



## 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-3577-2009 & EN 455-1:2000, EN 455-2:2011 & EN 455-3:2006, ISI 13422 & ISI 4148
- ▶ Registered with US FDA (510K)
- ▶ Certified to meet PPE Standards EN 374, EN 420 - Cat III
- ▶ CE Certified

### QUALITY CONTROL

- ▶ 100% Inspected
- ▶ Passes Viral Penetration Test - ASTM F1671.976
- ▶ AQL 1.5 for pin holes

Recommended for:

- ▶ All Surgeries



**Kanam**  
KANAM LATEX  
INDUSTRIES PVT. LTD.

The trusted name the world over

AN ISO 9001:2008, ISO 13485:2003 & ISO 14001:2004 CERTIFIED COMPANY

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This product is CE Certified

# 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/dm<sup>2</sup>

## STERILIZATION

Ethylene Oxide



## PHYSICAL DIMENSIONS

Size	Length (mm)		Palm Width (mm)		Average wt. per pair (gm)
	EN455-2	KANAM	EN455 2	KANAM	
5 1/2	250	270	72±4	74-75	15.0
6	260	280	77±5	81-82	16.8
6 1/2	260	280	83±5	84-85	18.2
7	270	280	89±5	91-92	19.4
7 1/2	270	285	95±5	98-99	21.0
8	270	285	102±6	103-104	22.0
8 1/2	280	285	108±6	108-109	23.2
9	280	285	114±6	113-114	24.6

Location	Minimum Thickness (mm)	
	ASTM D3577	KANAM
Cuff	0.1	0.14
Palm	0.1	0.17
Finger	0.1	0.19

## PHYSICAL PROPERTIES

Characteristics	Before Ageing		After Ageing 100±2°C for 22±0.3hrs	
	ASTM D 3577	KANAM	ASTM D 3577	KANAM
Tensile Strength (Mpa)	24 min	27 min	18 min	22 min
Ultimate Elongation (%)	750 min	900 min	560 min	860 min
Stress at 500% Elongation (Mpa)	5.5 max	2.5 max	N/A	N/A
Force at break (N)	EN 455-2	KANAM	EN 455-2	KANAM
	9.0 (min)	12 min	9.0 (min)	11 min

## PRE-SHIPMENT QUALITY INSPECTION

**Sampling Procedure:** ISO 2859 Part I

**Sampling Plan:** Single sampling, Normal Inspection

Characteristics	Inspection Level	Method	AQL
Freedom from Holes	G-1	ASTM D 5151:2011/EN 455-1:2000	1.5
Visual attributes – Major Defects	G-1	KL/SP/903	1.5
Visual attributes – Minor Defects	G-1	KL/SP/903	2.5
Physical Dimension	S-2 / N=13	ASTM D 3577: 2009/EN 455-2:2009+A2:2013	4.0
Physical Properties	S-2	ASTM D 3577: 2009	4.0
Force at break	N=13	EN 455-2:2009+A2:2013	N/A
Extractable Protein Content	N=3	ASTM D 5712:2010/EN 455-3:2015	N/A
Powder Amount	N=2	ASTM D 6124:011/ISO 21171:2006	N/A
Sterility (for sterile product)	N=5	EN ISO 11737-2:2009	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)

KLIP1.0916/Version (1)



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