

Surgicare[®] Premier

Excellent Polymer Coated Powderfree Surgical Gloves

www.kanamlatex.com

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.

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 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 11135:2014 norms SAL 10⁻⁶.
- ▶ 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 455-1:2020, EN 455-2:2015, EN 455-3:2015, ASTM D 3577:2019 & ISO 10282:2014
- ▶ CE Mark - MDD Class IIa / PPE Cat. III
- ▶ Registered with USFDA (510K)
- ▶ Passes Biocompatibility test as per ISO 10993-10

QUALITY CONTROL

- ▶ 100% Inspected
- ▶ Passes Viral Penetration Test - ASTM F 1671:2013
- ▶ Factory Standard of 0.65AQL for Pinholes
- ▶ Tested for Chemotherapy Drugs as per ASTM D 6978

Recommended for:

- ▶ **All Surgeries**



Kanam
KANAM LATEX
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The trusted name the world over



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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.

PRODUCT CODE - 019

PHYSICAL DIMENSIONS

Size	Length (mm)		Palm Width (mm)		Average wt. per pair (gm)	Minimum Thickness (mm)		
	EN455-2	KANAM	EN455-2	KANAM		Location	ASTM D 3577	KANAM
5 ½	250	270	72±4	74-75	15.5-16.0	Cuff	0.1	0.14
6	260	280	77±5	81-82	16.5-17.0			
6 ½	260	280	83±5	84-85	18.0-18.5	Palm	0.1	0.17
7	270	280	89±5	91-92	19.8-20.4			
7 ½	270	285	95±5	98-99	21.0-21.5	Finger	0.1	0.19
8	270	285	102±6	103-104	22.0-22.5			
8 ½	280	285	108±6	108-109	23.0-23.5			
9	280	285	114±6	113-114	24.5-25.0			

PHYSICAL PROPERTIES

Characteristics	Before Ageing		After Ageing 70±2°C for 166±2hrs	
	ASTM D 3577	KANAM	ASTM D 3577	KANAM
Tensile Strength (Mpa)	24 min	27 min	18 min	22 min
Ultimate Elongation (%)	750 min	900 min	560 min	860 min
Stress at 500% Elongation (Mpa)	5.5 max	2.0 max	N/A	N/A
Force at break (N)	EN 455-2	KANAM	EN 455-2	KANAM
	9.0 (min)	12 min	9.0 (min)	11 min

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	N=5	N/A

PACKAGING

Material	Quantity	Dimension (cm)
Paper Wallet(Folded)	One Pair	19(L) x 10(W)
Pouch	One Pair	26(L) x 13(W)
Inner Box	50 Pairs	26(L) x 13(W) x 20(H)
Master Carton	400 Pairs	53(L) x 27(W) x 41(H)
Container Quantities	20FCL: 1,87,600 pairs/40FCL: 3,96,000 pairs	



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