

Surgicare® Premier

Long Cuff/Elbow Length Powder Free Polymer Coated Surgical Latex Gloves for Gynaecological & Obstetrical use

Surgicare Premier 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. These gloves are non-chlorinated.

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.
- ▶ Latex protein no more than 50µg of protein per gram and dm², eliminates risk of latex Allergy - Type 1.
- ▶ 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).
- ▶ Chemical residue almost nil, eliminates risk of contact Dermatitis – Type IV Allergy.
- ▶ Absence of powder eliminates dangers associated with powder, preventing granulomas, adhesions, fibrosis and occupational asthma. Does not contaminates sterile work area.
- ▶ Inner polymer coating provides smooth and easy donning of gloves.
- ▶ 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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KANAM LATEX
INDUSTRIES PVT. LTD.

The trusted name the world over



Ooppottill 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

Powderfree Polymer Coated 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.

POWDERFREE RESIDUE

< 2 mg/glove

PROTEIN CONTENT

< 50µg/gm and 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	108 ± 6				

PHYSICAL PROPERTIES

Characteristics	Before Ageing	After Ageing 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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