

# POLYISOPRENE

SURGICAL UNDERGLOVES

Best Performance  
Non-latex Synthetic



## PM-8200-PIU Features:



**Perforation detection:** PM-8200-PIU Underglove is an ideal underglove when double gloving. Designed to interlock with PM-8100-PI overglove to deliver an excellent single glove experience. Our distinct blue colour aids in clearly and quickly alerting wearers to perforations in the outer glove. Designed to be comfortable and reliable for any type of surgical procedure.



**Protection:** Computer control and predictive quality analytics (AI) mean that each glove undergoes rigorous quality controls before release. In addition, each glove is 100% air-leaked and visually inspected.



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



**Consistent calibrated grip :** The outer surface of PM-8200-PIU 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. Bracestown Business Park, Clonree, 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 UNDER SURGICAL GLOVES

## PRODUCT INFORMATION

Product Name / Description	PM-8200-PIU POLYISOPRENE UNDERGLOVE , Sterile, Hand Specific, 280-300mm
Latex / Latex-free/ material	Latex-free, Polyisoprene
Color	Blue
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-8200-PIU	PM-8201-PIU	PM-8202-PIU	PM-8203-PIU	PM-8204-PIU	PM-8205-PIU	PM-8206-PIU	PM-8207-PIU
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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