

KALTEX®

POWDERED STERILE & NON-STERILE LATEX SURGICAL GLOVES

www.kanamlatex.com

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 10⁶, 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-3577-2019 & EN 455-1:2020, EN 455-2:2015 & EN 455-3:2015, 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
- ▶ AQL 1.5 for pin holes

Recommended for:

- ▶ **All Surgeries**



Kanam
KANAM LATEX
INDUSTRIES PVT. LTD.

The trusted name the world over

Ooppottil Buildings, K.K. Road
Kottayam-686 001, Kerala, India
Tel: 0481-2560108, 2563513
Fax: 0481-2563614

E-mail: customercare@kanamlatex.com
ho@kanamlatex.com

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 | Length (mm) | | Palm Width (mm) | | Average wt. per pair (gm) | Minimum Thickness (mm) | | |
|------|-------------|-------|-----------------|---------|---------------------------|------------------------|-----------|-------|
| | EN455-2 | KANAM | EN455-2 | KANAM | | Location | ASTMD3577 | KANAM |
| 5 ½ | 250 | 270 | 72±4 | 74-75 | 15.5-16.0 | Cuff | 0.1 | 0.14 |
| 6 | 260 | 280 | 77±5 | 81-82 | 16.5-17.0 | | | |
| 6 ½ | 260 | 280 | 83±5 | 84-85 | 18.0-18.5 | Palm | 0.1 | 0.17 |
| 7 | 270 | 280 | 89±5 | 91-92 | 19.8-20.4 | | | |
| 7 ½ | 270 | 285 | 95±5 | 98-99 | 21.0-21.5 | | | |
| 8 | 270 | 285 | 102±6 | 103-104 | 22.0-22.5 | Finger | 0.1 | 0.19 |
| 8 ½ | 280 | 285 | 108±6 | 108-109 | 23.0-23.5 | | | |
| 9 | 280 | 285 | 114±6 | 113-114 | 24.5-25.0 | | | |

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 | 3.0 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 5151:2019/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 (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) |



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