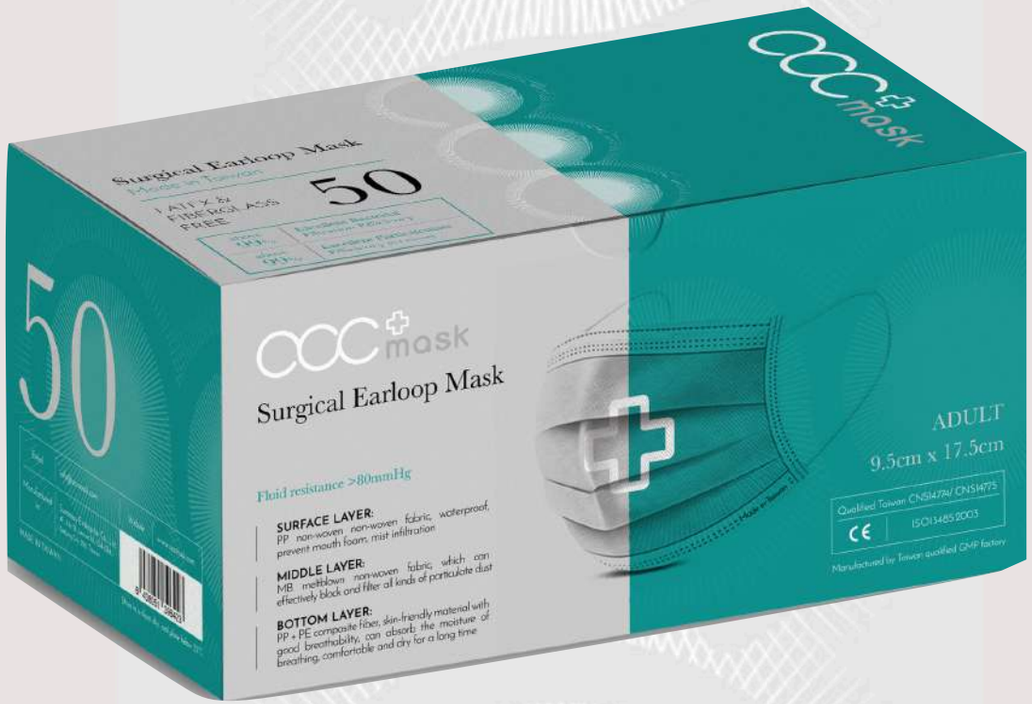
mask

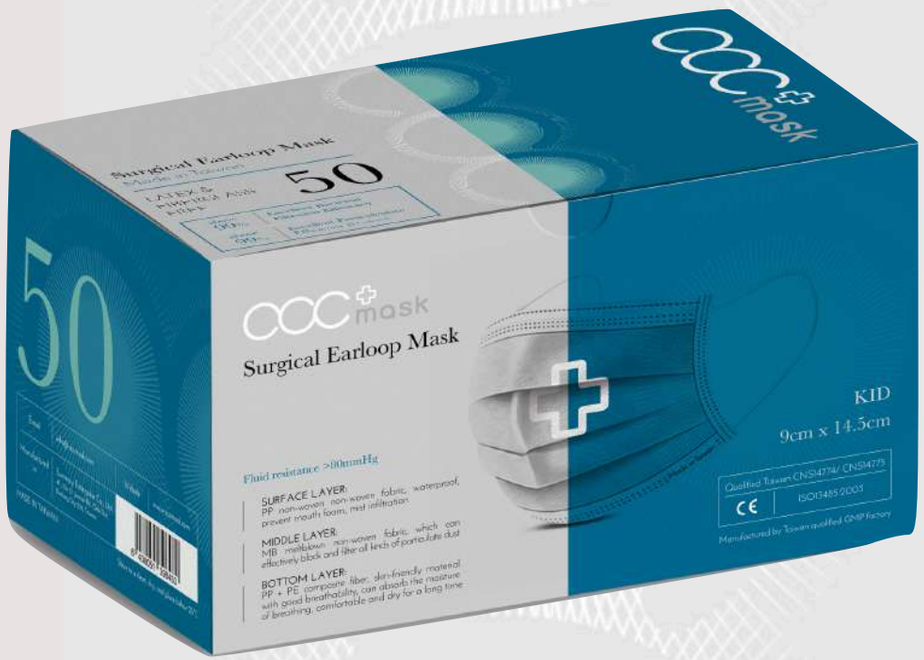
MADE IN TAIWAN

accmask Surgical Ear loop mask

mask.


Surgical Earloop Mask
Made in Taiwan
50
FREE
mask
Surgical Earloop Mask
Fluid resistance >80mmHg
SURFACE LAYER:
PP non-woven, non-woven fabric, waterproof, prevent mouth foam, mist infiltration
MIDDLE LAYER:
MB meltblown non-woven fabric, which can effectively block and filter all kinds of particulate dust
BOTTOM LAYER:
PP + PE composite fiber, skin-friendly material with good breathability, can absorb the moisture of breathing, comfortable and dry for a long time
ADULT
9.5cm x 17.5cm
Qualified Taiwan CNS14774/ CNS14775
ISO13485:2003
Manufactured by Taiwan qualified GMP factory

mask.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SURFACE LAYER:
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BOTTOM LAYER:
PP + PE composite fiber, skin-friendly material with good breathability, can absorb the moisture of breathing, comfortable and dry for a long time
KID
9cm x 14.5cm
ISO13485:2003
CE

certificate.

EN ISO 13485:2016 CERT
(NO. S20052002)

SGS

Certificate TW17/00370

The management system of

has been assessed and certified as meeting the requirements of

ISO 13485:2016
EN ISO 13485:2016

For the following activities

Manufacture of Medical Mask

This certificate is valid from 15 April 2019 until 15 April 2022 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 26 March 2022
Issue 2. Certified since 13 April 2017

Authorised by

UKAS MANAGEMENT SYSTEMS
0005

SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

HC SGS 13485 2016 0118

Page 1 of 1

Declaration of Conformity

No.: S20052001

CE

Object of the declaration:
Product: Medical Face Mask (Non-sterile)
Model/type: Various
Manufacture
Address: Keelung City 206, Taiwan
This declaration is issued under the sole responsibility of the manufacturer.

The object of declaration described above is in conformity with the relevant Union harmonization legislation:
93/42/EEC Annexl Concering Medical Devices

Conformity is shown by compliance with the applicable requirements of the following documents:

Reference & Date	Title
EN ISO 13485:2016	Medical Devices - Quality Management Systems-Requirements for regulatory purposes.

Signed for and on behalf of:
Place of issue: Keelung, Taiwan
Date of issue: 13 April 2017
Position: Management representative
Signature:

Chuang, Che-Chun

SUMEASY

SUM EASY Enterprise Co., Ltd.
2F., No. 53, Junxian Rd., Qidu Dist., Keelung City 206, Taiwan
www.sumeasy.com.tw Tel: 886-2-2456-0999

certificate.

BFE and Delta P Report

Nelson Labs.
A Sotera Health company

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

Test Article:	PID: 5CB031, Lot: 42264302
Purchase Order:	B109042209F
Study Number:	1296401-S01
Study Received Date:	05 May 2020
Testing Facility:	Nelson Laboratories, LLC 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A.
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0004 Rev 18
Deviation(s):	None

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

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

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

Test Side:	Inside
BFE Test Area:	~40 cm^2
BFE Flow Rate:	28.3 Liters per minute (L/min)
Delta P Flow Rate:	8 L/min
Conditioning Parameters:	85 ± 5% relative humidity (RH) and 21 ± 5°C for a minimum of 4 hours
Test Article Dimensions:	~172 mm x ~169 mm
Positive Control Average:	2.3 x 10^3 CFU
Negative Monitor Count:	<1 CFU
MPS:	2.8 µm

Reid Jones electronically approved for
Study Director James Luskin

22 May 2020 13:59 (+00:00)
Study Completion Date and Time

Results:

Test Article Number	Percent BFE (%)
1	99.6
2	99.5
3	99.5
4	99.8
5	99.3

Test Article Number	Delta P (mm H_2O/cm^2)	Delta P (Pa/cm^2)
1	2.5	24.5
2	2.6	25.4
3	2.6	25.3
4	2.6	25.3
5	2.6	25.3

The filtration efficiency percentages were calculated using the following equation:

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

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

certificate.

PFE Latex Particle Challenge Report

Nelson Labs.
A Sotera Health company

Latex Particle Challenge Final Report

Test Article:	PID: 5CB031, Lot: 42264302
Purchase Order:	B109042209F
Study Number:	1296400-S01
Study Received Date:	05 May 2020
Testing Facility:	Nelson Laboratories, LLC 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A.
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0005 Rev 07
Deviation(s):	Quality Event (QE) Number(s): QE22125

Summary: This procedure was performed to evaluate the non-viable particle filtration efficiency (PFE) of the test article. Monodispersed polystyrene latex spheres (PSL) were nebulized (atomized), dried, and passed through the test article. The particles that passed through the test article were enumerated using a laser particle counter.

A one-minute count was performed, with the test article in the system. A one-minute control count was performed, without a test article in the system, before and after each test article and the counts were averaged. Control counts were performed to determine the average number of particles delivered to the test article. The filtration efficiency was calculated using the number of particles penetrating the test article compared to the average of the control values.

The procedure employed the basic particle filtration method described in ASTM F2299, with some exceptions; notably the procedure incorporated a non-neutralized challenge. In real use, particles carry a charge, thus this challenge represents a more natural state. The non-neutralized aerosol is also specified in the FDA guidance document on surgical face masks. All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Test Side:	Inside
Area Tested:	91.5 cm^2
Particle Size:	0.1 µm
Laboratory Conditions:	20°C, 29% relative humidity (RH) at 1405; 20°C, 27% RH at 1510
Average Filtration Efficiency:	99.75%
Standard Deviation:	0.062

Christopher Acker electronically approved for Curtis Gerow
Study Director

30 May 2020 20:18 (+00:00)
Study Completion Date and Time

certificate.

VFE Report

Nelson Labs.
A Sotera Health company

Keelung City, 206
TAIWAN

Viral Filtration Efficiency (VFE) Final Report

Test Article:	PID: 5CB031, Lot: 42264302
Purchase Order:	B109042209F
Study Number:	1296399-S01
Study Received Date:	05 May 2020
Testing Facility:	Nelson Laboratories, LLC 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A.
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0007 Rev 16
Deviation(s):	None

Summary: The VFE test is performed to determine the filtration efficiency of test articles by comparing the viral control counts upstream of the test article to the counts downstream. A suspension of bacteriophage ΦX174 was aerosolized using a nebulizer and delivered to the test article at a constant flow rate and fixed air pressure. The challenge delivery was maintained at 1.1 - 3.3 x 10^3 plaque forming units (PFU) with a mean particle size (MPS) of 3.0 µm ± 0.3 µm. The aerosol droplets were drawn through a six-stage, viable particle, Andersen sampler for collection. The VFE test procedure was adapted from ASTM F2101.

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

Test Side:	Inside
Test Area:	~40 cm^2
VFE Flow Rate:	28.3 Liters per minute (L/min)
Conditioning Parameters:	85 ± 5% relative humidity (RH) and 21 ± 5°C for a minimum of 4 hours
Positive Control Average:	3.2 x 10^3 PFU
Negative Monitor Count:	<1 PFU
MPS:	3.1 µm

Results:

Test Article Number	Percent VFE (%)
1	99.5
2	99.5
3	99.3
4	99.6
5	99.0

Shelby Vaubel electronically approved for
Study Director James Luskin

30 May 2020 22:13 (+00:00)
Study Completion Date and Time

The filtration efficiency percentages were calculated using the following equation:

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

C = Positive control average

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

certificate.

CNS14774/CNS14775 CERT

黃哲諄 (2455-1596)

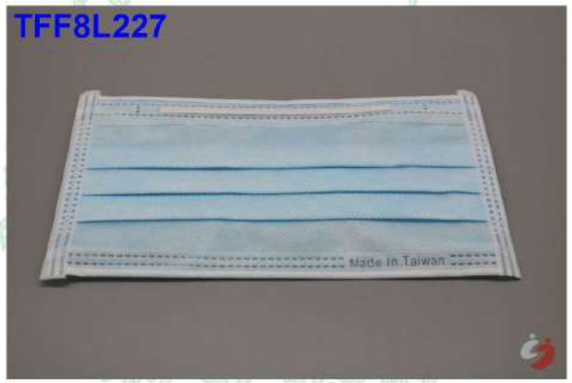
TTRI 財團法人紡織產業綜合研究所 Taiwan Textile Research Institute

日期 Date: 2019.12.19　收件日期 Date of Receipt: 2019.12.16　試驗報告 TEST REPORT　土城場區 TUCHENG

報告編號 Report No.: TFF8L227　數量 Quantity: 1件　報告頁次／頁數 Page Order/Pages: (P2/2)　來文字號 Ref. No.: 空　白

報告抬頭 Report Title: 有限公司　試件類別 Item: 口罩

地址 Address: 206



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Authorized by president of Taiwan Textile Research Institute

紡織產業綜合研究所檢測及驗證部 新北市土城區承天路6號
Department of Testing and Certification, Taiwan Textile Research Institute No.6, Chengtian Rd., Tucheng Dist., New Taipei City 23674, Taiwan (R.O.C.)
Tel : +886-2-22670321 ext. 7107, 7110
Fax : +886-2-22675108 , +886-2-22689839

黃哲諄 (2455-1596)

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報告編號 Report No.: TFF8L227-A　數量 Quantity: 1件　報告頁次／頁數 Page Order/Pages: (P1/2)　來文字號 Ref. No.: 空　白

報告抬頭 Report Title: 有限公司　試件類別 Item: 口罩

地址 Address: 206

試驗項目		試驗結果	試驗方法
細菌過濾效率(%)	1	99.7	CNS 14774 T5017-2018 9.2
金黃色葡萄球菌	2	99.7	CNS 14775 T4037-2003
ATCC 6538	3	99.8	
	4	99.8	
	5	99.8	

註: 對照組的平均菌落數：2534 CFU。
註: 平均粒徑：2.9 μm。
註: 測試面：外側。
註: 測試面積為39.5 cm²。
註: 依委託者所提供來樣資料為: "順易利"醫用口罩(未滅菌)
註: 試驗報告僅就委託者之委託事項提供試驗結果，不對產品合法性做判斷。

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Authorized by president of Taiwan Textile Research Institute

紡織產業綜合研究所檢測及驗證部 新北市土城區承天路6號
Department of Testing and Certification, Taiwan Textile Research Institute No.6, Chengtian Rd., Tucheng Dist., New Taipei City 23674, Taiwan (R.O.C.)
Tel : +886-2-22670321 ext. 7107, 7110
Fax : +886-2-22675108 , +886-2-22689839

certificate.

CNS14774/CNS14776 CERT

黃哲諄（2455-1596）

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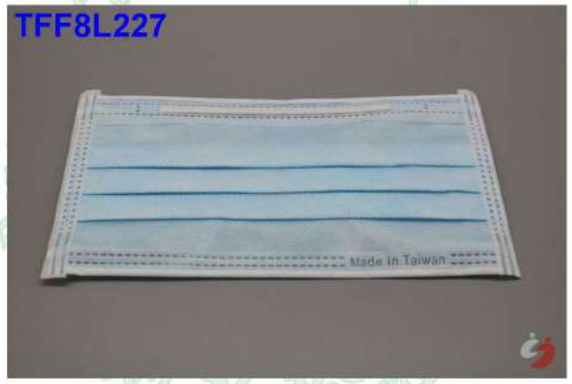
日期 Date: 2019.12.19　收件日期 Date of Receipt: 2019.12.16　試驗報告 TEST REPORT　土城場區 TUCHENG

報告編號 Report No.: TFF8L227　數量 Quantity: 1件　報告頁次／頁數 Page Order/Pages: (P2/2)　來文字號 Ref. No.: 空　白

報告抬頭 Report Title: 有限公司　試件類別 Item: 口罩

地址 Address: 206



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黃哲諄（2455-1596）

TTRI 財團法人紡織產業綜合研究所 Taiwan Textile Research Institute

TEST REPORT　TUCHENG

Date: Dec.25,2019　Date of Receipt: Dec.16,2019

Report No.: TFF8L229　Quantity: 1PC　Page Order/Pages: (P1/2)　Ref. No.: NIL

Report Title:　Item: Mask

Address:

Test Items		Test Results	Test Methods
Synthetic Blood Penetration Pressure: 160 mmHg	1	None seen	CNS 14774 T5017-2018 9.1
	2	None Seen	CNS 14776 T4038-2003
	3	None Seen	
	4	None Seen	
	5	None Seen	
	6	None Seen	
	7	None Seen	
	8	None Seen	
	9	None Seen	
	10	None Seen	
	11	None Seen	
	12	None Seen	
	13	None Seen	

Note: Sample description by the client: "SUMEASY"SURGICAL FACE MASK (NON-STERILE)

Note: The test report is the test results issued by the testing institution as requested by the consignor; it shall not determine the legitimacy of the product.

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Department of Testing and Certification, Taiwan Textile Research Institute
No.6, Chengtian Rd., Tucheng Dist., New Taipei City 23674, Taiwan (R.O.C.)
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certificate.

CNS14774/CNS14777 CERT

黃哲諄（2455-1596）

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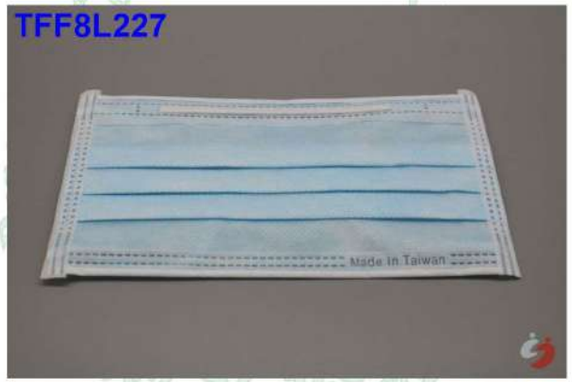
日期 Date: 2019.12.19　收件日期 Date of Receipt: 2019.12.16　試驗報告 TEST REPORT　土城場區 TUCHENG

報告編號 Report No.: TFF8L227　數量 Quantity: 1件　報告頁次／頁數 Page Order/Pages: (P2/2)　來文字號 Ref. No.: 空　白

報告抬頭 Report Title: 有限公司　試件類別 Item: 口罩

地址 Address: 206

TFF8L227



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黃哲諄（2455-1596）

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日期 Date: 2019.12.19　收件日期 Date of Receipt: 2019.12.16　試驗報告 TEST REPORT　土城場區 TUCHENG

報告編號 Report No.: TFF8L227　數量 Quantity: 1件　報告頁次／頁數 Page Order/Pages: (P1/2)　來文字號 Ref. No.: 空　白

報告抬頭 Report Title: 有限公司　試件類別 Item: 口罩

地址 Address: 206

試驗項目		試驗結果	試驗方法
空氣交換壓力差 (mmH2O/cm²)	1	3.6	CNS 14774 T5017-2011 9.3
	2	3.8	CNS 14777 T4039-2003
	3	3.9	
	4	3.9	
	5	3.7	

註：空氣交換壓力差，取5個樣品測試。

註：依委託者所提供來樣資料為："順易利"醫用口罩(未滅菌)

註：試驗報告僅就委託者之委託事項提供試驗結果，不對產品合法性做判斷。

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