

TECHNICAL DATA SHEET

Intended Use

The procedure masks are intended to be worn by personnel during surgical or other medical procedures to protect both the patient and the operating personnel from transfer of microorganisms, body fluids and particulate material transfer.

Characteristics		Specifications				
Description		Ergonomic Facemask with elastic Bras				
Material	Mask body composition	Woodpulp	55%			
	Elastic band composition	Polyester	45%			
Color outer material		White, Blue, Green, Dark Blue. (Esp. MEDBLUE)				
Dimension	Body size	Length	180 mm (5%)			
		Width	150 mm (5%)			
	Length of Elastic band	60 cm. To 65 cm. (5%)				
Characteristics B		UNIT	EN 13795 REQUIEREMENTS			
			Standard performance		High performance	
			Critical product area	Less critical product area	Critical product area	Less critical product area
Resistance to microbial penetration - Dry		CFU	NOT REQUIRED	<300	NOT REQUIRED	<300
Resistance to microbial penetration - Wet		/B	<2.8	NOT REQUIRED	6.0	NOT REQUIRED
Cleanliness - Microbial		CFU/100 cm2	<300	<300	<300	<300
Cleanliness - Particulate matter		IPM	<3.5	<3.5	<3.5	<3.5
Linting		Log(10) (Lint count)	<4.0	<4.0	<4.0	<4.0
Resistance to liquid penetration		cm H2O	>20	>10	>100	>10
Characteristics B		UNIT	RESULTS			
Resistance to microbial penetration - Dry		CFU			168	PASS
Resistance to microbial penetration - Wet		/B			4	PASS
Cleanliness - Microbial		CFU/100 cm2			40	PASS
Cleanliness - Particulate matter		IPM			3.3	PASS
Linting		Log(10) (Lint count)			3.6	PASS
Resistance to liquid penetration		cm H2O			24.3	PASS
Water Impact		9	g	AATCC 44		
AC Repellency		9	Rating	IST 80.10		
Hydrohead		27	cm	AATCC 129		
Grab Tensile Breaking Strength	MD	27	lb	ASTM D5034		
		120	N			
	XD	16	lb			
		71	N			
Textile Flammability		Class I flame spread				
Skin Irritation		Negligible				
Skin Sensitization		Negligible				
Packaging	Masks/bag		Bags/box			
	100 PCS		20 at 40			
ITEM	Description	Color	Specific Attribute			
CUP04	Procedure Face Mask Barrier Protection	medblue	Non-Sterile			

CERTIFICATE: ISO 13485, ISO 9001-2015

Reg. Cofepris: 1673C2017 SSA

Storage Conditions

Store under cool, clean and dry conditions.

Avoid excessive heat over 40C

Country of origin: Mexico

