DECLARATION OF CONFORMITY

Regarding Medical Device Regulation (EU) 2017/745

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

Address: 333 Yongke Road, Yongsheng Town, Wenjiang District, Chengdu City, Sichuan Province, China

EC Representative: SUNGO Europe B.V.

Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Product Name: Medical Face Mask HYGISUN®

SRN: /

Basic UDI-DI: /

Classification Class I

Rule: Rule 5, 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.

On behalf of SUNGO Europe office
EU REP of the company who issue

Sungo global service

Autho

EN ISO 14971: 2012
EN ISO 15223-1: 2016
EN 1041:2008+A1:2013
EN14683:2019+AC:2019

ISO 10993-1: 2018
EN ISO 10993-5: 2009
EN ISO 10993-10: 2013

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

Signature: Yingbo Tang

Name / Position: Yingbo Tang / General Manager

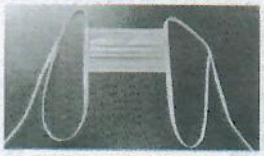
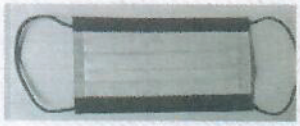
Date: 2020.11.23

Place: China

Sungo global service

Authorized Signature (S)

Annex

Product	Model	Basic UDI-DI	Picture
Medical Face Mask	Earloop Type 170*95MM		 
Medical Face Mask	Tie-on Type 170*95MM		 
Medical Face Mask	HS0402R （Black/Schwarz）		 
On behalf of SUNGO Europe office, I confirmed we are EU REP of the company who issue this document. Sungo global service *Authorized Signature (S)*			*I confirmed we are his document.* *zed Signature (S)*

Signature: Yingbo Tang

Name / Position: Yingbo Tang / General Manager

Date: 2020.11.23

Place: China

DECLARATION OF CONFORMITY

Regarding Medical Device Regulation (EU) 2017/745

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

Address: 333 Yongke Road, Yongsheng Town, Wenjiang District, Chengdu City, Sichuan Province, China

EC Representative: SUNGO Europe B.V.

Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Product Name: Surgical Mask HYGISUN®

SRN: /

Basic UDI-DI: /

Classification Class I

Rule: Rule 5, 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.

On behalf of SUNGO Europe
EU REP of the company who

EN ISO 14971: 2012	ISO 10993-1: 2018
EN ISO 15223-1: 2016	EN ISO 10993-5: 2009
EN 1041:2008+A1:2013	EN ISO 10993-10: 2013
EN14683:2019+AC:2019	

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

Signature: Yingbo Tang

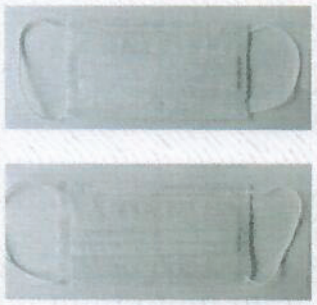
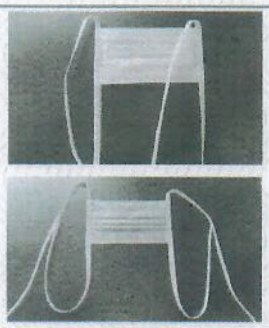
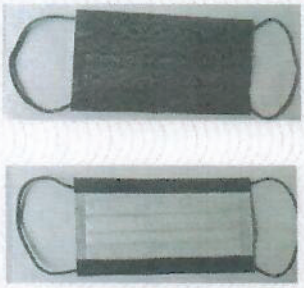
Name / Position: Yingbo Tang / General Manager

Date: 2020.11.23

Place: China

Authorized Signature (S)

Annex

Product	Model	Basic UDI-DI	Picture
Surgical Mask	Earloop Type 170*95MM Non-sterile		
Surgical Mask	Tie-on Type 170*95MM Non-sterile		
Surgical Mask	HS0402R （Black/Schwarz） Non-sterile		
On behalf of SUNGO Europe office, I confirmed we are EU REP of the company who issue this document.			*ffice, I confirmed we are sue this document.*
Sungo global service	*Authorized Signature (S)*		*thorized Signature (S)*

Signature: Yingbo Tang

Name / Position: Yingbo Tang / General Manager

Date: 2020.11.23

Place: China

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:
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Rijnstraat 50
2515 XP Den Haag

T 070 340 6161

http://hulpmiddelen.farmatec.nl

Inlichtingen bij:
M.P. Meijer - Michiels

medische_hulpmiddelen@minvws.nl

Ons kenmerk:
CIBG-20205750

Bijlagen
-

Uw aanvraag
1 december 2020

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

Datum: 15 december 2020
Betreft: notificatie medische hulpmiddelen klasse I

Geachte heer Luo,

Hierbij bevestig ik de ontvangst op 1 december 2020 van de notificatie van de medische hulpmiddelen klasse I, die bedrijf Sichuan Ai Doctor Medical Technology Co., Ltd., met Europees gemachtigde SUNGO Europe B.V. , als fabrikant overeenkomstig Verordening (EU) 2017/745 (MDR) op de markt wenst te gaan brengen.
De producten zijn onder volgend kenmerk geregistreerd. Ik verzoek u om in alle verdere correspondentie over een of meer van deze producten het bijbehorende kenmerk te vermelden en het bij telefoongesprekken bij de hand te houden.

Medical Face Mask
(geen merknaam) (NL-CA002-2020-54533)
Surgical Mask
(geen merknaam) (NL-CA002-2020-54534)

Ik wijs u erop dat medische hulpmiddelen die op de markt gebracht worden volgens de MDR over een systeem voor hulpmiddelindicatie (UDI) moeten beschikken[1] en dat fabrikanten, gemachtigden en importeurs in de Europese databank voor Europese hulpmiddelen (Eudamed) moeten worden geregistreerd[2]. Bijlage VI van de MDR bevat de bij de registratie te verstrekken gegevens.
Op dit moment is Eudamed nog niet in gebruik, zodat het wat betreft het bovenstaande voldoende is dat u uw producten overeenkomstig de huidige wet- en regelgeving hebt genotificeerd.

Zodra Eudamed volledig in gebruik is, wordt de fabrikant of diens gemachtigde geacht binnen achttien maanden bovenstaande hulpmiddelen te registreren in Eudamed.[3]

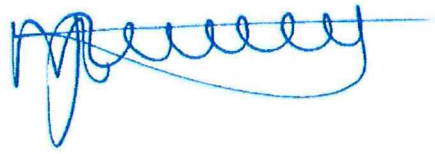
---

[1] O.g.v. art. 29 MDR.
[2] O.g.v. art. 31 MDR.
[3] www.camd-europe.eu/wp-content/uploads/2018/05/FAQ_MDR_180117_V1.0-1.pdf. Zie vraag en antwoord nummer 20.

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

De Minister voor Medische Zorg en Sport,
namens deze,

Afdelingshoofd
Farmatec



Dr. M.J. van de Velde

CMA
160000343608

中国认可
国际互认
检测
TESTING
CNAS L0412

检 测 报 告

(Test Report)

No. GOLCXHJP953425L1

样品名称 (Sample Description)	一次性医用口罩（非无菌） Medical Face Mask (non-sterile)
委托单位 (Applicant)	四川艾医生医疗科技有限公司 Sichuan Ai Doctor Medical Technology Co.,Ltd.

PONY 谱尼测试
Pony Testing International Group

声 明
Statement

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After the applicant finishes the procedure mentioned above, PONY shall arrange the retest as soon as possible. If the retest result accords with the applicant dissent, PONY shall refund the retest fees.

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上海实验室: (021) 64851999　长春实验室: (0431)85150908　石家庄实验室: (0311)85376660　温州实验室: (0577)88271060
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天津实验室: (022) 23607888　西安实验室: (029) 89608785　杭州实验室: (0571)85806807　厦门实验室: (0592)5568048
苏州实验室: (0512)62997900　太原实验室: (0351) 7555762　宁波实验室: (0574)87977185　成都实验室: (028) 87702708

检 测 结 果
(Test Results)

No. GOLCXHJP953425L1

样品名称 (Sample Description)	一次性医用口罩（非无菌） Medical Face Mask (non-sterile)	样品规格 (Sample Specification)	170mm*95mm
委托单位 (Applicant)	四川艾医生医疗科技有限公司 Sichuan Ai Doctor Medical Technology Co.,Ltd.	商标 (Trade Mark)	——
到样日期 (Received Date)	2020-11-27	生产日期或批号 (Manufacturing Date or Lot No.)	2020.11.01 20201101
检测日期 (Test Date)	2020-11-27~2020-12-07	样品等级 (Sample Grade)	——
样品状态 (Sample Status)	正常 Normal	检测类别 (Test Type)	委托检测 Commissioning Test
检测项目 (Test Items)	见下页 See next page	检测环境 (Test Environment)	符合要求 To meet the requirements
检测方法 (Test Methods)	见下页 See next page		
所用主要仪器 (Main Instruments)	口罩细菌过滤效率检测仪 等 Mask bacteria filtration efficiency detector etc.		
备注 (Note)	1.型号：Earloop Type Model：Earloop Type 2.生产单位/受检单位：四川艾医生医疗科技有限公司 Manufacturer/Tested company：Sichuan Ai Doctor Medical Technology Co.,Ltd. 3.以上样品信息由委托单位提供 The information of sample was provided by the applicant 4.该报告中检测方法由委托单位指定。 The testing methods mentioned in this report were designated by the applicant. 5.限值标准：BS EN 14683:2019（IIR 型） Limit Standard：BS EN 14683:2019(Type IIR)		
PONY 专用章 (Special Stamp of PONY)	编制人 (Edited by)		
	审核人 (Checked by)		
	批准人 (Approved by)		
	签发日期 (Issued Date)	2020 年 12 月 07 日	

谱尼测试集团股份有限公司 Pony Testing International Group Co. Ltd.
公司地址：北京市海淀区锦带路 66 号院 1 号楼 5 层 101
Address:101,5F,Building 1, No.66 Jindai Road,Haidian District, Beijing, China
电话：010-83055000 传真：010-82619629
Tel:010-83055000 Fax:010-82619629
检测地址：北京市海淀区锦带路 66 号院 1 号楼
Testing address: Building 1, No.66 Jindai Road,Haidian District, Beijing, China

检 测 结 果
(Test Results)

No. GOLCXHJP953425L1

序号 (S/N)	检测项目 (Test Item)	单位 (Unit)	限值 (Limit)	检测结果 (Test Result)			单项结论 (Evaluation)	检测方法 (Test Method)
1	细菌过滤效率（BFE） Bacterial filtration efficiency(BFE)	%	≥98	99.82			符合 Pass	BS EN 14683:2019 附录 B Appendix B
				99.91				
				99.87				
				99.91				
				99.78				
2	压力差 Differential pressure	Pa/cm²	＜60	A	B	C	符合 Pass	BS EN 14683:2019 附录 C Appendix C
				1-1	31.9	29.6		
				1-2	26.9			
				1-3	25.9			
				1-4	29.8			
				1-5	33.4			
				2-1	28.8	29.3		
				2-2	27.8			
				2-3	25.7			
				2-4	31.0			
				2-5	33.3			
				3-1	30.3	28.3		
				3-2	28.7			
				3-3	25.6			
				3-4	28.5			
				3-5	28.2			
				4-1	35.3	30.9		
				4-2	26.3			
				4-3	28.6			
				4-4	31.9			
				4-5	32.3			
				5-1	29.0	28.6		
				5-2	25.7			
				5-3	22.7			
				5-4	34.2			
				5-5	31.4			

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Tel:010-83055000 Fax:010-82619629
检测地址：北京市海淀区锦带路 66 号院 1 号楼
Testing address: Building 1, No.66 Jindai Road,Haidian District, Beijing, China

检 测 结 果
(Test Results)

No. GOLCXHJP953425L1

序号 (S/N)	检测项目 (Test Item)	单位 (Unit)	限值 (Limit)	检测结果 (Test Result)	单项结论 (Evaluation)	检测方法 (Test Method)
3	抗溅压力 Splash resistance pressure	kPa	≥16.0	32 个试样均＞16.0 Splash resistance pressure of 32 samples were all greater than 16.0	符合 Pass	ISO 22609:2004
4	微生物洁净度 Microbial cleanliness	cfu/g	≤30	23	符合 Pass	BS EN 14683:2019 附录 D Appendix D
				17		
				16		
				17		
				17		

备注 Note：A-试样编号-测试区域编号 Test Specimen number-Test area number；B-每个测试区域的压力差 Differential pressure for each test area；C-每个试样的平均压差 The averaged differential pressure for each test specimen。

照片 Photo：

产品合格证
QUALIFIED CERTIFICATE

产品名称：一次性医用口罩（非无菌）
Product Name: Medical Face Mask (Non-sterile)

产品编号：HS0402R
REF：HS0402R

数量：50 片
Quantity: 50PCS

产品规格：170mm*95mm
Size：170mm*95mm

执行标准：EN14683：2019+AC：2019 TYPE IIR
Executive Standard：EN14683：2019+AC：2019 TYPE IIR

生产日期：20201101
MFG：

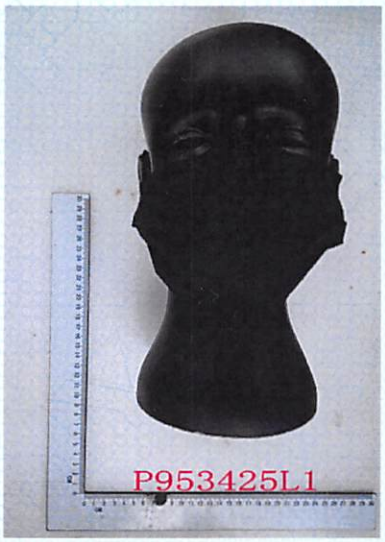
批次号：20201101
LOT

保质期：3 年
Preservative Period: 3 Years

材质：75%无纺布，25%熔喷布
Materials: 75% Non-woven fabrics, 25% Melt-blown nonwovens

生产企业：四川艾医生医疗科技有限公司
Manufactory: Sichuan AI Doctor Medical Technology Co., Ltd.

生产地址：四川省成都市温江区永盛镇永科路 333 号
Address: 333 Yongke Road, Yongsheng Town, Wenjiang District, Chengdu City, Sichuan Province, China



————以下空白————
(End of Report)

谱尼测试集团股份有限公司 Pony Testing International Group Co. Ltd.
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Address:101,5F,Building 1, No.66 Jindai Road,Haidian District, Beijing, China
电话：010-83055000 传真：010-82619629
Tel:010-83055000 Fax:010-82619629
检测地址：北京市海淀区锦带路 66 号院 1 号楼
Testing address: Building 1, No.66 Jindai Road,Haidian District, Beijing, China

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.
B-3/4, No.1999 Du Hui Road, Minhang District
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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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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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

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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-

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