



Presentation of the product

Packaging

- **Content:** 10 boxes of 100 units
- **Dimension:** 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
- AQL 1.5
- Expiration date
- EC Marking
- Size and number of units
- Single use
- Storage conditions
- Protection pictogram
- Legislation and Reference
- Uses, applications and warnings

General characteristics

Description: Black Nitrile gloves powder free.

Fine and extra sensitive to touch because the area of the fingers is textured for a better grip both wet and dry. Reinforced rolled sleeve.

The surface of the glove is treated with chlorine, this prevents the gloves from sticking together.

Interior covered with synthetic material, this helps to make them easier to put on and take off.

The nitrile offers three times more protection against the micro-holes present in conventional latex gloves, for this reason, it is the best choice when choosing a latex-free glove.

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: Black

Physical Properties

Composition : Acrylonitrile Butadiene Nitrile (NBR)


Features:

- Ambidextrous
- Latex free
- Powder free
- AQL 1.5
- Textured fingers
- 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	EN 455-1:2000
Dimensions	Pass	EN 455-2: 2015
Force to break	Pass (average = 6 N)	
Biological safety requirements	Pass	EN 455-3: 2015
Breaking Tensile Strength	14 Mpa	_____
Elongation	500%	_____
ASTM Standards		
Viral penetration	Pass	ASTM F 1671M-13
Residual dust in medical globes	Pass	ASTM D 6124-06/EN 455-3:2015
Medical globes NBR	Pass	ASTM D 6319-10
Personal Protection Equipment Regulation (EU) 2016/425		
Dexterity	5	EN ISO 21420:2020



Resistance to the permeation of microorganisms

Air leak test	Pass	UNE EN 374-2: 2016	
Water leak test	Pass		
Protection against bacteria and fungi	Pass	EN 374-5: 2016	 VIRUS
Protection against virus	Pass		

Resistance to chemical products permeation

(K) Sodium Hydroxyde (40%)	Level 6 / Permeation time > 480 min.	 KPT ISO 374-1:2016 EN 16523-1:2015+A1:2018
(P) Hydrogen peroxide (30%)	Level 2 / Permeation time > 30 min.	
(T) Formaldehyde (37%)	Level 5 / Permeation time > 240 min.	

Plastic materials intended to contact food Regulation 10/2011

Migration Test: <ul style="list-style-type: none"> • Acetic acid 3% • Ethanol 10% • Vegetable oil 	Pass	EN 1186-8:2002 EN 1186-9:2002	
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Sizes

Glove dimensions						
Size	Weight (g) ± 0.3	Length (mm)	Palm wide (mm) ± 10	Thickness (mm) ±0.02		
				Fingers	palm	sleeve
S	4,20	≥240	80	0.11	0.09	0.06
M	4,50	≥240	95	0.11	0.09	0.06
L	4,80	≥240	110	0.11	0.09	0.06
XL	5,20	≥240	>110	0.11	0.09	0.06



Logistic sheet

REF - Size	Cod. EAN		Kg Packaging	Volume m ³	Boxes/Pallet	Assembly/Pallet (Boxes x heights)
	Interior Box	Packaging				
GD21NB – S	8437022212791	8437022212807		0.15345	84	12 x 7
GD21NC – M	8437022212814	8437022212821		0.15345	84	12 x 7
GD21ND – L	8437022212838	8437022212845		0.15345	84	12 x 7
GD21NE - XL	8437022212852	8437022212869		0.15345	84	12 x 7

Uses and applications

In the **sanitary** field, gloves for the realization of medical **examinations**, dentistry, clinical examination, diagnostic and therapeutic procedures, for laboratory uses and in general for all the activities that require a glove that acts as a protective barrier against infectious bodies, as in the field of research and veterinary medicine.

Only for a low risk exposure level.

Its protection against **chemical** risks is low. It meets the requirements for the verification of microbiological safety and low chemical risk (EN374).

They are also used in the **food, electronics and cleaning** industry because the NBR does not contain latex or chemical accelerators, so that skin irritation problems due to allergic causes are reduced and others 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.



Directives and Reference Standards

- **EN ISO 374 / 1-2-4-5**; Protective gloves against chemicals and microorganisms.
- **EN ISO 21420**; Protective gloves, general requirements and test methods.
- **EN 1186/7: 2002**; Test methods for global migration in aqueous food simulators using a bag.
- **EN 14372: 2005**; regarding childcare articles. Cutlery and utensils for food. Safety requirements and tests.
- **EN 455 / 1-2-3-4**; Single-use medical protective gloves.
- **ISO 13485: 2003**, Quality System for the manufacture of Sanitary Products.
- **ASTM D 6124-06**, Residual Powder Content.
- **ASTM D 6319**, Standard Specification for Nitrile Examination Gloves for Medical Use.
- **Regulation 10/2011 (Regulation 2016/1416)**, on plastic materials and objects intended to come into contact with food Relevant text for the purposes of the EEE.
- **Royal Decree 866/2008**, on plastic materials intended to come into contact with food, which transposes directive 2002/72 / EEC, repealed by Regulation 10/2011 (Regulation 2016/1416).
- **Royal Decree 1591/2009**, which regulates Medical Devices, which transposes the European Directive 93/42 / EEC.
- **Regulation CE / 1935/2004**, on materials and objects intended to come into contact with food
- **Regulation (EU) 2016/1416**, which modifies and corrects Regulation (EU) No. 10/2011 on plastic materials and objects intended to come into contact with food
- **Regulation (EU) 2016/425** referring to Personal Protective Equipment.
- **Regulation (EU) 2017/745**, which regulates Medical Devices.

Management system

Quality management system according to ISO 13485.

Product conformity

