

PRODUCT CATALOGUE

PRODUCT : LATEX SURGICAL GLOVES, STERILE, POWDERED
 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.
- Lightly powdered with USP grade bio-absorbable cornstarch.
- 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		0.12	Palm		0.14	Finger		0.16

Physical Properties

- | | |
|---------------------------------------------|---------------------------------------------------|
| 1) Tensile Strength before ageing : 24 Mpa | 5) Total Protein content : <150µg/dm ² |
| 2) Ultimate elongation before ageing : 750% | 6) Powder amoun : <15µg/dm ² |
| 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

Shelf life

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

USE INSTRUCTIONS

MEDICAL DEVICE: LATEX SURGICAL GLOVES, STERILE, POWDERED

Intended applications:

Surgical Rubber Gloves –Sterile – Powdered 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 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.
- Gloves should therefore be used during all patient-care activities that may involve exposure to blood and all other body fluid (including contact with mucous membrane and non-intact skin), during contact precautions and outbreak situations.

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.