

# KALTEX<sup>®</sup> EC

## POWDERFREE STERILE LATEX SURGICAL GLOVES

Kaltex Powderfree Surgical Gloves is made from Natural Rubber Latex. The glove is anatomically shaped, 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 Powderfree Surgical Gloves provides excellent barrier protection for both doctor and patient.

### SAFETY FEATURES

- ▶ Enhanced elasticity, tear strength and donning of powderfree gloves.
- ▶ Absence of powder eliminates dangers associated with powder, preventing granulomas, adhesions, fibrosis and occupational asthma. Does not contaminate sterile work area.
- ▶ Manufactured in clean environment with low bio burden and therefore reduced pyrogen.
- ▶ Sterilized in a validated process cycle as per ISO 11135:2014 norms.

### STANDARDS

- ▶ ASTM D-3577-2019 & EN 455-1:2020, EN 455-2:2015 & EN 455-3:2015, ISI 13422 & ISO 10282:2014
- ▶ CE Mark - MDD Class IIa

### QUALITY CONTROL

- ▶ AQL 1.5 for pin holes

Recommended for:

- ▶ **Surgeries & Ward Use**



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# Product Information

## TYPE

Powderfree Latex Surgical Gloves.

## PRIMARY MATERIAL

Natural Rubber Latex.

## COLOUR

White to Pale Yellow.

## DESIGN

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

## POWDER AMOUNT

<2mg/dm<sup>2</sup>

## STERILIZATION

Ethylene Oxide

## SHELF LIFE

3 years in original packing if stored as per storage instructions.



## PHYSICAL DIMENSIONS

Size	Length (mm)		Palm Width (mm)		Average wt. per pair (gm)	Minimum Thickness (mm)		
	EN455-2	KANAM	EN455-2	KANAM		Location	ASTM D3577	KANAM
5 ½	250	250	72±4	72±4	16.0 – 16.5	Cuff	0.1	0.13 - 0.14
6	260	260	77±5	77±5	16.5 – 17.0			
6 ½	260	260	83±5	83±5	17.0 – 17.5	Palm	0.1	0.16 - 0.17
7	270	270	89±5	89±5	17.5 – 18.0			
7 ½	270	270	95±5	95±5	18.0 – 18.5			
8	270	270	102±6	102±6	19.0 – 20.0	Finger	0.1	0.17 - 0.18
8 ½	280	280	108±6	108±6	23.0 – 23.5			
9	280	280	114±6	114±6	24.5 – 25.0			

## PHYSICAL PROPERTIES

Characteristics	Before Ageing	After Ageing 70±2°C for 166±2hrs
Tensile Strength (Mpa) min.	24 min	18 min
Ultimate Elongation (%) min.	750 min	560 min
Stress at 500% Elongation (Mpa)	5.5 max	N/A
Force at break (N) Min.	9.0 min	9.0 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 5151:2019/EN 455-1:2020	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: 2019/EN 455-2:2015	4.0
Physical Properties	S-2	ASTM D 3577: 2019	4.0
Force at break	N=13	EN 455-2:2015	N/A
Extractable Protein Content	N=3	ASTM D 5712:2015/EN 455-3:2015	N/A
Powder Amount	N=2	ASTM D 6124:2017/ISO 21171:2006	N/A
Sterility (for sterile product)	N=5	EN ISO 11737-2:2009	N/A

## PACKAGING

Material	Quantity	Dimension (cm)
Paper Wallet(Folded)	One Pair	19(L) x 10(W)
Pouch	One Pair	26(L) x 13(W)
Inner Box	50 Pairs	26(L) x 13(W) x 20(H)
Master Carton	400 Pairs	53(L) x 27(W) x 41(H)



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