

GAMMEX[®] Non-Latex Sensitive

SURGICAL GLOVES

GENERAL DESCRIPTION

Material	Neoprene (Polychloroprene)
Powder Content	Powder-Free
Color	Natural
Shape	Anatomic with Curved Fingers
Internal Glove Surface	Polymer Coated with DERMASHIELD™ Technology
External Glove Surface	Smooth with Micro-Textured Finish
Cuff Style	Beaded with SUREFIT™ Technology

PHYSICAL PROPERTIES

Thickness Typical Average (mm/mils)	Finger	Palm	Cuff
	0.14 ± 0.03 / 5.51 ± 1.18	0.13 ± 0.03 / 4.92 ± 1.18	0.14 ± 0.03 / 5.51 ± 1.18
Glove Length Typical (mm/in)	301 / 11.9		
Strength Minimum	Before Aging / Fresh		
	ASTM ¹	EN ²	ISO ³
Elongation At Break (%)	≥ 650	-	≥ 600
Force At Break (N)	-	≥ 9.0	≥ 9.0
Tensile Strength (MPa)	≥ 17	-	-
	After Aging / After Challenge		
	ASTM ¹	EN ²	ISO ³
Elongation At Break (%)	≥ 490	-	≥ 500
Force At Break (N)	-	≥ 9.0	≥ 9.0
Tensile Strength (MPa)	≥ 12	-	-
Comfort Maximum		ASTM ¹	ISO ³
Force at 300% Elongation (N)		-	≤ 3.0
Force at 500% Elongation (MPa)		≤ 7.0	-

ALLERGENIC SAFETY PROFILE

Vulcanization Chemical Accelerators	None
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	N/A: contains no natural rubber latex
Allergy Prevention	Latex (Type I), Chemical (Type IV)

SAFETY STANDARDS

Freedom From Holes (AQL)	0.65 AQL
Sterilization Method	GAMMA irradiation (25 kGy)
Tested For Use With Chemotherapy Drugs	Yes, in accordance with ASTM D6978 and US FDA cleared
Viral Penetration	Passes ASTM F1671 using Phi X 174, Passes ISO 16604 using Phi X 174

STANDARDS AND CERTIFICATIONS

Product Standards	AS/NZS 4179, ASTM D3577, ASTM D6978, ASTM D7160, ASTM F739, EN 16523-1, EN 421:2010, EN 455 1-4, EN ISO 21420:2020, EN ISO 374-1:2016, EN ISO 374-5:2016
Quality / Environmental Standards	EN 556, ISO 11137-Part 1, ISO 13485, ISO 14001, ISO 9001, Korean GMP
Medical Registration	BFE = Bacterial Filtration Efficiency, PFE = Submicron Particle Filtration Efficiency
Product Certification	EU: CE Marked to Medical Device Regulation (EU) 2017/745 (Class IIa), PPE Regulation (EU) 2016/425 (Cat. III risks) US: 510K # K151694, Class I / CA: MDALL # 98079, Class 2 AU: TGA # 277420

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

Contact your Ansell representative for ordering or more information.

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S U R G I C A L G L O V E S

PACKAGING AND STORAGE

Packaging	50 pairs per box; 4 boxes per carton/case; 200 pairs per carton/case
Shelf Life	3 years
Shared 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
5.5	340007055	6	340007060	6.5	340007065
7	340007070	7.5	340007075	8	340007080
8.5	340007085	9	340007090		



EN ISO 374-1:2016



K L T

EN ISO 374-5



VIRUS

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