



FDA TEST REPORT

For

N95 Face Masks

Model: N/A

Brand: N/A

Report No.: ENC2003192GZ39E1

Date of Issue: Mar. 20, 2020

Prepared For

King Year Printing and Packaging Company Limited

**No.30 LongHua Branch RD, Wentang Industry Zone, Dongcheng District,
Dongguan**

Prepared By

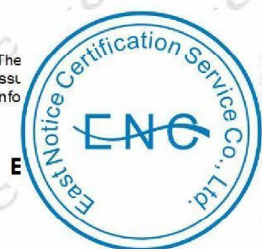
East Notice Certification Service Co., Ltd.

**1/F, Haohui Commercial Building, Zhuji Street, Dongpu Town, Tianhe District,
Guangzhou City, China**

TEL: +86-20-2331 4234

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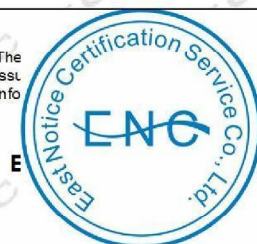
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TEST REPORT ASTM F2101-2019 Medical face masks — Requirements and test methods	
Report reference No.	ENC2003192GZ39E1
Tested by	5.1.2e
Review by (+ Signature)	_____
Approved by (+ signature)	5.1.2e _____
Date of issue	Mar. 20, 2020
Contents	Total 4 pages
	
Testing laboratory	
Name	East Notice Certification Service Co., Ltd.
Address	1/F, Haohui Commercial Building, Zhuji Street, Dongpu Town, Tianhe District, Guangzhou City, China
Testing location	Same as above
Application	
Name	King Year Printing and Packaging Company Limited
Address	No.30 LongHua Branch RD, Wentang Industry Zone, Dongcheng District, Dongguan
Manufacturer	
Name	King Year Printing and Packaging Company Limited
Address	No.30 LongHua Branch RD, Wentang Industry Zone, Dongcheng District, Dongguan
Test specification	
Standard	ASTM F2101-2019
Establishment ID. :	E2003166
Procedure deviation	N/A
Non-standard test method	N/A
Test Report Form/blank test report	
Test Report Form No.	ENCASTMF2101-A2
TRF originator.	ENC
Test item	
Description	N95 Face Masks
Brand name	N/A
Model	N/A
Classification	Type I

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**Testing**

Date of receipt of test item	Mar. 13, 2020
Date(s) of performance of test	Mar. 13, 2020 - Mar. 20, 2020
Test Side	Either Side
BFE Area Tested	~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.
Positive Control Average	2.0x10 ³ CFU
Negative Monitor Count	<1 CFU
MPS	3.0 μm

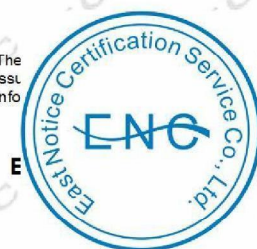
Summary of testing

The BFE test is performed to determine the filtration efficiency by comparing the upstream bacterial control counts to downstream test article counts. A suspension of *Staphylococcus aureus* was aerosolized using a nebulizer and delivered to the test article at a constant flow rate and challenge delivery. The challenge delivery is maintained at 1.7 - 2.7 x 10³ colony forming units (cfu) with a mean particle size (MPS) at 3.0 μm ± 0.3 μm. The aerosol droplets were drawn through a six-stage, viable particle, Andersen sampler for collection. This procedure allows a reproducible bacterial challenge to be delivered to test materials. This test method complies with ASTM F2101-2019.

The Delta P test determines the breathability 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 was designed to comply with MIL-M-36954C, Section 4.4.1.2.

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.

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Test results:

Sample No.	Bacterial filtration efficiency (BFE), (%)	Differential pressure (Pa/cm ²)	Splash resistance Pressure (kPa)	Microbial cleanliness (cfu/g)	Verdict
1	98.4	23.4	Not required	17.8	PASS
2	98.1	23.0	Not required	17.9	PASS
3	98.3	23.1	Not required	17.6	PASS
4	98.2	23.4	Not required	18.1	PASS
5	98.5	23.2	Not required	18.2	PASS

The filtration efficiency percentages were calculated using the following equation:

$$\%BEF = \frac{C - T}{C} \times 100$$

C = Positive control average

T = Plate count total recovered downstream of the test article

Note: The plate count total is available upon request

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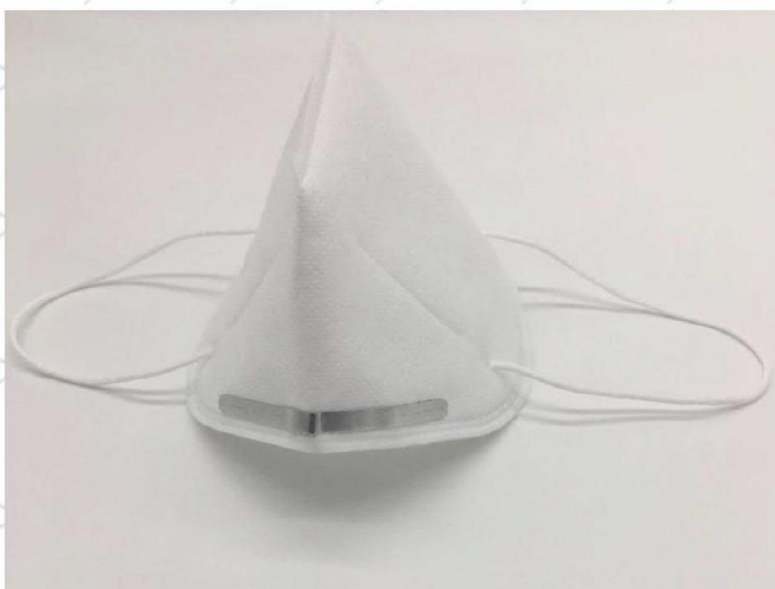
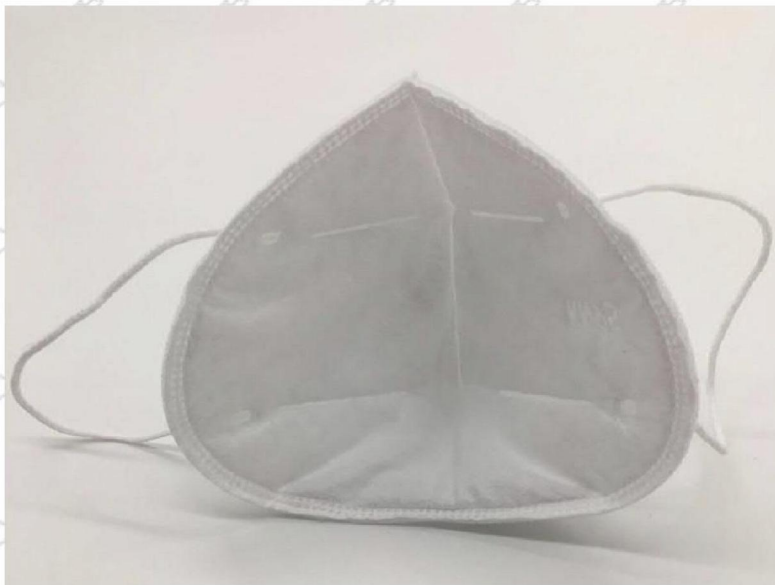
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**APPENDIX A
PHOTO(S) OF PRODUCT**



-----END OF REPORT-----

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