DYLOR

Disposable Protective Mask

ASTM F2100-19 Level 1

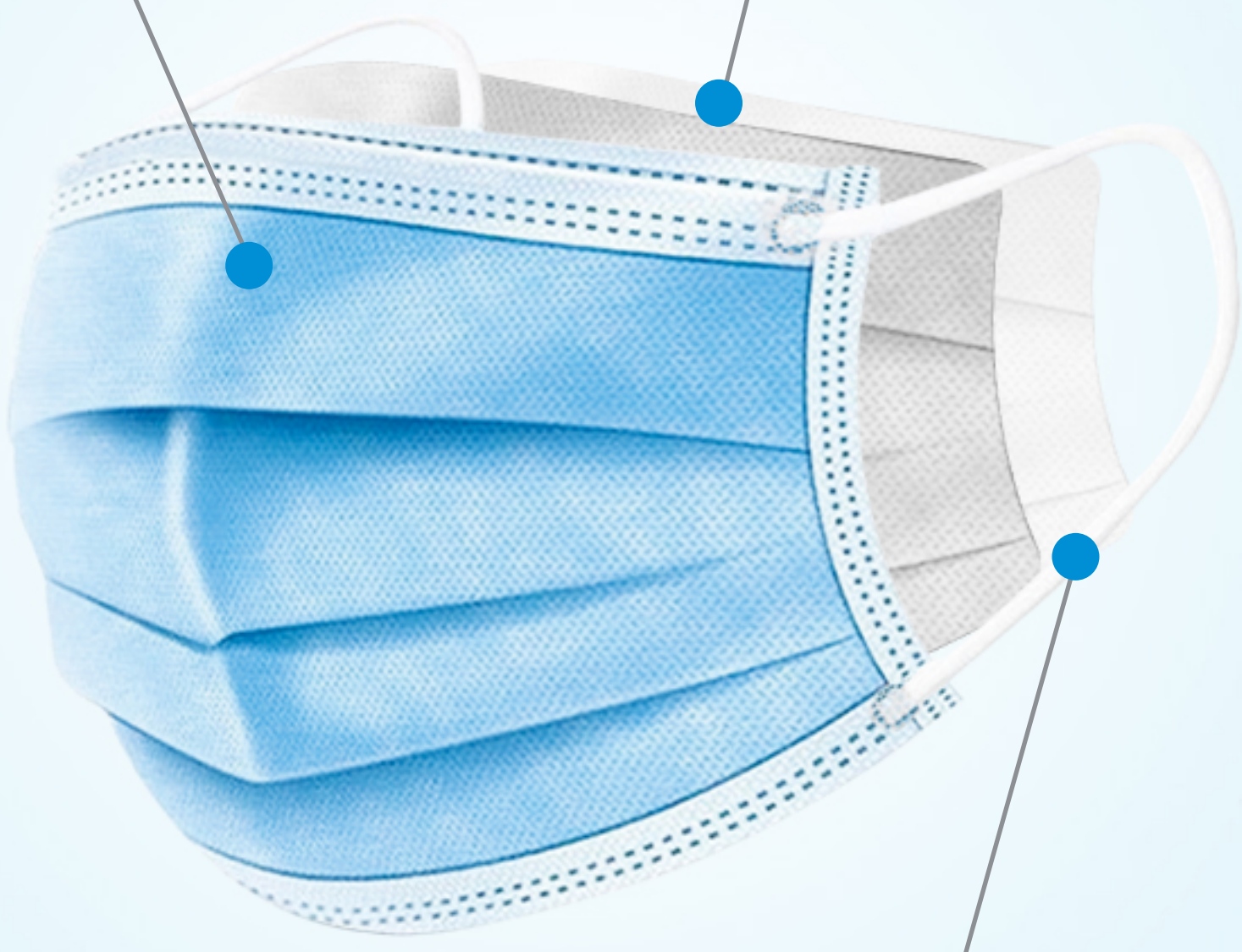
MAKE YOUR BREATH MORE COMFORTABLE

3M Certified Material Supplier
Nelson Lab approved ASTM test report

Three layer filtration

Specialty High Fluid Resistance Outer-Layer for Blood Penetration Protection

High BFE/PFE Melt-blown Filtration Layer



Flat Earloop,
More Comfortable for Longer time usage

MAKE YOUR BREATH MORE COMFORTABLE

DYLOR ASTM Level 1

Blue Mask w. Earloop

>95%
Bacterial Filtration Efficiency

>95%
Submicron Particle Filtration Efficiency

<60
Differential Pressure

80mmHg Pass
Fluid Resistance (Splash Resistance Pressure)

Class1
Flammability 16 CFR part 1610

MAKE YOUR BREATH MORE COMFORTABLE

Manufacturer Information

Zhejiang Dylor New Material Co., Ltd.
is a specially designated material supplier
for personal care products of 3M in China.

3M

3M Authorizes:

Zhejiang Dylor New Material Co., Ltd.

To be specially designated **3M** personal care products manufacturer.

Authorization Period: 2019/7/17 to 2020/12/30
Production region: Mainland China
Production Market: Personal Care Materials Market

Authorization No. LkM8hzCN201912004
Check for Authenticity on www.3m.com.cn

This certificate is valid only for the authorized party, it is not intend to be transferred to any other parties.

To verify
please scan the QR

President:Stephen M.Shafer 3M中国

3M China

Fiscal Year 2020

CERTIFICATION OF FDA REGISTRATION

This certifies that:

ZHEJIANG DYLOR NEW MATERIAL CO., LTD
Address: NO. 153 GUANG AN ROAD TONGXIANG
TONGXIANG CITY, ZHEJIANG, CHINA, 314500

has completed the FDA Establishment Registration and Device Listing with the US Food & Drug Administration, through

Owner/Operator Number: 10074510

Device Listing # :

Listing No	Code	Device Name	Proprietary Name
D399285	QKR	Face mask(except N95respirator) for general public/healthcare personnel per IIE guidance	

Dylor Inc. has verified and declares that the above stated facility is registered with the US Food & Drug Administration, Center for Drug Evaluation and Research, Office of Drug Registration and Listing pursuit to the Code of Federal Regulation 21 CFR 207, on the data state above, and makes no other representations and warranties, nor does this certificate makes other representations and warranties to other person or entity other than the name certificate holder, for whose sole benefit it is issued. Dylor Inc. assumes no liability to any person or entity in connection with the foregoing.

Dylor Inc.
Expiration Date: 2020-12-31

The data can be checked below:
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm
Web: http://www.fda.gov Tel:1-888-INFO-FDA(1-888-463-6332) e-mail:webmail@oc.fda.gov

Test Reports

ASTM Level 1 reports by Nelson Lab.

Nelson Labs
A Sotera Health company

Sponsor:
Yingkai Tang
Zhejlang Dylor New Materials Co.,Ltd
No. 153 Guang'An Road
Tongxiang, Zheijang Province,
CHINA

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

Test Article:	Disposable Protective Mask, DM20200101, Non-woven fabric 65%, Melt-blown fabric 35%, Batch number202005
Purchase Order:	20-577A
Study Number:	1306401-S01
Study Received Date:	03 Jun 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 ~155 mm
Positive Control Average:	2.8 x 10^3 CFU
Negative Monitor Count:	<1 CFU
MPS:	2.8 µm

James Luskin electronically approved — Study Director James Luskin

09 Jul 2020 14:52 (+00:00) — Study Completion Date and Time

Results:

Test Article Number	Percent BFE (%)
1	97.4
2	98.1
3	98.7
4	99.5
5	99.8

Test Article Number	Delta P (mm H_2O/cm^2)	Delta P (Pa/cm^2)
1	3.9	37.9
2	3.8	37.3
3	3.9	37.8
4	3.8	37.3
5	3.8	37.7

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

Test Reports

ASTM Level 1 reports by Nelson Lab.

Nelson Labs
A Sotera Health company

Sponsor:
Yingkai Tang
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Tongxiang, Zheijang Province,
CHINA

Synthetic Blood Penetration Resistance Final Report

Test Article:	Disposable Protective Mask, DM20200101, Non-woven fabric 65%, Melt-blown fabric 35%, Batch number202005
Purchase Order:	20-577A
Study Number:	1306405-S01
Study Received Date:	03 Jun 2020
Testing Facility:	Nelson Laboratories, LLC 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A.
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0012 Rev 09
Deviation(s):	None

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

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

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

Number of Test Articles Tested:	32
Number of Test Articles Passed:	32
Test Side:	Outside
Pre-Conditioning:	Minimum of 4 hours at 21 ± 5°C and 85 ± 5% relative humidity (RH)
Test Conditions:	23.4°C and 22% RH

Brent Shelley electronically approved for — 19 Jun 2020 17:14 (+00:00)
Study Director James Luskin — Study Completion Date and Time

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

Test Pressure: 80 mmHg (10.7 kPa)

Test Article Number	Synthetic Blood Penetration
1-32	None Seen

Test Reports

ASTM Level 1 reports by Nelson Lab.

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A Sotera Health company

Sponsor:
Yingkai Tang
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Latex Particle Challenge Final Report

Test Article:	Disposable Protective Mask, DM20200101, Non-woven fabric 65% Melt-blown fabric 35%, Batch #202005
Purchase Order:	20-577A
Study Number:	1306403-S01
Study Received Date:	03 Jun 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:	21°C, 31% relative humidity (RH) at 8:42 AM; 21°C, 31% RH at 9:50 AM
Average Filtration Efficiency:	97.5%
Standard Deviation:	0.15

ilac-MRA ANAB ACCREDITED ISO/IEC 17025 TESTING LABORATORY

McKenna Wild electronically approved for Curtis Gerow
Study Director

23 Jul 2020 18:40 (+00:00)
Study Completion Date and Time

Deviation Details: Controls and sample counts were conducted for one minute instead of an average of three one minute counts. This change shortens the total test time for each sample but will still provide an accurate determination of the particle counts. An equilibrate is a dwell period where the challenge is being applied to the test article for a certain period of time before test article counts are counted. The equilibrate period was reduced from 2 minutes to a minimum of 30 seconds which is sufficient time to clear the system of any residual particles, and establish a state of stable equilibrium before sample counts are taken. Test method acceptance criteria were met, results are valid.

Results:

Test Article Number	Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	301	12,535	97.6
2	307	12,876	97.6
3	360	13,233	97.3
4	348	13,150	97.4
5	339	13,500	97.5

Test Reports

ASTM Level 1 reports by Nelson Lab.

Nelson Labs
A Sotera Health company

Sponsor:
Yingkai Tang
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No 153 Guang'An Rd.
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CHINA

Flammability of Clothing Textiles Final Report

Test Article:	Disposable Protective Mask, DM20200101, Non-woven fabric 65% Melt-blown fabric 35%, Batch #202005
Purchase Order:	20-577A
Study Number:	1306404-S01
Study Received Date:	03 Jun 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: STP0073 Rev 06
Deviation(s):	None

Summary: This procedure was performed to evaluate the flammability of plain surface clothing textiles by measuring the ease of ignition and the speed of flame spread. The parameter of time is used to separate materials into different classes, thereby assisting in a judgment of fabric suitability for clothing and protective clothing material. The test procedure was performed in accordance with the test method outlined in 16 CFR Part 1610 (a) *Step 1 - testing in the original state*. Step 2 - *Refurbishing and testing after refurbishing*, was not performed. 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 Article Side Tested:	Outside Surface
Orientation:	Machine

Test Criteria for Specimen Classification (See 16 CFR Part 1610.7):

Class	Plain Surface Textile Fabric
1	Burn time ≥3.5 seconds
2	Not applicable to plain surface textile fabrics
3	Burn time <3.5 seconds

The 16 CFR Part 1610 standard specifies that 10 replicates are to be tested if, during preliminary testing, only 1 test article exhibits flame spread and it is less than 3.5 seconds or the test articles exhibit an average flame spread less than 3.5 seconds. Five replicates are to be tested if no flame spread is observed upon preliminary testing, if only 1 test article exhibits flame spread and it is equal to or greater than 3.5 seconds, or if the average flame spread is equal to or greater than 3.5 seconds. In accordance with the standard, 5 replicates were tested for this study.

Sean Shepherd electronically approved for Curtis Gerow
Study Director

06 Jul 2020 20:48 (+00:00)
Study Completion Date and Time

Results:

Replicate Number	Time of Flame Spread
1	DNI
2	DNI
3	DNI
4	DNI
5	DNI

DNI = Test Article did not ignite

Packaging & Shipping Size

50 pcs / box

40 boxes / Ctn
Ctn Size: 57×38.5×37 CM

30 Ctns / Pallet (Can be changed upon request)
Pallet Size: 42×48×93 IN.
Pallet Weight: Approx. 800 lbs.

1 Pallet = 30 Ctns = 1200 boxes = 60000 pcs

Sample Pallet Ex.