Folitex® Anti-fog tie-on

MOUTH AND NOSE COVERING SURGICAL MASK | TECHNICAL DATA

PRODUCT CLASSIFICATION	Medical Device Class I
QUALITY CERTIFICATES	ISO 9001, ISO 13485
APPLIED STANDARDS	EN 14683, ISO 22609, ISO 10993
INTENDED USE ACC. EN 14683:2019	The main intended use of medical face masks is to protect the patient from infective acc. EN 14683:2019 agents and, additionally, in certain circumstances to protect the wearer against splashed of potentially contaminated liquids. Medical face masks may also be intended to be worn by patients and other persons to reduce the risk of spread of infections, particularly in epidemic or pandemic situations.
MANUFACTURER	priMED Medical Products Inc., 200, 2003 91 St. SW, Edmonton, AB, Canada T6X 0W8
IMPORTER	B. Braun Melsungen AG Carl-Braun-Str. 1, 34212 Melsungen Germany

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MEDICAL DEVICE INFORMATION	Medical device class I, EN 14683	
		
MASK DESIGN	Colour	denim blue
	Layers	3ply, folded, ultrasonically welded
	Fixation	ties, flexible nose clip
MATERIAL	Outer layer	spunbond polypropylene, denim blue
	Filter layer	melt-blown polypropylene
	Inner layer	spunbond polypropylene, white
	Anti-fog feature	polyurethane foam strip, blue
	Nose clip	aluminum strip
	Ties	spundbond polypropylene
	Free of natural rubber latex	
PHYSICAL PROPERTIES	Protection type	type IIR
	Barrier efficiency	≥ 98 % bacterial filtration efficiency BFE
	Breathability	< 60 Pa/cm² differential pressure for air permeation
	Splash resistance	withstanding penetration of artificial blood at a pressure of ≥ 16 kPa
	Microbial cleanliness	≤ 30 CFU/g (colony forming units)
DIMENSIONS	Mask	180 mm width/93 mm height
	Ties (total)	≥ 91 cm length
	Nose Fixation	140 mm length
LOGISTIC INFORMATION	REF	6073313
	Dispenser pack	50 pieces 190 x 110 x 150 mm (L x W x H)
	Transportation carton	6 dispenser packs 460 x 230 x 20 mm (L x W x H)
	Storage conditions	protect from direct heat, lighting or sunlight/UV radiation, store clean and dry at ambient temperature