

# POLYISOPRENE

## SURGICAL GLOVES

Best Performance  
Non-latex Synthetic



## PM-8100-PI series Features



**Latex-free:** Super soft polyisoprene formulation that is also tough to protect you and patients from pathogens. Exceeds all strength requirements according to USA and EU International standards.



**Skin-friendly formulation:** Our unique chlorine-free formulation production processes combined with the absence of chemical accelerators known to cause allergic responses mean skin irritations are minimised or eliminated. Tested according to ISO EN 10993.



**Easy donning:** Skin friendly polymer coated for easy donning even with damp hands saving you time.



**Consistent calibrated grip :** The outer surface of PM-8100-PI surgical gloves are specially treated to provide a consistent grip . The grip is monitored and controlled during production and each lot must pass stringent internal grip controls before being released.

CE 0344	DEKRA Certification B.V. Medical Device Directive 93/42/EEC
CE 2777	SATRA Technology Europe Europe Limited. Bracktown Business Park Clonoe, D15 YN2P, Ireland Regulation (EU) 2016/425 EU Type Examination, and ongoing conformity

### Complies with the following Standards and Regulations:

Quality: ISO 9001, EN ISO 13485

Compliance EU: CE Mark, MDR, EN 455 1-4, EN ISO 374 1-5

Compliance USA: 510K, ASTM D3577

Environment: EN ISO 14001:2015

# POLYISOPRENE SURGICAL GLOVES

## PRODUCT INFORMATION

Product Name / Description	Polyisoprene PM-8100-PI serie, Sterile, Hand Specific, 280-300mm
Latex / Latex-free/ material	Latex-free, Polyisoprene
Color	White Cream
Cuff type	Beaded cuff
Accelerators used	ZDEC
Texture / Grip	Micro textured, calibrated grip, medium
Sterile / Non-Sterile / Method	Sterile,E-Beam / Gamma
Powder / Powder-free	Powder-free
Design	Anatomical, forward thumb ball, hand Specific
AQL value	0.65
International Product Standards	EN 455 1-4, EN ISO 374 1-5:2016, EN ISO 21420:2019, ASTM D3577, ASTM D6978, ASTM F739, ISO 10993, AS/NZS 4179, ISO 10282, JIS T9107
Quality/Environmental Standards	ISO 9001, ISO 13485:2016, ISO 14001
Shelf Life	3 Years
Compliance to regulations	EU MDD 93/42, USA 510k, MDSAP
Notified body/ Test Laboratories	DEKRA, SATRA, ARDL, BSI
PPE compliance / Type	PPE Regulation (EU) 2016/425, Type B
Biological Evaluation	EN 10993, Primary Skin Irritation Test, Dermal Sensitization Assay, Cytotoxicity Test
Additional tests	Viral Penetration PPE Compliance (ASTM F1671), Chemotherapy Drugs (ASTM D6978), Chemical Residue

## PRODUCT SPECIFICATION

Item No.	PM-8100-PI	PM-8101-PI	PM-8102-PI	PM-8103-PI	PM-8104-PI	PM-8105-PI	PM-8106-PI	PM-8107-PI
Size	5.5#	6.0#	6.5#	7.0#	7.5#	8.0#	8.5#	9.0#
Length(±5mm)	280	280	280	285	285	290	290	300
Thickness(±0.03mm)	Fingertip:0.22		Palm:0.19			Cuff:0.16		

## PACKING INFORMATION

Pouch material	Long or square plastic peel pouch		
Packing Quantity	Pouch	Inner box	Shipping Carton
	1pairs/pouch	50pairs/box	200pairs/carton

## REPRESENTATION

EC Rep	PIXIMED, Boucherville, Quebec, Canada
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