



Premium Powderfree Polymer Coated Surgical Gloves

Kaltex Powderfree Polymer Coated Gloves is made from Natural Rubber Latex. The glove is anatomically shaped with thumb ball effect, reducing hand fatigue during surgical procedures. Kaltex Powderfree Polymer Coated Gloves provides excellent barrier protection for both doctor and patient.

SAFETY FEATURES

- ▶ Enhanced elasticity, tear strength and donning of powderfree gloves.
- ▶ Latex protein no more than 50µg of protein per dm², eliminates risk of Latex Allergy - Type 1.
- ▶ Chemical residue almost nil, eliminates risk of contact Dermatitis - Type IV Allergy.
- ▶ Sterilized in a validated process cycle as per ISO 11135:2007 norms.
- ▶ Absence of powder eliminates dangers associated with powder, preventing granulomas, adhesions, fibrosis and occupational asthma. Does not contaminate sterile work area.
- ▶ Manufactured in dust free environment with low bioburden and therefore reduced pyrogen.
- ▶ High tactile sensitivity, good grip and excellent tear resistance.

STANDARDS

- ▶ EN 455 – I: 2000, EN 455 – II: 2011, EN 455 – III: 2006 & ASTM D 3577: 2009
- ▶ CE Certified
- ▶ Registered with USFDA (510K)
- ▶ Certified as PPE (Personal Protective Equipment)

QUALITY CONTROL

- ▶ 100% Inspected
- ▶ Passes Viral Penetration Test - ASTM F 1671:2007
- ▶ Factory Standard of AQL 0.65

Recommended for:

- ▶ **All Surgeries**



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Product Information

TYPE

Powder Free Polymer Coated Latex Surgical Gloves. Sterilized by ETO.

PRIMARY MATERIAL

Natural Rubber Latex.

DESIGN

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

POWDER FREE RESIDUE

<2mg/glove

STERILIZATION

Ethylene Oxide / Gamma
as per Customer requirement.

PHYSICAL DIMENSIONS

| Size | Length (mm) Min | Palm Width (mm) min | Thickness (mm) Min | | |
|------|-----------------|---------------------|--------------------|------|--------|
| | | | Cuff | Palm | Finger |
| 5 ½ | 250 | 72 ± 4 | 0.13 | 0.16 | 0.16 |
| 6 | 280 | 77 ± 5 | | | |
| 6 ½ | | 83 ± 5 | | | |
| 7 | | 89 ± 5 | | | |
| 7 ½ | | 95 ± 5 | | | |
| 8 | | 102 ± 6 | | | |
| 8 ½ | | 108 ± 6 | | | |
| 9 | | 114 ± 6 | | | |

PHYSICAL PROPERTIES

| Characteristics | Before Ageing | After Ageing 70±2°C for 166±2hrs |
|--------------------------------------|---------------|-------------------------------------|
| Tensile Strength (Mpa) min. | 24 | 18 |
| Ultimate Elongation (%) min. | 750 | 560 |
| Stress at 500% Elongation (Mpa) Max. | 5.5 | - |
| Force at break (N) Min. | 9.0 | 9.0 |

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 | 1.5 |
| 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 free residue | N=5 | N/A |
| Sterility (for sterile product) | N=5 | N/A |

PACKAGING

| Material | Quantity | Dimension (cm) |
|----------------------|---|-------------------------|
| Paper Wallet(Folded) | One Pair | 20(L) x 11.5(W) |
| Pouch | One Pair | 27(L) x 15(W) |
| Inner Box | 50 Pairs | 27(L) x 15(W) x 21(H) |
| Master Carton | 400 Pairs | 62(L) x 28.5(W) x 44(H) |
| Container Quantities | 20FCL: 1,50,800 pairs/40FCL: 3,16,000 pairs | |

KLPL0213/Revised Version (4)



Excellent Polymer Coated Powderfree Surgical Gloves