

### Product : Powder Free Sterile Latex Dual Surgical Gloves

#### Product Description

Description	Under glove	Over glove
Material	Natural Rubber Latex	Natural Rubber Latex
Colour	Green	White to Pale Yellow
Shape	Anatomic	Anatomic
Cuff	Beaded	Beaded
External Surface	Chlorinated & Siliconized	Antitack Polymer Treated
Internal Surface	Polymer Coated	Polymer Coated
Shelf Life	3 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

➔ 4 boxes x 25 units / 200 units 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 Level 1, AQL 2.5
Protein Content	: < 50 µg/dm <sup>2</sup>
Powder Amount	: < 2 mg/glove



#### Physical Dimension (Underglove & Overglove)

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 (Underglove & Overglove)

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 (Underglove & Overglove)

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	20 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)	EN 455-2	Kanam	EN 455-2	Kanam
	9 min	12 min	9 min	11 min