



# DISPOSABLE FACE MASK

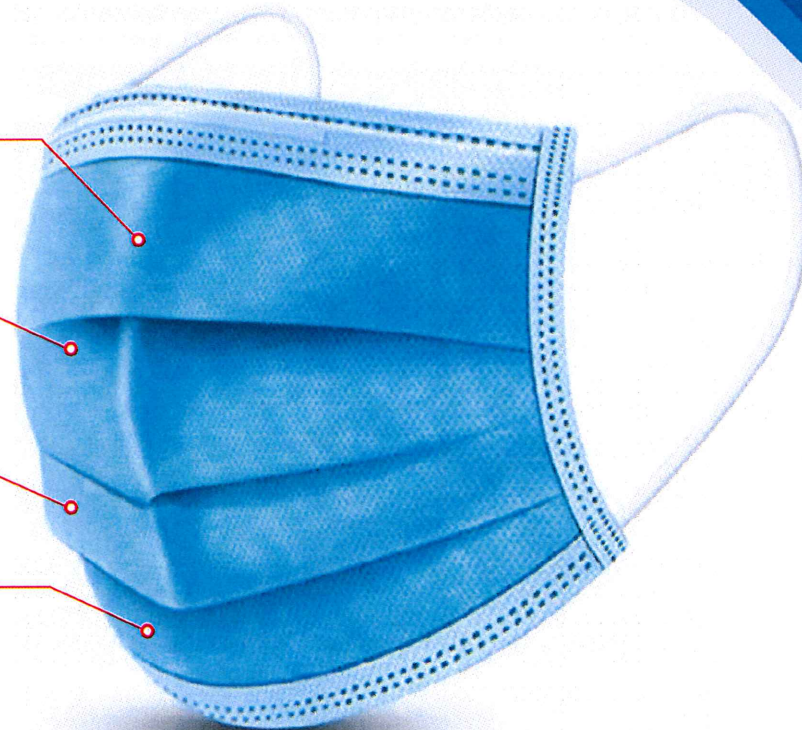
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Disposable face mask 3-ply  
Facemasks with earloops

PP 20/25/25 gsm  
PP nonwoven  
+ filter paper  
+ PP nonwoven

High BFE 99%,  
masks no stamp,  
nonsterile

Blue/white color



### Packing:

50pcs/box, 2000pcs/carton (40 boxes)  
Carton dimension: 52\*38\*30cm  
Carton N.W. 6.5KGS, G.W. 7.5KGS

**Future Health Concept's, Inc**  
**Model F104**

**Product Technical Specification Sheet**

[Name] 3-PLY FACE MASK, EARLOOP, BLUE
[Type] automatic ultrasonic welded type, nose bar adaptable
[General Description]: Lightweight facemasks are intended to cover the nose and mouth in order to minimise the incidence of cross infection in clean or sensitive environments.
[Material] The masks are constructed of 3-ply, spun bonded polypropylene non-woven fabric with filter in between and with an integral aluminium strip above the nose, for optimum fit.  <u>Specific Materials are:</u> Outer Coverstock - 20 gsm Middle Filter Medium - White 25gsm Inner Coverstock - 25gsm Loops - Elasticated, polypropylene covered
<u>Benefits are:-</u> * Lightweight & Comfortable ● Anatomically Shaped ● Free of glass fibre, 100% latex free ● Hypoallergenic *Excellent breathability & bacterial filtration
[Style] Earloop type
[Bacterial Filtration Efficiency] (BFE) 99%
[Shelf Life] 5 years (established for the time being).
[Colour] Blue
[Packing] Interior: 50pcs/box Box size: 18x10x7 cm ( earloop type), Exterior: 52x38x30cm (earloop type), 2000pcs /carton G.W.: 7.50kgs N.W.: 6.50kgs
[Dimension] 17.5 x 9.2 cm
[Use ] Daily use

**SUGGESTED STORAGE**

[Temperature] Between -15°C and 40°C
[Humidity] Below 80%
[Sunlight] Not to expose to direct sunlight.
[Frequency] To keep away from high frequency equipment.



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

Test Article: TDK-22  
 Laboratory Number: 804545  
 Study Received Date: 17 Feb 2015  
 Test Procedure(s): Standard Test Protocol (STP) Number: STP0004 Rev 11

**Summary:** 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  $2,200 \pm 500$  colony forming units (CFU) with a mean particle size (MPS) at  $3.0 \mu\text{m} \pm 0.3 \mu\text{m}$ . 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 F2101-07 and EN 14683:2014, Annex B.

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 and complies with EN 14683:2014, Annex C.


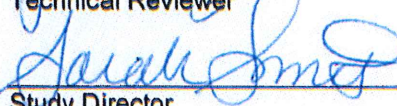
All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

BFE Area Tested:  $\sim 45.6 \text{ cm}^2$   
 BFE Flow Rate: 28.3 Liters per minute (L/min)  
 Delta P Flow Rate: 8 L/min  
 Conditioning Parameters:  $85 \pm 5\%$  relative humidity (RH) and  $21 \pm 5^\circ\text{C}$  for a minimum of 4 hours.

**Results:**

Test Article Number	Percent BFE (%)	Delta P (mm H <sub>2</sub> O/cm <sup>2</sup> )	Delta P (Pa/cm <sup>2</sup> )
1	99.7	1.6	16.0
2	99.8	1.8	17.4
3	99.7	1.7	17.0
4	99.9	1.7	16.3
5	99.7	1.7	17.1

Positive Control Average: 2,083 CFU  
 Negative Monitor Count: <1 CFU  
 MPS: 3.0  $\mu\text{m}$

  
 Technical Reviewer  
  
 Study Director  
 Sarah Smit, B.S.



  
 Study Completion Date



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

Note: The plate count total is available upon request