

**PRODUCT CATALOGUE**

**PRODUCT** : LATEX SURGICAL GLOVES, LONG CUFF, STERILE, GYNAECOLOGICAL, PRE-POWDERED/POWDER FREE  
**BRAND NAME** : AGE.CARE  
**COMPLYING STANDARDS** : ASTM D 3577:2009/ EN 455-1:2000, EN 455-2:2011 and EN 455-3:2006

**Specification**

- Made from high quality natural rubber latex
- Natural white/pale yellow colour
- Anatomically shaped, hand specific- extra long cuff
- Micro rough surface texture provides enhanced instrument grip
- Substantially low protein level to minimize the risk of allergen
- Lightly powdered with USP grade bio-absorbable cornstarch for powdered gloves
- Polymer coated or chlorinated for powder free gloves
- Packed in medical grade inner wallet and pouch
- E.T.O Sterilized as standard (or Gamma sterilization on request)
- Ring rolled bead and extra length for extra protection
- Complies with International Standard ASTM D3577/ EN 455/ IS 13422: 1992



**Physical Dimensions**

SIZE	Small (6½")		Medium (7½")		Large (8½")	
Length (mm)	400 to 480 mm					
Width ( Palm) mm	83±5		95±6		108 ±6	
Thickness at (mm)	Cuff	0.15±2	Palm	0.17±2	Finger	0.17±2

**Physical Properties**

- |   |   |
|---|---|
| 1) Tensile Strength before ageing : 24 Mpa  | 5) Total Protein content : <150µg/dm <sup>2</sup>   |
| 2) Ultimate elongation before ageing : 750% | 6) Powder amount (Powdered) : <15mg/dm <sup>2</sup> |
| 3) Tensile Strength after ageing : 18 Mpa   | 7) Powder amount (Powder Free) : <2mg/glove         |
| 4) Ultimate elongation after ageing : 560%  |   |

**Performance criteria (Sampling plan as per ISO 2859)**

Sr.No.	Characteristics	Related defects	Inspection Levels	AQL
01	Freedom from holes	Pin hole, cuff hole, palm holes	G-1	0.65
02	Physical Dimensions	Length, Width, Thickness	S-2	4.0
03	Physical Properties	Before & after ageing	S-2	4.0
04	Powder amount	Exceeds maximum amount	N=3	N/A

**Shelf life**

The shelf life of the gloves is 3 years from the date of manufacture.

## USE INSTRUCTIONS

**MEDICAL DEVICE: : LATEX SURGICAL GLOVES, LONG CUFF, STERILE, GYNAECOLOGICAL, PRE-POWDERED/ POWDER FREE**

### ***Intended applications:***

LATEX SURGICAL GLOVES –LONG CUFF- STERILE are classified as Class IIa Medical Device as per Rule 6 of Annex IX as per MDD/93/42/EEC as amended. These are intended for use by Surgeon in the obstetrics and Gynaecological purpose.

- It helps to protect the risk of contamination of surgeon's hands up to forearm with blood, amniotic and other body fluids during the obstetrical procedures.
- Reduce the risk of germ dissemination to the environment and of transmission from the health-care worker to the patient and vice versa, as well as from one patient to another.

### ***Contra indications:***

- Latex Surgical gloves are manufactured from NATURAL RUBBER LATEX

#### **CAUTION!**

"This product contains natural rubber latex which may cause allergic reaction to some individuals. if any allergic reaction is observed discontinue the use and consult a physician"

### ***Instructions for use***

- Each pouch contains one pair separate gloves for left and right hand.
- Size No is marked for Selection of gloves of appropriate size.
- Do not use the sterilized gloves if package is opened or damaged. Do not re-sterilize damaged or opened pouches.
- Must see the date of Manufacturing and expiry date, Lot/Batch No, Sterilization Date & Manufacturers address.
- Must see the product specification standard reference ( ASTM/EN Standard ) and AQL Level.
- For powdered gloves after donning remove powder by wiping gloves thoroughly with wet sterile cloth/sponge or other effective method.
- Make sure the powder does not contaminate the sterile working area.
- Use micro roughened glove for added instrument grip.
- Limit "Touch Contamination" with soiled gloves.
- Do not store gloves exposed to direct sunlight, fluorescent lighting or under high Humidity areas and protect from Ozone atmosphere.
- Store gloves under cool dry place where temperature does not rise above 40°C.
- The device is for single use only.
- Disposal after use as per local, state, national regulatory rules.