

POLYISOPRENE

SURGICAL GLOVES

Best Performance Non-latex Synthetic





Medispo® PI 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 Medispo 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	Medispo® Polyisoprene, 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 MDR 2017/745, 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.	MPIG-5.5	MPIG-6.0	MPIG-6.5	MPIG-7.0	MPIG-7.5	MPIG-8.0	MPIG-8.5	MPIG-9.0	
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 Quantity	1pair/pouch	50pairs/box	200pairs/carton			

EUROPEAN REPRESENTATION				
EC Rep & Registration No.	HBM Medical, Coliemore House, 3 Coliemore Road, Dalkey, Co Dublin, Ireland: 653382			
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