

Product : Powder Free Non – Sterile Synthetic Nitrile Examination Gloves

Product Description

Material	: Synthetic Nitrile Rubber Latex
Colour	: Bluple
Shape	: Ambidextrous
Cuff	: Beaded
External Surface:	Finger textured and Chlorinated
Internal Surface:	Polymer coated
Shelf Life	: 3 Years
Basic UDI DI	: 806363SNGNFF3

Product Classification

Medical Device	: Class I, Rule 05
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Product Compliance

- ✓ EN 455 Parts 1,2,3 & 4
- ✓ ASTM D 6319, IS 15354, ISO 11193-1
- ✓ EN ISO 15223-1, EN 1041
- ✓ EN ISO 10993 Parts 1,5,10 & 23
- ✓ ISO 9001, ISO 14001, ISO 13485, EN ISO 14971

Product Packaging

➔ 10 boxes x 100 pcs / 1000 pcs 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)
	ASTM D 6319	EN 455-2	ISO 11193-1 & IS 15354		
X Small	220	240	220	70 ± 10	4.2 – 4.4
Small	220	240	220	80 ± 10	4.5 – 4.7
Medium	230	240	230	95 ± 10	4.8 – 5.0
Large	230	240	230	110 ± 10	5.2 – 5.5
X-Large	230	240	230	120 ± 10	5.5 – 5.7

Thickness

Location	Minimum Thickness (mm)		
	ASTM D 6319	ISO 11193-1 & IS 15354	
		Smooth	Texture
Finger (13±3 mm from finger tip)	0.05	0.08	0.11
Palm (Center of the palm)	0.05	0.08	0.11

Physical Properties

Characteristics	Before Ageing			After Ageing (70±2°C for 166±2 h)		
	ASTM D 6319	EN 455-2	ISO 11193-1 & IS 15354	ASTM D 6319	EN 455-2	ISO 11193-1 & IS 15354
Tensile Strength (Mpa)	14 min	-	-	14 min	-	-
Ultimate Elongation (%)	500 min	-	500 min	400 min	-	500 min
Stress @ 500% Elongation (Mpa)	-	-	-	N/A	-	N/A
Force @ Break (N)	-	6 min	7 min	-	6 min	7 min