

## 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
- Expiration date
- EC Marking
- Uses, applications and warnings
- Size and number of units
- Single use
- Storage conditions
- Protection pictograms
- Legislation and Reference

## General characteristics

**Description:** Nitrile gloves powderfree purple.

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**; *Royal Decree 1591/2009, Regulation (EU) 2017/745.*  
 PPE **Category III**; *Royal Decree 1407/1992; Regulation (EU) 2016/425*

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

**Colour:** PINK

**Physical Properties**




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

**Features:**

- Ambidextrous
- Latex free
- Powderfree
- AQL 1.5
- Textured fingers
- Free of proteins
- 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 ( AQL 1.5)	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
<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 ISO 21420:2020					
<b>Resistance to the permeation of microorganisms</b>							
Air leak test	Pass	EN ISO 374-2: 2016					
Water leak test	Pass						
Protection against bacteria and fungi	Pass	EN ISO 374-5:		2016	VIRUS		
Virus protection	Pass						
<b>Resistance to chemical products permeation</b>							
(K) Sodium hydroxide (40%)	Level 6 / Permeation time > 480 min	EN ISO 374-1:2014 EN 16523-1:2015+ A1;2008  KPT					
(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 10/2011							
Migration Test:		<ul style="list-style-type: none"> <li>• Acetic acid 3%</li> <li>• 10%, ethanol</li> <li>• Vegetable oil</li> </ul>			<ul style="list-style-type: none"> <li>• Pass</li> <li>• Pass</li> <li>• Pass</li> </ul>		
<b>Sizes</b>							
Glove dimensions							
Size	Weight (g) ± 0.3	Length (mm)	Palm wide (mm) ± 10	Thickness (mm) ±0.02			
				Fingers	palm	sleeve	
XS	2,80	≥240	≤ 80	0.08	0.07	0.05	
X	3,00	≥240	80	0.08	0.07	0.05	
M	3,50	≥240	95	0.08	0.07	0.05	
L	3,90	≥240	110	0.08	0.07	0.05	
XL	4,40	≥240	≥110	0.08	0.07	0.05	

**Logistic sheet**

REF - Size	Cod. EAN		Kg Packaging	Volume m <sup>3</sup>	Boxes/Pallet	Assembly/Pallet (Boxes x heights)
	Interior Box	Packaging				
GD20RA- XS	8437022212463	8437022212470		0,015345	84	12 x 7
GD20RB- S	8437022212487	8437022212494		0,015345	84	12 x 7
GD20RC- M	8437022212500	8437022212517		0,015345	84	12 x 7
GD20RD- L	8437022212524	8437022212531		0,015345	84	12 x 7
GD20RE- XL	8437022212548	8437022212555		0,015345	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.

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 / 1-2-3-4**; Medical protection gloves for single use.
  
- **Royal Decree 1407/1992**, referring to the Individual Protection Equipment, which transposes the European Directive 89/686/EEC.
- **Regulation (EU) 2016/425**, on personal protective equipment and repealing Council Directive 89/686/EEC
- **EN ISO 21420**; Protective gloves, general requirements and test methods.
- **EN ISO 374 / 1-2-4-5**; Protective gloves against chemical products and microorganisms.
- **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

