

Product : Powder Free Sterile Synthetic Polychloroprene Surgical Gloves

Product Description

Material	: Synthetic Rubber Latex
Colour	: Green
Shape	: Anatomic
Cuff	: Beaded
External Surface	: Textured
Internal Surface	: Polymer Coated
Shelf Life	: 3 Years
Sterilization	: Gamma
Basic UDI DI	: 806363SPGFN6



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 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 2.5
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	19.0 - 19.5
6.0	260	290	77±5	80 - 81	21.5 - 22.0
6.5	260	290	83±5	83 - 84	24.0 - 24.5
7.0	270	290	89±5	90 - 91	25.5 - 26.0
7.5	270	290	95±5	96 - 97	27.0 - 27.5
8.0	270	290	102±6	105 - 106	28.0 - 28.5
8.5	280	290	108±6	107 - 108	30.0 - 30.5
9.0	280	290	114±6	112 - 113	32.0 - 32.5

Thickness

Location	Minimum Thickness (mm)	
	ASTM D 3577	Kanam
Finger (13±3 mm from finger tip)	0.1	0.17
Palm (Center of the palm)	0.1	0.16
Cuff (25±5 mm from cuff edge)	0.1	0.12

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)	17 min	18 min	12 min	15 min
Ultimate Elongation (%)	650 min	800 min	490 min	750 min
Stress @ 500% Elongation (Mpa)	7.0 max	4.5 max	N/A	N/A
Force @ Break (N)	EN 455-2	Kanam	EN 455-2	Kanam
	9 min	9 min	9 min	9 min