



## Presentation of the product

### Packaging

- **Content:** 10 boxes of 100 units
- **Dimension:** 310 x 225 x 210 mm

### Box of 100 units

- **Content:** 100 units
- **Dimension:** 200 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 pictograms
- Legislation and Reference
- Uses, applications and warnings

## General characteristics

**Description:** Blue 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

**Classification:**

Medical Device **Class I**; *Regulation (EU) 2017/745.*

PPE **Category III**. *Regulation (EU) 2016/425*

**Sizes:** Small, Medium, Large, Extra Large

**Colour:** Blue

**Physical Properties**

**Composition :** Acrylonitrile Butadiene Nitrile (NBR)




**Features:**

- Ambidextrous
- Latex free
- Powderfree
- Chlorinated
- AQL 1.5
- Textured fingers
- Free of Tiuram, animal tissue or other biological substances



Property	Level/Result	Applied Standards
<b>Medical Devices Regulation (EU) 2017/745</b>		
Absence of holes	Pass	EN 455-1:2000
Dimensions	Pass	EN 455-2: 2015
Force to break	Pass (average = 6.6 N)	
Biological safety requirements	Pass	EN 455-3: 2015
<b>ASTM Standards</b>		
Viral penetration	Pass	ASTM F 1671-07
Residual dust in medical globes	Pass	ASTM D 6124-06
Medical globes NBR	Pass	ASTM D 6319
Breaking Tensile Strength	14 Mpa	ASTM D 6319-10
Elongation	500%	ASTM D 6319-10



Personal Protection Equipment Regulation (EU) 2016/425						
Dexterity	5	EN 420:2003+A1:2009				
<b>Resistance to the permeation of microorganisms</b>						
Air leak test	Pass	UNE EN 374-2: 2016		 VIRUS		
Water leak test	Pass	EN 374-5:2016				
<b>Resistance to chemical products permeation</b>						
(P) Hydrogen Peroxide (30%)	Clase 2/ Tiempo de permeación >30 min		 KPT  EN 374-1:2014 EN 16523-1:2015 +A1:2018			
(K) Sodium hydroxide (40%)	Clase 6/ Tiempo de permeación >480 min					
(T) Formaldehyde (37 %)	Clase 5/ Tiempo de permeación >240 min					
Plastic materials intended to contact food Regulation 10/2011 ( (EU) 2016/1416))						
Migration Test:		<ul style="list-style-type: none"> <li>Acetic acid 3%</li> <li>Ethanol 10%, 20% and 50%</li> <li>Vegetable oil</li> </ul>		<ul style="list-style-type: none"> <li>Pass</li> <li>Pass</li> <li>Pass</li> </ul>		EN 14372 EN 1186-7:2002  
<b>Sizes</b>						
Glove dimensions						
Size	Weight (g) ± 0.3	Length (mm)	Palm wide (mm) ± 10	Thickness (mm) ±0.02		
				fingers	palm	sleeve
XS	2,6	≥240	75	0.05	0.05	0.04
S	2,8	≥240	80	0.05	0.05	0.04
M	3,0	≥240	95	0.05	0.05	0.04
L	3,5	≥240	110	0.05	0.05	0.04
XL	4,0	≥240	≥110	0.05	0.05	0.04



## Logistic sheet

REF - Size	Cod. EAN		Kg Packaging	Volume m <sup>3</sup>	Boxes/ Pallet	Assembly/ Pallet (Boxes x heights)
	Interior Box	Packaging				
GD19BA-XS	8437022212029	8437022212036	3.58	0.0146	84	12 x 7
GD19BB- S	8437014559002	8437014559040	3,65	0.0146	84	12 x 7
GD19BC- M	8437014559019	8437014559057	4	0.0146	84	12 x 7
GD19BD- L	8437014559026	8437014559064	4,5	0.0146	84	12 x 7
GD19BE- XL	8437014559033	8437014559071	5	0.0146	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 ( EN374-1 and EN374-2).

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

- **Royal Decree 1591/2009**, by which Sanitary Products are regulated.
- **Regulation (EU) 2017/745** on medical devices, amending Directive 2001/83 / EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385 / EEC and 93/42 / EEC (relevant text for the purposes of the EEA).
- **EN 455 / 1-2-3**; Medical protection gloves for single use.
  
- **Regulation (EU) 2016/425**, on personal protective equipment and repealing Council Directive 89/686/EEC
- **EN 420**; Protective gloves, general requirements and test methods.
- **EN 374 / 1-2-4-5**; Protective gloves against chemical products and microorganisms.
  
- **Regulation EC/1935/2004**, on materials and objects intended to come into contact with food.
- **Royal Decree 866/2008**, concerning plastic materials intended to come into contact with food, which transposes directive 2002/72 / EEC, repealed by **Regulation 10/2011 (Regulation 2016/1416)**.
- **Regulation (EU) 2016/1416**, which modifies and corrects Regulation (EU) No. 10/2011 on plastic materials and articles intended to come into contact with food
- **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 EEA.
- **EN 1186-7**; Test methods for global migration in simulators of aqueous foods using a bag.
- **ASTM D 6124-06**, residual powder content.
- **ASTM D 6319**, Standard Specification for nitrile examination gloves for medical use.

## Management system

Quality management system according to ISO 13485.

## Product conformity

