

Surgicare® Gynaecological

Long Cuff/Elbow Length Prepowdered Surgical Latex Gloves for Gynaecological & Obstetrical use

Surgicare Gynaecological gloves are made from Natural Rubber Latex. The extra length provides an excellent barrier protection from cross contamination. The anatomical shape with thumb ball effect prevents hand fatigue during surgery and obstetrical use.

SAFETY FEATURES

- ▶ Extra long cuff covers the obstetricians gown sleeves, and protects the users forearm against fluid contamination.
- ▶ For manual removal of placenta and for surgery of cervix, the extra length of cuff is of great advantage.
- ▶ The micro rough texture of glove surface helps in firm grip of the newborn baby and gives good grip of surgical instruments during episotomy.
- ▶ The anatomical shape gives comfort and prevents muscle cramps during long surgical procedures.
- ▶ Protects sensitive tissues against contact with abrasive materials.
- ▶ Extra length protects against AIDS/HIV infections.
- ▶ Elbow length gynaecological is a must in PPH Procedures (Post Partum haemorrhage).
- ▶ Lightly powdered with Modified Bio-Absorbable Corn starch, to prevent wound infections and granulomas.
- ▶ 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 4mg/unit.
- ▶ Manufactured in clean environment to reduce bio-burden level prior to sterilization. This achieves low Pyrogen level after sterilization.
- ▶ Manufactured in a clean environment to comply with EN 556 & ISO 13485 requirements.

STANDARDS

- ▶ ASTM: D-3577 & EN 455-1, EN 455-2, EN 455-3 & ISO 10282
- ▶ CE Mark - MDR: Regulation (EU) 2017/745, Class IIa
- ▶ PPE: Regulation (EU) 2016/425, Cat. III

QUALITY CONTROL

- ▶ 100% Inspected
- ▶ Factory Standard of 0.65AQL for Pinholes

Recommended for:

- ▶ **Obstetrical & Gynaecological Use**



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AN ISO 9001:2015, ISO 13485:2016 & ISO 14001:2015 CERTIFIED COMPANY

This product is CE Certified
www.kanamlatex.com

Product Information

TYPE

Powdered Latex Surgical Gloves for Obstetric and Gynaecological use.

PRIMARY MATERIAL

Natural Rubber Latex (NR).

COLOUR

Natural Creamy White.

DESIGN

Anatomically shaped, Curved Fingers, Beaded cuff, Micro Rough textured for 400mm.

Hand Specific, Straight Fingers, Beaded cuff, Micro Rough textured for 480mm.

POWDER CONTENT

< 15 mg/dm².

STERILIZATION

Ethylene Oxide / Gamma as per Customer requirement.

SHELF LIFE

5 years in original packaging if stored as per storage instructions.



PHYSICAL DIMENSIONS

| Size | Length (mm) | Palm Width (mm) | Thickness (mm) | | |
|------|-------------|-----------------|----------------|------|--------|
| | | | Cuff | Palm | Finger |
| 6 ½ | 400 | 83 ± 5 | 0.14 | 0.18 | 0.19 |
| 7 ½ | | 95 ± 5 | | | |
| 8 ½ | 480 | 108 ± 6 | | | |

PHYSICAL PROPERTIES

| Characteristics | Before Ageing | After Ageing 100±2°C for 22±0.3hrs (70±2°C for 166±2hrs) |
|--------------------------------|---------------|--|
| EN 455-2 | | |
| Force @ Break (N) | 12 min | 10 min |
| ISO 10282/IS 13422 | | |
| Force @ Break (N) | 15 min | 11 min |
| Ultimate Elongation (%) | 850 min | 700 min |
| Stress @ 300% Elongation (N) | 2.0 max | - |
| ASTM D 3577 | | |
| Tensile Strength (Mpa) | 27 min | 22 min |
| Ultimate Elongation (%) | 900 min | 800 min |
| Stress @ 500% Elongation (Mpa) | 4.0 max | - |

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 | 0.65 |
| 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 |
| Sterility | N=5 | N/A |

PACKAGING - 400 mm & 480 mm

| Material | Dimension (cm) | | | |
|------------------------------|--------------------|-------------------------------|--------------------|-------------------------------|
| | Long Cuff - 400 mm | | Long Cuff - 480 mm | |
| | Quantity (Pairs) | Paper Pouch/ Peelable Plastic | Quantity (Pairs) | Paper Pouch/ Peelable Plastic |
| Paper Wallet | 1 | 25(L) x 11(W) | 1 | 29(L) x 11(W) |
| Pouch | 1 | 32(L) x 15(W) | 1 | 36(L) x 15(W) |
| Inner Box | 50 | 32(L) x 15(W) x 23(H) | 50 | 36(L) x 15(W) x 22(H) |
| Master Carton | 250 | 76(L) x 32.5(W) x 24(H) | 200 | 37(L) x 31(W) x 45(H) |
| Container Quantities (Pairs) | 20 FCL | 1,17,000 | 20 FCL | 1,05,000 |
| | 40 FCL | 2,43,000 | 40 FCL | 2,23,000 |



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