

# Surgicare® Premier

Excellent Polymer Coated Powderfree Surgical Gloves

Surgicare Premier is made from Natural Rubber Latex. The glove is anatomically shaped with thumb ball effect, reducing hand fatigue during surgical procedures. Surgicare Premier provides excellent barrier protection for both doctor and patient. These gloves are non-chlorinated.

## SAFETY FEATURES

- ▶ Enhanced elasticity, tear strength and donning of powderfree gloves.
- ▶ Inner Polymer Coating provides smooth and easy donning of gloves.
- ▶ Micro textured surface for excellent instrument grip and anti-slip finish.
- ▶ Latex protein no more than 50µg of protein per gram and dm<sup>2</sup>, 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 norms SAL 10<sup>-6</sup>.
- ▶ Absence of powder eliminates dangers associated with powder, preventing granulomas, adhesions, fibrosis and occupational asthma. Does not contaminate sterile work area.
- ▶ Manufactured in a clean environment to comply with EN 556 & ISO 13485 requirements.
- ▶ Manufactured in a dust free environment with low bioburden and therefore reduced pyrogen.

## STANDARDS

- ▶ EN 455-1, EN 455-2 & EN 455-3, ASTM D 3577 & ISO 10282
- ▶ CE Mark - MDR: Regulation (EU) 2017/745, Class IIa
- ▶ PPE: Regulation (EU) 2016/425, Cat. III
- ▶ Registered with USFDA (510K)
- ▶ Passes Biocompatibility test as per ISO 10993 (Part 5, 10, 11 & 23)

## QUALITY CONTROL

- ▶ 100% Inspected
- ▶ Passes Viral Penetration Test - ASTM F 1671
- ▶ Factory Standard of 0.65AQL for Pinholes
- ▶ Tested for Chemotherapy Drugs as per ASTM D 6978

Recommended for:

- ▶ **All Surgeries**



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## Product Information

### TYPE

Powder Free Polymer Coated Latex Surgical Gloves.

### PRIMARY MATERIAL

Natural Rubber Latex (NR).

### COLOUR

White to Pale Yellow

### DESIGN

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

### POWDER FREE RESIDUE

<2mg/glove

### 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 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        | 12 min                           |
| Ultimate Elongation (%)        | 900 min       | 800 min                          |
| Stress @ 300% Elongation (N)   | 1.5 max       | -                                |
| <b>ASTM D 3577</b>             |               |                                  |
| Tensile Strength (Mpa)         | 27 min        | 22 min                           |
| Ultimate Elongation (%)        | 900 min       | 800 min                          |
| Stress @ 500% Elongation (Mpa) | 2.5 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  |
| Powder free residue               | N=5              | N/A  |
| Sterility                         | N=5              | N/A  |

## PACKAGING

| Material                     | Quantity (Pairs) | Dimension (cm)        |                       |                       |                       |
|------------------------------|------------------|-----------------------|-----------------------|-----------------------|-----------------------|
|                              |                  | Paper Pouch           | Peelable 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)         | 19(L) x 10(W)         |
| Pouch                        | 1                | 26(L) x 13(W)         | 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) | 26(L) x 13(W) x 21(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 27(W) x 43(H) | 53(L) x 25(W) x 43(H) | 53(L) x 33(W) x 30(H) |
| Container Quantities (Pairs) | 20FCL            | 1,87,600              | 1,76,000              | 1,92,000              | 2,07,200              |
|                              | 40FCL            | 3,96,000              | 3,69,600              | 4,04,800              | 4,31,200              |

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