

Sterile latex gynecological gloves –Powder free (polymer coated)

DESCRIPTION:

- Gloves compounded primarily from natural rubber latex (Type-1).
- Powder free gloves coated with unique blend of polymer to provide excellent donning capability.
- Creamy white to pale yellow in color (Natural).
- Excellent barrier protection due to its extra length preventing cross contamination.
- Free from dirt marks, oil stains, embedded foreign particles, coagulum etc.
- EO sterilized

DESIGN & FEATURES:

- Anatomically shaped medical gloves with the thumb positioned towards the palmar surface of the index finger rather than lying flat
- The cuff shall fit closely without being constrictive and it shall not roll back or ruckle while in use.
- Anatomically shaped with micro rough surface in palm and finger area.
- Products have shelf-life of 3 years from the date of manufacturing
- Each glove has non- detectable level of chemical residue.
- Sterilized by validated procedure as per ISO 11135:2014 which maintains the EO residue below 4mg/unit and sterility assurance level is 10^{-6}
- Passes Viral Penetration test as per ASTM F 1671
- Biologically compatible as per ISO 10993-Part 5, 7, 10 & 11.
- Passes Bacterial Endotoxin test as per EN 455-3:2006
- Manufactured in clean environment to reduce bio burden level prior to sterilization.

GENERAL INSTRUCTIONS:

- Keep the gloves in cool, dry place and away from direct sun light.
- Sterile Gloves for single use only. Sterile until package is opened or damaged.
- This product contains natural rubber latex which may cause allergic reaction to some individuals. In case of latex allergy discontinues use and consults a physician.
- Reuse of gloves may cause infection, allergic reaction and poor barrier protection.
- For transient use (normally intended for continuous use for less than 60 minutes)
- Dispose after use as per hospital policies or country's regulatory norms.

INTENDED USE:

- Gloves intended to be worn once and then discarded. The glove is worn on the hand of surgeon and health care personnel to prevent cross contamination between healthcare personnel and patient's body, fluids, waste or environment. The gloves are designed for transient use and are intended for gynecological and obstetrical use.

PHYSICAL DIMENSION

(ASTM D 3577: 2019, EN 455-2:2009+ A2:2013, IS: 13422:1992)

Size	Length (mm)min	Width (mm) min	Thickness (mm) min			
			Finger	Palm	Cuff	
6½	14 inch	355 mm	83 ± 5	0.20	0.18	0.12
	16 inch	400 mm				
	18 inch	450 mm				
7½	14 inch	355 mm	95 ± 5	0.20	0.18	0.12
	16 inch	400 mm				
	18 inch	450 mm				
8½	14 inch	355 mm	108 ± 6	0.20	0.18	0.12
	16 inch	400 mm				
	18 inch	450 mm				

PHYSICAL PROPERTIES:

Characteristics	Before Ageing	After Ageing (70 ± 2 °C for 168 hrs)
ASTM D 3577:2019, IS 13422:1992		
Tensile Strength (Mpa) min.	24	18
Ultimate Elongation (%) min.	750	560
Stress at 500% Elongation (Mpa) Max.	5.5	NA
EN 455-2:2009+A2:2013		
Minimum force at break	9.0 N	9.0 N

Sterilization (for sterile product)	Ethylene Oxide
Sterility	Shall pass Sterility test as per US/ IP/EU Pharmacopeia
Packing : <ul style="list-style-type: none">• 1 Pair (1 left and 1 right) of gloves per innerwrapper.• 1 inner wrapper per pouch.• 25 pouches per inner (dispenser) box.• 8 dispenser box(200 pairs) in an outercarton	
Labeling	Shall comply with government regulatory requirement for and customer requirements.

PERFORMANCE REQUIREMENTS AS PER ASTM 3577:2019 & EN 455-1: 2000, EN 455-2:2009+A2:2013 & EN 455-3:2006

Sampling procedure: ISO 2859
Part-I
Sampling
plan
i. General Inspection Level - For freedom from pinholes
ii. Special Inspection Level – For Physical Dimension and Physical
Properties (Before ageing and after ageing)

Characteristic	Inspection Level	AQL
Freedom from holes	G-1	1.5
Physical Dimensions	S2	4.0
Physical Properties	S2	4.0
Sterility	N=5	N/A
Labelling	S2	1.5
Packing	S2	1.5