

UNDERGLOVE

LATEX SURGICAL GLOVES

Easy-don Colored Undergloves Perforation Detection System







Perforation detection: PM-7300-UG TPC Underglove is an ideal underglove when dou- ble-gloving. Designed to interlock with PM-7300-UG TPC overglove to deliver an excellent single glove experience. Our distinct green color aids in 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-7300-UG 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

UNDERGLOVE LATEX SURGICAL GLOVES

PRODUCT INFORMATION					
Product Name / Description	PM-7300-UG Latex Underglove, Sterile, Hand Specific, 280-300mm				
Latex / Latex-free/ material	Natural rubber latex with H-Gel [™] coating				
Color	Green				
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-7300-UG	PM-7301-UG	PM-7302-UG	PM-7303-UG	PM-7304-UG	PM-7305-UG	PM-7306-UG	PM-7307-UG	
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	
racking equalitity	1pairs/pouch	50pairs/box	200pairs/carton	

REPRESENTATION	
EC Rep	PIXIMED, Boucherville, Quebec, Canada
EC Rep Contact Details	Info@piximed.com, Telephone +1 514 447 8008 , www.piximed.com