

Presentation of the product

Packaging 1000 Units

- **Content:** 10 boxes of 100 units
- **Dimensions:** 315 x 255 x 245 mm

Box of 100 units

- **Content:** 100 units
- **Dimensions:** 230 x 125 x 60mm



Labeling

- Name and address of the manufacturing company
- Product name and commercial reference
- CE Marking
- Expiration
- Recommendations for use and precautions in different languages
- Pictograms
- Reference regulations
- Batch and barcode
- Size and Content

General specifications

Description: Black latex gloves.

Very silky and soft, they offer greater comfort and extreme sensitivity to the touch. Cuff rolled

Shelf life: 3 years

Classification:

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

Category III PPE; Regulation (EU) 2016/425

Sizes: Extra Small, Small, Medium, Large and Extra large

Colour: Black

Physical Properties

Composition: Natural Rubber Latex, Sulfur, Rubber Accelerator, Zinc Oxide, Potassium Hydroxide, Polymer Coatings, Titanium Dioxide.

Features:



- Contains latex
- Ambidextrous
- AQL 1.5

Property	Level/Result	Applied Standards
Medical Devices Regulation (EU) 2017/745		
Absence of holes	Pass	EN 455-1
Dimensions	Pass	EN 455-2
Force to break	Pass (average > 6 N)	
Biological safety requirements	Pass	EN 455-3
Individual Protection Equipment Regulation (EU) 2016/425		
Dexterity	5	EN ISO 21420
Resistance to the permeation of microorganisms		
Air leak test	Pass	EN ISO 374-2
Water leak test	Pass	
Protection against bacteria and fungi	Pass	EN ISO 374-5
Virus protection	Pass	
 VIRUS		
Resistance to chemical products permeation		
(T) Formaldehyde (37 %)	Level 5 / Permeation time > 240 min	 KPT EN ISO 374-1 EN 16523-1
(L) Sulphuric Acid (96%)	Level 1 / Permeation time > 10 min	
(P) Hydrogen Peroxide (30%)	Level 1 / Permeation time > 10 min	
(M) Nitric acid (65%)	Level 1 / Permeation time > 10 min	

GD06N
BLACK POWDER FREE LATEX GLOVE
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(K) Sodium hydroxide
(40%)

Level 6/ Permeation time >
480 min

Plastic materials intended to contact food Regulation 10/2011

Migration Test:

- 10%, 20% and 50% ethanol
- Vegetable oil

Pass

EN 1186-8:2002
EN 1186-9:2002


Sizes
Glove dimensions

Size	Length (mm) ± 3	Palm wide (mm) ± 10	Thickness Palm (mm) ±0.02	Weight (g) ± 0.3
XS	240	<= 80	0.10	4,6
S	240	80	0.10	5.0
M	240	95	0.10	5,5
L	240	110	0.10	6,2
XL	240	≥110	0.10	6,7

Logistic sheet

REF - Size	Cod. EAN		Kg Packaging	Volume m ³	Boxes/ Pallet	Assembly/ Pallet (Boxes x heights)
	Interior Box	Interior Box				
GD06NA- XS	8436613860007	8436613860052	5.50	0.01984	70	10 x 7
GD06NB- S	8436613860014	8436613860069	5.75	0.01984	70	10 x 7
GD06NC- M	8436613860021	8436613860076	6.30	0.01984	70	10 x 7
GD06ND- L	8436613860038	8436613860083	7.20	0.01984	70	10 x 7
GD06NE-XL	8436613860045	8436613860090	8.20	0.01984	70	10 x 7

Uses and applications

Exploration gloves in the **health** field, medical or dental use; its use is intended to protect the patient and the user against low biological and chemical risk, meets the requirements for the verification of microbiological safety and low chemical risk. It is recommended for tasks of short duration and with a high frequency of change.

They are widely used in **light industry** and in the **domestic sphere**. They can also be used in the **food industry** because these gloves comply with the requirements of Regulation 10/2011 regarding materials intended to come into contact with food.

Do not use for handling with organic solvents. This product contains natural rubber latex that can cause allergic reactions. DO NOT REUSE

Storage conditions

Keep stored in a cool and dry place. Avoid excess heat and protect from direct sunlight or fluorescent lighting.

Do not store these gloves with organic solvents since they can degrade them.

Ventilation is not necessary under normal storage conditions.



Reference Directives and Standards

- **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.
- **ASTM D 6124-06**, residual powder content.
- **ISO 13485:2003**, Quality system for Medical Device manufacturing.
- **EN 455 / 1-2-3**; Medical protection gloves for single use.
- **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

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Council Directives 90/385 / EEC and 93/42 / EEC (relevant text for the purposes of the EEA).

- **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.

Management system

Quality management system according to ISO 13485:2016.

Conformidad del Producto

