

KALTEX[®] EC

POWDERED STERILE LATEX SURGICAL GLOVES

www.kanamlatex.com

Kaltex Powdered 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 Powdered Surgical Gloves provides excellent barrier protection for both doctor and patient.

SAFETY FEATURES

- ▶ Powdered with Modified Bio-Absorbable Corn starch, 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.

STANDARDS

- ▶ ASTM : D-3577-2009 & EN 455-1:2000, 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**



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.

COLOUR

Natural Creamy White.

DESIGN

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

POWDER AMOUNT

<15mg/dm²

STERILIZATION

Ethylene Oxide

SHELF LIFE

5 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 D 3577 | KANAM |
| 6 | 260 | 270 | 77±5 | 81-82 | 16.5 – 17.0 | Cuff | 0.1 | 0.10 |
| 6½ | 260 | 270 | 83±5 | 84-85 | 17.0 – 17.5 | | | |
| 7 | 270 | 270 | 89±5 | 91-92 | 17.5 – 18.0 | Palm | 0.1 | 0.14 |
| 7½ | 270 | 270 | 95±5 | 98-99 | 18.0 – 18.5 | | | |
| 8 | 270 | 270 | 102±6 | 103-104 | 18.5 – 19.0 | Finger | 0.1 | 0.15 |
| 8½ | 280 | 280 | 108±6 | 108-109 | 23.0 – 23.5 | | | |
| 9 | 280 | 280 | 114±6 | 113-114 | 24.5 – 25.0 | | | |

PHYSICAL PROPERTIES

| Characteristics | Before Ageing | After Ageing (100±2°C for 22±0.3h/70°C for 7 days) |
|---------------------------------|---------------|---|
| 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 5151:2011/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

| Material | Quantity | Dimension (cm) |
|----------------------|-----------|---------------------------|
| Paper Wallet(Folded) | One Pair | 19(L) x 10(W) |
| Pouch | One Pair | 24(L)x13(W) / 24(L)x14(W) |
| Inner Box | 25 Pairs | 26(L)x14(W)x10(H) |
| | 50 Pairs | 24(L)x13(W)x20(H) |
| Master Carton | 400 Pairs | 53(L)x25(W)x41(H) |
| | 500 Pairs | 53(L)x29(W)x52(H) |



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