

### Product : Powder Free Sterile Latex Examination Gloves

#### Product Description

Material	: Natural Rubber Latex
Colour	: White to Pale Yellow
Shape	: Ambidextrous
Cuff	: Beaded
External Surface	: Textured
Internal Surface	: Chlorinated/Polymer Coated
Shelf Life	: 3 Years
Sterilization	: EO
Basic UDI DI	: 806363LEGFJW

#### Product Classification

Medical Device	: Class Is, Rule 05
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 3578, IS 15354
- ✓ EN ISO 15223-1, EN 1041
- ✓ EN 556-1, EN ISO 11135, EN ISO 11737-1 & 2,  
EN ISO 11138-2
- ✓ EN ISO 10993 Parts 1,5,10 & 23
- ✓ ISO 9001, ISO 14001, ISO 13485, EN ISO 14971

#### Product Packaging

➔ 6 boxes x 50 pairs / 300 pairs per Carton

#### Product Safety

Freedom from Holes	: Inspection Level 1, AQL 1.5
Visual Major Defects	: Inspection Level 1, AQL 1.5
Visual Minor Defects	: Inspection Level1, AQL 2.5
Protein Content	: < 50 µg/dm <sup>2</sup>
Powder Amount	: < 2 mg/dm <sup>2</sup>



#### Physical Dimension

Size	Minimum Length (mm)		Palm Width (mm)		Weight/ glove (g)
	EN 455-2	Kanam	EN 455-2	Kanam	
X Small	240	240	≤ 80	74 - 75	5.0 - 5.5
Small	240	240	80 ± 10	84 - 85	5.5 - 6.0
Medium	240	240	95 ± 10	95 - 96	6.0 - 6.5
Large	240	240	110 ± 10	106 - 107	6.5 - 7.0
X-Large	240	240	≥ 110	112 - 113	7.0 - 7.5

#### Thickness

Location	Minimum Thickness (mm)	
	ASTM D 3578	Kanam
Finger (13±3 mm from finger tip)	0.08	0.11
Palm (Center of the palm)	0.08	0.10

#### Physical Properties

Characteristics	Before Ageing		After Ageing (70±2°C for 166±2 h)	
	ASTM D 3578	Kanam	ASTM D 3578	Kanam
Tensile Strength (Mpa)	18min	22 min	14 min	18 min
Ultimate Elongation (%)	650 min	800 min	500 min	600 min
Stress @ 500% Elongation (Mpa)	5.5 max	5.5 max	N/A	N/A
Force @ Break (N)	EN 455-2	Kanam	EN 455-2	Kanam
	6 min	6 min	6 min	6 min