

### Product : Powder Free Sterile Latex Surgical Gloves for Gynaecological Use – 480 mm

#### Product Description

Material	: Natural Rubber Latex
Colour	: Creamy White
Shape	: Hand Specific
Cuff	: Beaded
External Surface	: Chlorinated
Internal Surface	: Chlorinated
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 pairs / 100 pairs per Carton
- ➔ 4 boxes x 50 pairs / 200 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	: < 50 µg/dm <sup>2</sup>
Powder Amount	: < 2 mg/ glove



#### Physical Dimension

Size	Minimum Length (mm)	Palm Width (mm)		Weight/pair (g)
		EN 455-2	Kanam	
6.5 (S)	480	83±5	84 - 85	35.0 – 36.0
7.5 (M)	480	95±5	95 - 96	37.0 - 38.0
8.5 (L)	480	108±6	105 - 106	39.0 – 40.0

#### 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	0.18
Cuff (25±5 mm from cuff edge)	0.1	0.14

#### 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	4.0 max	N/A	N/A
Force @ Break (N)	EN 455-2	Kanam	EN 455-2	Kanam
	9 min	12 min	9 min	10 min