technology Co., Ltd. met Europees gemachtigde SUNGO Europe B.V. onderstaand medisch hulpmiddel, ingedeeld in risicoklasse I, aflevert. Het product is onder volgend kenmerk geregistreerd. Ik verzoek u om in alle verdere correspondentie betreffende dit product het bijbehorende kenmerk te vermelden.

Surgical Mask (Non-sterile)
(geen merknaam) (NL-CA002-2020-51493)

Toekomstige wijzigingen in bovengenoemde gegevens – waaronder een eventuele wijziging van de indeling in risicoklasse in verband met wijzigingen van Europese regelgeving inzake de classificatie van medische hulpmiddelen, en aan voortschrijdend wetenschappelijk inzicht (zie art.9, lid 3 van Europese Richtlijn 93/42/EEG) – dient u te zijner tijd mede te delen.

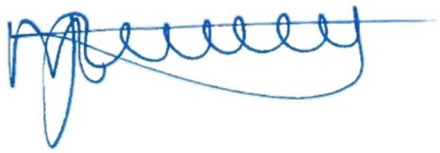
Volledigheidshalve wijs ik u erop dat het - ongeacht uw mededeling – verboden is een medisch hulpmiddel ter aflevering voorhanden te hebben, dan wel af te leveren indien niet aan de voor dat medisch hulpmiddel geldende regels gesteld bij of krachtens de Wet op de Medische Hulpmiddelen (WMH) wordt voldaan. Met name wijzen wij u op de Nederlandse-taaleis, de eisen voor het ter beschikking houden van de technische documentatie en de plicht tot het hebben van een Post Market Surveillance- en vigilantiesysteem.

Tevens wijs ik u er voor de goede orde nog op dat de registratie van uw mededeling betreffende de aflevering van het bovengenoemde product slechts een administratieve handeling betreft. Deze ontvangstbevestiging behelst dan ook geen besluit betreffende de kwalificatie van het desbetreffende product als medisch hulpmiddel in de zin van art. 1 WMH, noch betreffende de indeling in risicoklasse I.

zer niet gedefinieerd.

De Minister voor Medische Zorg en Sport,
namens deze,

Afdelingshoofd
Farmatec



Dr. M.J. van de Velde

SUBJECT	**Physical & Microbiological Test**
TEST LOCATION	**TÜV SÜD China** TÜV SÜD Products Testing (Shanghai) Co., Ltd. B-3/4, No.1999 Du Hui Road, Minhang District Shanghai 201108, P.R. China
CLIENT NAME	**Sichuan Ai Doctor Medical Technology Co.,Ltd.**
CLIENT ADDRESS	No.333, Yongke Road, Yongsheng Town, Chengdu Cross-strait Science And Technology Industial Development Park, Wenjiang District, Chengdu, Sichuan, China
TEST PERIOD	26-Apr-2020~08-May-2020

Prepared By

Bella Xu

(Bella Xu)
Report Drafter

Authorized By

TÜV SÜD PRODUCTS TESTING (SHANGHAI) CO., LTD. 上海德商品检测(上海)有限公司 检测报告专用章

Leo Liu

(Leo Liu)
Authorized Signatory

Note: (1) General Terms & Conditions as mentioned overleaf. (2) The results relate only to the items tested.(3) The test report shall not be reproduced except in full without the written approval of the laboratory.(4) Without the agreement of the laboratory , the client is not authorized to use the test results for unapproved propaganda.

Chemical/Microbiology Laboratory:
TÜV SÜD Products Testing (Shanghai) Co., Ltd.
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Shanghai
201108
P.R. China

Phone : +86 (21) 6037 6375
Fax : +86 (21) 6037 6345
Email: food.chem@tuv-sud.cn
Webpage: www.tuv-sud.cn

Regional Head Office:
TÜV SÜD Certification and Testing (China) Co., Ltd.
No.151 Heng Tong Road Shanghai
200 070 P.R.China

TEST REPORT

Sample Description	:	Surgical Mask
Sample Quantity	:	50 pieces
Lot Number/Batch Code	:	20200401
Specification	:	Earloop Type
Size	:	/
Brand Name	:	/

Remark: The above information was provided by applicant.

Summary of Test Results

No.	Test Item	Test Method	Test Standard Type ⅡR	Judgement
1	Bacterial Filtration Efficiency Test (BFE), %	EN 14683:2019+AC:2019(E) Annex B	≥ 98	Pass
2	Differential Pressure Test (Pa/cm^2)	EN 14683:2019+AC:2019(E) Annex C	< 60	Pass
3	Synthetic Blood Penetration Test (kPa)	ISO 22609:2004	≥ 16.0	Pass
4	Microbial Cleanliness Test (CFU/g)	EN 14683:2019+AC:2019(E) Annex D	≤ 30	Pass

Note: Pass = Meet customer requirements;
Fail = Fail customer requirements;
# = No comment;
N.D. = Not detected.

Photo of Samples

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200 070 P.R.China

Results

No.	Test Item	Test Result
1	Bacterial Filtration Efficiency (BFE) Test	Specimen 1#: 98.2% Specimen 2#: 98.0% Specimen 3#: 98.1% Specimen 4#: 98.1% Specimen 5#: 98.1%
2	Differential Pressure Test	26.6 Pa/cm^2
3	Synthetic Blood Penetration Test	Specimen 1#~32#: None seen
4	Microbial Cleanliness Test	Specimen 1#: <1 CFU/g Specimen 2#: 1 CFU/g Specimen 3#: <1 CFU/g Specimen 4#: <1 CFU/g Specimen 5#: <1 CFU/g

Bacterial Filtration Efficiency (BFE) Test

1. Purpose

For evaluating the bacterial filtration efficiency (BFE) of mask.

2. Sample description was given by client

Sample description : Surgical Mask
Specification : Earloop Type
Lot Number : 20200401
Sample Receiving Date : 2020-04-26

3. Test Method

EN 14683:2019+AC:2019(E) Annex B

4. Apparatus and materials

4.1 *Staphylococcus aureus* ATCC 6538.
4.2 Peptone water.
4.3 Tryptic Soy Broth(TSB).
4.4 Tryptic Soy Agar(TSA).
4.5 Bacterial filtration efficiency test apparatus.
4.6 Six-stage viable particle Anderson sampler.
4.7 Flow meters.

5. Test specimen

5.1 As requested by client, take a total of 5 test specimens.
5.2 Prior to testing, condition all test specimens for a minimum of 4 h at (21±5)°C and (85±5)% relative humidity.

6. Procedure

6.1 Preparation of the bacterial challenge: Dilute the cultutre in peptone water to achieve a concentration of approximately 5×10^5 CFU/mL.
6.2 Adjust the flow rate through the Anderson sampler to 28.3 L/min.
6.3 Deliver the challenge to the nebulizer using a syringe pump. Purge tubing and nebulizer of air bubbles.
6.4 Perform a positive control run without a test specime to determine the number of viable aerosol particles being generated. The mean particle size (MPS) of the aerosol will also be calculated from the results of these positive control plates.
  6.4.1 Initiate the aerosol challenge by turning on the air pressure and pump connected to the nebulizer. Immediaterly begin sampling the aerosol using the Anderson sampler.
  6.4.2 Time the challenge suspension to be delivered to the nebulizer for 1 min.
  6.4.3 Time the air pressure and Anderson sampler to run for 2 min.
  6.4.4 At the conclusion of the positive control ran, remove plates from the Anderson sampler.
6.5 Place new agar plates into Anderson sampler and clamp the test specimen into the top of the Anderson sampler, with the inside of the specimen facing towards the bacterial challenge (test area: 77cm^2).
6.6 Repeat the challenge procedure for each test specimen.
6.7 Repeat a positive control after completion of the sample set.
6.8 Perform a negative control run by collecting a 2 min sample of air from the aerosol chamber. No bacterial challenge should be pumped into the nebulizer during the collection of the negative control.
6.9 Incubate agar plates at (37±2)°C for (20 to 52) h.
6.10 Count each of the six-stage plates of the Anderson sampler.

7. Calculation

Total the count from each of the six plates for the test specimens and positive controls, as specified by the manufacture of Anderson sampler. The filtration efficiency percentages are calculated as follows:

$$BFE=(C-T) / C \times 100$$

T is the total plate count for the test specimen.

C is the mean of the total plate counts for the two positive controls.

8. Test results*

P Value / Stage Number	Positive Control (A)	Positive Control (B)	Negative Control	Specimen 1#	Specimen 2#	Specimen 3#	Specimen 4#	Specimen 5#
1	53	98	0	0	0	0	1	1
2	112	136	0	2	1	1	2	1
3	130	165	0	1	1	2	6	1
4	213	298	0	3	1	6	7	6
5	1518	1518	0	26	29	27	27	29
6	434	475	0	16	19	13	7	12
Total (*T*), CFU	2460	2690	<1	48	51	49	50	50
Average (C), CFU	2.6 x10^3= (P_A+P_B) / 2							
BFE ,%				98.2	98.0	98.1	98.1	98.1
Requirements	≥ 98							
Remarks	*P* is the value of corresponding corrected particle counts as specified by the manufacturer of the cascade impactor. *T* is the total of *P* value for the test specimen. *C* is the mean of the total of *P* value of the two positive controls.							

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200 070 P.R.China

Differential pressure Test

1.Purpose

The purpose of the test was to measure the differential pressure of masks.

2.Sample description was given by client

Sample description	:	Surgical Mask
Specification	:	Earloop Type
Lot Number	:	20200401
Sample Receiving Date	:	2020-04-26

3.Test Method

EN 14683:2019+AC:2019(E) Annex C

4. Apparatus and materials

Differential pressure testing instrument

5.Test specimen

5.1 Test specimen are complete masks or shall be cut from masks. Each specimen shall be able to provide 5 different circular test areas of 2.5 cm in diameter.
5.2 Prior to testing, condition all test specimens for a minimum of 4 h at (21±5) ºC and (85±5)% relative humidity.

6. Procedure

6.1 Without a specimen in place, the holder is closed and the differential manometer is zeroed. The pump is started and the flow of air adjusted to 8 L/min.
6.2 The pretreated specimen is placed across the orifice (total area 4.9cm^2, test area diameter 25mm) and clamped into place so as to minimize air leaks.
6.3 Due to the presence of an alignment system the tested area of the specimen should be perfectly in line and across the flow of air.
6.4 The differential pressure is read directly.
6.5 The procedure described in steps 6.1-6.4 is carried out on 5 different areas of the mask and readings averaged.

Results:

Specimen	Test Results* (Pa/cm^2)	Average （Pa/cm^2）	Requirements	Judgement
1#	27.4	26.6	< 60	Pass
2#	29.1			
3#	22.6			
4#	27.5			
5#	26.5			

Synthetic Blood Penetration Test

1.Purpose

For evaluation of resistance of masks to penetration by a fixed volume of synthetic blood at a high velocity.

2.Sample description was given by client

Sample description	:	Surgical Mask
Specification	:	Earloop Type
Lot Number	:	20200401
Sample Receiving Date	:	2020-04-26

3.Test Method

ISO 22609:2004

4.Apparatus and materials

4.1 Synthetic blood.
4.2 Tensiometer.
4.3 Synthetic blood penetration test apparatus;
4.4 Targeting plate.
4.5 Air pressure source.
4.6 Ruler.
4.7 Balance.
4.8 Controlled temperature and humidity chamber.

5.Test specimen

5.1 As requested by client, take a total of 32 test specimens.
5.2 Prior to testing, condition all test specimens for a minimum of 4h at (21±5)°C and (85±5) % relative humidity.

6.Procedure

6.1 Prepare the synthetic blood (40~44 mN/m) for the test.
6.2 Determine the density of the synthetic blood.
6.3 Fill the reservoir with new synthetic blood.
6.4 Position the test specimen 30.5 cm (12 in.) from the exit of the canula.
6.5 Set the reservoir pressure to the approximate pressure.
6.6 Place the targeting plate approximately 1 cm away from the mask.
6.7 Set the valve timer to 0.5 s. Collect and weigh the amount of fluid delivered (before the targeting hole).

6.8 Set the valve timer to 1.5 s. Collect and weigh the amount of fluid delivered (before the targeting hole).

6.9 Calculate the difference in weight of the two spurts. For a test fluid with a density of 1.003, Table 1 gives the target difference in weight plus lower and upper limits for a velocity range within 2% of the target.

Table 1 Target weight difference

Fluid Pressure (mmHg)	Weight difference for 1s difference in spurt duration (g)		
	Min.	Target	Max.
120	3.002	3.063	3.124

6.10 Adjust the reservoir pressure and repeat steps 6.7 to 6.9 until the weight difference is within the target range.

6.11 Record the weight difference for the spurts exiting the nozzle.

6.12 Record the pressure in the reservoir.

6.13 Set the valve time to 0.5 s. Collect and weigh the amount of fluid passing through the targeting hole.

6.14 Set the valve time to 1.5 s. Collect and weigh the amount of fluid passing through the targeting hole.

6.15 The difference in weight between the 0.5 s and 1.5 s spurts through the targeting plate shall be within +2 % ~ -5 % of the difference in weight from the nozzle.

6.16 If the differential weight is less than 95 % of the weight difference exiting the nozzle, check the aim of the stream to make sure it is passing cleanly through the targeting hole.

6.17 If the differential weight is more than 102 % of the weight difference exiting the nozzle, repeat the weight measurements exiting the nozzle (steps 6.7 to 6.11).

6.18 For standard synthetic blood, the timer duration can be estimated using the formula:
(p is the density of the test fluid.) $t = 0.5 + (2\times p$ - g at 0.5 s) / (g at 1.5 s - g at 0.5 s).

6.19 Record the timer setting to use as the starting point for subsequent testing.

6.20 Mount a test specimen on the specimen holding fixture. If the mask contains pleats, spread the pleats out when mounting the mask onto the fixture to present a single layer of material as the target area.

6.21 Squirt the synthetic blood onto the test specimen for the calculated time. Ensure that the synthetic blood hits the target area of mask.

6.22 Inspect the inside surface for synthetic blood penetration within 10 s of squirting the synthetic blood against the target area.

6.23 Report the results (none / penetration) for each test specimen at the test pressure.

Results:

Specimen	Test Results*	Requirements	Judgement
1#	None Seen	Pass Pressure at 16.0 kPa (120mmHg)	Pass
2#	None Seen		Pass
3#	None Seen		Pass
4#	None Seen		Pass
5#	None Seen		Pass
6#	None Seen		Pass
7#	None Seen		Pass
8#	None Seen		Pass
9#	None Seen		Pass
10#	None Seen		Pass
12#	None Seen		Pass
13#	None Seen		Pass
14#	None Seen		Pass
15#	None Seen		Pass
16#	None Seen		Pass
17#	None Seen		Pass
18#	None Seen		Pass
19#	None Seen		Pass
20#	None Seen		Pass
22#	None Seen		Pass
23#	None Seen		Pass
24#	None Seen		Pass
25#	None Seen		Pass
26#	None Seen		Pass
27#	None Seen		Pass
28#	None Seen		Pass
29#	None Seen		Pass
30#	None Seen		Pass
31#	None Seen		Pass
32#	None Seen		Pass

Chemical/Microbiology Laboratory:
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Microbial Cleanliness Test

1. Purpose

The purpose of the test was to measure microbial cleanliness of mask.

2. Sample description was given by client

Sample description	:	Surgical Mask
Specification	:	Earloop Type
Lot Number	:	20200401
Sample Receiving Date	:	2020-04-26

3. Test Method

According to EN ISO 11737-1:2018 to determine the microbial cleanliness of mask material, and refer to the procedure as described in EN 14683:2019+AC:2019(E) Annex D

4. Apparatus and materials

4.1 Orbital shaker.
4.2 0.45 um filter.
4.3 Tryptic Soy Agar (TSA).
4.4 Sabouraud Dextrose Ager (SDA) with chloramphenicol.
4.5 Formula of Extraction Liquid: 1g/L peptone, 5g/L NaCl and 2g/L Tween 20.
4.6 Extraction apparatus.

5. Test specimen

5.1 As requested by client, take a total of 5 mask samples.
5.2 Mask samples for testing are provided in the original primary packaging.
5.3 Condition at (18 to 26)℃ and (45 to 65)% relative humidity during testing.

6. Procedure

6.1 Five test specimens are selected from the top, bottom and 3 randomly chosen marks.
6.2 The mask is aseptically removed from the packaging and placed in a sterile 500 mL bottle containing 300 mL of extraction liquid.
6.3 The bottle is laid down on an orbital shaker and shaken for 5 min at 250 rpm.
6.4 After extracting, 100mL of the extraction liquid is filtered through a 0.45 um filter and laid down on a TSA plate for the total viable aerobic microbial count. Another 100 mL aliquot of the same extraction liquid is filtered in the same way and the filter plated on SDA for fungi enumeration.
6.5 The plates are incubated for 3 days at 30°C and 7 days at (20 to 25)°C for TSA and SDA plates respectively.
6.6 Calculate the colonies of each agar plate.

7. Calculation

For each test specimen calculate the microbial cleanliness as follows by counting the total colonies of the TSA and SDA plates.

Results*:

Specimen	Colonies of the TSA Plate	Colonies of the SDA Plate	Microbial Cleanliness, (CFU/g)	Requirements	Judgement
1#	0	0	<1	EN14683:2019+AC:2019(E) Annex D EN ISO 11737-1:2018 ≤ 30 CFU/g	Pass
2#	0	1	1		
3#	0	0	<1		
4#	0	0	<1		
5#	0	0	<1		

Note:

1.*denotes this test was carried out by external laboratory assessed as competent.

2.This report is for internal use only such as internal scientific research ,education, quality control, product R&D.

-END OF THE TEST REPORT-

Chemical/Microbiology Laboratory:
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[HYGCEN AUSTRIA GMBH | WERKSGELÄNDE 28 | 5500 BISCHOFSHOFEN]

Sunbeam International GmbH

Schumanstr. 12

52146 Würselen

Deutschland

Akkreditierte
Prüfstelle nach
ÖNORM EN ISO 17025

Bischofshofen, 30.09.2020

Prüfbericht / *test report* B 25536

Labor-Nr. / *identification of the test laboratory:*	B 25536
Prüfprodukt / *test product*:	Hygisun (HS0402R)
Musterbezeichnung / *sample designation:*	Hygisun (HS0402R)
Auftraggeber / *ordered by*:	Sunbeam International GmbH
Auftragsdatum / *date of order*:	2020-08-27
Materialeingang / *date of delivery*:	2020-09-01/ 22.09.2020
Prüfzeitraum / *period of analysis*:	2020-09-07 bis / *to* 2020-09-30
Prüfbedingungen / *test conditions:*	Die Prüfung erfolgte im Anlieferungszustand. / *The test was done in the delivery state.*
Prüfauftrag / *test order:*	Medizinische Gesichtsmasken - Anforderungen und Prüfverfahren / *Medical face masks - Requirements and test methods* EN 14683:2019+AC:2019

Prüfmethoden / *test methods*:	SOP 13-002 Bakteriellen Filtrationsleistung (BFE) / *bacterial filtration efficacy (BFE)* EN 14683 Anhang / *annex* B SOP 13-001 Atmungs-Eignungsprüfung, differentialer Druck / *breathability test, differential pressure* EN 14683 Anhang / *annex* C SOP 13-003 Bestimmung der Widerstandsfähigkeit gegen Flüssigkeitsspritzer (Splash-Test) / *test method for the splash resistance of facemasks (splash test)* ISO 22609 SOP 07-014 Mikrobiologische Reinheit / *Determination of a population of micro-organisms* EN ISO 11737-1

Ergebnis der Prüfung der Filterwirksamkeit für Bakterien für Masken / *test results of bacterial filtration efficacy of masks*
EN 14683 / SOP 13-002

Information: 5.2.2 der EN 14683:2019+AC:2019

Prüfprodukt / *test product*:	Hygisun (HS0402R)
Prüfdatum / *date of testing*:	2020-09-11
Anzahl der Prüfkörper / number of samples:	5
Volumenfluss / *volume flow:*	28.3 l/min
Größe der Prüfkörper / *sample size*:	10cm x 10cm
Geprüfter Bereich des Prüfkörpers / *sample area tested:*	50 cm^2
Prüfseite / *test side*:	Innenseite zum Aerosol / *inside facing the aerosol*
Prüfbereich / *test area*:	Kapitel 5.2.2; Absatz 2 und 3 treffen aufgrund der Beschaffenheit der Maske nicht zu / *chapter 5.2.2; clause 2 and 3 does not apply due to the nature of the mask*
Prüfkeim / *test strain*:	*Staphylococcus aureus* ATCC 6538
KBE der Ausgangskeimsuspension / *cfu of test suspension:*	1.69 x 10^3/ml
Mittelwert positive Kontrolle / *mean particle size (MPS):*	2.8 µm
Mittelwert Negativkontrolle / *mean value negative control*	0 KBE / *cfu*
Inkubation / *incubation:*	48 h bei / *at* 36 ± 1 °C
Raumtemperatur / *room temperature*:	21.9 °C
Luftfeuchte / *relative humidity*:	47 %
Temperatur während der Konditionierung / *temperature during conditioning (4h):*	22.0 °C
Luftfeuchte während der Konditionierung / *relative humidity during conditioning (4h)*:	88 %

Ergebnis der Prüfung der Filterwirksamkeit für Bakterien für Masken / *test results of bacterial filtration efficacy of masks*
EN 14683 / SOP 13-002

Innenseite zum Aerosol / *inside facing the aerosol*

Gezählte KBE/Platte / *counted cfu per plate*

	Ebene 1 KBE/Platte *level 1 cfu/plate*	Ebene 2 KBE/Platte *level 2 cfu/plate*	Ebene 3 KBE/Platte *level 3 cfu/plate*	Ebene 4 KBE/Platte *level 4 cfu/plate*	Ebene 5 KBE/Platte *level 5 cfu/plate*	Ebene 6 KBE/Platte *level 6 cfu/plate*	KBE gesamt *total cfu*
PK1	400	400	295	300	341	315	**2051**
PK2	400	400	270	248	261	298	**1877**
NK	0	0	0	0	0	0	**0**

Gezählte KBE/Platte nach Umrechnung mit „Positive hole conversion table“ /
Counted cfu per plate after conversion with “positive hole conversion table”

	Ebene 1 KBE/Platte *level 1 cfu/plate*	Ebene 2 KBE/Platte *level 2 cfu/plate*	Ebene 3 KBE/Platte *level 3 cfu/plate*	Ebene 4 KBE/Platte *level 4 cfu/plate*	Ebene 5 KBE/Platte *level 5 cfu/plate*	Ebene 6 KBE/Platte *level 6 cfu/plate*	KBE gesamt *total cfu*
PK1	400	400	535	555	766	620	**3276**
PK2	400	400	450	387	423	547	**2607**
NK	0	0	0	0	0	0	**0**

Gezählte KBE/Platte / *counted cfu per plate*

Probe / *sample*	Ebene 1 KBE/Platte *level 1 cfu/plate*	Ebene 2 KBE/Platte *level 2 cfu/plate*	Ebene 3 KBE/Platte *level 3 cfu/plate*	Ebene 4 KBE/Platte *level 4 cfu/plate*	Ebene 5 KBE/Platte *level 5 cfu/plate*	Ebene 6 KBE/Platte *level 6 cfu/plate*	KBE gesamt *total cfu*
1	0	0	0	0	0	13	**13**
2	0	0	0	2	2	20	**24**
3	0	0	0	0	0	11	**11**
4	0	0	0	1	0	8	**9**
5	0	0	0	0	0	10	**10**

Gezählte KBE/Platte nach Umrechnung mit „Positive hole conversion table“ /
Counted cfu per plate after conversion with “positive hole conversion table”

Probe / *sample*	Ebene 1 KBE/Platte *level 1 cfu/plate*	Ebene 2 KBE/Platte *level 2 cfu/plate*	Ebene 3 KBE/Platte *level 3 cfu/plate*	Ebene 4 KBE/Platte *level 4 cfu/plate*	Ebene 5 KBE/Platte *level 5 cfu/plate*	Ebene 6 KBE/Platte *level 6 cfu/plate*	KBE gesamt *total cfu*
1	0	0	0	0	0	13	**13**
2	0	0	0	2	2	21	**25**
3	0	0	0	0	0	11	**11**
4	0	0	0	1	0	8	**9**
5	0	0	0	0	0	10	**10**

Legende / *legend*:

KBE / cfu	=	Kolonie bildende Einheiten / *colony forming units*
PK	=	Positivkontrolle / *positive control*
NK	=	Negativkontrolle / *negative control*

Bewertung der Filterwirksamkeit / *rating of bacterial filtration efficacy*
EN 14683 / SOP 13-002

Probe / *sample*	Filterwirksamkeit *filtration efficacy* [%]
1	99.56
2	99.15
3	99.63
4	99.69
5	99.66
Mittelwert *mean value*	**99.54%**

Berechnungsformel / *calculation formula*: $B = \frac{(C - T)}{C \times 100}$

C = Mittelwert der gesamten Plattenauszählung für die beiden positiven Kontrolläufe
plate count average of both positive control runs
T = gesamte Plattenauszählung für das Prüfstück
total plate count of the sample

Ergebnis der Atmungs-Eignungsprüfung, differentialer Druck, in Übereinstimmung mit U. S. Militär-Spezifikation-MIL-M-36954 C (Luft-Austausch-druck) / *breathability test result, differential pressure, in accordance with U.S. Military Specification MIL-M-36954 C (Air Exchange Pressure)*
EN 14683 / SOP 13-001

Information: 5.2.3 der EN 14683:2019+AC:2019

Prüfprodukt / *test product*:	Hygisun (HS0402R)
Prüfdatum / *date of testing*:	2020-09-11
Anzahl der Prüfkörper / number of samples:	5
Anzahl der Prüfungen pro Prüfkörper / *number of tests per sample:*	5
Größe der Prüfkörper / *sample size*:	10cm x 10cm
Geprüfter Bereich des Prüfkörpers / *sample area tested:*	kreisförmig, Durchmesser 2,5 cm / *circular, diameter 2.5 cm*
Prüfbereich / *test area*:	Kapitel C 4.4; Absatz 2 trifft aufgrund der Beschaffenheit der Maske nicht zu / *chapter C 4.4; clause 2 does not apply due to the nature of the mask*
Geprüfter Bereich des Prüfkörpers / *tested area of the test sample*:	4.9 cm²
Luftstrom / *airflow*:	8 l/min ± 0.2 l/ innen nach außen/inside to outside
Raumtemperatur / *room temperature*:	22 °C
Luftfeuchte / *relative humidity*:	51 %
Temperatur während der Konditionierung/ *temperature during conditioning (4h):*	23.0 °C
Luftfeuchte während der Konditionierung / *relative humidity during conditioning (4h)*:	87 %
Standardabweichung / *standard deviation:*	2.14

Probe / *sample*	Pos. 1 Pa	Pos. 2 Pa	Pos. 3 Pa	Pos. 4 Pa	Pos.5 Pa	Mittelwert / *mean value* Pa	ΔP [Pa/cm²]
1	151.51	167.35	139.08	135.83	185.72	**155.90**	**31.82**
2	153.78	186.40	149.24	130.48	137.12	**151.40**	**30.90**
3	163.32	206.85	167.69	156.15	193.71	**177.54**	**36.23**
4	157.24	182.35	122.57	140.07	165.46	**153.54**	**31.33**
5	137.36	203.80	140.02	154.36	220.77	**171.26**	**34.95**
Mittelwert / *mean value*							**33.05**

Legende / *legend*:
Pa = Pascal

Berechnungsformel / *calculation formula* = Differentialdruck / *differential pressure* $\Delta P = \frac{\bar{x}\,m_2 - \bar{x}\,m_1}{4{,}9}$

Ergebnis der Prüfung der Widerstandsfähigkeit gegen Flüssigkeitsspritzer / *test result of the splash resistance of facemasks*
ISO 22609 / SOP 13-003

Information: 5.2.4 der EN 14683:2019+AC:2019

Prüfprodukt / *test product*:	Hygisun (HS0402R)
Prüfdatum / *date of testing*:	2020-09-08
Geprüfter Bereich des Prüfkörpers / *sample area tested:*	kreisförmig, Durchmesser 5 cm / *circular, diameter 5 cm*
Geprüfter Bereich des Prüfkörpers / *tested area of the test sample*:	19.6 cm²
Anzahl der Prüfkörper / number of samples:	32 je Druck / *per pressure*
Prüfeinstellungen / *test settings*:	10.6 kPa (80 mmHg) 16.0 kPa (120 mmHg) 21.3 kPa (160 mmHg)
Volumen synthetisches Blut / *volume of synthetic blood*:	2.0 ml
Raumtemperatur während der Prüfung/ *room temperature during the test*:	24.7 °C
Luftfeuchte während der Prüfung / *relative humidity during the test*:	45.8 %
Temperatur während der Konditionierung/ *temperature during conditioning:*	22.0 °C
Luftfeuchte während der Konditionierung / *relative humidity during conditioning*:	88 %

Ergebnis der Prüfung der Widerstandsfähigkeit gegen Flüssigkeitsspritzer / *test result of the splash resistance of facemasks*
ISO 22609 / SOP 13-003

	Druck / *pressure*: 10.6 kPa			**Druck / *pressure*: 16.0 kPa**			**Druck / *pressure*: 21.3 kPa**		
	Volumen-test / *volume test*	erfüllt / *fullfilled*		**Volumen-test / *volume test***	erfüllt / *fullfilled*		**Volumen-test / *volume test***	erfüllt / *fullfilled*	
		ja / *yes*	nein / *no*		ja / *yes*	nein / *no*		ja / *yes*	nein / *no*
1	2.0 ml	☒	☐	2.0 ml	☒	☐	2.0 ml	☒	☐
2		☒	☐		☒	☐		☒	☐
3		☒	☐		☒	☐		☒	☐
4		☒	☐		☒	☐		☒	☐
5		☒	☐		☒	☐		☒	☐
6		☒	☐		☒	☐		☒	☐
7		☒	☐		☐	☒		☒	☐
8		☒	☐		☒	☐		☒	☐
9	2.0 ml	☒	☐	2.0 ml	☒	☐	2.0 ml	☒	☐
10		☒	☐		☒	☐		☒	☐
11		☒	☐		☒	☐		☒	☐
12		☒	☐		☒	☐		☒	☐
13		☒	☐		☒	☐		☒	☐
14		☒	☐		☒	☐		☒	☐
15		☒	☐		☒	☐		☒	☐
16		☒	☐		☒	☐		☒	☐
17	2.0 ml	☒	☐	2.0 ml	☒	☐	2.0 ml	☒	☐
18		☒	☐		☒	☐		☒	☐
19		☒	☐		☒	☐		☒	☐
20		☒	☐		☒	☐		☒	☐
21		☒	☐		☒	☐		☒	☐
22		☒	☐		☒	☐		☒	☐
23		☒	☐		☒	☐		☒	☐
24		☒	☐		☒	☐		☒	☐
25	2.0 ml	☒	☐	2.0 ml	☒	☐	2.0 ml	☒	☐
26		☒	☐		☒	☐		☒	☐
27		☒	☐		☒	☐		☒	☐
28		☒	☐		☒	☐		☒	☐
29		☒	☐		☒	☐		☒	☐
30		☒	☐		☒	☐		☒	☐
31		☒	☐		☒	☐		☒	☐
32		☒	☐		☒	☐		☒	☐

Akzeptables Qualitätslimit / *acceptable quality limit* (AQL)	**erfüllt / *fullfilled***	
	ja / *yes*	**nein / *no***
4.0% bei / *at* 16 kPa	☒	☐

Bestimmung der Population von Mikroorganismen auf Produkten, Mikrobiologische Reinheit / *Determination of a population of micro-organisms on products*
EN ISO 11737-1 / SOP 07-014

Information: 5.2.5 der EN 14683:2019+AC:2019

Ergebnis der Validierung des Ablösungsverfahrens mittels wiederholender Rückgewinnung / *Result of the validation of the elution procedure using the method of repeated recovery*

Prüfprodukt / *test product*:	Hygisun (HS0402R)
Prüfdatum / *date of testing*:	2020-09-23
Probengewicht / *sample weight*:	3.23 g
Anzahl der Prüfkörper gesamt / *total number of samples*:	6
Ablösungsverfahren / *dissolution procedure*:	1 Maske wurde bei höchster Stufe im Stomacher 5 min mit Verdünnungslösung eluiert / *1 mask was processed 5 min in a stomacher by highest speed with dilution solution*
Raumtemperatur / *room temperature*:	22.8 °C
Luftfeuchte / *relative humidity*:	49 %
Inkubation / *incubation*:	Bebrütung des Membranfilters auf CSA (30±1°C – 72h) und SDA (20-25°C – 7d) / *Incubation of the membrane filter on TSA (30±1°C – 72h) and SDA (20-25°C – 7d)*

Anzahl Tests / *number of tests*	**Volumen Eluierungsmittel / *volume elution medium***	**KBE / Prüfkörper / *cfu / test body***		
		CSA / *TSA*	**SDA**	**Gesamt / *total***
1a	20 ml	40	2	**42**
1b	20 ml	35	6	**41**
1c	20 ml	18	1	**19**
1d	20 ml	6	1	**7**

Berechnung der Ergebnisse / *calculation of the results*

Ablösung / *dissolution* in %: 38.53 %

Korrekturfaktor / *correction factor:* 2.60

Legende / *Legend*:

VF	=	Verdünnungslösung / *dilution solution* (0.85% NaCl, 0.1% Trypton)
KBE / cfu	=	Kolonie bildende Einheiten / *colony forming units*
CSA / *TSA*	=	Caseinpepton Sojamehlpepton Agar / *Tryptone Soy Agar*
SDA	=	Sabouraud-Dextrose-Agar mit Chloramphenicol / *with chloramphenicol*

$$\text{Ablösung / } \textit{dissolution in \%} = \frac{\text{Anzahl der Mikroorganismen nach der 1. Eluierung / } \textit{number of micro-organisms after the 1. elution}}{\text{Anzahl der Mikroorganismen von Eluierung 1 – 4 / } \textit{number of micro-organisms after elution 1 – 4}} \times 100$$

$$\text{Korrekturfaktor / } \textit{correction factor:} = \frac{100}{\text{Ablösung / } \textit{dissolution in \%}}$$

Bestimmung der Population von Mikroorganismen auf Produkten, Mikrobiologische Reinheit / *Determination of a population of micro-organisms on products*
EN ISO 11737-1 / SOP 07-014

Prüfprodukt / *test product*:	Hygisun (HS0402R)
Prüfdatum / *date of testing*:	2020-09-23
Anzahl der Prüfkörper gesamt / *total number of samples*:	6
Ablösungsverfahren / *dissolution procedure*:	1 Maske wurde bei höchster Stufe im Stomacher 5 min mit Verdünnungslösung eluiert / *1 mask was processed 5 min in a stomacher by highest speed with dilution solution*
Raumtemperatur / *room temperature*:	22.8 °C
Luftfeuchte / *relative humidity*:	49 %
Inkubation / *incubation*:	Bebrütung des Membranfilters auf CSA (30±1°C – 72h) und SDA (20-25°C – 7d) / *Incubation of the membrane filter on TSA (30±1°C – 72h) and SDA (20-25°C – 7d)*
Korrekturfaktor / *correction factor:**	2.60

Nr. / *No.*	**CSA / *TSA***	**SDA**	**Gesamtkeimzahl / KBE / PK *total count cfu / PK***	**Gesamtkeimzahl x Korrekturfaktor *total count x correction factor****	**Proben-gewicht / *sample weight:***	**KBE / g *cfu / g***
Test 2	5	9	14.00	36.33	3.25	11.18
Test 3	1	1	2.00	5.19	3.30	1.57
Test 4	4	1	5.00	12.98	3.24	4.00
Test 5	3	3	6.00	15.57	3.22	4.84
Test 6	4	0	4.00	10.38	3.17	3.27
					Resultat / *result*:	4.97

Legende / *Legend*:

VF	=	Verdünnungslösung / *dilution solution* (0.85% NaCl, 0.1% Trypton)
CSA / TSA	=	Caseinpepton Sojamehlpepton Agar / *Tryptone Soy Agar*
SDA	=	Sabouraud-Dextrose-Agar mit Chloramphenicol / *with chloramphenicol*
KBE / *cfu*	=	Kolonie bildende Einheiten / *colony forming units*
PK	=	Prüfkörper / *test body*
n	=	nicht zählbar / *not countable*

Schlussfolgerung / *conclusion*:

Die überprüfte Maske Hygisun (HS0402R) entspricht den Vorgaben der EN14683:2019+AC:2019, für Masken des Typs IIR.

The tested mask Hygisun (HS0402R) fulfils the requirements of EN 14683:2019+AC:2019, for type IIR masks.

Prüfung / *test*	**Leistungsanforderungen für chirurgische Masken (EN 14683:2019+AC:2019, Kapitel 5.2.7) / *performance requirements for surgical masks (EN 14683:2019+AC:2019, chapter 5.2.7)***		
	erfüllt / *fullfilled*		**entfällt / *not required***
	ja / *yes*	**nein / *no***	
Bakterielle Filterleistung / *bacterial filtration efficiency* (BFE) %	☒	☐	☐
Druckdifferenz / *differential pressure* Pa/cm²	☒	☐	☐
Druck des Spritzwiderstandes / *splash resistance pressure* kPa	☒	☐	☐
Mikrobiologische Reinheit (KBE/g) / *bioburden (cfu/g)*	☒	☐	☐

Archivierung / *Archiving:* Eine Ausfertigung des Berichtes wird zusammen mit den Rohdaten im Archiv der HygCen Austria GmbH aufbewahrt. / *A copy of this report is kept together with the raw data in the archive of HygCen Austria GmbH.*

Hinweis / *Note*: Der vorliegende Prüfbericht bezieht sich ausschließlich auf die dem Labor vorliegenden Prüfgegenstände. Jede auszugsweise Vervielfältigung bedarf der schriftlichen Genehmigung durch die HygCen Austria GmbH. / *The present test report refers exclusively to the test objects available to the laboratory. Any duplication in extracts requires the written permission of HygCen Austria GmbH.*

Prof. Dr. med. H.-P. Werner
Technischer Leiter / *technical manager*

Monika Feltgen
Stellvertretender technischer Leiter / *vice technical manager*

Anhang zum Prüfbericht B 25536
attachment to test report B 25536

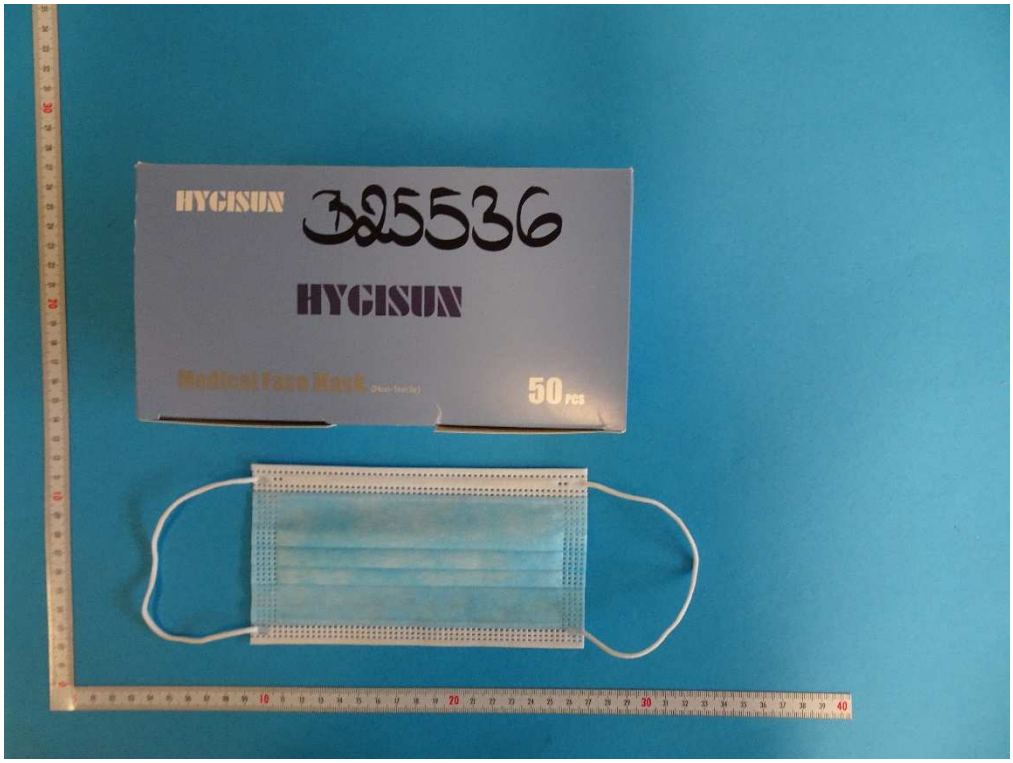


Abb. 1: Hygisun (HS0402R)

Anhang / ***attachment***
Erläuterung zum Prüfbericht B 25536
Comment to test report B 25536

1. Leistungsanforderungen für chirurgische Masken entsprechend / *performance requirements for surgical masks* EN 14683:2019+AC:2019

Prüfung / ***test***	**Typ** / ***type*** **I**	**Typ** / ***type*** **II**	**Typ** / ***type*** **IIR**
Bakterielle Filterleistung / *bacterial filtration efficiency* (BFE) %	≥ 95	≥ 98	≥ 98
Druckdifferenz / *differential pressure* Pa/cm²	<40	<40	<60
Druck des Spritzwiderstandes / *splash resistance pressure* kPa	entfällt / *not required*	entfällt / *not required*	≥ 16.0
Mikrobiologische Reinheit (KBE/g) / *bioburden (cfu/g)*	≤ 30	≤ 30	≤ 30

2. Verfahren für die in-vitro Bestimmung der bakteriellen Filterleistung / *method for in vitro determination of bacterial filtration efficiency* (BFE)

Historie / ***history***
Der Aufbau der Prüfung der Filterwirksamkeit für Bakterien für Masken wurde erstmals in der Militär-Spezifikation MIL-M-36954C *„Mask, Surgical, Disposable“* aus dem Jahr 1975 beschrieben.
Seitdem wurde die Prüfung der Filterwirksamkeit in weiteren internationalen Normen umgesetzt:

von EDANA (European Disposables And Nonwovens Association) und INDA (Association of Nonwoven Fabrics Industry) in WSP 300.0 (05) *„Standard Test Method for Nonwovens Bacterial Filtration Efficiency“*,

von ASTM (American Society for Testing and Materials) in ASTM F 2101-07 „*Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus“* und

von CEN (Europäischen Normungskommission) in EN 14683 *“Chirurgische Masken – Anforderungen und Prüfverfahren”.*

The structure of the test method of the bacterial filtration efficiency for surgical masks was described for the first time in military specification MIL-M-36954C "Masks, Surgical, Disposable" from the year 1975. Since then the testing of the bacterial filtration efficiency was converted into further international standards:

by EDANA (European Disposables and Nonwovens Association) and INDA (Association OF Nonwoven Fabrics Industry) in WSP 300,0 (05) "standard test Method for Nonwovens Bacterial filtration Efficiency",

by ASTM (American Society for Testing and of material) in ASTM F 2101-07 "standard test Method for Evaluating the Bacterial filtration Efficiency (BFE) OF Medical Face MASK of material, Using A Biological aerosol OF Staphylococcus aureus"

and by the CEN (European standardization commission) in EN 14683 "surgical masks - requirements and testing methods".

Testprinzip / ***test principle***
Eine Probe des Maskenmaterials wird zwischen ein sechsstufiges Kaskaden-Aufprallgerät (Andersen Sampler) und eine Aerosolkammer eingeklemmt. In die Aerosolkammer wird ein Aerosol von *Staphylococcus aureus* eingeführt und unter Vakuum durch das Maskenmaterial und das Aufprallgerät gezogen.
Die bakterielle Filterleistung der Maske wird durch die Anzahl der koloniebildenden Einheiten angegeben, die durch die Maske hindurchgehen, angegeben als Prozentsatz der im Belastungsmaterial vorliegenden koloniebildenden Einheiten.

A specimen of the mask material is clamped between a six-stage cascade impactor and an aerosol chamber. An aerosol of Staphylococcus aureus is introduced into the aerosol chamber and drawn through the mask material and the impactor under vacuum.

The bacterial filtration efficiency of the mask is given by the number of colony forming units passing through the surgical mask material expressed as a percentage of the number of colony forming units present in the challenge aerosol.

Auswertung der Prüfung / ***evaluation of the examination***
Es wird eine Umrechnung der Keimzahlen auf den Ebenen 3-6 des sechsstufigen Kaskaden-Aufprallgerätes mit der „positive hole conversion table“ von Andersen A. A. (1958) durchgeführt.

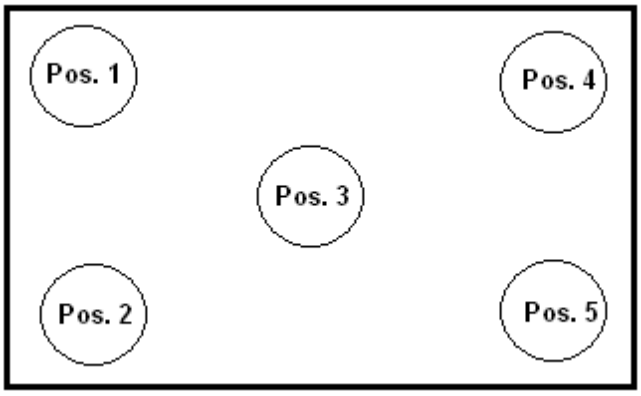
The colony forming units on the levels 3-6 of the six-level cascade impact are converted with the "positive hole conversion table" described by Andersen A. A. (1958).

3. Verfahren zur Bestimmung der Atmungsaktivität (Druckdifferenz) / *method for the determination of the breathability (differential pressure)*

Testprinzip / ***test principle***
In einem Versuchsaufbau wird die Druckdifferenz gemessen, indem Luft bei einem Luftstrom von 8l/min durch eine definierte Grundfläche des Materials gezogen wird.

Die Druckdifferenz wird mit einem Druckmessmodul gemessen. Gilmont-Instrumente-Flowmeter oder ein Flowmeter von vergleichbarer Präzision werden für die Messung des Luftstroms benutzt. Das Probenmaterial wird zwischen die Prüfflächen geklemmt, so dass das Probenmaterial quer zum Luftdurchfluss in der Strömung platziert ist. Die Vakuumpumpe wird eingeschaltet und die Durchflussrate der Luft wird am Flowmeter über ein Nadelventil auf 8l/min eingestellt. Durch das Druckmessmodul wird der Druck m1 und m2 gemessen und aufgezeichnet.

Dieses Verfahren wird an 5 unterschiedlichen Stellen der Materialien angewendet und der Mittelwert ermittelt.



In an experimental setup the differential pressure is measured, as air is pulled with an air flow by 8l/min through a defined surface area of the material.

The differential pressure is measured with a pressure measuring module. Gilmont-Instrumente-Flowmeter or a flowmeter of comparable precision are used for the measurement of the air flow. The sample material is wedged between the test surfaces, so that the sample material is placed transverse to the air flow. The vacuum pump is switched on and the flow rate of air is adjusted at the flowmeter over a needle valve to 8l/min. The pressure m1 and m2 is measured and noted with the pressure measuring module.

This procedure will be performed at 5 different places of the materials and the mean value is determined.

4. Probenentnahmeverfahren für Prüfung der mikrobiologischen Reinheit / *sampling procedure for testing of microbial cleanliness (bioburden)*

Wenn die Proben durch den Auftraggeber in einer originalen Primärverpackung bereitgestellt werden, also genau so wie sie dem Endbenutzer angeboten werden, dann werden 5 Prüfkörper wie folgt entnommen:
Die oberste und die unterste sowie 3 weitere zufällig gewählte Masken.

If the samples are provided by the client in original primary packaging, i.e. exactly as they are offered to the end user, then 5 test samples are taken out as follows:
The top and bottom and 3 others randomly chosen masks.

附件

China

TÜV SÜD China, Shanghai Branch
No. 88 Heng Tong Road, Shanghai 200 070, P.R. China

Choose certainty.
Add value.

声明

致上海生物材料测试研究中心：

2020-04分包的样品，医用外科口罩Surgical Mask，客户四川艾医生医疗科技有限公司Sichuan Ai Doctor Medical Technology Co.,Ltd.

吸收容量如下：

以每单件样品的总表面积为323cm2，作为一单元来计算样品吸收容量。

（1）当浸提介质为MEM、浸提条件为37℃、24h时，单件样品的总吸收容量为15ml；

（2）当浸提介质为0.9%氯化钠注射液、浸提条件为70℃、24h时，单件样品的总吸收容量为9ml；

（3）当浸提介质为棉籽油、浸提条件为70℃、24h时， 单件样品的总吸收容量为14ml；

烦请实验室安排，谢谢！

联系人：张敏
南德认证检测（中国）有限公司上海分公司
TUV SUD China
2020.06.15

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TESTING
CNAS L1538

Test Report

TEST ITEMS

Test for irritation (Animal skin irritation test)

TEST ARTICLE

Surgical Mask
<Product Type: Earloop Type; LOT: 20200401>

IDENTIFICATION №

2004119

MANUFACTURER

Sichuan Ai Doctor Medical Technology Co., Ltd.
<Address: No.333, Yongke Road, Yongsheng Town, Wenjiang District, Chengdu City, Sichuan Province, China>

SPONSOR

TÜV SÜD Certification and Testing (China) Co., Ltd. Shanghai Branch
<Address: 3-13, No.151 Heng Tong Road>

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SUMMARY

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

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

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

Study and Supervisory Personnel: YE Zhongjie
MA Jiadong
LU Hua

Study Director: Sun Jiao SUN Jiao, Ph.D. June 16. 2020 Date Completed

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INTRODUCTION

This study was conducted to determine whether the test extract would cause local dermal irritant effects following contacted the rabbit skin. This study was conducted based on the requirements of ISO 10993-10:2010: Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization. The test article was received on Apr. 30, 2020. Treatment began on May 17, 2020, and the final observations were concluded on May 22, 2020.

This study was completed in the Lab of Shanghai Biomaterials Research & Test Center (SBRTC). SBRTC was conducted in accordance with the provisions of the ISO/IEC 17025-2005.

MATERIALS

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

Test Article:	Surgical Mask <Product Type: Earloop Type; LOT: 20200401>
Identification №:	2004119
Storage Conditions:	Room temperature
Sterilization Status:	STERILE
Extraction Vehicles:	0.9% Sodium Chloride Injection (SC) Cotton Seed Oil (CSO)
Test Extract Preparation:	According to the statement of the sponsor, the absorption capacity of each piece of test sample was 9ml SC and 14ml CSO [Volume of extraction vehicle to 323cm^2 of the test sample] separately. Based on the ISO 10993-12:2012, the ratio of 6cm^2/ml [Surface area of the test sample to volume of extraction vehicle], 323cm^2 of the test samples were covered with 53.8ml of extraction vehicles, then added an additional 9ml SC and additional 14ml CSO separately under aseptic conditions for preparing test extracts at 70℃ for 24h with continuously agitation during extraction respectively. The extracts were used after extraction.
Reagent Controls:	Two extraction vehicles without the test sample were similarly prepared respectively.
Condition of Extracts:	All the extracts of the test samples and controls were clear, no suspended particulates and without any special treatments.

In addition, according to the requirement of ISO 10993-10:2010, 10% Sodium Dodecyl Sulfate as a positive control was used previously for another study (2020.3.23-2020.3.27). Complete data was traceable in laboratory records.

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METHODS

Test System:

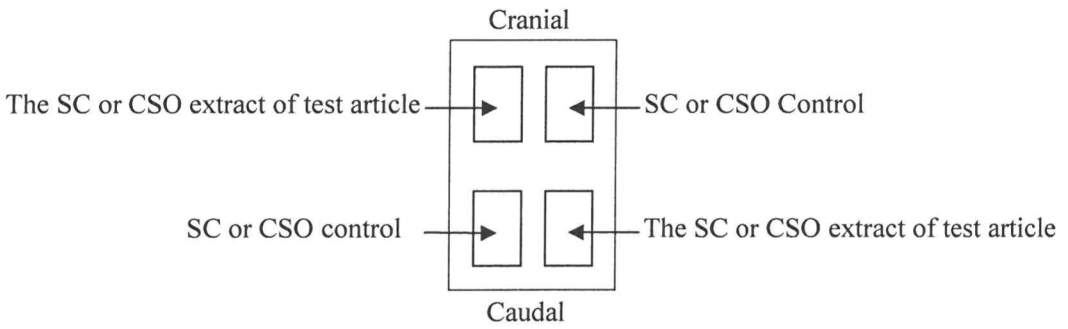
Species:	Rabbit
Strain:	New Zealand White
Source:	SHANGHAI SONGLIAN LAB ANIMAL-FIELD
Sex:	Half males and half females
Body weight range:	2.3 kg ~ 2.6 kg
Age:	Young adult
Number of animals:	Six

Animal Management:

Husbandry:	Conditions conformed to "Laboratory animal-Requirements of environment and housing facilities".
Food:	Diet was provided from Shanghai Pu Lu Teng Biological Technology Co. Ltd.
Housing:	Healthy animals were acclimatized to the laboratory conditions for 7 days before the treatment, and then they were individually housed in stainless steel suspended cages identified by a card indicating the Identification № of the test article and first treatment date.
Environmental:	The room temperature and humidity were monitored daily. The room temperature range was from 20℃ to 26 ℃. The room humidity range was from 50 % to 70 %.
Personnel:	Associates involved were appropriately qualified and trained.
Selection:	Only healthy, previously unused rabbits were selected.

Experimental Procedure:

On the day before the test, the rabbits were closely clipped the fur on the backs of the animals, and both sides of the spinal for application and observation of all test sites, approximately 10cm× 15cm. A 25mm×25mm section of absorbent gauze patch was saturated with freshly prepared the extract, and then was applied to test sites. The extract of the test article and the reagent control were applied to the region as illustrated below:



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

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

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

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

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

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RESULTS

All animals appeared clinically normal throughout the study. All sites of the test extracts and the reagent controls appeared normal following removal the patches; the score of the test extracts and the reagent controls all were 0.
The Primary Irritation Index (PII) of each test extract was all 0.0.

Results and conclusions applied only to the test article tested. No further evaluation of these results was made by Shanghai Biomaterials Research & Test Center.

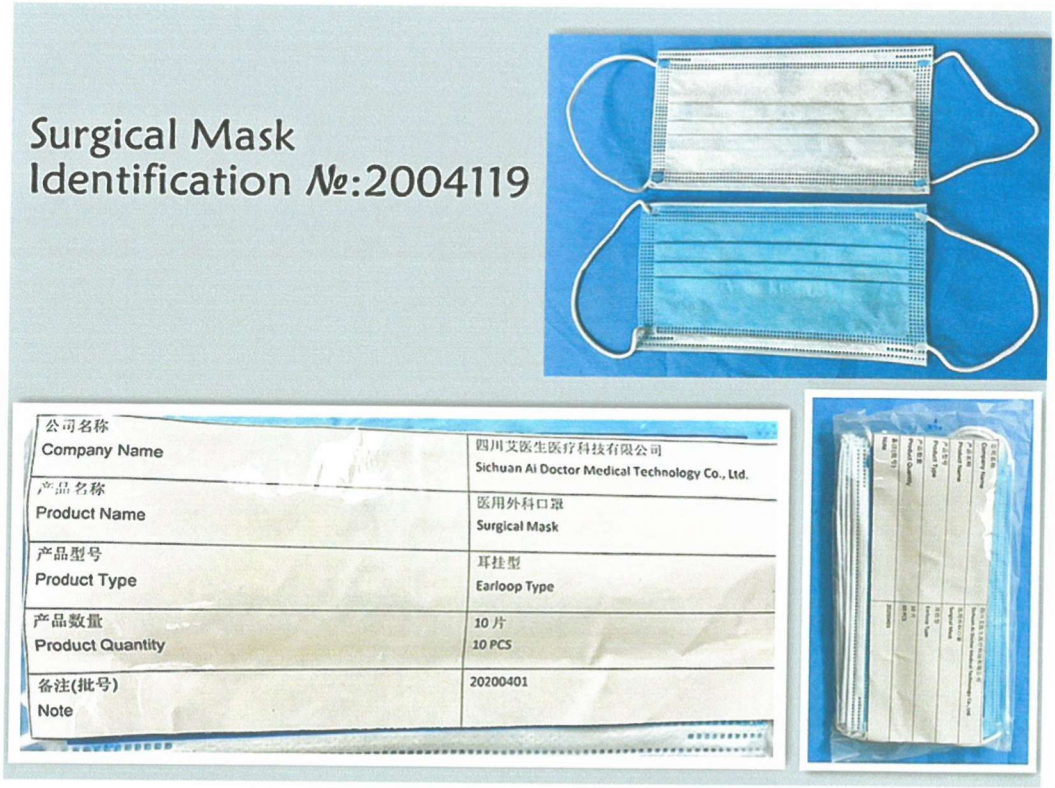
CONCLUSION

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

RECORD STORAGE

All raw data pertaining to this study and a copy of the final report were stored in the designated archive files at Shanghai Biomaterials Research & Test Center.

PHOTOGRAPH OF THE TEST ARTICLE



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CNAS L1538

Test Report

TEST ITEMS

Test for skin sensitization (Maximization test)

TEST ARTICLE

Surgical Mask
<Product Type: Earloop Type; LOT: 20200401>

IDENTIFICATION №

2004119

MANUFACTURER

Sichuan Ai Doctor Medical Technology Co., Ltd.
<Address: No.333, Yongke Road, Yongsheng Town, Wenjiang District, Chengdu City, Sichuan Province, China>

SPONSOR

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SUMMARY

A guinea pig maximization test of the test article, Surgical Mask, was conducted to evaluate the skin sensitizing potential. This study was based on the International Organization for Standardization ISO 10993-10:2010: Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization; ISO 10993-12:2012: Biological evaluation of medical devices Part 12: Sample preparation and reference materials.

The test sample was extracted in 0.9% sodium chloride injection (SC) and cotton seed oil (CSO). Each extract was injected intradermally and patched occlusively to ten test guinea pigs (per extract) in an attempt to induce sensitization. The vehicle was similarly injected and patched occlusively to five reagent control guinea pigs (per vehicle). Following a recovery period, the test and reagent control animals were received a challenge patch of the appropriated test sample extract and the reagent control. All sites were scored at 24h and 48h after patch removal.

Under the conditions of this study, the SC and CSO extracts of the test samples showed no evidence of causing sensitization in the guinea pigs.

Study and Supervisory Personnel: YE Zhongjie
JIN Ruifen
LIU Siyuan
LU Hua

Study Director: Sun Jiao June 16. 2020
SUN Jiao, Ph.D. Date Completed

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INTRODUCTION

A guinea pig maximization study of the test article identified below was conducted to evaluate the potential to cause contact sensitization. This test was conducted based on the requirements of ISO 10993-10:2010: Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization. The test article was received on Apr. 30, 2020. Treatment began on May 10, 2020, and the final observations were concluded on Jun. 5, 2020.

This study was completed in the lab of Shanghai Biomaterials Research & Test Center (SBRTC). SBRTC was conducted in accordance with the provisions of the ISO/IEC 17025-2005.

MATERIALS

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

Test Article:	Surgical Mask <Product Type: Earloop Type; LOT: 20200401>
Identification №:	2004119
Sterilization Status:	STERILE
Storage Conditions:	Room Temperature
Extraction Vehicles:	0.9% Sodium Chloride Injection (SC) Cotton seed oil (CSO)
Test Extract Preparation:	According to the statement of the sponsor, the absorption capacity of each piece of test sample was 9ml SC and 14ml CSO [Volume of extraction vehicle to 323cm^2 of the test sample] separately. Based on the ISO 10993-12:2012, the ratio of 6cm^2/ml [Surface area of the test sample to volume of extraction vehicle], 323cm^2 of the test samples were covered with 53.8ml of extraction vehicles, then added an additional 9ml SC and additional 14ml CSO separately under aseptic conditions for preparing test extract at 70℃ for 24h with continuously agitation during extraction respectively. The extracts were used after extraction.
Reagent Controls:	Two extraction vehicles without the test sample were similarly prepared respectively.
Condition of Extracts:	All the extracts of the test samples and controls were clear, no suspended particulates and without any special treatments.
Additional Materials:	Freund's Complete Adjuvant (FCA) was mixed 50:50 (v/v) with the vehicle. A 10% (w/w) sodium dodecyl sulfate suspension in paraffin.

In addition, according to the requirement of ISO 10993-10:2010, 5% mercaptobenzothiazole (dissolved in DMSO) as a positive control was used previously for another study (2020.4.7-2020.5.2). Complete data was traceable in laboratory records.

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METHODS

Test System:

Species:	Albino guinea pig
Source:	SHANGHAI SONGLIAN LAB ANIMAL-FEILD
Sex:	Half males and half females (females were nonpregnant)
Body Weight Range:	300. 4g to 355. 0g
Age:	Young adult
Number of animals:	Thirty

Animal Management:

Husbandry:	Conditions conformed to "Laboratory animal-Requirements of environment and housing facilities"; "ISO 10993-2:2006: Biological evaluation of medical devices Part 2: Animal welfare requirements".
Food:	Diet was provided from Shanghai Pu Lu Teng Biological Technology Co. Ltd.
Housing:	Healthy animals were acclimatized to the laboratory conditions for 5 days before the treatment, and then they were randomized and assigned to groups in cages identified by a card indicating the Identification № of the test article and first treatment date.
Environmental:	The room temperature and humidity were monitored daily. The room temperature range was from 20℃ to 26℃. The room humidity range was from 50% to 70 %.
Personnel:	Associates involved were appropriately qualified and trained.
Selection:	Only healthy, unused animals were selected.

Experimental Procedure:

1. Intradermal induction phase (Induction I):

The day prior to treatment, the fur was clipped on all treatment sites with an electric clipper. The 1st day, the test animals were injected with the fresh extracts of test sample and the control animals were injected with the reagent control. Three rows of intradermal injections (two per row) were given to each animal within an approximate 2cm×4cm boundary of the fur clipped area as illustrated below:

Cranial

a	a
b	b
c	c

Caudal

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Test Animals:

a) 0.1ml of 50:50(v/v) mixture of FCA and the chosen vehicle
b) 0.1ml of test extract
c) 0.1ml of 50:50(v/v) mixture of a and b

Control Animals:

a) 0.1ml of 50:50(v/v) mixture of FCA and the vehicle
b) 0.1ml of vehicle
c) 0.1ml of 50:50(v/v) mixture of a and b

2. Topical induction phase (Induction II):

At 7th day after completion of the intradermal induction phase, the same area was clipped free of fur and treat with 10% sodium dodecyl sulfate suspension in paraffin. The suspension was massaged into the skin over the injection site to provoke a mild acute inflammation. The area was left uncovered.

At 8th day, a 20mm×40mm section of absorbent gauze patch, saturated with freshly prepared the extract of the test sample, and then was topically applied to the previously injected sites of the test animals. The control animals were similarly patched with the appropriate reagent control. Each patch was secured with an occlusive dressing. The dressings and patches were removed after 48h.

3. Challenge phase

At 22nd day, the fur was clipped and shaved from the left flank areas. At 23rd day, absorbent gauze patches were soaked with the corresponding solution at the concentration of site C, and patched on the left upper flank of each animal in test and reagent control group. Then the animals were secured with an occlusive dressing. The dressings and patches were removed after 24h.

4. Observation of animals

The appearance of the challenge skin sites of the test and control animals was observed respectively at 24h and 48h after removal of the dressing. The skin reactions for erythema and swelling were described and graded in according with the criteria shown below:

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

If the grades of less than 1 are seen in reagent control animals, grades of 1 or greater in the test group were generally indicated sensitization.

RESULTS

Clinical Observation:

All animals appeared clinically normal throughout the study.

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Dermal Observations:

No evidence of sensitization was observed. Individual results of dermal scoring for the challenge phase shown below:

	Hours following patch removal			
Time	24h		48h	
Vehicle	SC	CSO	SC	CSO
Test sample	0	0	0	0
Reagent Control	0	0	0	0

Results and conclusions applied only to the test article tested. No further evaluation of these results was made by Shanghai Biomaterials Research & Test Center.

CONCLUSION

Under the conditions of this study, the SC and CSO extracts of the test samples showed no evidence of causing sensitization in the guinea pigs.

RECORD STORAGE

All raw data pertaining to this study and a copy of the final report were stored in the designated archive files at Shanghai Biomaterials Research & Test Center.

PHOTOGRAPH OF THE TEST ARTICLE

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CNAS L1538

Test Report

TEST ITEMS

Test for *in vitro* cytotoxicity (MTT cytotoxicity test)

TEST ARTICLE

Surgical Mask
<Product Type: Earloop Type; LOT: 20200401>

IDENTIFICATION №

2004119

MANUFACTURER

Sichuan Ai Doctor Medical Technology Co., Ltd.
<Address: No.333, Yongke Road, Yongsheng Town, Wenjiang District, Chengdu City, Sichuan Province, China>

SPONSOR

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<Address: 3-13, No.151 Heng Tong Road>

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SUMMARY

An in vitro cytotoxicity study was conducted to assess the potential for cytotoxicity of the test article, Surgical Mask, basd on the International Organization for Standardization ISO 10993-5:2009: Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity; ISO 10993-12:2012: Biological evaluation of medical devices - Part 12: Sample preparation and reference materials.

Four concentrations (100%, 75%, 50%, and 25%) of the test sample extracts, the blank, 100% of the negative control and the positive control were prepared using Minimum Essential Medium (MEM) supplemented with 10% fetal bovine serum. The semi-confluent monolayers of L-929 mouse fibroblast cells were incubated with the test extract, the blank and other two controls, supplemented with 10% fetal bovine serum in a 96-well microplate respectively at 37℃ under the condition of 5% CO_2. At 24h, the MTT colorimetric assay was employed and the plate was read on a microplate reader at 570 and 650 nm. The viability of the cells was calculated.

Under the condition of this study, the viability of 100% extract of the test sample was 84 %. It can be considered that the test sample extracts had not a cytotoxic potential.

Study and Supervisory
Personnel: XU Yuan
HUANG Zhewei

Study Director: Sun Jiao — June 16, 2020
SUN Jiao, Ph.D. Date Completed

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INTRODUCTION

The study was performed in order to determine whether leachables extracted from the test article would cause cytotoxicity. This test was conducted based on the requirements of ISO 10993-5:2009: Biological evaluation of medical devices - Part 5: Tests for *in vitro* cytotoxicity. The test article was received on Apr. 30, 2020. The cells were first exposed to the extract May 14, 2020 and the final observations were concluded on May 15, 2020.

This study was completed in the Lab of Shanghai Biomaterials Research & Test Center (SBRTC). SBRTC was conducted in accordance with the provisions of the ISO/IEC 17025-2005.

MATERIALS

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

Test Article:	Surgical Mask <Product Type: Earloop Type; LOT: 20200401>
Identification №:	2004119
Sterilization Status:	Sterile
Storage Temperature:	Room temperature
Extraction Vehicle:	gibco's Minimum Essential Medium supplemented with L-glutamine and 10% fetal bovine serum
Test Extract Preparation:	According to the statement of the sponsor, the absorption capacity was 15ml/one piece [Volume of extraction vehicle to 323cm^2 of the test sample]. Based on the ISO 10993-12:2012, the ratio of 6cm^2/ml [Surface area of the test sample to volume of extraction vehicle], 323cm^2 of the whole test samples were covered with 53.8ml of extraction vehicles, then added an additional 15ml of extraction vehicles under aseptic conditions for preparing the test extract at 37℃ for 24 hours with continuously agitation during extraction. The extract was used immediately after extraction.
Blank Preparation:	The extraction vehicle not containing the test sample, retained in a vessel identical to that which holds the test sample and subjected to conditions identical to those to which the test sample is subjected during its extraction.
Negative Control Preparation :	Current SBRTC negative control, the ratio of 3cm^2 High-density polyethylene film : 1ml [surface area of the test sample to volume of extraction vehicle] was used and extracted at 37℃ for 24 hours.
Positive Control Preparation:	Current SBRTC positive control, the ratio of 6cm^2 Polyurethane film containing 0.1% zinc diethyldithiocarbamate (ZDEC) : 1ml [surface area of the test sample to volume of extraction vehicle] was used and extracted at 37℃ for 24 hours.
Condition of Extracts:	All the extracts of the test and controls were clear, no suspended particulates and without any special treatments.

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METHODS

Test System Management:

Mouse fibroblast cells (L 929, from the cell bank of Shanghai Institutes for Biological Sciences), were cultured in MEM supplemented with L-glutamine and 10% fetal bovine serum at 37℃ in a gaseous environment of 5% carbon dioxide (CO_2). A 96-well microplate method was employed for the MTT colorimetric assay. Each well was seeded 100μl suspension of 1×10^4 cells, and incubated at 37℃ in 5% CO_2 atmosphere for 24h prior to use.

Experimental Procedure:

After incubation, the growth medium was replaced with 100μl four concentrations (100%, 75%, 50% and 25%) of the test extract, 100% of the negative control and the positive control, the blank (row 2 and 11) respectively. Six replicates were prepared for each group. The 96-well plate were incubated at 37℃ in 5% CO_2 for 24h.

After 24 h treatment, the culture medium was removed carefully from the plates. 50μl of the MTT (1mg/mL) solution was then added to each test well and the plates were further incubated for 2 h at 37℃ in a 5% CO_2 atmosphere. Then the MTT solution was removed and 100μl isopropanol per well was added and shake for 10min by gently. The plate was read on a microplate reader at 570 nm (reference wavelength 650 nm). The viability of the cells was calculated according to the formula below:

$$\text{Viab. \%} = \frac{100 \times OD_{570e}}{OD_{570b}}$$

Where

OD_{570e} is the mean value of the measured optical density of the extracts of the test sample;

OD_{570b} is the mean value of the measured optical density of the blanks;

A test meets acceptance criteria if the left and the right mean of the blanks do not differ by more than 15% from the mean of all blanks. If the viability of the test sample was reduced to <70% of the blank, it had a cytotoxic potential. The 50% extract of the test sample should have at least the same or a higher viability than the 100% extract; otherwise the test should be repeated.

RESULTS

Group	The optical density (570nm−650 nm)	Viab. %
100% of the negative control	0.791±0.030	100
100% of the test extract	0.669±0.019	84
75% of the test extract	0.700±0.024	88
50% of the test extract	0.720±0.015	91
25% of the test extract	0.743±0.030	94
100% of the positive control	0.038±0.006	5
The blank (row 2)	0.788±0.027	/
The blank (row 11)	0.796±0.027	/

Note: n=6

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The mean value of optical density of the blank was 0.792±0.026. Both the left (row 2) and the right (row 11) mean of the blanks were less than 15% from the mean of all blanks.

Results and conclusions apply only to the test article tested. No further evaluation of these results was made by Shanghai Biomaterials Research & Test Center.

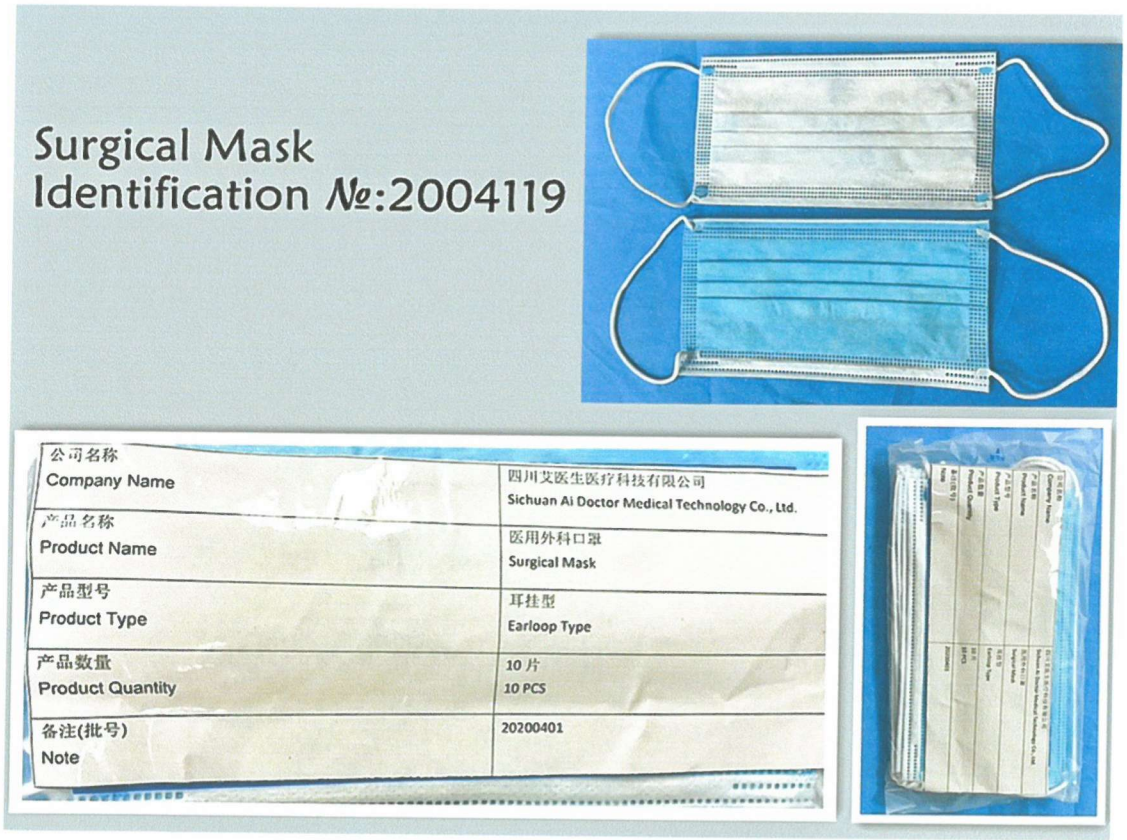
CONCLUSION

Under the condition of this study, the viability of 100% extract of the test sample was 84%. It can be considered that the test sample extracts had not a cytotoxic potential.

RECORD STORAGE

All raw data pertaining to this study and a copy of the final report are to be stored in the designated archive files at Shanghai Biomaterials Research & Test Center.

PHOTOGRAPH OF THE TEST ARTICLE



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