

## Presentation of the product



### Packaging

- **Content:** 10 boxes of 100 units
- **Dimensions:** 310 x 225 x 220 mm

### Box of 100 units

- **Content:** 100 units
- **Dimensions:** 210 x 110 x 60mm

### Labeling for the 100-unit box

- Name and address of the manufacturing company
- Name of the product in several languages
- Commercial reference and batch number
- Manufacturing and expiration dates
- EC Marking
- Barcode (EAN) and UDI code
- Size and number of units
- Single use
- Storage conditions
- Protection icons
- Legislation and Reference
- Uses, applications, and warnings

## General characteristics

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### Description:

Powder-Free Nitrile Examination Gloves – Non-Sterile

Thin and extra sensitive to touch due to textured fingertips, providing enhanced grip in both wet and dry conditions. Reinforced rolled cuff. The glove surface is chlorinated to prevent gloves from sticking together. The interior is coated with synthetic material, making them easier to put on and take off.

Nitrile offers three times more protection against micro-perforations compared to conventional latex gloves; for this reason, it is the best choice when selecting a latex-free glove.

**Shelf life:** 5 years

### Clasification:

- Class I Medical Device; Regulation (EU) 2017/745
- Category III PPE: Regulation (EU) 2016/425
- Suitable for contact with food, except acidic foods

**Sizes:** Extra small (XS), Small (S), Medium (M), Large (L), Extra Large (XL)

**Colors:**

- Blue – GD20BA (XS), GD20BB (S), GD20BC (M), GD20BD (L), GD20BE (XL)
- Black – GD20NA (XS), GD20NB (S), GD20NC (M), GD20ND (L), GD20NE (XL)
- Cobalt Blue – GD20CA (XS), GD20CB (S), GD20CC (M), GD20CD (L), GD20CE (XL)
- Purple – GD20PA (XS), GD20PB (S), GD20PC (M), GD20PD (L), GD20PE (XL)
- Magenta – GD20MA (XS), GD20MB (S), GD20MC (M), GD20MD (L), GD20ME (XL)
- Pink – GD20RA (XS), GD20RB (S), GD20RC (M), GD20RD (L), GD20RE (XL)
- White – GD20WA (XS), GD20WB (S), GD20WC (M), GD20WD (L), GD20WE (XL)
- Green – GD20GA (XS), GD20GB (S), GD20GC (M), GD20GD (L), GD20GE (XL)

## Physical Properties

### Composition and Features

Acrylonitrile Butadiene Nitrile (NBR)

- Ambidextrous
- Chlorinated
- Textured fingers
- Non-Sterile
- AQL 1.5
- Latex-Free
- Powder-Free
- Tiuram-Free
- Free from animal tissue and other biological substances

Property	Performance level /Result	Applied Standards	
<b>Medical Devices</b>		<b>Regulation (EU) 2017/745</b>	
Absence of holes	Pass (AQL 1.5)	EN 455-1:2020	
Dimensions	Pass	EN 455-2: 2015	
Force to break	Pass (average >6 N)		
Biological safety requirements	Pass	EN 455-3: 2015	
Shelf life determination	Pass	EN 455-4:2010	
<b>Personal Protection Equipment</b>		<b>Regulation (EU) 2016/425</b>	
Dexterity	5	EN ISO 21420:2020	
Air leak test	Pass	EN ISO 374-2: 2019	
Water leak test	Pass		
Protection against bacteria and fungi	Pass	EN ISO 374-5: 2016	
Resistance to degradation by chemicals	Pass	EN ISO 374-4:2019	
Performance requirements for chemical risks	Pass	EN ISO 374-1:2016+A1:2018	
Resistencia a la permeación por productos químicos	Pass	EN 16523-1:2015+A1:2018	

<b>Resistance to chemical products permeation</b> (Refers to the sample tested under laboratory conditions and not to workplace conditions)		
(K) Sodium hydroxide (40%)	Level 6 / Permeation time >480 min	<b>TYPE B</b> EN ISO 374-1:2016 + A1:2018 EN 16523-1:2015+A1:2018
(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		<b>Regulation (EU) 10/2011</b>
Migration Test: - Acetic acid 3% - Ethanol 10% - Vegetable oil	Pass Pass Pass	(EU) No 10/2011 (EU) 2020/1245

## Sizes

Glove dimensions						
Size	Weight (g)±0,3	Length (mm)	Palm wide (mm) ± 10	Thickness (mm) ±0.03		
				Fingers	Palm	Sleeve
XS	2,80	≥240	≤ 80	0.10	0.08	0.07
S	3,10	≥240	80	0.10	0.08	0.07
M	3,50	≥240	95	0.10	0.08	0.07
L	3,80	≥240	110	0.10	0.08	0.07
XL	4,10	≥240	≥110	0.10	0.08	0.07

## Logistic sheet

REF - Size	EAN code		Carton box weight (Kg)	Carton box volume(m3)	Carton boxes / Pallet	Assembly/ Pallet (Carton boxes x layers)
	Interior box	Carton box				
GD20BA- XS	8437022212005	8437022212012	3,6	0,015345	88	11 x 8
GD20BB- S	8437001266906	8437001266944	3,9	0,015345	88	11 x 8
GD20BC- M	8437001266913	8437001266951	4,3	0,015345	88	11 x 8
GD20BD- L	8437001266920	8437001266968	4,8	0,015345	88	11 x 8

GD20BE- XL	8437001266937	8437001266975	5,2	0,015345	88	11 x 8
GD20NA- XS	8437022212562	8437022212579	3,6	0,015345	88	11 x 8
GD20NB- S	8437017506362	8437017506409	3,9	0,015345	88	11 x 8
GD20NC- M	8437017506379	8437017506416	4,3	0,015345	88	11 x 8
GD20ND- L	8437017506386	8437017506423	4,8	0,015345	88	11 x 8
GD20NE- XL	8437017506393	8437017506430	5,2	0,015345	88	11 x 8
GD20CA- XS	8436613860649	8436613860656	3,6	0,015345	88	11 x 8
GD20CB- S	8436613860663	8436613860670	3,9	0,015345	88	11 x 8
GD20CC- M	8436613860687	8436613860694	4,3	0,015345	88	11 x 8
GD20CD- L	8436613860700	8436613860717	4,8	0,015345	88	11 x 8
GD20CE- XL	8436613860724	8436613860731	5,2	0,015345	88	11 x 8
GD20PA- XS	8437022212364	8437022212371	3,6	0,015345	88	11 x 8
GD20PB- S	8437022212388	8437022212395	3,9	0,015345	88	11 x 8
GD20PC- M	8437022212401	8437022212418	4,3	0,015345	88	11 x 8
GD20PD- L	8437022212425	8437022212432	4,8	0,015345	88	11 x 8
GD20PE- XL	8437022212449	8437022212456	5,2	0,015345	88	11 x 8
GD20MA- XS	8437022212876	8437022212883	3,6	0,015345	88	11 x 8
GD20MB- S	8437022212890	8437022212906	3,9	0,015345	88	11 x 8
GD20MC- M	8437022212913	8437022212920	4,3	0,015345	88	11 x 8
GD20MD- L	8437022212937	8437022212944	4,8	0,015345	88	11 x 8
GD20ME- XL	8437022212951	8437022212968	5,2	0,015345	88	11 x 8
GD20RA- XS	8437022212463	8437022212470	3,6	0,015345	88	11 x 8
GD20RB- S	8437022212487	8437022212494	3,9	0,015345	88	11 x 8
GD20RC- M	8437022212500	8437022212517	4,3	0,015345	88	11 x 8
GD20RD- L	8437022212524	8437022212531	4,8	0,015345	88	11 x 8
GD20RE- XL	8437022212548	8437022212555	5,2	0,015345	88	11 x 8
GD20WA- XS	8437022212593	8437022212609	3,6	0,015345	88	11 x 8
GD20WB- S	8437017506201	8437017506249	3,9	0,015345	88	11 x 8
GD20WC- M	8437017506218	8437017506256	4,3	0,015345	88	11 x 8
GD20WD- L	8437017506225	8437017506263	4,8	0,015345	88	11 x 8
GD20WE- XL	8437017506232	8437017506270	5,2	0,015345	88	11 x 8
GD20GA - XS	8437022212616	8437022212623	3,6	0,015345	88	11 x 8

GD20GB	8437017506287	8437017506324	3,9	0,015345	88	11 x 8
GD20GC	8437017506294	8437017506331	4,3	0,015345	88	11 x 8
GD20GD	8437017506300	8437017506348	4,8	0,015345	88	11 x 8
GD20GE	8437017506317	8437017506355	5,2	0,015345	88	11 x 8

## Uses and applications

In the healthcare sector, these gloves are intended for use during medical examinations, dentistry, clinical assessments, diagnostic and therapeutic procedures, laboratory applications, and, in general, all activities requiring a glove that serves as a protective barrier against infectious agents, such as in research and veterinary fields. They are suitable only for low-risk exposure levels.

Their chemical risk protection is limited. These gloves meet the standards for microbiological safety and chemical risk assessment as specified in EN ISO 374-1:2016+A1:2018 and EN ISO 374-2:2019.

Additionally, they are utilized in the food industry and cleaning sectors due to the absence of latex in NBR, which provides a high level of comfort and elasticity. Within the food industry, these gloves comply with the requirements set forth in Regulation (EU) No 10/2011 (and its amendments), as well as Regulation (EU) No 1245/2020 concerning plastic materials intended to come into contact with foodstuffs.

Contact with acidic foods should be avoided.

## 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

- EN ISO 374: Protective gloves against dangerous chemicals and microorganisms
  - EN ISO 374-1:2016+A1:2018: Terminology and performance requirements for chemical risks
  - EN ISO 374-2:2019: Determination of resistance to penetration
  - EN ISO 374-4:2019: Determination of resistance to degradation by chemicals
  - EN ISO 374-5:2016: Terminology and performance requirements for microbial risks
- EN ISO 21420:2020: Protective gloves – General requirements and test methods
- EN 16523-1:2015+A1:2018: Determination of resistance of materials to chemical permeation
- Regulation (UE) 2016/425 Personal Protective Equipment

- EN 455: Single-use medical gloves
  - EN 455-1:2000: Requirements and tests for freedom from holes
  - EN 455-2:2015: Requirements and tests for physical properties
  - EN 455-3:2015: Requirements and tests for biological evaluation
  - EN 455-4:2009: Requirements and tests to determine shelf life
  
- Regulation (UE) 2017/745: Regulation on Medical Devices
- Regulation (UE) No 10/2011, on plastic materials and articles intended to come into contact with food
- EN 1186/7:2002: Test methods for overall migration in aqueous food simulants using a pouch
- Regulation (CE) N°1935/2004 of the European Parliament and of the Council on materials and articles intended to come into contact with food
- Regulation (UE) 2020/1245, amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food
- ISO 9001:2015: Quality management systems
- ISO 13485:2016: Quality management systems for medical devices
- ISO 14001:2015: Environmental management systems

## Management system

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Quality management system according to ISO 13485.

## Product conformity

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