

GD10

VINYL DISPOSABLE GLOVES



TDS



Packaging

1,000 p. outer case

- **Content:** 10 boxes of 100 pieces
- **Dimension:** 315 x 250 x 250 mm.

100 p. inner dispenser

- **Content:** 100 pieces
- **Dimension:** 230 x 125 x 60 mm.



Labelling

- | | |
|--|---|
| <ul style="list-style-type: none"> • Importer name and address • Product name in some languages • Commercial benchmark, lot number and barcode • AQL 1.5 • Expiration • CE marking | <ul style="list-style-type: none"> • Size and units quantity • Single-use • Storage conditions • Protection symbols • Regulatory compliance • Applications & warnings |
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General Characteristics

Description: Powdered free transparent vinyl gloves.

Smooth surface for greater sensitivity and beaded cuff.

Shelf life: 5 years

Classification:

Medical device: **Class I**; *European Directive 93/42/CEE*

PPE: **Category III**; *European Directive 89/686/CEE*

Sizes: S, M, L and XL



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Physical Properties

Composition: Polyvinyl Chloride (PVC)

Characteristics:

- AQL: 1.5
- Ambidextrous
- Latex free 
- Free of proteins and chemical accelerators
- Free of Tiuram, animal tissue or other biological substances

Property	Benefit level / Result	Standards applied
Healthcare products Directive 93/42/CEE		
Tests for freedom from holes	Compliant with	EN 455-1
Dimensions	Compliant with	EN 455-2
Force at break	Compliant with (average=4.8N)	
Biological safety requirements	Compliant with	EN 455-3
Tensile breaking strength	9 Mpa	_____
Elongation	300%	_____
Personal Protection Equipment Directive 89/686/CEE		
Dexterity	5	EN 420
Resistance to the permeation of microorganisms		
Air leak test	Compliant with	EN 374-2
Water leak test	Compliant with	
Resistance to chemical products permeation		
(J) n-Heptane	Class 0/ Permeation time < 10 min	EN 374-3
(k) Sodium Hydroxide (40%)	Class 6/ Permeation time > 480 min	
(L) Sulfuric Acid (96%)	Class 0/ Permeation time <10 min	
Plastic materials intended to come into contact with food Regulation 10/2011		
Phthalate content test	Compliant with	EN 14372
Migration Test	Compliant with	EN 1186/7:2002

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Dimensions

Glove dimensions					
Size	Length (mm)	Palm width (mm) ± 5	Thickness (mm) ± 0.02		
			Finger	Palm	Sleeve
P	≥ 240	85	0.08	0.07	0.06
M	≥ 240	95	0.08	0.07	0.06
G	≥ 240	105	0.08	0.07	0.06
XG	≥ 240	115	0.08	0.07	0.06

Finger dimensions								
Finger	Length (mm) ± 3				Width (mm) ± 3			
	S	M	L	XL	S	M	L	XL
Thumb	57	61	70	71	34	40	44	45
Index F.	66	75	81	83	29	33	36	39
Middle F.	72	81	92	95	28	34	38	39
Ring F.	67	76	84	88	27	30	35	38
Little F.	51	56	60	64	25	29	32	37

Logistic Data Sheet

Code - Size	EAN Code		Kg Package	Volume m3	Cases/ Pallet	Pallet Distr. (Cases x heights)
	Inner dispenser	Outer case				
GD48NB- S	8437001266128	8437001266081	5,0 KG	0,019	70	10x7
GD48NC- M	8437001266135	8437001266098	5,5 KG	0,019	70	10x7
GD48ND- L	8437001266142	8437001266104	6,0 KG	0,019	70	10x7
GD48NE- XL	8437001266159	8437001266111	6,5 KG	0,019	70	10x7

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Storage Conditions

Keep dry.
keep away from direct sunlight and fluorescent lighting.



Regulatory Compliance

- **European Directive: 93/42/CEE. Concerning medical devices.**
 - EN 455/1-2-3; Medical disposable gloves.
- **European Directive: 89/686/CEE. European Personal Protective Equipment.**
 - EN 420:2003; Protective gloves: General requirements.
 - EN 374/1-2-3; Protective gloves: Chemicals and Microorganisms permeation.
- **Regulation 10/2011 on plastic materials and articles intended to come into contact with food.**
 - EN 14372:2005; Cutlery and feeding utensils - Safety requirements and tests.
 - EN 1186/7:2002; Materials and articles in contact with foodstuffs – plastics.

ISO 13485:2003, Quality system for the healthcare products production.

Management System



Product Compliance

