

Presentation of the product

Packaging

- **Content:** 10 boxes of 100 units
- **Dimension:** 350 x 260 x 240 mm

Box of 100 units

- **Content:** 100 units
- **Dimension:** 230 x 125 x 68 mm



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 Standards

General characteristics

Description: Black Nitrile gloves powderfree. 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**. *Regulation (EU) 2016/425*

Sizes: Small, Medium, Large, Extra Large

Physical Properties

Composition : Acrylonitrile Butadiene Nitrile (NBR)




Features:

- Ambidextrous
- Latex free
- Powderfree
- Chlorinated
- 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	
Biological safety requirements	Pass	EN 455-3 :2015
Requirements for durability check	Pass	EN 455-4 : 2009
Breaking Tensile Strength	14 Mpa	_____
Elongation	500%	_____
Personal Protection Equipment Regulation (EU) 2016/425		
Dexterity	5	EN 420:2003+A1:2009
<i>Resistance to the permeation of microorganisms</i>		
Air leak test	Pass	UNE EN 374-2: 2016
Water leak test	Pass	

GD23	BLACK NITRILE GLOVE POWDERFREE	DATA SHEET
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Protection against bacteria and fungi	Pass	EN ISO 374-5: 2016 VIRUS	
Resistance to chemical products permeation			
(K) Sodium hydroxide (40%)	Level 6 / Permeation time >480 min	EN 374-1:2014 EN 16523-1:2015 +A1:2018	 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 (Regulation 10/2011 (EU 2016/1416))			
Phthalat content	Positive in Naphthalene		
Migration Test:		EN 1186-9:2002	
<ul style="list-style-type: none"> • Acetic acid 3% • Ethanol 10%, • 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
S	5,5	≥240	80	0.12	0.11	0.07
M	6,0	≥240	95	0.12	0.11	0.07
L	6,5	≥240	110	0.12	0.11	0.07
XL	6,8	≥240	≥110	0.12	0.11	0.07

Logistic sheet

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REF - Size	Cod. EAN		Kg Packaging	Volume m ³	Boxes/Pallet	Assembly/Pallet (Boxes x heights)
	Interior Box	Packaging				
GD23BB – S	8437001266623	8437001266661	6,2	0,02184	72	9 x 8
GD23BC – M	8437001266630	8437001266678	6,7	0,02184	72	9 x 8
GD23BD – L	8437001266647	8437001266685	7,2	0,02184	72	9 x 8
GD23BE - XL	8437001266654	8437001266692	7,7	0,02184	72	9 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.

It is suitable for all uses with a high level of demand. Protects the user against contamination of infectious materials, particularly bacteria, blood and infected body fluids. 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

- **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.

- **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.
- **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

