

# TECHNICAL DATA SHEET

**PRODUCT NAME: SINGLE USE LATEX MEDICAL EXAMINATION GLOVES**

## Product Information

Material: Natural Latex Rubber  
 Colour: Creamy White  
 Surface: Textured or Smooth  
 Powder: Powdered or Powder-free  
 Sterilization: None, Ethylene-Oxide (EO) or Gamma  
 Sizes: XS , S , M , L or XL  
 Weight: 6.0g / 6,5 g  
 Shelf Life: 3 years from date of manufacture  
 Intended Use: Used in medical field to protect patient and user from cross-contamination  
 Manufacturer: Fitone Latex Products Co., Ltd. Guangdong  
 Address: No.5 Tongyi Road, Lingbei Industrial Zone, Suixi, 524338 Zhanjiang, Guangdong, China.



## Physical Properties (ACC. EN 455-2:2015)

Size	Median length (mm)	Median width (mm)
XS	≥ 240	≤ 80
S	≥ 240	80 ± 10
M	≥ 240	95 ± 10
L	≥ 240	110 ± 10
XL	≥ 240	≥ 110

Thickness: ≥ 0.08 mm for Smooth surface  
 ≥ 0.11 mm for Textured surface

Force at break (after ageing\*): ≥ 6 N  
 Elongation at break (after ageing\*): ≥ 500%

\*ageing: 168h at 70±2°C

## Biological Safety (ACC. EN 455-3:2015 & EN ISO 10993:2009)

Chemicals that can cause adverse health effects:

Ethylene Chlorohydrin (ECH): ≤10 µg/cm<sup>2</sup> (for sterilized gloves)

Powder content: ≤ 2 mg per glove for Powder-free

Leachable proteins: ≤ 50 µg/g

### *Inspection Level* (ACC. ISO 2859-1)

Characteristic	Inspection Level	AQL	Standard
Water tightness	G-1	1,5	EN 455-1
Aspect – major defects	G-1	0.65	company standard
Aspect – minor defects	G-1	0.65	company standard
Dimensions	N = 13	4,0	EN 455-2
Tensile properties	N = 13	4,0	EN 455-2
Sterility	N = 20	N/A	EN 455-3
Powder content	N = 6	N/A	EN 455-3

Certifications: CE, ISO 13485, ISO 14001, ISO 18001

### *Packaging*

100pcs/box, 10 boxes/carton



### *Instructions for use*

#### **[How to use]**

1. Read the instructions carefully and make sure the gloves are with integrated package and within validity date.
2. Please do not use if the unit package is opened or damages in occasions where sterilization is required.
3. Please take off rings and ornaments and cut nails neatly before wearing gloves.
4. Take out and wear gloves of appropriate size, adjust in order to make the gloves fit appropriately for comfort, dexterity and sensitivity.
5. Used gloves shall be disposed as medical waste in order to prevent environmental pollution caused by bacteria

#### **[Cautions]**

1. Product is made from natural rubber Latex which can cause allergic reactions, including anaphylactic responses.
2. Before use, please remove powder on glove surface
3. Single-use only.

**[Storage conditions]**



1. This product should be stored in a dry, cool place away from direct sunlight and cannot get in touch with oil and acid.
2. This product should be stored at a temperature of 5-35°C. Relative humidity of 50-80% is recommended. Keep the product away from ozone and ultraviolet rays.