

# **PRODUCT SPECIFICATION**

PRODUCT NAME : LATEX SURGICAL GLOVES STERILE POWDERFREE BEADLESS (ULTRA NULIFE)

# **Special Features**

- Bead-less cuff for improved gown grip and to prevent roll down
- Micro rough surface for better instrument grip during operation
- · Reinforced cuff area to prevent tearing while donning gloves
- Enhanced comfort and flexibility
- Optimum moisture content: cuts down risk of electro-surgery shocks
- Packed in special Kangaroo wrap
- Packed in peel-open pouch for easy peelability.

#### **Product Information**

Material : Natural Rubber Latex

Colour : Creamy White

Design : Hand Specific, Beadless Cuff, Micro rough textured

Powder Content : 2mg max per one piece of gloves

Extractable Protein

Level : <50 micro gram/ dm2 per piece of gloves.

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	40 pairs
Master Carton	240 pairs (6 inner boxes)
20 feet container	1,34,400 pairs (560 Cartons)
40 feet HC container	3,26,000 pairs (1360 cartons)

Product Certificates : 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	300 <u>+</u> 10 mm							
Width (mm)	Size	5.5	6.0	6.5	7.0	7.5	8.0	8.5	9.0
	Width ( <u>+</u> 6)	70	76	83	89	95	102	108	114
Thickness(mm)	Cuff	0.20 Min							
Min	Palm	0.22 Min 0.25 Min							
	Finger								

# **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	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) ( <u>+</u> 6)	70	76	83	89	95	102	108	114

### 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.