

Product Specifications

Brand : Klinion[®] Personal Protection → Phthalate-Free
Product : Vinyl Phthalate-free Examination Gloves (Standard & Long)

Product description

Disposable, latex-free, phthalate-free, powder-free vinyl examination gloves

Intended use

The Klinion[®] Personal Protection Vinyl Phthalate-free Examination Gloves are intended to be worn on the hand for medical purposes and to help prevent contamination between patient and examiner.

User Info available at www.medeco.org

Classification

Class I under the Medical Devices Regulations 2002 (SI 2002 No. 618, as amended) and

Class I under Regulation (EU) 2017/745 Medical Device Regulation (MDR).

Category III under the Personal Protective Equipment Regulation (EU) 2016/425.

→ EU declaration of conformity at www.medeco.org

Packaging & Product Reference

Product Reference	Description	Size	Color	Box Dimension (mm)*	Inner carton /box	EAN IC	Outer Carton Dimension (mm)*	Outer Carton	EAN OC
75685220	Klinion Personal Protection Phthalate Free Vinyl Examination Glove	XS	Clear	230 x 125 x 60	100	8715343052310	315 x 258 x 245	1000	8715343052341
75685221	Klinion Personal Protection Phthalate Free Vinyl Examination Glove	S	Clear	230 x 125 x 60	100	8715343052365	315 x 258 x 245	1000	8715343052396
75685222	Klinion Personal Protection Phthalate Free Vinyl Examination Glove	M	Clear	230 x 125 x 60	100	8715343052419	315 x 258 x 245	1000	8715343052440
75685223	Klinion Personal Protection Phthalate Free Vinyl Examination Glove	L	Clear	230 x 125 x 60	100	8715343052464	315 x 258 x 245	1000	8715343052495
75685224	Klinion Personal Protection Phthalate Free Vinyl Examination Glove	XL	Clear	230 x 125 x 60	100	8715343052518	315 x 258 x 245	1000	8715343052549
75685129	Klinion Personal Protection Phthalate Free Vinyl Examination Glove, Long	XS	Clear	240 x 125 x 68	100	8715343052068	355 x 260 x 255	1000	8715343052099

Product Specifications

Product Reference	Description	Size	Color	Box Dimension (mm)*	Inner carton /box	EAN IC	Outer Carton Dimension (mm)*	Outer Carton	EAN OC
75685130	Klinion Personal Protection Phthalate Free Vinyl Examination Glove, Long	S	Clear	240 x 125 x 68	100	8715343052112	355 x 260 x 255	1000	8715343052143
75685131	Klinion Personal Protection Phthalate Free Vinyl Examination Glove, Long	M	Clear	240 x 125 x 68	100	8715343052167	355 x 260 x 255	1000	8715343052198
75685132	Klinion Personal Protection Phthalate Free Vinyl Examination Glove, Long	L	Clear	240 x 125 x 68	100	8715343052211	355 x 260 x 255	1000	8715343052242
75685133	Klinion Personal Protection Phthalate Free Vinyl Examination Glove, Long	XL	Clear	240 x 125 x 68	100	8715343052266	355 x 260 x 255	1000	8715343052297

* Sizes are approximate

Features

- Ambidextrous
- Smooth surface
- Beaded cuff
- Powder-free
- Suitable for handling food

Product component

- Synthetic Polyvinyl Chloride

Specifications

Dimensions (mm)

		Standard REF: 75685220-75685224	Long REF: 75685129-75685133
Width (mm)	XS	≤80	
	S	80 ± 10	
	M	95 ± 10	
	L	110 ± 10	
	XL	≥110	
Thickness (mm)	Finger	0.08 ± 0.03	0.09 ± 0.03
	Palm	0.08 ± 0.03	0.08 ± 0.03
	Cuff	0.06 ± 0.03	0.06 ± 0.03
Length (mm)		Min. 240	Min. 280

Product Specifications

Physical Properties

Force at Break	Unaged	Min. 3.6 N
	Aged	
Tensile Strength	Unaged	Min. 11MPa
	Aged	
Ultimate Elongation	Unaged	Min. 300%
	Aged	
Freedom from Holes	AQL 1.5	
Powder Residue	Max 2 mg/glove	
Glove Weight	Standard: 5.0 g ± 0.03 Long: 6.5 g ± 0.03	

Test results

Permeation	Sodium Hydroxide 40% (K)	Level 6
	Hydrogen Peroxide 30% (P)	Level 2
	Formaldehyde 37% (T)	Level 2
Degradation	Sodium Hydroxide 40% (K)	13.0%
	Hydrogen Peroxide 30% (P)	14.1%
	Formaldehyde 37% (T)	-12.1%

Quality Standards

- Manufactured in accordance with Quality Assurance ISO 13485
- Tested according to EN 455-1:2020+A1:2022; EN 455-2:2015; EN 455-3:2015, EN 455-4:2009; EN 16523-1:2015; EN ISO 374-4:2019
- Food safety in accordance with Regulation EU 1935/2004/EC, EU 10/2011 and it's amendments (EU) No.2018/213 & (EU) 2020/1245

Product Specifications

Absence of specific components

Component	Present
Latex	No
Phthalates	No
Substances of animal origin	No
Substances of human origin	No
Blood or blood derivatives	No
Medicinal substances	No

Sterilization

N/A - Product is provided non-sterile.

Storage conditions

Store gloves in original packing in a cool, dry and well-ventilated area, away from dust, direct sunlight, moisture, X-ray and excessive heat above 100F (37 C°). Improper storage may reduce shelf life.

Shelf life

5 years from production date, when stored under specified conditions.

Pictures



Ref. product 75685222



Ref. product 75685133

Product Specifications

Approval	Name	Date	Signature
Category & Product Development Manager	Lotte Byrum		
RA Specialist	Alexandra Duarte		