

Surgicare®

Excellent Powderfree Chlorinated Surgical Gloves

Surgicare is made from Natural Rubber Latex. The powderfree gloves, eliminates all risks associated with powder. The glove is anatomically shaped with thumb ball effect, reducing hand fatigue during surgical procedures. Surgicare provides excellent barrier protection for both doctor and patient.

SAFETY FEATURES

- ▶ 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.
- ▶ Absence of powder eliminates dangers associated with powder, preventing granulomas, adhesions, fibrosis and occupational asthma. Does not contaminate sterile work area.
- ▶ Latex film structure passes Viral Penetration Test (ASTM F1671:2013)
- ▶ 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.
- ▶ Sterilized in a validated process cycle to achieve sterility assurance level of 10⁻⁶, and air wash cycles to reduce sterility residue to less than 4mg/unit.

STANDARDS

- ▶ ASTM:D-3577-2019 & EN 455-1:2020, EN 455-2:2015, EN 455-3:2015 & ISO 10282:2014
- ▶ Registered with US FDA (510K)
- ▶ CE Mark - MDD Class IIa / PPE Cat. III

QUALITY CONTROL

- ▶ 100% Inspected
- ▶ Passes Viral Penetration Test - ASTM F 1671:2013
- ▶ Factory Standard of 0.65AQL for Pinholes

Recommended for:

- ▶ **All Surgeries**

www.kanamlatex.com



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

This product is CE Certified

Product Information

TYPE

Powder Free Chlorinated Latex Surgical Gloves.

PRIMARY MATERIAL

Natural Rubber Latex (NR).

COLOUR

Natural White to Light 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

3 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	15.5-16.0	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
Tensile Strength (Mpa) min.	24	18
Ultimate Elongation (%) min.	750	560
Stress at 500% Elongation (Mpa) Max.	5.5	NA
Force at break (N) Min.	9.0	9.0

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	One Pair	19(L) x 10(W)
Pouch	One Pair	24(L) x 14(W)
Inner Box	50 Pairs	24(L) x 13(W) x 10.5(H)
Master Carton	400 Pairs	50(L) x 41.5(W) x 34(H)



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