

Product : Powdered Non-Sterile Latex Examination Gloves

Product Description

Material	: Natural Rubber Latex
Colour	: Creamy White
Shape	: Ambidextrous
Cuff	: Beaded
External Surface	: Smooth
Internal Surface	: Powdered
Shelf Life	: 3 Years
Basic UDI DI	: 806363LEGNPBB



Physical Dimension

Size	Minimum Length (mm)			Palm Width (mm)	Weight/glove (g)
	ASTM D 3578	EN 455-2	ISO 11193-1 & IS 15354		
X Small	220	240	220	70 ± 10	4.0 – 4.5
Small	220	240	220	80 ± 10	4.5 – 5.0
Medium	230	240	230	95 ± 10	5.0 – 5.5
Large	230	240	230	110 ± 10	5.5 – 6.0
X-Large	230	240	230	120 ± 10	6.0 – 6.5

Product Classification

Medical Device : Class I, Rule 05

Product Compliance

- ✓ EN 455 Part 1,2,3 & 4
- ✓ ASTM D 3578, 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

➔ 20 boxes x 100 pcs / 2000 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
 Protein Content : < 200 µg/dm²
 Powder Amount : < 10 mg/dm²

Thickness

Location	Minimum Thickness (mm)		
	ASTM D 3578	ISO 11193-1 & IS 15354	
		Smooth	Texture
Finger (13±3 mm from finger tip)	0.08	0.08	0.11
Palm (Center of the palm)	0.08	0.08	0.11

Physical Properties

Characteristics	Before Ageing			After Ageing (100±2°C for 22±0.3 h)		
	ASTM D 3578	EN 455-2	ISO 11193-1 & IS 15354	ASTM D 3578	EN 455-2	ISO 11193-1 & IS 15354
Tensile Strength (Mpa)	18 min	-	-	14 min	-	-
Ultimate Elongation (%)	650 min	-	650 min	500 min	-	500 min
Stress @ 500% Elongation (Mpa)	5.5 max	-	-	N/A	-	N/A
Force @ Break (N)	-	6 min	7 min	-	6 min	6 min