



## Product Presentation

### Package of 500 Units

- **Contents:** 10 boxes of 50 units
- **Dimensions:** 340 x 260 x 270 mm

### Box of 50 Units

- **Contents:** 50 units
- **Dimensions:** 260 x 125 x 65 mm



### Labelling

- |  |   |
|--|---|
| <ul style="list-style-type: none"> <li>- Name and address of the Manufacturer</li> <li>- Product name in different languages</li> <li>- Commercial reference, Batch and bar code</li> <li>- AQL 1.5</li> <li>- Expiry</li> <li>- CE Marking</li> </ul> | <ul style="list-style-type: none"> <li>• Size and number of units</li> <li>• Disposable</li> <li>• Storage conditions</li> <li>• Protection pictograms</li> <li>• Laws and Standards of reference</li> <li>• Uses, applications and warnings</li> </ul> |
|--|---|

## General Characteristics

**Description:** Extra-strong and extra-long powder-free blue nitrile glove.

Thin and extra sensitive to the touch due to the finger area being textured for better grip in dry and wet conditions. Reinforced rolled cuff.

The surface of the glove is treated with chlorine to prevent the gloves from sticking together and for easier on and off.

The nitrile offers three times greater protection against the micro-orifices present in conventional latex gloves, making it the best choice for 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

**Colour:** Blue.

Property	Performance level/Result	Standards applied
<b>Medical devices Regulation (EU) 2017/745</b>		
Absence of holes	Compliant	EN 455-1
Dimensions	Compliant	EN 455-2
Breaking strength	Compliant (average=13 N)	
Biological safety requirements.	Compliant	EN 455-3
Breaking tensile strength	13 Mpa	_____
Elongation	500%	_____
<b>ASTM Standards</b>		
NBR medical gloves	Compliant	ASTM D6319 – 10
Residual powder	Compliant	ASTM D6124 - 06
Permeability to cytostatics	Compliant	ASTM D6978 - 05
<b>Personal Protective Equipment Regulation (EU) 2016/425</b>		
Dexterity	5	EN 420:2003+A1:2009
<b>Resistance to permeation by micro-organisms</b>		
Air leak test	Compliant	EN 374-2:2016
Water leak test	Compliant	EN 374-5:2016
		 VIRUS
<b>Resistance to permeation by chemical products</b>		
(J) n-Heptane	Class 1/ Permeation time >10 min	 KPT
(K) Sodium Hydroxide (40%)	Class 6/ Permeation time >480 min	
Methanol in water (1.5%)	Class 6/ Permeation time >480 min	
Phenol (0.1%)	Class 6/ Permeation time >480 min	
		EN 374-1:2016 EN 16523-1: 2015



Glutaraldehyde (50%)	Class 6/ Permeation time >480 min
(P) Hydrogen peroxide (30%)	Class 5 / Permeation time > 240 min
(T) Formaldehyde (37%)	Class 6/ Permeation time >480 min
Ethidium Bromide (5%)	Class 6/ Permeation time >480 min

Plastic materials intended to come into contact with food Regulation ((EU) 2016/1416)

Migration		EN 1186-7:2002	
- Acetic	Compliant	EN 1186-14:2002	
- Ethanol 10% /20% and 50%	Compliant		
- Vegetable oil	Compliant		

## Physical Properties

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

**Characteristics:**

- AQL: 1.5
- Ambidextrous
- Chlorinated
- Textured Fingers
- Latex-Free
- Powder-Free
- Free from Proteins and chemical accelerants
- Free from Thiuram, animal tissue and other biological substances

## Sizes

Dimensions of the Glove

Size	Weight (g)±0.3	Length (mm)	Palm width (mm) ± 5	Thickness (mm) ±0.02		
				Finger	Palm	Cuff (25 cm long)
S	8.4	≥285	85	0.17	0.11	0.08
M	8.8	≥285	95	0.17	0.11	0.08
L	9.2	≥285	106	0.17	0.11	0.08
XL	9.6	≥285	116	0.17	0.11	0.08



## Logistics sheet

REF - Size	EAN Code		Kg Packages	Volume m <sup>3</sup>	Boxes/Pallet	Assembly/Pallet (Boxes x heights)
	Inner box	Package				
GD24BB- S	8437001266708	8437001266746	5.10	0.023868	63	9x7
GD24BC- M	8437001266715	8437001266753	5.45	0.023868	63	9x7
GD24BD- L	8437001266722	8437001266760	5.60	0.023868	63	9x7
GD24BE- XL	8437001266739	8437001266777	6.00	0.023868	63	9x7

## Uses and applications

In the **medical** field, gloves for doing **medical examinations**, orthodontics, clinical examinations, diagnostic and therapeutic procedures, for laboratory use, and in general for all activities which require gloves to create a protective barrier against infectious bodies, like in the fields of research and veterinary science.

They are suitable for all uses requiring high performance. They protect users against contamination from potentially infectious materials, such as viruses, bacteria, blood and infected body fluids and other contaminating materials. They offer low protection against **chemical** risks. They comply with requirements for confirming microbiological safety and low chemical risk (EN374-2 and EN374-4).

They are also used in the **food**, **electronics** and **cleaning** industries, because NBR does not contain latex or chemical accelerants, so they reduce skin irritation due to allergies and provide acceptable comfort and elasticity. In the food sector, these gloves comply with the requirements of Regulation 10/2011 regarding plastic materials intended to come into contact with food.

## Storage Conditions

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





## Directives and Standards of reference

- EN 374/1-2-4-5: Protective gloves against chemicals and micro-organisms.
- EN 420: Protective gloves, general requirements and testing methods.
- EN 1186/7:2002: Testing methods for overall migration into aqueous food simulants using a pouch.
  
- EN 455/1-2-3: Disposable medical protective gloves.
- ISO 13485:2003: Quality System for the manufacturing of Medical Devices.
- ASTM D 6124-06: Residual powder content.
- ASTM D 6319: Standard specification for nitrile examination gloves for medical use.
- ASTM D 6978-05: Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs.
- Regulation 10/2011 on plastic materials and articles intended to come into contact with food. Text relevant for the purposes of the EEE.
- Royal Decree 866/2008, regarding plastic materials intended to come into contact with food which transposes directive 2002/72/EEC, repealed by Regulation 10/2011.
- Regulation (EU) 2017/745, which regulates Medical Devices.
- Regulation (EU) 2020/1245, which modifies and corrects Regulation (EU) 10/2011 on plastic materials and objects intended to come into contact with food.

## Management System

Management System compliant with the ISO 13485 standards.

## Product Conformity

