

### Presentation of the product

#### Packaging 1000 Units

- **Content:** 10 boxes of 100 units
- **Dimensions:** 385 x 258 x 235 mm

#### Box of 100 units

- **Content:** 100 units
- **Dimensions:** 225 x 125 x 75mm



#### 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:** White latex gloves.  
Very silky and soft, they offer greater comfort and extreme sensitivity to the touch. Cuff rolled

**Shelf life:** 5 years

**Classification:**  
Medical Device **Class I**; Royal Decree 1591/2009, Regulation (EU) 2017/745.

**Category III PPE**; Royal Decree 1407/1992, Regulation (EU) 2016/425

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







### Physical Properties

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

**Features:**



- Contains latex
- Ambidextrous
- Biodegradable
- Protein content <50 mg per gram
- 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   |
| Dimensions  | Pass                               | EN 455-2   |
| Force to break  | Pass (average = 4.8 N)             |  |
| Biological safety requirements                                  | Pass                               | EN 455-3   |
| Resistance to breaking stress                                   | 21 Mpa                             | ASTM D 6319-10   |
| Elongation  | 700 %                              | ASTM D 6319-10   |
| <b>Individual Protection Equipment Regulation (EU) 2016/425</b> |                                    |  |
| Dexterity   | 5                                  | EN 420   |
| <b>Resistance to the permeation of microorganisms</b>           |                                    |  |
| Air leak test   | Pass                               | EN 374-2            |
| Water leak test   | Pass                               |  |
| <b>Resistance to chemical products permeation</b>               |                                    |  |
| (T) Formaldehyde (37 %)   | Class 5/ Permeation time > 240 min | <br>EN 374-1<br>KLT |
| (K) Sodium hydroxide (40%)                                      | Class 3/ Permeation time >60 min   |  |
| (L) Sulfuric Acid (96%)   | Class 1/ Permeation time >10 min   |  |

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Plastic materials intended to contact food Regulation 10/2011 ( Regulation 10/2011 (EU 2016/1416))

Migration Test:

- Acetic acid 3%
- 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) ± 5 | Thickness Palm (mm) ±0.02 | Weight (g) ± 0.2 |
| XP               | ≥230            | 75                 | 0.8                       | 4.6              |
| P                | ≥230            | 85                 | 0.8                       | 5.0              |
| M                | ≥230            | 95                 | 0.8                       | 5.4              |
| G                | ≥230            | 106                | 0.8                       | 5.8              |

### Logistic sheet

| REF - Size | Cod. EAN      |               | Kg Packaging | Volume m <sup>3</sup> | Boxes/ Pallet | Assembly/ Pallet (Boxes x heights) |
|------------|---------------|---------------|--------------|-----------------------|---------------|------------------------------------|
|            | Interior Box  | Interior Box  |              |                       |               |                                    |
| GD05NA- XP | 8437014559477 | 8437014559514 |              | 0.02334255            |               |                                    |
| GD05NB- P  | 8437014559484 | 8437014559521 |              | 0.02334255            |               |                                    |
| GD05NC- M  | 8437014559491 | 8437014559538 |              | 0.02334255            |               |                                    |
| GD05ND- G  | 8437014559507 | 8437014559545 |              | 0.02334255            |               |                                    |

### 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 (EN374-1/2/4/5). It is

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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 EN 1186 and 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

- **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 420**; Protective gloves, general requirements and test methods.
- **EN 374 / 1-2-4-5**; Protective gloves against chemical products and microorganisms.
  
- **ASTM D 6124-06**, residual powder content.
- **ASTM D 6319**, Standard Specification for nitrile examination gloves for medical use.
  
- **ISO 13485:2003**, Quality system for Medical Device manufacturing.
  
- **EN 455 / 1-2-3-4**; Medical protection gloves for single use.
  
- **Royal Decree 1591/2009**, by which Sanitary Products are regulated.

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- **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).
- **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.

## Management system

Quality management system according to ISO 13485:2016.

## Conformidad del Producto

