

**NORDISK FORHANDLER AF  
/  
NORDIC DISTRIBUTOR OF**



## Presentation of the product

### Packaging

- **Content:** 10 boxes of 100 units
- **Dimension:** 310 x 225 x 210 mm

### Box of 100 units

- **Content:** 100 units
- **Dimension:** 200 x 110 x 60mm



### Labelling

- Name and address of the manufacturing company
- Name of the product in several languages
- Commercial reference, batch and barcode
- AQL 1.5
- Expiration date
- EC Marking
- Size and number of units
- Single use
- Storage conditions
- Protection pictograms
- Legislation and Reference
- Uses, applications and warnings

## General characteristics

**Description:** Blue 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

GD19

BLUE NITRILE GLOVE POWDERFREE



DATA SHEET



**Classification:**

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

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


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

**Colour:** Blue

**Physical Properties**

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

**Features:**

- Ambidextrous
- Latex free 
- Powderfree
- Chlorinated
- AQL 1.5
- Textured fingers
- Free of proteins and chemical accelerators
- 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 455-1:2000
Dimensions	Pass	EN 455-2: 2015
Force to break	Pass (average = 6.6 N)	
Biological safety requirements	Pass	EN 455-3: 2015
<b>ASTM Standards</b>		
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	ASTM D 6319-10
Elongation	500%	ASTM D 6319-10

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Personal Protection Equipment Regulation (EU) 2016/425		
Dexterity	5	EN 420:2003+A1:2009
<b>Resistance to the permeation of microorganisms</b>		
Air leak test	Pass	UNE EN 374-2: 2016
Water leak test	Pass	
<b>Resistance to chemical products permeation</b>		
(F) Tolueno	Level 1/ Permeation time >10 min	EN 374-1:2014 FKT
(K) Sodium hydroxide (40%)	Level 6 / Permeation time >480 min	
(T) Formaldehyde (37 %)	Level 3/ Permeation time >60 min	
Plastic materials intended to contact food Regulation 10/2011 ( (EU) 2016/1416)		
Migration Test:		
<ul style="list-style-type: none"> <li>Isooctane</li> <li>Acetic acid 3%</li> <li>10%, 20% and 50% ethanol</li> <li>Vegetable oil</li> </ul>	<ul style="list-style-type: none"> <li>Pass</li> <li>Pass</li> <li>Pass</li> <li>Pass</li> </ul>	EN 14372 EN 1186-7:2002

### Sizes

Glove dimensions						
Size	Weight (g) ± 0.2	Length (mm) ± 3	Palm wide (mm) ± 10	Thickness (mm) ±0.02		
				fingers	palm	sleeve
P	2,8	≥240	85	0.05	0.05	0.04
M	3,0	≥240	95	0.05	0.05	0.04
G	3,5	≥240	105	0.05	0.05	0.04
XG	4,0	≥240	115	0.05	0.05	0.04

### Logistic sheet

REF - Size	Cod. EAN		Kg Packaging	Volume m <sup>3</sup>	Boxes/ Pallet	Assembly/ Pallet (Boxes x heights)
	Interior Box	Packaging				
GD19BB- P	8437014559002	8437014559040		0.0146	80	10x8
GD19BC- M	8437014559019	8437014559057		0.0146	80	10x8
GD19BD- G	8437014559026	8437014559064		0.0146	80	10x8
GD19BE- XG	8437014559033	8437014559071		0.0146	80	10x8

Paseo de la Castellana nº 141. Plantas 18 y 19. 28046 Madrid Tel: 902367762	<a href="http://www.santex.es">www.santex.es</a> <a href="mailto:calidad@santex.es">calidad@santex.es</a> <a href="mailto:santex@santex.es">santex@santex.es</a>	Edited by: <b>Manuel Guerrero</b> Last edition <b>08/01/2020</b>	Page <b>3</b> of <b>5</b>
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### 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 ( EN374-1 and EN374-2).

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 420**; Protective gloves, general requirements and test methods.
- **EN 374 / 1-2-4-5**; Protective gloves against chemical products and microorganisms.

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- **Regulation EC/1935/2004**, on materials and objects intended to come into contact with food.
- **Royal Decree 866/2008**, concerning plastic materials intended to come into contact with food, which transposes directive 2002/72 / EEC, repealed by **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

