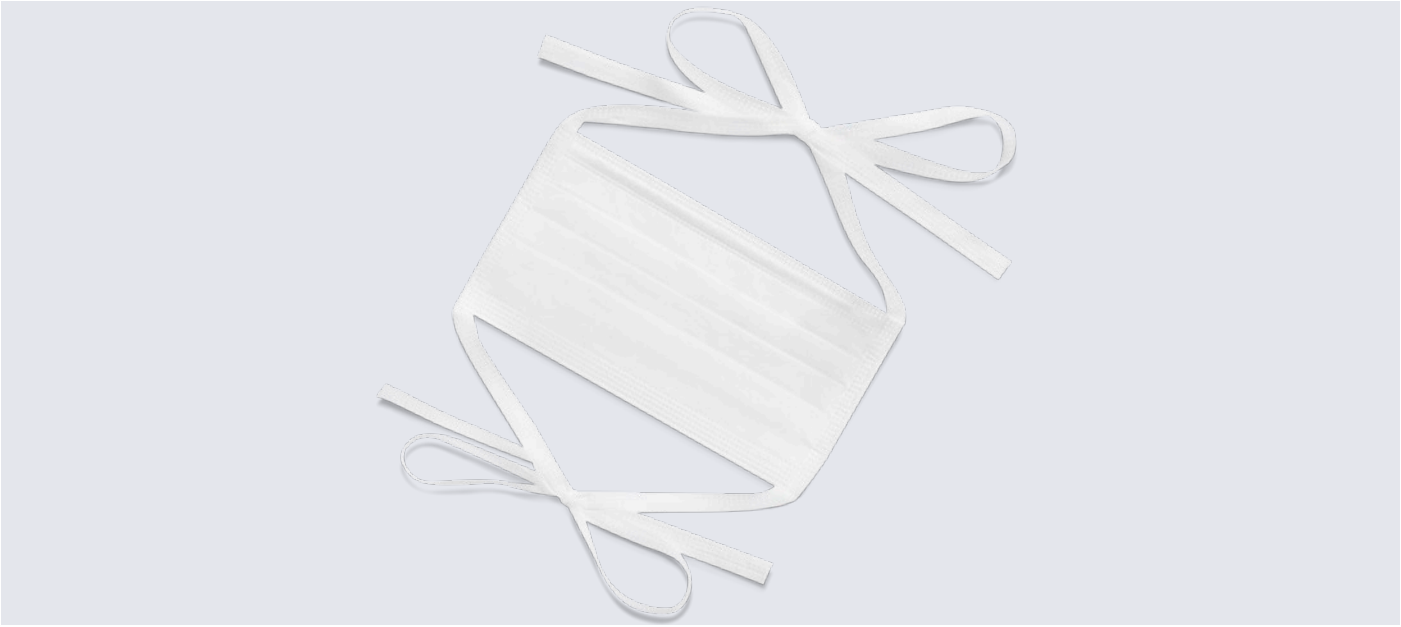
Folitex® Sensitive tie-on

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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SHARING EXPERTISE

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MEDICAL DEVICE INFORMATION	Medical device class I, EN 14683		
MASK DESIGN	Colour	white	
	Layers	3ply, folded, ultrasonically welded	
	Fixation	ties, flexible nose clip	
MATERIAL	Outer layer	spunbond polypropylene, white	
	Filter layer	melt-blown polypropylene	
	Inner layer	non-woven polyethylene/polypropylene bi-component, white	
	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	6073312	
	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	

All data refer to typical single values and may be subject to alterations. Edition: 11/2020