

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 white.

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: Extra Small, Small, Medium, Large, Extra Large

Colour: White

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
Medical Devices Regulation (EU) 2017/745		
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
ASTM Standards		
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 (before aging) 14 Mpa (after aging)	ASTM D 6319-10
Elongation	500%	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	EN ISO 374-2: 2016				
Water leak test	Pass					
Protection against bacteria and fungi	Pass	EN ISO 374-5:		2016	VIRUS	
Virus protection	Pass					
Resistance to chemical products permeation						
(K) Sodium hydroxide (40%)	Level 6 / Permeation time > 480 min	EN ISO 374-1:2014 EN 16523-1:2015+ A1;2008  KPT				
(T) Formaldehyde (37 %)	Level 2/ Permeation time > 30 min					
(P) Hydrogen peroxide (30 %)	Level 4/ Permeation time >120 min					
Plastic materials intended to contact food Regulation 10/2011						
Migration Test:						
<ul style="list-style-type: none"> Acetic acid 3% 10%, ethanol Vegetable oil 		<ul style="list-style-type: none"> Pass Pass Pass 				
Sizes						
Glove dimensions						
Size	Weight (g) ± 0.3	Length (mm)	Palm wide (mm) ± 10	Thickness (mm) ±0.02		
				Fingers	palm	sleeve
XS	2,60	≥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 ³	Boxes/Pallet	Assembly/Pallet (Boxes x heights)
	Interior Box	Packaging				
GD20WA-XS	8437022212593	8437022212609	3,2	0,015345	88	11 x 8
GD20WB- S	8437017506201	8437017506249	3,5	0,015345	88	11 x 8
GD20WC- M	8437017506218	8437017506256	4,0	0,015345	88	11 x 8
GD20WD- L	8437017506225	8437017506263	4,5	0,015345	88	11 x 8
GD20WE- XL	8437017506232	8437017506270	5	0,015345	88	11 x 8

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

