



Presentation of the product

Packaging

- **Content:** 10 boxes of 100 units
- **Dimensions:** 315 x 225 x 225 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

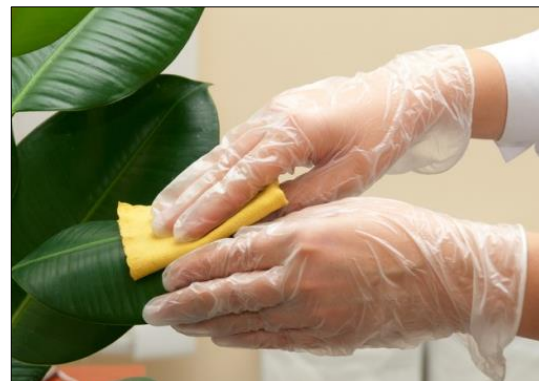
General characteristics

Description: Blue 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: Blue








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
Medical Devices Regulation (EU) 2017/745		
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 %	_____
Individual Protection Equipment Regulation (EU) 2016/425		
Dexterity	5	EN 420
Resistance to the permeation of microorganisms		
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	
Resistance to chemical products permeation		
(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	
Plastic materials intended to contact food Regulation 10/2011		
		EN 14372:2004 
Migration Test	Pass	EN 1186/7:2002



Sizes

Size	Glove dimensions					
	Length (mm)	Wide (mm) ± 10	Thickness (mm) ±0.02			Weight (g±0.3)
			Finger	Palm	Sleeve	
S	≥240	80	0.05	0.05	0.04	4.2
M	≥240	90	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 ³	Boxes/ Pallet	Assembly/ Pallet (Boxes x heights)
	Interior Box	Packaging				
GD14BB- S	8437001266289	8437001266241	5.00	0,019344	84	12 x 7
GD14BC- M	8437001266296	8437001266258	5.10	0,019344	84	12 x 7
GD14BD- L	8437001266302	8437001266265	5.55	0,019344	84	12 x 7
GD14BE- XL	8437001266319	8437001266272	6.10	0,019344	84	12 x 7

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 1935/2004**, on materials and objects intended to come in contact with food.
- **Royal Decree 866/2008**, relating to plastic materials intended to come into contact with food, which transposes Directive 2002/72 /EEC, repealed by **Regulation 10/2011** (Regulation 2016/1416).

Management system

Quality management system according to ISO 13485.

Product conformity

