

PRODUCT SPECIFICATION

PRODUCT NAME : GYNAECOLOGY (ELBOW LENGTH) LATEX SURGICAL GLOVES
STERILE POWDERED.

Special Features

- Elbow length gloves help doctors avoid direct contact with blood and mucous membranes that occurs in 25% of vaginal deliveries and 35% of caesarean section
- These gloves also protect doctors from significant blood and amniotic fluid contamination
- Useful in pharmaceutical factories in plant & packaging

Product Information

Material : Natural Rubber Latex
Colour : Creamy White
Design : Hand Specific, Beaded Cuff, Micro rough textured
Powder Content : < 15 mg / dm²
Extractable Protein
Level : <200 micro gram/ dm²
Sterilization : Ethylene Oxide / Gamma irradiated as per customer requirement
Labeling : Shall comply with the corresponding labeling 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	25 pairs
Master Carton	300 pairs (12 inner boxes)
20 feet container	1,05,000 pairs (350 Cartons)
40 feet HC container	2,55,000 pairs (850 Cartons)

Certifications : CE
ISO 9001 : 2008
ISO 13485 : 2003

Quality Standard : ASTM 3577, EN455

Physical Dimensions

Length(mm) Min	Size	Small	Medium	Large
	Length (mm) Min.	400mm, 450mm and 480mm.		
Width (mm)	Size	Small	Medium	Large
	Width (±6)	83±6	95±6	108±6
Thickness(mm) Min	Cuff	0.15 Min		
	Palm	0.17 Min		
	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	Small	Medium	Large
Width Range (mm) (±6)	83±6	95±6	108±6

1.2 How to use

- Dry hands before donning the gloves.
- Take out the product after checking pouch.
- 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 only.
- 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.