

Surgicare®

PREPOWDERED

Sterile Latex Surgical Gloves

www.kanamlatex.com

Surgicare Prepowdered gloves is made from Natural Rubber Latex. 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 Prepowdered 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 4mg/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.
- ▶ The protein content is less than $200\mu\text{g}/\text{dm}^2$ to reduce the risk of user being sensitized to Latex Protein Allergy Type 1.
- ▶ 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-3577-2009 & EN 455-1:2000, EN 455-2:2015 & EN 455-3:2015, ISO 10282:2014 & IS 13422.
- ▶ Registered with US FDA (510K).
- ▶ CE Mark - MDD Class IIa / PPE Cat. III.

QUALITY CONTROL

- ▶ 100% Inspected.
- ▶ Passes viral penetration test - ASTM F 1671:2007.
- ▶ AQL 1.5 for pin holes.

Recommended for:

- ▶ **All Surgeries**



Kanam
KANAM LATEX
INDUSTRIES PVT. LTD.

The trusted name the world over

Ooppotttil 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

Prepowdered Latex Surgical Gloves.

PRIMARY MATERIAL

Natural Rubber Latex (NR).

COLOUR

Natural Creamy White.

DESIGN

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

POWDER AMOUNT

<15mg/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)		Average wt. per pair (gm)	Minimum Thickness (mm)		
	EN455-2	KANAM	EN455-2	KANAM		Location	ASTM D3577	KANAM
5 ½	250	270	72±4	74-75	15.0	Cuff	0.1	0.14
6	260	280	77±5	81-82	16.8			
6 ½	260	280	83±5	84-85	18.2			
7	270	280	89±5	91-92	19.4	Palm	0.1	0.17
7 ½	270	285	95±5	98-99	21.0			
8	270	285	102±6	103-104	22.0	Finger	0.1	0.19
8 ½	280	285	108±6	108-109	23.2			
9	280	285	114±6	113-114	24.6			

PHYSICAL PROPERTIES

Characteristics	Before Ageing		After Ageing 100±2°C for 22±0.3hrs	
	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	2.5 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	Method	AQL
Freedom from Holes	G-1	ASTM D 5151:2011/EN 455-1:2000	1.5
Visual attributes – Major Defects	G-1	KL/SP/903	1.5
Visual attributes – Minor Defects	G-1	KL/SP/903	2.5
Physical Dimension	S-2 / N=13	ASTM D 3577: 2009/EN 455-2:2009+A2:2013	4.0
Physical Properties	S-2	ASTM D 3577: 2009	4.0
Force at break	N=13	EN 455-2:2009+A2:2013	N/A
Extractable Protein Content	N=3	ASTM D 5712:2010/EN 455-3:2015	N/A
Powder Amount	N=2	ASTM D 6124: 011/ISO 21171:2006	N/A
Sterility	N=5	EN ISO 11737-2:2009	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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