

PRODUCT CATALOGUE

PRODUCT : **LATEX SURGICAL GLOVES, STERILE, POWDER FREE**
 BRAND NAME : **IndiSAFE**
 COMPLYING STANDARDS : **ASTM D 3577/ EN 455/ IS 13422:1992**
 Average weight for size 7½ : **16-17 gm/Pair**

Specification

- Made from high quality natural rubber latex.
- Natural white/pale yellow colour.
- Anatomically shaped.
- Micro rough surface texture provides enhanced instrument grip.
- Substantially low protein level to minimize the risk of allergen.
- Chlorinated / Polymer Coated for Powder Free.
- 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.
- Quality standard as per AQL1.5 or better.
- Complies with International Standard ASTM D3577/ EN 455/ IS 13422: 1992.

Physical Dimensions

SIZE	5½"	6.0"	6½"	7.0"	7½"	8.0"	8½"	9.0"	Tol.
Length (mm)	250	280							Min
Width (Palm) mm	70	76	83	89	95	102	108	114	±6
Thickness at (mm)	Cuff		0.13	Palm		0.17	Finger		0.19

Physical Properties

- | | |
|---|--|
| 1) Tensile Strength before ageing : 24 Mpa | 5) Total Protein content : <50µg/dm ² |
| 2) Ultimate elongation before ageing : 750% | 6) Powder amount : <2mg/Glove |
| 3) Tensile Strength after ageing : 18 Mpa | 7) Moisture content : <1% |
| 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	1.5
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

USE INSTRUCTIONS

MEDICAL DEVICE: LATEX SURGICAL GLOVES -STERILE –POWDER FREE BRAND: IndiSAFE

Intended applications:

Surgical Rubber Gloves –Sterile – Powder FREE are classified as Class II Medical Device as per Rule 6 of Annex IX as per MDD/93/42/EEC as amended. These are intended for use by an operating personnel or healthcare workers for following purpose:

- To reduce the risk of contamination of health-care workers hands with blood and other body fluids.
- To 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.
- To reduce the cause of postoperative adhesions, granulomas, delayed wound healing, increased risk of infection and occupational asthma.
- Low protein level reduces the cause for latex allergy.
- In Laboratory/Pharma manufacturing sector where powder may affect the quality of the product especially in clean rooms, Powder Free Gloves are commonly used.

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.
- 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.

Shelf life (Use before date)

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