

ORTHOPAEDIC

POLYISOPRENE SURGICAL GLOVES

Thicker And Stronger For Added Protection



PM-8300-PIO Orthopaedic Features:



Robust protection: PM-8300-PIO Orthopaedic is our thickest glove in the PI portfolio. Our proprietary mould and microtextured finish delivers comfort with tactile sensitivity. Dark brown colour reduces glare from surgical lighting.



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 PIO 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

PI ORTHOPAEDIC SURGICAL GLOVES

PRODUCT INFORMATION

Product Name / Description	PM-8300-PIO Polyisoprene Orthopaedic, Sterile, Hand Specific, 280-300mm
Latex / Latex-free/ material	Latex-free, Polyisoprene
Color	Dark Brown
Cuff type	Non-beaded design
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-8300-PIO	PM-8301-PIO	PM-8302-PIO	PM-8303-PIO	PM-8304-PIO	PM-8305-PIO	PM-8306-PIO	PM-8307-PIO
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: 0.30		Palm:0.20			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
EC Rep Contact Details	Info@piximed.com, Telephone +1 514 447 8008 , www.piximed.com