

# Product Specifications

**Brand** : Klinion® Personal Protection → ULTRA COMFORT  
**Product** : Nitrile, powder-free, non-sterile, examination gloves

## Product description

Disposable, latex-free, powder-free examination gloves made of nitrile butadiene rubber.

## Intended use

The Klinion Personal Protection examination gloves are intended to be worn on the hand for medical purposes and to help prevent contamination between patient and examiner. Also suitable for chemical handling. User Info available at [www.medeco.org](http://www.medeco.org)

## Classification

Class I under the Medical Devices Regulations (SI 2002 No. 618, as amended) and  
Class I under Regulation (EU) 2017/745 Medical Device Regulation (MDR).  
PPE Regulation (EU) 2016/425 Category III  
→ EU declaration of conformity at [www.medeco.org](http://www.medeco.org)

## Packaging & Product Reference

Product Reference	Description	Size	EAN Box	Box Dimension (mm)*	Pieces per Box	EAN Carton	Outer Carton Dimension (mm)*	Boxes per Outer Carton
103525	Klinion Personal Protection ULTRA COMFORT Nitrile Exam Glove, White	XS	8715343748459	230*120 *70	150	8715343748442	365*255 *250	1500
103526	Klinion Personal Protection ULTRA COMFORT Nitrile Exam Glove, White	S	8715343748435	230*120 *70	150	8715343748428	365*255 *250	1500
103527	Klinion Personal Protection ULTRA COMFORT Nitrile Exam Glove, White	M	8715343748411	230*120 *70	150	8715343748404	365*255 *250	1500
103528	Klinion Personal Protection ULTRA COMFORT Nitrile Exam Glove, White	L	8715343748398	230*120 *70	150	8715343748381	365*255 *250	1500
103529	Klinion Personal Protection ULTRA COMFORT Nitrile Exam Glove, White	XL	8715343748374	230*120 *70	150	8715343748367	365*255 *250	1500

\*Sizes are approximate

# Product Specifications

## Features

- Beaded cuff
- Ambidextrous, suitable for left and right hand
- Non-Sterile
- Powder-Free ( $\leq 2$ mg/glove)
- Fingertips-Textured
- Medical Grade with AQL 1.5
- Tested Against Opioid Solution (ASTM D6978)

## Product components

- Acrylonitrile Butadiene Rubber (NBR)
- Products listed on this specification are:
  - Latex-free
  - Phthalate-free
  - Absent of human or animal tissue
  - Absent of blood or blood derivative
  - Absent of medicinal substances

## Specifications

### Product Dimensions (mm)

Width	XS	75 ± 5
	S	80 ± 10
	M	95 ± 10
	L	110 ± 10
	XL	115 ± 5
Thickness	Cuff in MM	Min. 0.04
	Palm in MM	Min. 0.05
	Finger in MM	Min. 0.06
Length	Total in MM	Min. 240

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### Physical Properties

Unaged	Tensile Strength (MPa)	Min. 14 MPa
	Elongation at Break (%)	Min. 500 %
	Force at Break (N)	Min. 6.0 N
Aged	Tensile Strength	Min. 14 MPa
	Elongation at Break	Min. 400 %
	Force at Break	Min. 6.0 N
Freedom from Holes	AQL 1.5	
Powder Residue	Max 2 mg/glove	

### Quality Standards

- Manufactured in accordance with Quality Assurance ISO 13485 and ISO 9001
- In compliance with:
- EN420 : 2003+A1:2009, EN ISO 21420:2020
  - EN ISO 374-1:2013+A1:2018, EN 374-2:2019, EN 374-4:2019, EN ISO 374-5:2016
  - EN 455-1:2020, EN 455-2:2015, EN455-3:2015, EN455-4:2009
  - EN 16523-1:2015 + A1:2018

#### Sterilization

Non-sterile

#### Storage conditions

Store in a cool and dry place. Opened boxes should be kept away from fluorescent and sunlight. Gloves are packed in dispenser which is suitable for transport. Keep the gloves in the box

# Product Specifications

when not in use.

Shelf life

5 years

Pictures

