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 Nitrile Examination Gloves – Non-Sterile

Thin and extra sensitive to touch due to textured fingertips, providing enhanced grip in both wet and dry conditions. Reinforced rolled cuff. The glove surface is chlorinated to prevent gloves from sticking together. The interior is coated with synthetic material, making them easier to put on and take off.

Nitrile offers three times more protection against micro-perforations compared to conventional latex gloves; for this reason, it is the best choice when selecting a latex-free glove.

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

- Blue – GD21BB (S), GD21BC (M), GD21BD (L), GD21BE (XL)
- Black – GD21NB (S), GD21NC (M), GD21ND (L), GD21NE (XL)

Physical Properties

Composition and Features

Acrylonitrile Butadiene Nitrile (NBR)

- Ambidextrous
- Chlorinated
- Textured fingers
- Non-Sterile
- AQL 1.5
- Latex-Free
- 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 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 4/ Permeation time >120 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
S	4,00	≥240	80	0.11	0.09	0.08
M	4,50	≥240	95	0.11	0.09	0.08
L	4,80	≥240	110	0.11	0.09	0.08
XL	5,10	≥240	≥110	0.11	0.09	0.08

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				
GD21BB- S	8437014559316	8437014559354	4,90	0,015345	88	11 x 8
GD21BC- M	8437014559323	8437014559361	5,20	0,015345	88	11 x 8
GD21BD- L	8437014559330	8437014559378	5,60	0,015345	88	11 x 8
GD21BE- XL	8437014559347	8437014559385	6,10	0,015345	88	11 x 8
GD21NB- S	8437022212791	8437022212807	4,90	0,015345	88	11 x 8
GD21NC- M	8437022212814	8437022212821	5,20	0,015345	88	11 x 8
GD21ND- L	8437022212838	8437022212845	5,60	0,015345	88	11 x 8
GD21NE- XL	8437022212852	8437022212869	6,10	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 due to the absence of latex in NBR, which provides a high level of comfort and elasticity. 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.
Contact with acidic foods should be avoided.

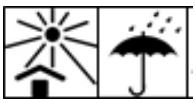
Directives and Reference Standards

- 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 Equipement
- 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) Nº1935/2004 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

CE