

### Product : Powder Free Polymer Coated Sterile Latex Surgical Gloves

#### Product Description

Material	: Natural Rubber Latex
Colour	: Natural White
Shape	: Anatomically Shaped with hand specific thumb position and curved fingers and micro textured surface
Cuff	: Beaded
External Surface	: Textured (Antitack Polymer Treated)
Internal Surface	: Polymer Coated
Shelf Life	: 5 Years
Sterilization	: EO/ Gamma
Basic UDI DI	: 806363LSGFM4

#### Product Classification

Medical Device	: Class IIa, Rule 06
Notify Body No.	: 2460
Regulatory Authority	: DNV Product Assurance AS Norway.
PPE Device	: Category III (Module D)
Notify Body No.	: 0598
Regulatory Authority	: SGS Fimko Oy, Finland

#### Product Compliance

- ✓ EN 455 Parts 1,2,3 & 4
- ✓ ASTM D 3577, IS 13422, ISO 10282
- ✓ EN ISO 374 Parts 1,2,4 & 5, EN 16523, EN ISO 21420
- ✓ EN ISO 15223-1, EN 1041
- ✓ EN 556-1, EN ISO 11135, EN ISO 11137-1, EN ISO 11737-1 & 2, EN ISO 11138-2
- ✓ EN ISO 10993 Parts 1,5,7,10,11 & 23
- ✓ ISO 9001, ISO 14001, ISO 13485, EN ISO 14971

#### Product Packaging

➔ 8 boxes x 50 pairs / 400 pairs per Carton

#### Product Safety

Freedom from Holes	: Inspection Level 1, AQL 0.65
Visual Major Defects	: Inspection Level 1, AQL 1.5
Visual Minor Defects	: Inspection Level1, AQL 4.0
Protein Content	: ≤ 50 µg/g
Powder Amount	: ≤ 2 mg/glove



#### Physical Dimension

Size	Minimum Length (mm)		Palm Width (mm)		Weight/ pair (g)
	EN 455-2	Kanam	EN 455-2	Kanam	
5.5	250	290	72±4	74 - 75	17.0 – 18.0
6.0	260	290	77±5	81 - 82	19.0 – 20.0
6.5	260	290	83±5	84 - 85	21.0 – 22.0
7.0	270	290	89±5	91 - 92	23.0 – 24.0
7.5	270	290	95±5	98 - 99	24.0 – 25.0
8.0	270	290	102±6	103 - 104	25.0 – 26.0
8.5	280	290	108±6	108 - 109	26.0 – 27.0
9.0	280	290	114±6	113 - 114	28.0 – 29.0

#### Thickness

Location	Minimum Thickness (mm)	
	ASTM D 3577	Kanam
Finger (13±3 mm from finger tip)	0.1	0.23 ± 0.02
Palm (Center of the palm)	0.1	0.20 ± 0.02
Cuff (25±5 mm from cuff edge)	0.1	≥ 0.17

#### Physical Properties

Characteristics	Before Ageing		After Ageing (70±2°C for 166±2 h)	
	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	800 min
Stress @ 500% Elongation (Mpa)	5.5 max	2.5 max	N/A	N/A
Force @ Break (N)	<b>EN 455-2</b>	<b>Kanam</b>	<b>EN 455-2</b>	<b>Kanam</b>
	9 min	14 min	9 min	12 min