Ansell

GAMMEX® Latex Glove-in-Glove™ System

SURGICAL GLOVES

GENERAL DESCRIPTION

Material	Natural Rubber Latex
Powder Content	Powder-Free
Color	Natural, Green
Shape	Anatomic with Curved Fingers
Internal Glove Surface	Coated with HYDRASOFT™ Technology
External Glove Surface	Textured Fingers and Palm
Cuff Style	Beaded with SUREFIT™ Technology

PHYSICAL PROPERTIES

Thickness Typical Average (mm/mils)	**Finger**	**Palm**	**Cuff**
	0.44 ± 0.05 / 17.13 ± 1.97	0.37 ± 0.05 / 14.37 ± 1.97	0.32 ± 0.05 / 12.40 ± 1.97
Glove Length Typical (mm/in)	Outer: 302 / 11.9; Inner: 302 / 11.9		
Strength Minimum	**Before Aging / Fresh**		
	ASTM[1]	**EN[2]**	**ISO[3]**
Elongation At Break (%)	≥ 750	-	≥ 700
Force At Break (N)	-	≥ 9.0	≥ 12.5
Tensile Strength (MPa)	≥ 24	-	-
	After Aging / After Challenge		
	ASTM[1]	**EN[2]**	**ISO[3]**
Elongation At Break (%)	≥ 560	-	≥ 550
Force At Break (N)	-	≥ 9.0	≥ 9.5
Tensile Strength (MPa)	≥ 18	-	-
Comfort Maximum		**ASTM[1]**	**ISO[3]**
Force at 300% Elongation (N)		-	≤ 2.0
Force at 500% Elongation (MPa)		≤ 5.5	-

ALLERGENIC SAFETY PROFILE

Vulcanization Chemical Accelerators	Zinc Diethyldithiocarbamate (ZDEC), Zinc Dibutyldithiocarbamate (ZDBC)
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 as per EN 455, 50 µg/dm⊠ or less of total extractable protein as per ASTM D5712
Allergy Prevention	None

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 (Not listed in the US FDA 510k)
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, EN 16523-1, EN 455 1-4, EN ISO 21420:2020, EN ISO 374-1:2016, EN ISO 374-5:2016, ISO 10282
Quality / Environmental Standards	EN 556, ISO 11137-Part 1, ISO 13485, ISO 14001, ISO 9001
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 # K983489 Class I / CA: MDALL # 14561, Class 2

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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SURGICAL GLOVES

PACKAGING AND STORAGE

Packaging	2 pairs per pouch; 50 pairs per box (25 pouches); 4 boxes per carton/case; 200 pairs per carton/case (100 pouches)
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	330083055	6	330083060	6.5	330083065
7	330083070	7.5	330083075	8	330083080
8.5	330083085	9	330083090		

A.R.T.™ Pinhole Barrier Technology

DERMASHIELD™ Donning Aid Technology

HYDRASOFT™ Skin Moisturizing Technology

EN ISO 374-1:2016 Type B
KPT

EN ISO 374-5
VIRUS

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