

## PRODUCT SPECIFICATION

**PRODUCT NAME** : GYNAECOLOGY (ELBOW LENGTH) LATEX SURGICAL GLOVES  
STERILE POWDER FREE

### 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
- We suggest use of powder-free gloves as the powder on gloves can enter patient's body during surgery, which may trigger an inflammatory response by the immune system, leading to the formation of fibrous bands and post-operative adhesions.
- 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 : 2 mg / dm<sup>2</sup>  
Extractable Protein  
Level : <50 micro gram/ dm<sup>2</sup>  
Sterilization : Ethylene Oxide / Gamma irradiated as per customer requirement  
Labeling : Shall comply with the corresponding labeling specification and customer requirement.  
Shelf Life : 3 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	<b>Small (6.5)</b>	<b>Medium (7.5)</b>	<b>Large (8.5)</b>
	Length (mm) Min.	400mm, 450mm and 480mm.		
Width (mm)	Size	<b>Small</b>	<b>Medium</b>	<b>Large</b>
	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) ( $\pm 6$ )	83 $\pm 6$	95 $\pm 6$	108 $\pm 6$

### **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.
- 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 3 years from the date of manufacture.