

## Product Specification

### Product : Powder Free Sterile Synthetic Nitrile Examination Gloves (480 mm)

#### Product Description

Material	: Synthetic Nitrile Rubber Latex
Colour	: Blue
Shape	: Ambidextrous
Cuff	: Beaded
External Surface	: Textured
Internal Surface	: Polymer Coated
Shelf Life	: 3 Years
Sterilization	: EO
Basic UDI DI	: 806363SNGFMU

#### 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 6319, 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

- ➔ 5 boxes x 50 pairs / 250 pairs per Carton
- ➔ 4 boxes x 25 pairs / 100 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
Powder Amount	: < 2 mg/glove



#### Physical Dimension

Size	Minimum Length (mm)	Palm Width (mm)		Weight/ glove (g)
		EN 455-2	Kanam	
X Small	480	≤ 80	74 - 75	15.0 - 15.5
Small	480	80 ± 10	84 - 85	16.0 - 16.5
Medium	480	95 ± 10	95 - 96	16.5 - 17.0
Large	480	110 ± 10	106 - 107	17.0 - 17.5
X-Large	480	≥ 110	112 - 113	17.5 - 18.0

#### Thickness

Location	Minimum Thickness (mm)	
	ASTM D 6319	Kanam
Finger (13±3 mm from finger tip)	0.05	0.20
Palm (Center of the palm)	0.05	0.18

#### Physical Properties

Characteristics	Before Ageing		After Ageing (70±2°C for 166±2 h)	
	ASTM D 6319	Kanam	ASTM D 6319	Kanam
Tensile Strength (Mpa)	14 min	14 min	14 min	14 min
Ultimate Elongation (%)	500 min	500 min	400 min	400 min
Force @ Break (N)	EN 455-2	Kanam	EN 455-2	Kanam
	6 min	6 min	6 min	6 min