

### Product : Powdered Sterile Latex Surgical Gloves

#### Product Description

Material	: Natural Rubber Latex
Colour	: Creamy White
Shape	: Anatomic
Cuff	: Beaded
External Surface	: Textured (Finger-Micro Textured Palm-Reduced Textured)
Internal Surface	: Powdered
Shelf Life	: 5 Years
Sterilization	: EO/ Gamma
Basic UDI DI	: 806363LSGPMQ

#### 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
- ➔ 10 boxes x 50 pairs / 500 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
Protein Content	: <100 µg/dm <sup>2</sup>
Powder Amount	: <15 mg/dm <sup>2</sup>



#### Physical Dimension

Size	Minimum Length (mm)		Palm Width (mm)		Weight/pair (g)
	EN 455-2	Kanam	EN 455-2	Kanam	
5.5	250	270	72±4	74 - 75	15.5 – 16.0
6.0	260	280	77±5	81 - 82	16.5 – 17.0
6.5	260	280	83±5	84 - 85	18.0 – 18.5
7.0	270	280	89±5	91 - 92	19.8 – 20.4
7.5	270	285	95±5	98 - 99	21.0 – 21.5
8.0	270	285	102±6	103 - 104	22.0 – 22.5
8.5	280	285	108±6	108 - 109	23.0 – 23.5
9.0	280	285	114±6	113 - 114	24.5 – 25.0

#### Thickness

Location	Minimum Thickness (mm)	
	ASTM D 3577	Kanam
Finger (13±3 mm from finger tip)	0.1	0.19
Palm (Center of the palm)	0.1	0.17
Cuff (25±5 mm from cuff edge)	0.1	0.14

#### Physical Properties

Characteristics	Before Ageing		After Ageing (100 ± 2°C for 22 ± 0.3 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	860 min
Stress @ 500% Elongation (Mpa)	5.5 max	3.0 max	N/A	N/A
Force @ Break (N)	EN 455-2	Kanam	EN 455-2	Kanam
	9 min	12 min	9 min	11 min