

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
- **Dimensions:** 210 x 110 x 60mm



Labeling for the 100-unit box

- Name and address of the manufacturing company
- Name of the product in several languages
- Commercial reference and batch number
- Manufacturing and expiration dates
- EC Marking
- Barcode (EAN) and UDI code
- Size and number of units
- Single use
- Storage conditions
- Protection icons
- Legislation and Reference
- Uses, applications, and warnings

General characteristics

Description:

Powder-Free Vinyl Examination Gloves – Non-Sterile

Made from high-quality material, they offer great tactile sensitivity and a completely smooth surface on the cuff, palm, and fingers. Reinforced rolled cuff.

Shelf life: 5 years

Clasification

- Class I Medical Device; Regulation (EU) 2017/745
- Category III PPE: Regulation (EU) 2016/425
- Suitable for contact with food, except fatty foods

Sizes: Small (S), Medium (M), Large (L), Extra Large (XL)

Colors:

- Transparent – GD10NB (S), GD10NC (M), GD10ND (L), GD10NE (XL)
- Blue – GD14BB (S), GD14BC (M), GD14BD (L), GD14BE (XL)

Physical Properties

Composition and Features

Polyvinyl Chloride (PVC)

- Ambidextrous
- Non-Sterile
- AQL 1.5
- Free from animal tissue and other biological substances
- Latex-Free
- Powder-Free
- Tiuram-Free

Property	Performance level /Result	Applied Standards
Medical Devices		Regulation (EU) 2017/745
Absence of holes	Pass (AQL 1.5)	EN 455-1:2020
Dimensions	Pass	EN 455-2: 2015
Force to break	Pass (average >3,6 N)	
Biological safety requirements	Pass	EN 455-3: 2015
Shelf life determination	Pass	EN 455-4:2010
Personal Protection Equipment		Regulation (EU) 2016/425
Dexterity	5	EN ISO 21420:2020
Air leak test	Pass	EN ISO 374-2: 2019
Water leak test	Pass	
Protection against bacteria and fungi	Pass	EN ISO 374-5: 2016
Resistance to degradation by chemicals	Pass	EN ISO 374-4:2019
Performance requirements for chemical risks	Pass	EN ISO 374-1:2016+A1:2018
Resistencia a la permeación por productos químicos	Pass	EN 16523-1:2015+A1:2018

Resistance to chemical products permeation

(Refers to the sample tested under laboratory conditions and not to workplace conditions)

(K) Sodium hydroxide (40%)	Level 6 / Permeation time >480 min	TIPO B EN ISO 374-1:2016+A1:2018 EN 16523-1:2015+A1:2018
(P) Hydrogen peroxide (30%)	Level 2/ Permeation time >30 min	
(T) Formaldehyde (37 %)	Level 2/ Permeation time >30 min	
Plastic materials intended to contact food		Regulation (EU) 10/2011
Migration Test: - Acetic acid 3% - Ethanol 10%	Pass Pass	(EU) No 10/2011 (EU) 2020/1245

Sizes

Glove dimensions						
Size	Weight (g)±0,3	Lenght (mm)	Plam wide (mm) ± 10	Thickness (mm) ±0.03		
				Fingers	Palm	Sleeve
S	4,00	≥240	80	0.08	0.08	0.06
M	4,50	≥240	95	0.08	0.08	0.06
L	5,00	≥240	110	0.08	0.08	0.06
XL	5,50	≥240	≥110	0.08	0.08	0.06

REF - Size	EAN code		Carton box weight (Kg)	Carton box volume(m3)	Carton boxes / Pallet	Assembly/ Pallet (Carton boxes x layers)
	Interior box	Carton box				
GD10NB- S	8437001266128	8437001266081	4,90	0,015345	88	11 x 8
GD10NC- M	8437001266135	8437001266098	5,40	0,015345	88	11 x 8
GD10ND- L	8437001266142	8437001266104	5,90	0,015345	88	11 x 8
GD10NE- XL	8437001266159	8437001266111	6,40	0,015345	88	11 x 8
GD14BB- S	8437001266289	8437001266241	4,90	0,015345	88	11 x 8
GD14BC- M	8437001266296	8437001266258	5,40	0,015345	88	11 x 8
GD14BD- L	8437001266302	8437001266265	5,90	0,015345	88	11 x 8
GD14BE- XL	8437001266319	8437001266272	6,40	0,015345	88	11 x 8

Uses and applications

In the healthcare sector, these gloves are intended for use during medical examinations, dentistry, clinical assessments, diagnostic and therapeutic procedures, laboratory applications, and, in general, all activities requiring a glove that serves as a protective barrier against infectious agents, such as in research and veterinary fields. They are suitable only for low-risk exposure levels.

Their chemical risk protection is limited. These gloves meet the standards for microbiological safety and chemical risk assessment as specified in EN ISO 374-1:2016+A1:2018 and EN ISO 374-2:2019.

Additionally, they are utilized in the food industry and cleaning sectors. Within the food industry, these gloves comply with the requirements set forth in Regulation (EU) No 10/2011 (and its amendments), as well as Regulation (EU) No 1245/2020 concerning plastic materials intended to come into contact with foodstuffs. **DO NOT USE IN CONTACT WITH FATTY FOODS.**

Directives and Reference Standards

- EN ISO 374: Protective gloves against dangerous chemicals and microorganisms
 - EN ISO 374-1:2016+A1:2018: Terminology and performance requirements for chemical risks
 - EN ISO 374-2:2019: Determination of resistance to penetration
 - EN ISO 374-4:2019: Determination of resistance to degradation by chemicals
 - EN ISO 374-5:2016: Terminology and performance requirements for microbial risks
- EN ISO 21420:2020: Protective gloves – General requirements and test methods
- EN 16523-1:2015+A1:2018: Determination of resistance of materials to chemical permeation
- Regulation (UE) 2016/425 Personal Protective Equipment
- EN 455: Single-use medical gloves
 - EN 455-1:2000: Requirements and tests for freedom from holes
 - EN 455-2:2015: Requirements and tests for physical properties
 - EN 455-3:2015: Requirements and tests for biological evaluation
 - EN 455-4:2009: Requirements and tests to determine shelf life
- Regulation (UE) 2017/745: Regulation on Medical Devices
- Regulation (UE) No 10/2011, on plastic materials and articles intended to come into contact with food
- EN 1186/7:2002: Test methods for overall migration in aqueous food simulants using a pouch
- Regulation (CE) N°1935/2004 of the European Parliament and of the Council on materials and articles intended to come into contact with food
- Regulation (UE) 2020/1245, amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food

- ISO 9001:2015: Quality management systems
- ISO 13485:2016: Quality management systems for medical devices
- ISO 14001:2015: Environmental management systems

Storage conditions

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



Management system

Quality management system according to ISO 13485.

Product conformity

