

GAMMEX[®] Latex Underglove

SURGICAL GLOVES

GENERAL DESCRIPTION	
Material	Natural rubber latex
Powder Content	Powder-free
Color	Green
Shape	Anatomic with straight fingers
Internal Glove Surface	Coated with HYDRASOFT [™] Technology
External Glove Surface	Smooth with micro-textured finish
Cuff Style	Straight with SUREFIT [™] Technology

PHYSICAL PROPERTIES			
Thickness	Finger	Palm	Cuff
Typical Single Wall (mm/mils)	0.23 ± 0.02 / 9.06 ± 0.79	0.21 ± 0.02 / 8.27 ± 0.79	0.19 ± 0.02 / 7.48 ± 0.79
Glove Length	290 / 11.4		
Typical (mm/in)			
Strength	Before Aging / Fresh		
Minimum	ASTM ¹	EN ²	ISO ³
Elongation At Break (%)	-	-	≥ 700
Force At Break (N)	-	≥ 9.0	≥ 12.5
Tensile Strength (MPa)	-	-	-
	After Aging / After Challenge Test		
	ASTM ¹	EN ²	ISO ³
Elongation At Break (%)	-	-	≥ 550
Force At Break (N)	-	≥ 9.0	≥ 9.5
Tensile Strength (MPa)	-	-	-
Comfort			
Maximum	ASTM ¹	ISO ³	
Force At 300% Elongation (N)	-	≤ 2.0	
Stress At 500% Elongation (MPa)	-	-	

ALLERGENIC SAFETY PROFILE	
Vulcanization Chemical Accelerators	Xanthogen polysulphides, Sodium di-n-butylthiocarbamate (SDBC), Zinc diethylthiocarbamate (ZDEC)
Primary Skin Irritation	Not considered a primary irritant as per FHSA Regulation guidelines 16 CFR 1500 / ISO 10993-10
Skin Sensitization	No evidence of delayed dermal contact sensitization as per ISO 10993-10
Protein Level	30 µg/g or less of total extractable protein

¹ ASTM standards refer to ASTM D3577. ² EN standards refer to EN 455-2. ³ ISO standards refer to ISO 10282.

SAFETY STANDARDS	
Freedom From Holes (AQL)	Manufacturing final release: 0.65 (Inspection level GI)
Sterilization Method	GAMMA irradiation (25 kGy)
Tested For Use With Chemotherapy Drugs	Yes, in accordance with ASTM D6978 (Not listed in the US FDA 510k)
Viral Penetration	Passes ASTM F1671 using Phi X 174

STANDARDS AND CERTIFICATIONS	
Product Standards	EN 455 Part 1-4, EN ISO 374-1, EN 374-2 and -4, EN 16523-1, EN ISO 374-5, EN 420, AS/NZS 4179
Quality / Environmental Standards	ISO 9001, ISO 13485, ISO 14001, ISO 11137-Part 1, EN 556, Korean GMP
Product Certification	EU: CE Marked to MDD 93/42/EEC (Class IIa), PPE Regulation (EU) 2016/425 (Cat. III risks) AU: TGA # 201049

PACKAGING AND STORAGE	
Packaging	50 pairs per box; 4 boxes per carton/case; 200 pairs per carton/case
Shelf Life	3 years
Storage Instructions	Keep out of direct sunlight; store in a cool and dry place. Keep away from sources of ozone or ignition.
Disposal Recommendations	Gloves and pouch should be disposed of as clinical waste. Paper inner wrap, box and carton/case are recyclable but can be disposed of as clinical waste.

ANSELL PRODUCT CODES					
Size	Code	Size	Code	Size	Code
5 ½	330050055	7	330050070	8 ½	330050085
6	330050060	7 ½	330050075	9	330050090
6 ½	330050065	8	330050080		

Contact your Ansell representative for ordering or more information.

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