

KALTEX®

POWDERED STERILE & NON-STERILE LATEX SURGICAL GLOVES

Kaltex Powdered gloves is made from Natural Rubber Latex. The glove is anatomically shaped with thumb ball effect, reducing hand fatigue during surgical procedures. The precision design fit and micro rough surface provides optimum comfort and better instrument grip without compromising on sensitivity. Kaltex Powdered gloves provides excellent barrier protection for both doctor and patient.

SAFETY FEATURES

- ▶ Sterilized in a validated process cycle to achieve sterility assurance level of 10^6 , and air wash cycles to reduce sterilant residue to less than 5 ppm
- ▶ Chemical residue almost nil, eliminates risk of Contact Dermatitis - Type IV Allergy.
- ▶ Powdered with Modified Bio-Absorbable Corn starch USP Grade, to prevent wound infections and granulomas.
- ▶ Manufactured in clean environment to achieve bio burden level of less than 20 cfu prior to sterilization. This achieves low Pyrogen level (dead bacteria) after sterilization.
- ▶ Manufactured in a clean environment to comply with EN 556 & ISO 13485 requirements.

SPECIAL FEATURES OF OUR FORMER

- ▶ Ergonomically designed to produce gloves of high comfort.
- ▶ Designed to mimic the shape of the relaxed hand.
- ▶ Anatomically designed.
- ▶ Curved Fingers follow the natural fingers shape at rest to reduce fatigue and increase finger dexterity even during rigorous procedures.
- ▶ Minimizes resistance in forming the normal working hand postures.
- ▶ Projected thumb ball to reduce stress on Thumb.
- ▶ Reduces upto 20% less effort to form a closed hand.
- ▶ Less stress on glove/hand especially over extended period of use, and enables long wearability.
- ▶ The multi-contoured palm and fingers ensure comfort for precision surgery.

STANDARDS

- ▶ ASTM D 3577 & EN 455-1, EN 455-2 & EN 455-3, IS 13422 & IS 4148
- ▶ Registered with US FDA (510K)
- ▶ Certified to meet PPE Standards EN 374, EN 420
- ▶ CE Certified - MDR: Regulation (EU) 2017/745, Class IIa
PPE: Regulation (EU) 2016/425, Cat. III

QUALITY CONTROL

- ▶ 100% Inspected
- ▶ Passes Viral Penetration Test - ASTM F1671
- ▶ AQL 0.65 for pin holes

Recommended for:

- ▶ **All Surgeries**



Kanam
KANAM LATEX
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The trusted name the world over



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Product Information

TYPE

Powdered Latex Surgical Gloves.

PRIMARY MATERIAL

Natural Rubber Latex.

DESIGN

Hand Specific, Curved finger, Beaded cuff, Micro rough textured.

POWDER AMOUNT

<15mg/dm²

STERILIZATION

Ethylene Oxide



PHYSICAL DIMENSIONS

Size	Min. Length (mm)	Palm Width (mm)	Min. Thickness (mm)		
			Cuff	Palm	Finger
5 ½	270	72 ± 4	0.14	0.17	0.19
6	280	77 ± 5			
6 ½		83 ± 5			
7		89 ± 5			
7 ½	285	95 ± 5			
8		102 ± 6			
8 ½		108 ± 6			
9		114 ± 6			

PHYSICAL PROPERTIES

Characteristics	Before Ageing	After Ageing (100±2°C for 22±0.3h)/ (70±2°C for 166±2h)
EN 455-2		
Force @ Break (N)	12 min	11 min
ISO 10282/IS 13422		
Force @ Break (N)	15 min	12 min
Ultimate Elongation (%)	850 min	700 min
Stress @ 300% Elongation (N)	1.5 max	-
ASTM D 3577		
Tensile Strength (Mpa)	27 min	22 min
Ultimate Elongation (%)	900 min	860 min
Stress @ 500% Elongation (Mpa)	3.0 max	-

PRE-SHIPMENT QUALITY INSPECTION

Sampling Procedure: ISO 2859 Part I

Sampling Plan: Single sampling, Normal Inspection

Characteristics	Inspection Level	AQL
Freedom from Holes	G-1	0.65
Visual attributes – Major Defects	G-1	1.5
Visual attributes – Minor Defects	G-1	2.5
Physical Dimension	S-2 / N=13	4.0
Physical Properties	S-2	4.0
Force at break	N=13	N/A
Extractable Protein Content	N=3	N/A
Powder Amount	N=2	N/A
Sterility (for sterile product)	N=5	N/A

PACKAGING (in cm)

Material	Quantity	Dimension (Sterile)	Dimension (Non-Sterile)
Paper Wallet(Folded)	One Pair	19(L) x 10(W)	
Pouch	One Pair	24(L) x 14(W)	
Inner Box	25 Pairs	26(L) x 14(W) x 10(H)	30(L) x 12(W) x 8(H)
Master Carton	500 Pairs	53(L) x 29(W) x 52(H)	50(L) x 31.5(W) x 41.5(H)

KLP/C26/Rev#04

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