

GD21

NITRILE DISPOSABLE GLOVES

TDS



Packaging

1,000 p outer case

- **Content:** 10 boxes of 100 pieces
- **Dimension:** 370 x 260 x 250 mm

100 p. inner dispenser

- **Content:** 100 pieces
- **Dimension:** 235 x 125 x 70mm



Labelling

- Importer name and address
- Product name in some languages
- Commercial benchmark, lot number and barcode
- AQL 1.5
- Expiration
- CE label
- Size and units quantity
- Single-use
- Storage conditions
- Protection symbols
- Regulatory compliance
- Applications & warnings

General Characteristics

Description: Blue nitrile gloves powder free.

Smooth surface for greater sensitivity and beaded cuff.

Glove Surface treated with chlorine in order to prevent the gloves to be stuck-together and it helps to put and take off the glove easily.

Nitrile gloves offer three times more protection against micro-holes in conventional latex gloves.

Shelf life: 5 years

Classification:

Medical device: **Class I**; *European Directive 93/42/CEE*

PPE: **Category III**; *European Directive 89/686/CEE*

Size: S, M, L and XL

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Physical Properties

Composition: 100% Nitrile butadiene rubber (NBR)

Characteristics:

- AQL: 1.5
- Ambidextrous
- Chlorinated
- Textured fingers
- Latex free 
- Powder free
- Free of proteins and chemical accelerators
- Free of Tiuram, animal tissue or other biological substances

Property	Benefit level / Result	Standards applied
Healthcare products Directive 93/42/CEE		
Tests for freedom from holes	Compliant with	EN 455-1
Dimensions	Compliant with	EN 455-2
Force at break	Compliant with (av.=6.0 N)	
Biological safety requirements	Compliant with	EN 455-3
Tensile breaking strength	14 Mpa	_____
Elongation	500%	_____
ASTM Standards		
Permeation by chemotherapy drugs	Compliant with	ASTM D 6978-05
Bacteriophage Penetration	Compliant with	ASTM F 1671-07
NBR gloves for medical application	Compliant with	ASTM D 6319
Residual powder on medical gloves	Compliant with	ASTM D 6124-06
Personal Protection Equipment Directive 89/686/CEE		
Dexterity	5	EN 420
Resistance to the permeation of microorganisms		
Air leak test	Compliant with	EN 374-2
Water leak test	Compliant with	
Resistance to chemical products permeation		
(J) n-Heptane	Class 5/ Permeation time >240 min	

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(k) Sodium Hydroxide (40%)	Class 6/ Permeation time > 480 min	EN 374-3	
(L) Sulfuric Acid (96%)	Class 0/ Permeation time <10 min		
Plastic materials intended to come into contact with food Regulation 10/2011			
Migration test: - Acetic acid 3% - Ethanol 10% / 95% - Vegetable oil	Compliant with	EN 1186, EN13130 CN/TS 14234	

Dimensions

Glove dimensions					
Size	Length (mm)	Palm width (mm) ± 10	Thickness (mm) ±0.02		
			Finger	Palm	Sleeve
S	≥240	84	0.11	0.09	0.06
M	≥240	94	0.11	0.09	0.06
L	≥240	105	0.11	0.09	0.06
XL	≥240	113	0.11	0.09	0.06

Logistic Data Sheet

Code - Size	EAN Code		Kg Package	Volume m3	Cases/ Pallet	Pallet Distr. (Cases x heights)
	Inner dispenser	Outer case				
GD21BB – S	8437014559316	8437014559354	4,2 KG	0,022491	70	10 x 7
GD21BC – M	8437014559323	8437014559361	4,5 KG	0,022491	70	10 x 7
GD21BD – L	8437014559330	8437014559378	4,8 KG	0,022491	70	10 x 7
GD21BE – XL	8437014559347	8437014559385	5,2 KG	0,022491	70	10 x 7

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Storage Conditions

Keep dry.
keep away from direct sunlight and fluorescent lighting.



Regulatory Compliance

- **European Directive: 93/42/CEE. Concerning medical devices.**
 - EN 455/1-2-3; Medical disposable gloves.
- **European Directive: 89/686/CEE. European Personal Protective Equipment.**
 - EN 420:2003; Protective gloves: General requirements.
 - EN 374/1-2-3; Protective gloves: Chemicals and Microorganisms permeation.
- **Regulation 10/2011 on plastic materials and articles intended to come into contact with food.**
 - EN 1186/7:2002; Materials and articles in contact with foodstuffs – plastics.
- **ASTM D 6978-05**, Resistance of medical gloves to permeation by chemotherapy drugs.
- **ASTM F 1671-07**, Resistance of materials used in protective clothing to penetration by blood-borne pathogens using Phi-X174.
- **ASTM D 6124-06**, Residual powder on medical gloves.
- **ASTM D 6319**, Standard specification for nitrile examination gloves for medical application.
- **ISO 9001:2008**, Requirements for a quality management system.
- **ISO 13485:2003**, Quality system for the healthcare products production.
- **ISO 10993-10:2011**, Biological evaluation of medical devices.

Management System



Product Compliance

