Test Report

Company Name & Address:	**Zhuhai Herald Datanetics Limited Building #2, No. 1, Ping Xi Road 6, Nanping Science and Technology Park, ZhuHai , Guangdong, China**
Product Description:	**Single-use medical face mask**
Model(s)/Type References:	**HD0969**
Brand Name(s):	**Not Applicable**
Standard(s)/Specifications:	**Bacterial Filtration Efficiency includes Diff. Pressure for breathability Standard Test Protocol (STP) Number: STP0004 Rev 18 EN 14683:2019 (Annex B) ASTM F2101-19 ASTM F2100-19 Flammability Test Standard Test Protocol (STP) Number: STP0073 Rev 06 16 CFR Part 1610 (a) Step 1 testing in the original state Synthetic Blood Penetration for Face Masks ASTM F1862 and ISO 22609 (as reference in EN14683:2019 and AS4381:2015) Particle Filtration Efficiency Standard Test Protocol (STP) Number: STP0005 Rev 08 ASTM 2299 – exceptions (see details in corresponding section)**
Report Issuing (Office Name & Address):	**Intertek Testing Services Hong Kong Ltd. 2/F., Garment Centre, 576 Castle Peak Road, Kowloon, Hong Kong SAR, China.**
Date of Tests:	**24 Aug 2020 to 02 Nov 2020**
Test Report Number(s):	**20110321HKG-001**

Technical review was conducted upon the examination of adequacy of applied assessments on the products, compliance of regulatory requirement against ASTM F2100:2019 and competence/accredited status of the service provider of testing.

It is verified that the product has been tested and found comply with the requirements of Level 3 of ASTM F2100:2019.

Signature: 

Digitally signed by Lawrence Chow
DN: cn=Lawrence Chow, o=Intertek Testing Services Hong Kong Limited, ou, email=lawrence.chow@intertek.com, c=HK

Name: **Chow Hin Chung, Lawrence**
Position: **Assistant Manager**
Date: **06 Nov 2020**

Total Quality. Assured.

TEST REPORT

1. Bacterial Filtration Efficiency (BFE) & Differential Pressure (ΔP)

Test 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 ASTM F2100-19 and EN 14683:2019, Annex C.

All test method acceptance criteria were met.

Test Side:	Inside
BFE Test Area:	~40 cm^2
BFE Flow Rate:	28.3 Liters per minute (L/min)
Della P Flow Rate:	8 Liters per minute (L/min)
Conditioning Parameters:	85 ± 5% relative humidity (RH) and 21 ± 5ºC for a minimum of 4 hours
Test Article Dimensions:	~174 mm x ~161 mm
Positive Control Average:	2.8 x 10^3 CFU
Negative Monitor Count	<1 CFU
Mean Particle Size (MPS):	3.1 μm

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TEST REPORT

Result :

Sample number	Percent BFE (%)[1]	Δp (mm H_2O/cm^2)	Δp (Pa/cm^2)
1	99.4	3.8	36.8
2	99.8	3.7	36.7
3	99.7	3.5	34.6
4	99.8	3.9	38.6
5	99.8	4.3	41.8
Requirement[2]			
Level 2	≥98%	<6.0	--

Remarks:

1 = The filtration efficiency percentages were calculated using the following equation:

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

C = Positive control average

T = Plate count total recovered downstream of the test article

2 = Requirements as per ASTM F2100-19 standard specification for performance of materials used in medical face masks.

This is a subcontracting item.

Total Quality. Assured.

TEST REPORT

2. Flammability

Test 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.

Test Side:	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.

Result :

Sample number	Time of Flame Spread
1	IBE
2	IBE
3	IBE
4	IBE
5	IBE
IBE = Test Article ignited, but extinguished	

Remarks:
1 = Requirement Level 1, 2 & 3 – Class 1

2 = Requirements as per ASTM F2100-19 Standard Specification for Performance of Materials used in Medical Face Masks.

This is a subcontracting item.

Total Quality. Assured.

TEST REPORT

3. Synthetic Blood Penetration Resistance

Test summary:

Ref: ASTM F2100-2019 and ASTM F1862-2017

Specimen(s)	Face Mask	Specimen(s)	Face Mask
1	None seen	17	None seen
2	None seen	18	None seen
3	None seen	19	None seen
4	None seen	20	None seen
5	None seen	21	None seen
6	None seen	22	None seen
7	None seen	23	None seen
8	None seen	24	None seen
9	None seen	25	None seen
10	None seen	26	None seen
11	None seen	27	None seen
12	None seen	28	None seen
13	None seen	29	None seen
14	None seen	30	None seen
15	None seen	31	None seen
16	None seen	32	None seen

For 160mmHg

Sample number	Synthetic blood penetration
1-32	None seen
Requirement:	An acceptable quality limit of 4% is met for a normal single sampling plan when 29 of 32 test specimens show passing result (none seen).
Conclusion:	Passed at 160mmHg (21.3 kPa)

Remark:

1 = Requirements as per ASTM F2100-19 Standard Specification for Performance of Materials used in Medical Face Masks.

This is a subcontracting item

Total Quality. Assured.

TEST REPORT

4. Latex Particle Challenge

Test 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.

Three one-minute counts were performed, with the test article in the system, and the results averaged. Three one-minute control counts were 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 average 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.

Test Side:	Inside
Area Tested:	91.5cm^2
Particle Size:	0.1μm
Laboratory conditions:	21ºC, 29% relative humidity (RH) at 0818; 21ºC, 30% (RH) at 0914
Average Filtration Efficiency:	99.87%
Standard Deviation:	0.039

Result :

Sample number	Test article counts	Average control counts	Filtration efficiency (%)
1	24	13,350	99.82
2	18	13,437	99.87
3	10	13,332	99.925
4	17	13,280	99.87
5	21	13,452	99.84
Requirement[1]	Level 2 - ≥98% at 0.1 μm		

Remark :

1 = Requirements as per ASTM F2100-19 standard specification for performance of materials used in medical face masks.

This is a subcontracting item

TEST REPORT

Remark:

Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210. 211 and 820.

All tests were performed at subcontracted laboratory – Nelson Labs (accredited by ANAB), The Hong Kong Standards and Testing Centre Limited

This report should be read in conjunction with original test reports.

At no time will Intertek have responsibility in case doubting on reviewed test result, report and certificate, genuineness of the provided test result, report and certificate depends on the provided/published information, evidences and accessibility of laboratory(ies) that under review.

This verification applies only the product as well as mentioned test report that submitted/received.

No surveillance or control process of manufacturer were conducted