

# Surgicare®

## Low PRO

### Powdered Sterile Latex Surgical Gloves

Surgicare Low Pro gloves is made from Natural Rubber Latex. The protein content is less than  $100\mu\text{g}/\text{dm}^2$  to reduce risk of user being sensitized to Latex Protein Allergy Type I. 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. Surgicare Low Pro gloves provides excellent barrier protection for both doctor and patient.

#### SAFETY FEATURES

- ▶ 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  $4\text{mg}/\text{unit}$ .
- ▶ Chemical residue almost nil, eliminates risk of Contact Dermatitis - Type IV Allergy.
- ▶ Lightly powdered with Modified Bio-Absorbable Corn starch to prevent wound infections and granulomas.
- ▶ Manufactured in a clean environment to achieve low 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 & IS 13422.
- ▶ Registered with US FDA (510K).
- ▶ CE Mark - MDR: Regulation (EU) 2017/745, Class IIa  
PPE: Regulation (EU) 2016/425, Cat. III.

#### QUALITY CONTROL

- ▶ 100% Inspected.
- ▶ Passes viral penetration test-ASTM F1671.
- ▶ Factory Standard 0.65AQL for Pinholes.
- ▶ Passes Biocompatibility test as per ISO 10993 (Part 5, 10, 11 & 23).

Recommended for:

- ▶ **All Surgeries**



**Kanam**  
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](mailto:customercare@kanamlatex.com)  
[ho@kanamlatex.com](mailto:ho@kanamlatex.com)

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

This product is CE Certified  
[www.kanamlatex.com](http://www.kanamlatex.com)

# Product Information

## TYPE

Powdered Latex Surgical Gloves.

## PRIMARY MATERIAL

Natural Rubber Latex (NR).

## COLOUR

Creamy White.

## DESIGN

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

## POWDER AMOUNT

<15mg/dm<sup>2</sup>.

## 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) Min	Palm Width (mm)	Thickness (mm) Min		
			Cuff	Palm	Finger
5 ½	270	72 ± 4	0.14	0.17	0.19
6	280	77 ± 5			
6 ½		83 ± 5			
7		89 ± 5			
7 ½	285	95 ± 5			
8		102 ± 6			
8 ½		108 ± 6			
9		114 ± 6			

## PHYSICAL PROPERTIES

Characteristics	Before Ageing	After Ageing 100±2°C for 22±0.3hrs (70±2°C for 166±2hrs)
<b>EN 455-2</b>		
Force @ Break (N)	12 min	11 min
<b>ISO 10282/IS 13422</b>		
Force @ Break (N)	15 min	10 min
Ultimate Elongation (%)	850 min	700 min
Stress @ 300% Elongation (N)	1.5 max	-
<b>ASTM D 3577</b>		
Tensile Strength (Mpa)	27 min	22 min
Ultimate Elongation (%)	900 min	860 min
Stress @ 500% Elongation (Mpa)	3.0 max	-

## PRE-SHIPMENT QUALITY INSPECTION

Sampling Procedure: ISO 2859 Part 1

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
Powder free residue	N=5	N/A
Sterility	N=5	N/A

## PACKAGING

Material	Quantity (Pairs)	Dimension (cm)		
		Paper Pouch	Blister (Full Fold)	Blister (Half Fold)
Paper Wallet	1	19(L) x 10(W)	19(L) x 10(W)	19(L) x 10(W)
Pouch	1	26(L) x 13(W)	24(L) x 13(W)	16(L) x 13(W)
Inner Box	50	26(L) x 13(W) x 20(H)	24(L) x 13(W) x 21(H)	16(L) x 13(W) x 28(H)
Master Carton	400	53(L) x 27(W) x 41(H)	53(L) x 25(W) x 43(H)	53(L) x 33(W) x 30(H)
Container Quantities (Pairs)	20FCL	1,87,600	1,92,000	2,07,200
	40FCL	3,96,000	4,04,800	4,31,200

**Surgicare**<sup>®</sup>  
*Low PRO*  
 Powdered Sterile Latex Surgical Gloves

