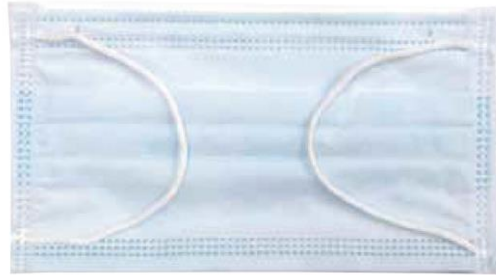


PRODUCT SPECIFICATION TECHNICAL DATASHEET

3-Ply Non-Woven Ear Loop Surgical Face Mask: EN14683 Type II & ASTM 2100 Level 2

Intended Use

Procedure masks are intended to be worn by personnel during medical procedures to protect both the patient and the operating personnel from transfer of microorganisms, body fluids and particulate material transfer. Latex free.



For Information Purposes Only

ASTM F 2100 – Level 2 Barrier Protection

Characteristic	Testing Methodology	Acceptable Limit & Results
Bacterial Filtration Efficiency (BFE)	ASTM F2101-19 BS EN 14683:2019	BFE @ 3.0 μm $\pm 0.3\mu\text{m}$ Bacteria $\geq 98\%$
Particulate Filtration Efficiency (PFE)	ASTM F2299	PFE @ 0.1 μm large Latex particules $\geq 98\%$
Differential Pressure (ΔP)	EN 14683	$\Delta\text{P} < 4.0$ mm of $\text{H}_2\text{O}/\text{cm}^2$
Fluid Resistance Synthetic Blood Penetration	ASTM F1862-17	Resistant @ 80mmHg (Level 1) Resistant @ 120mmHg (Level 2)
Microbial Cleanliness	EN 14684	≤ 30 cfu/g
Textile Flammability Flame Spread	ASTM F2100-19 16 CFR 1610	Class 1

Facemasks exceed the EN14683 Type II & ASTM 2100 Level 2 standard class for bacterial filtration efficiency (BFE) $\geq 98\%$.

Facemasks comply with the requirements of Type II as defined by EN 14683 & Level 2 as defined by ASTM 2100

FDA Listing Number : D401926

Product Code : FXX

Manufacturer FDA Facility Registration Number : 9710609

Technical Specifications

Body

Material of Outer Layer	25 GSM Spunbond Non Woven Blue Fabric
Material of Center Layer	25 GSM SSMMS HO, White
Material of Inner Layer	25 GSM Spunbond Non Woven White Fabric
Length	175.0 ± 5.0 mm
Width	95.0 ± 3.0 mm

Ear Loop

Material of Ear Loop	Spandex + Dacron
Length	150mm ± 10 mm
Colour	White

Nose Bend

Nose Bend Position	Fixed in center of the top
Material	Galvanized Iron wire with PE Outer Layer
Length	100.0mm ± 5.0 mm

Mask Efficiency

Bacteria Filtration Efficiency ASTM F2101-19 BS EN 14683:2019	BFE @ 3.0 µm ±0.3µm Bacteria ≥ 98%
Particle Filtration Efficiency ASTM F2299	PFE @ 0.1 µm large Latex particules ≥ 98%
Differential Pressure (ΔP) EN 14683	ΔP < 4.0 mm of H ₂ O/cm ²
Fluid Resistance Synthetic Blood Penetration ASTM F1862-17	PASS Resistant @ 80mmHg (Level 1) PASS Resistant @ 120mmHg (Level 2)
Microbial Cleanliness EN 14684	PASS: ≤30 cfu/g
Textile Flammability Class I flame spread ASTM F2100-19 Clause 6.2/9.5 (test as specified in 16 CFR 1610)	PASS

Packaging

Packaging	50 pcs/ box
	Ionized and packed in box