



# GAMMEX® PI Plus Glove-in-Glove™ System

## SURGICAL GLOVES

### GENERAL DESCRIPTION

Material	PI (Polyisoprene)
Powder Content	Powder-Free
Color	White, Green
Shape	Anatomic with Curved Fingers
Internal Glove Surface	Polymer Coated with DERMASHIELD™ Technology
External Glove Surface	Textured Fingers and Palm
Cuff Style	Beaded with SUREFIT™ Technology

### PHYSICAL PROPERTIES

Thickness Typical Average (mm/mils)	Finger	Palm	Cuff
		0.43 ± 0.05 / 16.93 ± 1.97	0.40 ± 0.05 / 15.55 ± 1.97
Glove Length Typical (mm/in)	Outer: 305 / 12.0; Inner: 303 / 11.9		
Strength Minimum	Before Aging / Fresh		
	ASTM <sup>1</sup>	EN <sup>2</sup>	ISO <sup>3</sup>
Elongation At Break (%)	≥ 650	-	≥ 600
Force At Break (N)	-	≥ 9.0	≥ 9.0
Tensile Strength (MPa)	≥ 17	-	-
	After Aging / After Challenge		
	ASTM <sup>1</sup>	EN <sup>2</sup>	ISO <sup>3</sup>
Elongation At Break (%)	≥ 490	-	≥ 500
Force At Break (N)	-	≥ 9.0	≥ 9.0
Tensile Strength (MPa)	≥ 12	-	-
Comfort Maximum		ASTM <sup>1</sup>	ISO <sup>3</sup>
Force at 300% Elongation (N)		-	≤ 3.0
Force at 500% Elongation (MPa)		≤ 7.0	-

### ALLERGENIC SAFETY PROFILE

Vulcanization Chemical Accelerators	Xanthates, Zinc Dialkyldithiocarbamate
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)

### 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 D7160, ASTM F739, EN 16523-1, EN 455 1-4, EN ISO 21420:2020, EN ISO 374-1:2016, EN ISO 374-5:2016, ISO 10282, JIS T9107
Quality / Environmental Standards	EN 556, ISO 11137-Part 1, ISO 13485, ISO 14001, ISO 9001
Product Certification	EU: CE Marked to Medical Device Regulation (EU) 2017/745 (Class IIa), PPE Regulation (EU) 2016/425 (Cat. III risks) US: 510K # K071746, Class I / CA: MDALL # 72514, Class 2 AU: TGA # 298982

<sup>1</sup> ASTM standards refer to ASTM D3577. <sup>2</sup> EN standards refer to EN 455-2. <sup>3</sup> ISO standards refer to ISO 10282.

Contact your Ansell representative for ordering or more information.

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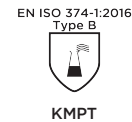
S U R G I C A L   G L O V E S

## PACKAGING AND STORAGE

<b>Packaging</b>	2 pairs per pouch; 50 pairs per box (25 pouches); 4 boxes per carton/case; 200 pairs per carton/case (100 pouches)
<b>Shelf Life</b>	3 years
<b>Shared Storage Instructions</b>	Keep out of direct sunlight; store in a cool and dry place. Keep away from sources of ozone or ignition.
<b>Disposal Recommendations</b>	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	340082055	6	340082060	6.5	340082065
7	340082070	7.5	340082075	8	340082080
8.5	340082085	9	340082090		



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