

**NORDISK FORHANDLER AF
/
NORDIC DISTRIBUTOR OF**



Presentation of the product

Packaging

- **Content:** 10 boxes of 100 units
- **Dimensions:** 315 x 225 x 225 mm

Box of 100 units

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



Labelling

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

General characteristics

Description: Transparent vinyl gloves.
Fine and sensitive to touch, because its external surface is smooth in fist, palm and fingers.
Cuff rolled

Useful life : 3 years

Clasification:
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: Transparent











Physical Properties

Composition : Polyvinyl Chloride (PVC)

Features:

- Ambidextrous
- Latex free 
- Free of proteins and chemical accelerators
- Free of Tiuram, animal tissue or other biological substances

| Property | Level/Result | Applied Standards |
|--|-----------------------------------|---|
| Medical Devices Regulation (EU) 2017/745 | | |
| 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 | 11 Mpa | _____ |
| Elongation | 350 % | _____ |
| Individual Protection Equipment Regulation (EU) 2016/425 | | |
| Dexterity | 5 | EN 420 |
| Resistance to the permeation of microorganisms | | |
| Air leak test | Pass | EN 374-2 |
| Water leak test | Pass | |
| Protection against bacteria and fungi | Pass | EN 374-5  VIRUS |
| Protection against virus | Pass | |
| Resistance to chemical products permeation | | |
| (K) Sodium hydroxide (40%) | Class 6/Permeation time >480 min | EN 374-1 EN 16523-1  KPT |
| (P) Hydrogen peroxide (30%) | Class 5/Permeation time >240 min | |
| (T) Formaldehyde (37%) | Class 6/ Permeation time >480 min | |
| Plastic materials intended to contact food Regulation 10/2011 | | |
| | | |

| | | | | |
|-------------|--------------------------------|--|-------------------|---|
| GD10 | POWDER FREE VINYL GLOVE |  | DATA SHEET |    |
|-------------|--------------------------------|--|-------------------|---|

| | | | |
|---|------|---------------------------------|---|
| Migration Test Ethanol 10% 20 % Acetic Acid 3 % | Pass | EN 14372:2004 EN 1186/7:2002 |   |
|---|------|---------------------------------|---|

Sizes

| Glove dimensions | | | | | | |
|------------------|-------------|---------------|----------------------|------|--------|----------------|
| Size | Length (mm) | Wide (mm) ± 5 | Thickness (mm) ±0.02 | | | Weight (g±0.3) |
| | | | Finger | Palm | Sleeve | |
| S | ≥240 | 85 | 0.05 | 0.05 | 0.04 | 4.2 |
| M | ≥240 | 95 | 0.05 | 0.05 | 0.04 | 4.5 |
| L | ≥240 | 105 | 0.05 | 0.05 | 0.04 | 5.0 |
| XL | ≥240 | 115 | 0.05 | 0.05 | 0.04 | 5.1 |

Logistic sheet

| REF - Size | Cod. EAN | | Kg Packaging | Volume m ³ | Boxes/Pallet | Assembly/Pallet (Boxes x heights) |
|------------|---------------|---------------|--------------|-----------------------|--------------|-----------------------------------|
| | Interior Box | Packaging | | | | |
| GD10NB- S | 8437001266128 | 8437001266081 | 4,95 Kg | 0,019344 | 84 | 12 x 7 |
| GD10NC- M | 8437001266135 | 8437001266098 | 5,10 Kg | 0,019344 | 84 | 12 x 7 |
| GD10ND- L | 8437001266142 | 8437001266104 | 5,63 Kg | 0,019344 | 84 | 12 x 7 |
| GD10NE- XL | 8437001266159 | 8437001266111 | 6,07 Kg | 0,019344 | 84 | 12 x 7 |

Uses and applications

Exploration gloves in the **health, medical or dental fields** use, complies with the regulations and standards of medical protective gloves (EN 455); its use is intended for the protection of the patient and the user against low **biological and chemical** risk, meets the requirements for the verification of microbiological safety and low chemical risk (EN 374). It is recommended for tasks of short duration and with a high frequency of change.

They are widely used in the **food industry, electronics and cleaning** because PVC does not contain latex or chemical accelerators, so that the problems of skin irritation due to allergic causes are reduced and, in addition, they 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.



Reference Directives and Standards

- **EN 455/1-2-3**; Medical protection gloves for single use.
- **Royal Decree 1407/1992**, regarding Personal Protection Equipment.
- **Regulation (EU) 2016/425**, regarding Personal Protection Equipment
- **EN 374/1-2-4-5**; Protective gloves against chemicals and microorganisms.
- **EN 16523-1:2015+A1:2018**; Determination of material resistance to permeation by chemicals - Part 1: Permeation by potentially hazardous liquid chemicals under conditions of continuous contact.
- **EN 420**; Protective gloves, general requirements and test methods.
- **ASTM D 6124-06**, Residual dust content.
- **EN 1186/7:2002**; Test methods for global migration in aqueous food simulators using a bag.
- **EN 14372:2005**; referring to childcare articles. Cutlery and utensils for food. Safety requirements and tests.
- **ISO 13485:2003**, Quality System for the manufacture of Medical Devices.
- **Royal Decree 1591/2009**, by which the Medical Devices are regulated, which transposes the European Directive 93/42/EEC.
- **Regulation 1935/2004**, on materials and objects intended to come in contact with food.
- **Royal Decree 866/2008**, relating to plastic materials intended to come into contact with food, which transposes Directive 2002/72 /EEC, repealed by **Regulation 10/2011** (Regulation 2016/1416).

Management system

Quality management system according to ISO 13485.

Product conformity

