

PRODUCT DATASHEET

Product Name	i-Pro [™] Personal Respiratory Protective Mask, Medium/Large		
Reference numbers	2019111		
Product Type	PRP Mask		
Manufacturer	Intersurgical		
Materials	PP TPE PP based filter m Elastic	edia	
Packaging			
Unit Packaging	Individually packaged		
Box quantity Pallet quantity	1280		
Pallet quantity	1200		
Instructions for Use	Instructions for use with product	No	
	Instructions for use with each box	Yes	
CE Class	I		
Applicable Standards	BS EN ISO 13485: Medical devices — Quality management sy — Requirements for regulatory purposes		
	ISO 9001: Quality Management Systems - Requirements		
	ISO 15223-1: Medical Devices - Symbols to be Used with Medical Device Labels, Labelling, & Information to be Supplied BS EN 14683: Medical face masks. Requirements and test methodology. TEB-APR-STP-0007: Determination of Inhalation Resistance TEB-APR-STP-0003: Determination of Exhalation Resistance TEB-APR-STP-0059: Determination of Particulate Filter Efficiency		
	Level for N95 Series Filters Against Solid Particulate Powered, Air-Purifying Respirators	9 IOI INOII-	
Sterile	No		
Shelf life	3 years		
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Disposal Methods	As hospital guidelines		

Product characteristics

Technical information

Description	i-Pro personal respiratory protection (PRP) mask
Bacterial Filtration Efficiency (%)	> 99.999
Viral Filtration Efficiency (%)	> 99.999
Salt Penetration (%)	0.02
Filtration efficiency when challenged at 85 LPM (%)	> 99
Average Inhalation Resistance at 85 LPM (cmH ₂ O)	1.2
Average Exhalation Resistance at 85 LPM (cmH ₂ O)	1.3
Carbon Dioxide content of inhaled air (%)	< 1.0







Material Abbreviations

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ABS	Acrylonitrile Butadiene Styrene	
AL	Aluminium	
CR	Polychloroprene Rubber	
EDPM	Ethylene Propylene Terpolymer Rubber	
HDPE	High Density Polyethylene	
HIPS	High Impact Polystyrene	
LDPE	Low Density Polyethylene	
LSR	Liquid Silicone Rubber	
MBS	Methacrylate Butadiene Styrene	
NRL	Natural Rubber Latex	
PA	Polyamide (Nylon)	
PC	Polycarbonate	
PE	Polyethylene	
POM	Polyoxymethylene	
PP	Polypropylene	
PS	Polystyrene	
PSU	Polysulfone	
PU	Polyurethene	
PVC	Poly Vinyl Chloride	
SB	Styrene Butadiene	
Si	Silicone	
SS	Stainless Steel	
TPE	Thermoplastic Elastomer	
SBC	Styrene Butadiene Copolymer	
SEBS	Styrene-Ethylene-Butadiene-Styrene	

