bastion

Junior Surgical Face Masks with Earloops

ARTG number: 195663
Re-order Code: BNR22152

Caution: Not suitable for use by children under 3 years

Junior Surgical Face Masks with Earloops

Product: Disposable Junior Surgical Face Mask (Non sterile)
Suitable for children aged 3 – 12
Material: 3 Ply Fabric
Type: 2 / BFE > 99% Risk IIR
Design: Adjustable Nose Bar
Feature: Lightweight and comfortable, Excellent breathability, Adjustable nose bar
Fluid resistant & Latex Free
Usage: Single Use only
Colour: Green
Packaging: 100 ± 1 pcs/inner, 10 inners/carton

Bacterial filtration efficiency (BFE) and Differential Pressure (Delta P) Final Report

Test Side: Inside
BFE Test Area: ~40 cm2
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: ~152 mm x ~151 mm
Positive Control Average: 2.7 x 103 CFU
Negative Monitor Count: <1 CFU
MPS: 2.8 µm

Results:

Test Article Number	Percent BFE (%)
1	99.7
2	99.5
3	99.9
4	99.9
5	99.9

Test Article Number	Delta P (mm H_2O/cm^2)	Delta P (Pa/cm^2)
1	4.1	40.1
2	4.5	43.7
3	4.1	40.5
4	3.9	38.3
5	4.3	41.9

The filtration efficiency percentages were calculated using the following equation:

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

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

Microbial Cleanliness (Bioburden) of Junior Surgical Face Masks Final Report

Summary: The testing was conducted in accordance with EN 14683:2019, with the exception of approximate volumes of eluent used when performing the extraction procedure and a temperature range of 30-35°C used for aerobic incubation. When bioburden results are calculated using a software program, manual calculations may differ slightly due to rounding. The counts determined on products are colony forming units and may not always reflect individual microorganisms. The sponsor performs any statistical analysis and determines the acceptable limits. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Results:

Unit Number	Weight (g)	Aerobic	Fungal	Total Bioburden (CFU/mask)	Total Bioburden (CFU/g)
1	2.8	<3	<3	<6.0	<2.2
2	2.7	<3	<3	<6.1	<2.3
3	2.7	<3	<3	<5.8	<2.2
4	2.8	<3	<3	<5.9	<2.1
5	2.7	<3	<3	<6.0	<2.2
Recovery Efficiency	UTD[a]				

Synthetic Blood Penetration Resistance Final Report

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 Condition: 21.2°C and 22% RH

Results: Per ASTM F1862 ISO 22609, an acceptable quality limit of 4% is met for normal single sampling plan when ≥29 of 32 test articles show passing results.

Test Pressure: 120 mm Hg	
Test Article Number	Synthetic Blood Penetration
1-32	None Seen