

PRODUCT SPECIFICATION

PRODUCT NAME : LATEX SURGICAL GLOVES STERILE POWDERED

Special Features

• Lower modulus for better comfort

• Low powder content that minimizes skin irritation

• Thicker gloves for enhanced safety

Product Information

Material : Natural Rubber Latex

Colour : Creamy White

Design : Hand Specific, Beaded Cuff, Micro rough textured

Powder content : $< 15 \text{ mg} / \text{dm}^2$

Extractable Protein

Level : <200 micro gram/ dm².

Sterilization : Ethylene Oxide / Gamma irradiated as per customer requirement

Labelling : Shall comply with the corresponding labelling specification and customer requirement.

Shelf Life : 5 years from the date of manufacture.

Storage condition : Shall be stored in cool dry place and away from direct light.

Packaging Details

Wrapper	1 pair
Pouch	1 pair
Inner Box	50 pairs
Master Carton	500 pairs (10 inner boxes)
20 feet container	2,34,500 pairs (469 Cartons)
40 feet HC container	5,69,500 pairs (1139 Cartons)

Certifications : CE

ISO 9001 : 2008 ISO 13485 : 2003

Quality Standard : ASTM D 3577, EN455 1 & 2



Physical Dimensions

Length(mm) Min	Size	5.5	6.0	6.5	7.0	7.5	8.0	8.5	9.0
	Length	290 <u>+</u> 10 mm							
\Midth /mm\	Size	5.5	6.0	6.5	7.0	7.5	8.0	8.5	9.0
Width (mm)	Width (<u>+</u> 6)	70	76	83	89	95	102	108	114
Thickness(mm)	Cuff	0.13 Min 0.15 Min							
Min	Palm								
	Finger	0.18 Min							

Physical Properties

Characteristics	Before Ageing	After Ageing (70± 2°C for 166 ± 2 hrs)
Tensile Strength (Mpa) min.	24 mpa Min	18 mpa Min
Ultimate Elongation (%) min.	750% Min	560% Min
Stress at 500% Elongation (Mpa) Max.	5.5 mpa	NA
Force at break (N) Min.	12	9

Inspection Level (Pre-Shipment)

Characteristics	Inspection Level	AQL
Freedom from Holes	G-1	1.5
Visual attributes – Major Defects	G-1	1.5
Visual attributes – Minor Defects	G-1	2.5
Physical Dimension	S-2/N=13	4.0
Physical Properties	S-2	4.0
Force at Break	N=3	N/A
Extractable Protein Content	N=3	N/A
Powder free residue	N=5	N/A
Sterility (for sterile product)	N=5	N/A



Directions for use:

1.1 Preparation for use : Ensure selection of gloves with correct size.

Below is the correct glove size width:

Size	5.5	6.0	6.5	7.0	7.5	8.0	8.5	9.0
Width Range (mm) (+6)	70	76	83	89	95	102	108	114

1.2 How to use

- Dry hand before donning the gloves.
- Take out the product after checking package.
- Gloves need to be donned carefully; do not apply excessive force to pull the gloves when donning.
- Keep the fingernails short and change gloves frequently to avoid tearing issue.
- The gloves should be discarded with an appropriate waste disposal container after use according to local disposal regulations.

1.3 Cautions for Use

- The product is for single use.
- Sterility guaranteed until package is opened or damaged.
- Users should consider the circumstances of use in deciding whether to remove any residual powder on gloves after donning. Powder can be removed by wiping gloves thoroughly with a sterile wet sponge, sterile wet towel or other effective method.
- Isolated cases of allergic reactions to latex product or powder have been reported. If you
 experience a reaction to this product, discontinue use immediately and seek medical help.

1.4 Storage Condition

- The atmosphere must always be conducive to the storage of the gloves.
- Gloves before opened for use shall be stored in dark, cool and dry place.
- Gloves need to avoid area with excessive heat. The storage areas need to be controlled below 40°C/ 104 °F.
- Gloves need to be stored at the areas with good air ventilation.
- Gloves need to be shielded from direct sunlight and fluorescent lighting.
- Gloves need to be stored far away from any energy radiating and heat generating equipment.

1.5 Expiration Date

The shelf life of the gloves is 5 years from the date of manufacture.