

## **T-POLYURE COATED**

LATEX SURGICAL GLOVES

Powder Free Latex
Our Best Value Product







Comfort, dexterity and protection: Building upon 20 years feedback from Our customers PIXI have designed a new mould to better fit with clinician's hands. Our new mould offers high-level comfort and dexterity. You may use PM-7200-TPC as your only glove, or as an overglove when double-gloving with a PM-7300-UG Latex Underglove to help protect you and your patients with perforation detection.



**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.



**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-7200-TPC 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.



## **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



PRODUCT INFORMATION				
Product Name / Description	PM-7200-TPC, Sterile, Hand Specific, 280-300mm			
Latex / Latex-free/ material	Natural rubber latex with H-Gel <sup>™</sup> coating			
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-7200-TPC	PM-7201-TPC	PM-7202-TPC	PM-7203-TPC	PM-7204-TPC	PM-7205-TPC	PM-7206-TPC	PM-7207-TPC
Size	5.5#	6.0#	6.5#	7.0#	7.5#	8.0#	8.5#	9.0#
Length <sub>(±5mm)</sub>	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		
Packing Quantity	1pairs/pouch	50pairs/box	200pairs/carton		

REPRESENTATION		
EC Rep	PIXIMED, Boucherville, Quebec, Canada	
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