

## Presentation of the product

### Packaging

- **Content:** 10 boxes of 100 units
- **Dimensions:** 310 x 225 x 220 mm

### Box of 100 units

- **Content:** 100 units
- **Dimension:** 210 x 110 x 60mm



### Labelling

- Name and address of the manufacturing company
- Name of the product in several languages
- Commercial reference, batch and barcode
- Expiration
- EC Marking
- AQL 1.5
- Size and number of units
- Single use
- Storage conditions
- Protection pictograms
- Legislation and Reference std
- Uses, applications and warnings

## General characteristics

**Description:** Transparent vinyl gloves.  
Fine and sensitive to touch, because its external surface is smooth in fist, palm and fingers.  
Cuff rolled

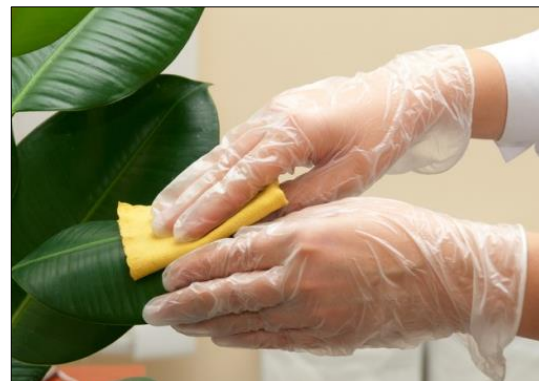
**Useful life :** 5 years

### Clasification:

Medical Device **Class I**; *Royal Decree 1591/2009, Regulation (EU) 2017/745.*  
PPE **Category III** *Regulation (EU) 2016/425*

**Sizes:** Small, Medium, Large, Extra Large

**Colour:** Transparent






## Physical Properties

**Composition :** Polyvinyl Chloride (PVC)

**Features:**

- Ambidextrous
- Latex free 
- Free of proteins
- Free of Tiuram, animal tissue or other biological substances

Property	Level/Result	Applied Standards
<b>Medical Devices Regulation (EU) 2017/745</b>		
Absence of holes	Pass (AQL 1.5)	EN 455-1
Dimensions	Pass	EN 455-2
Force to break	Pass (average = 4.8 N)	
Biological safety requirements.	Pass	EN 455-3
Resistance to breaking stress	11 Mpa	_____
Elongation	350 %	_____
<b>Individual Protection Equipment Regulation (EU) 2016/425</b>		
Dexterity	5	EN 420
<b>Resistance to the permeation of microorganisms</b>		
Air leak test	Pass	EN 374-2
Water leak test	Pass	
Protection against bacteria and fungi	Pass	EN 374-5  VIRUS
Protection against virus	Pass	
<b>Resistance to chemical products permeation</b>		
(K) Sodium hydroxide (40%)	Class 6/Permeation time >480 min	EN 374-1 EN 16523-1  KPT
(P) Hydrogen peroxide (30%)	Class 5/Permeation time >240 min	
(T) Formaldehyde (37%)	Class 6/ Permeation time >480 min	
<b>Plastic materials intended to contact food Regulation 10/2011</b>		
Migration Test Ethanol 10% 20 % Acetic Acid 3 %	Pass	EN 14372:2004 EN 1186/7:2002 

<b>GD10</b>	<b>POWDER FREE VINYL GLOVE</b>	<b>DATA SHEET</b>
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### Sizes

Size	Glove dimensions					Weight (g±0.3)
	Length (mm)	Wide (mm) ± 5	Thickness (mm) ±0.02			
			Finger	Palm	Sleeve	
S	≥240	85	0.05	0.05	0.04	4.2
M	≥240	95	0.05	0.05	0.04	4.5
L	≥240	105	0.05	0.05	0.04	4.8
XL	≥240	115	0.05	0.05	0.04	5.1

### Logistic sheet

REF - Size	Cod. EAN		Kg Packaging	Volume m <sup>3</sup>	Boxes/ Pallet	Assembly/ Pallet (Boxes x heights)
	Interior Box	Packaging				
GD10NB- S	8437001266128	8437001266081	4,9 Kg	0,015345	88	11 x 8
GD10NC- M	8437001266135	8437001266098	5,1 Kg	0,015345	88	11 x 8
GD10ND- L	8437001266142	8437001266104	5,6 Kg	0,015345	88	11 x 8
GD10NE- XL	8437001266159	8437001266111	6,1 Kg	0,015345	88	11 x 8

### Uses and applications

Exploration gloves in the **health, medical or dental fields** use, complies with the regulations and standards of medical protective gloves (EN 455); its use is intended for the protection of the patient and the user against low **biological and chemical** risk, meets the requirements for the verification of microbiological safety and low chemical risk (EN 374). It is recommended for tasks of short duration and with a high frequency of change.

They are widely used in the **food industry, electronics and cleaning** because PVC does not contain latex or chemical accelerators, so that the problems of skin irritation due to allergic causes are reduced and, in addition, they offer acceptable comfort and elasticity. In the field of food, these gloves comply with the requirements of regulation 10/2011 regarding plastic materials intended to come into contact with food.

## Storage conditions

Keep stored in a cool and dry place. Avoid excess heat and protect from direct sunlight or fluorescent lighting.



## Reference Directives and Standards

- **EN 455/1-2-3**; Medical protection gloves for single use.
- **Royal Decree 1407/1992**, regarding Personal Protection Equipment.
- **Regulation (EU) 2016/425**, regarding Personal Protection Equipment
- **EN 374/1-2-4-5**; Protective gloves against chemicals and microorganisms.
- **EN 16523-1:2015+A1:2018**; Determination of material resistance to permeation by chemicals - Part 1: Permeation by potentially hazardous liquid chemicals under conditions of continuous contact.
- **EN 420**; Protective gloves, general requirements and test methods.
- **ASTM D 6124-06**, Residual dust content.
- **EN 1186/7:2002**; Test methods for global migration in aqueous food simulators using a bag.
- **EN 14372:2005**; referring to childcare articles. Cutlery and utensils for food. Safety requirements and tests.
- **ISO 13485:2003**, Quality System for the manufacture of Medical Devices.
- **Royal Decree 1591/2009**, by which the Medical Devices are regulated, which transposes the European Directive 93/42/EEC.
- **Regulation 10/2011**. relating to plastic materials intended to come into contact with food.
- **Regulation 1935/2004**, on materials and objects intended to come in contact with food.

## Management system

Quality management system according to ISO 13485.

## Product conformity

