

Presentation of the product

Packaging

- **Content:** 10 boxes of 100 units
- **Dimensions:** 310 x 245 x 220 mm

Box of 100 units

- **Content:** 100 units
- **Dimensions:** 210 x 120 x 60 mm



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:

Gloves made from high-quality natural latex, non-sterile and powder-free.

They feature a silky texture and a smooth surface that provides great comfort upon contact with the skin. Their excellent elasticity and anatomical fit offer superior tactile sensitivity.

The rolled cuff reinforces the glove's structure and facilitates donning, providing greater security during use.

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 acidic foods

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

Color:

- Natural/White – GD05NA (XS), GD05NB (S), GD05NC (M), GD05ND (L), GD05NE (XL)

Physical Properties

Composition and Features

Natural rubber latex, sulfur, rubber accelerator – dithiocarbamate, zinc oxide, potassium hydroxide, polymeric coatings, titanium dioxide, calcium carbonate.

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

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 >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 4 / Permeation time >120 min	TIPO B EN ISO 374-1:2016+A1:2018 EN 16523-1:2015+A1:2018
(P) Hydrogen peroxide (30%)	Level 6/ Permeation time >480 min	
(L) Sulphuric Acid (96%)	Level 1/ Permeation time >10 min	
(M) Nitric Acid (65%)	Level 1/ Permeation time >10 min	
(T) Formaldehyde (37 %)	Level 6/ Permeation time >480 min	
Plastic materials intended to contact food Regulation (EU) 10/2011		
Migration Test: - Acetic acid 3% - Ethanol 10% - Vegetable oil	Pass 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
XS	4,00	≥240	75	0.12	0.09	0.07
S	4,50	≥240	80	0.12	0.09	0.07
M	5,00	≥240	95	0.12	0.09	0.07
L	5,50	≥240	110	0.12	0.09	0.07
XL	6,50	≥240	≥110	0.12	0.09	0.07

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				
GD05NA- XS	8437014559477	8437014559514	4,90	0,016709	88	11 x 8
GD05NB- S	8437014559484	8437014559521	5,40	0,016709	88	11 x 8
GD05NC- M	8437014559491	8437014559538	5,90	0,016709	88	11 x 8
GD05ND- L	8437014559507	8437014559545	6,40	0,016709	88	11 x 8
GD05NE- XL	8437017506164	8437017506171	7,40	0,016709	80	10 x 8

Uses and applications

Examination gloves for healthcare, medical, or dental use; intended to protect both the patient and the user against biological and low chemical risks. These gloves meet the requirements for microbiological safety and low chemical risk testing (EN ISO 374-1:2016+A1:2018, EN ISO 374-2:2019, EN ISO 374-4:2019, EN ISO 374-5:2016). Recommended for short-duration tasks with a high frequency of glove changes.

Widely used in light industry and domestic settings. They are also suitable for use in the food industry as these gloves comply with the requirements of EN 1186 under Regulation 10/2011 regarding materials intended to come into contact with food. Avoid contact with acidic foods.

Not to be used for handling organic solvents. This product contains natural rubber latex which may cause allergic reactions. DO NOT REUSE.

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. Do not store these gloves with organic solvents as they may degrade them.



Management system

Quality management system according to ISO 13485.

Product conformity

