

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

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

Packaging & Product Reference

Product Reference	Description	Size	EAN Box	Box Dimension (mm)*	Pieces per Box	EAN Carton	Outer Carton Dimension (mm)*	Pieces per Outer Carton
103520	Klinion Personal Protection ULTRA COMFORT Nitrile Exam Glove, Blue	XS	8715343749401	214*114*60	100	8715343749395	298*330*233	1000
1035202	Klinion Personal Protection ULTRA COMFORT Nitrile Exam Glove, Blue	XS	8715343747995	240*125*80	200	8715343747988	415*216*235	2000
103521	Klinion Personal Protection ULTRA COMFORT Nitrile Exam Glove, Blue	S	8715343749388	214*114*60	100	8715343749371	298*330*233	1000
1035212	Klinion Personal Protection ULTRA COMFORT Nitrile Exam Glove, Blue	S	8715343747971	240*125*80	200	8715343747964	415*216*235	2000
103522	Klinion Personal Protection ULTRA COMFORT Nitrile Exam Glove, Blue	M	8715343749364	214*114*60	100	8715343749357	298*330*233	1000
1035222	Klinion Personal Protection ULTRA COMFORT Nitrile Exam Glove, Blue	M	8715343747957	240*125*80	200	8715343747940	415*216*235	2000
103523	Klinion Personal Protection ULTRA COMFORT Nitrile Exam Glove, Blue	L	8715343749340	214*114*60	100	8715343749333	298*330*233	1000
1035232	Klinion Personal Protection ULTRA COMFORT Nitrile Exam Glove, Blue	L	8715343747933	240*125*80	200	8715343747926	415*216*235	2000
103524	Klinion Personal Protection ULTRA COMFORT Nitrile Exam Glove, Blue	XL	8715343749326	214*114*60	100	8715343749319	298*330*233	1000
1035242	Klinion Personal Protection ULTRA COMFORT Nitrile Exam Glove, Blue	XL	8715343747919	240*125*80	200	8715343747902	415*216*235	2000

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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

Features

- Beaded cuff
- Ambidextrous, suitable for left and right hand
- Non-Sterile
- Powder-Free (≤ 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

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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

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	

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Quality Standards

- Manufactured in accordance with Quality Assurance ISO 13485 and ISO 9001

In compliance with:

- EN 420:2003+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+A1:2022, 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 sun- light. Gloves are packed in dispenser which is suitable for transport. Keep the gloves in the box when not in use.

Shelf life

5 years

Pictures



Product Specifications

Approval	Name	Date	Signature
Product Manager	Lotte Byrum	Lotte Byrum	Digitally signed by Lotte Byrum Date: 2024.02.06 15:25:21 +01'00'
RA Specialist	Alexandra Duarte	Alexandra Duarte	Digitally signed by Alexandra Duarte Date: 2024.02.06 12:56:13 +01'00'