sanicen

The world of gloves on your hands
*PPE, Medical Device, cleaning & house care*

COD: FTSAN-11001
DATE: 27/01/2025
ED: 13

**PRODUCT SPECIFICATION**
**PRODUCT: BLUE POWDER FREE NITRILE GLOVE**

**BRAND: NEW MARK**

## I – PRODUCT

| | |
|---|---|
| Ref. SANICEN | N/A |
| Product | DISPOSABLE GLOVE |
| Composition | NITRILE (LATEX FREE) |
| Colour | BLUE |
| Units/inner box | 100 Units. |
| PPE | PPE GLOVE - CAT III (TYPE B) |
| Medical Device | EXAMINATION GLOVES - CLASS I |
| Basic Features | NON-REUSABLE |
| | AMBIDEXTROUS |
| | NON-STERILE |
| | POWDER FREE |
| | A.Q.L. 1.5 |


**Product description:**

Elastic nitrile glove that provides high sensitivity to the user and conforms to the hand without causing discomfort. The cuff features an anti-drip and reinforced edge, preventing the glove from rolling up while facilitating easy placement. It has a microtextured external surface on the fingertips for enhanced grip, while the internal surface is chlorinated and smooth (providing comfort).

**Use and application by category:**

- **General**: Minimize the exposure of the user's hands to dirt, dust, foreign bodies, moisture, and water during the execution of household and/or industrial tasks.
- **PPE CAT III**: Protect the user's hands against risks and/or hazards detailed in the labelling, provided that the product is used in accordance with the use instructions.
- **Medical Device**: Reduce the risk of contamination and/or infection in the patient undergoing a physical examination, interventions and/or healthcare tasks that do not require a sterile glove (dentistry, medical examinations, patient care, etc.). Additionally, it minimizes the risk of contamination of the user's hands.

**Use and storage recommendations**:

- Disposable gloves (single use – do not reuse).
- Verify the integrity of the product before use.
- Use the glove with dry and clean hands.
- Remove the glove by folding the cuff to turn the product inside out (do not touch the outer part).
- After use, wash and hydrate your hands.
- Keep the product in the original packaging, in dry places and avoid exposure to direct light.
- Due to its low absorption capacity, the glove should be worn for a limited period, allowing the hands to rest.

**Composition and allergies:**

Nitrile gloves **recommended for users allergic to latex**. In the initial formulation of the glove, accelerators associated with mild dermatitis (carbamates and other non-volatile residues) are used, which, once the manufacturing process is complete, may be present in the form of residual traces.

**Physical measures**:

| Size | Weight (g) | Length (mm) | Width (mm) | Thickness (mm) | | |
|---|---|---|---|---|---|---|
| | | | | Finger | Palm | Cuff |
| S | 4,7 ±0,3 | ≥ 240 | 85 ±5 | 0,12 ±0,03 | 0,10 ±0,03 | 0,08 ±0,03 |
| M | 5,0 ±0,3 | ≥ 240 | 95 ±5 | 0,12 ±0,03 | 0,10 ±0,03 | 0,08 ±0,03 |
| L | 5,3 ±0,3 | ≥ 240 | 105 ±5 | 0,12 ±0,03 | 0,10 ±0,03 | 0,08 ±0,03 |
| XL | 5,6 ±0,3 | ≥ 240 | 115 ±5 | 0,12 ±0,03 | 0,10 ±0,03 | 0,08 ±0,03 |

**Size**:

| Commercial size | XS | S | M | L | XL |
|---|---|---|---|---|---|
| Hand size according to EN ISO 21420:2020 | 5 - 6 | 6 - 7 | 7 - 8 | 8 - 9 | 9 - 10 |

| Hand size according to EN ISO 21420:2020) | 5 | 6 | 7 | 8 | 9 | 10 |
|---|---|---|---|---|---|---|
| Hand length (mm) | 149 | 160 | 171 | 182 | 192 | 204 |
| Hand perimeter (mm) | 127 | 152 | 178 | 203 | 229 | 254 |

**Logistic information**:

- 100 gloves per dispenser box (recyclable cardboard case).
- Dispenser box with pre-cut on the top for an easy glove extraction.
- Labelling in multiple languages: ES, EN, PT, IT, DE and FR.
- Clear indication of size on the dispenser box and the secondary box.
- The dispenser box includes a hand gauge to facilitate size selection.

| Ref | EAN | DUN | Gloves | Disp./Box | Box/Pallet |
|---|---|---|---|---|---|
| 11003 (S) | 8431026110039 | 28431026110033 | 100 | 10 | 60 |
| 11001 (M) | 8431026110015 | 28431026110019 | 100 | 10 | 60 |
| 11002 (L) | 8431026110022 | 28431026110026 | 100 | 10 | 60 |
| 11004 (XL) | 8431026110046 | 28431026110040 | 100 | 10 | 60 |

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## II – TECHNICAL DATA

**Legislation and standards:**

| Medical Device | Info |
|---|---|
| Reg. (UE) 2017/745 | Medical Devices. |
| RD 192/2023 | Medical Devices (Spain regulation) |
| EN 455 1-2-3-4 | One-use medical gloves |
| **PPE** | **Info** |
| Reg. (UE) 2016/425 | Personal protective equipment and repealing Council Directive 89/686/EEC. |
| EN ISO 21420:2020 | Protective gloves - General requirements and test methods. |
| EN ISO 374-1:2016/A1:2018 | Protective gloves against dangerous chemicals and micro-organisms. |
| EN ISO 374-2:2019 | Determination of resistance to penetration. |
| EN 16523-1:2015+A1:2018 | Determination of material resistance to permeation by chemicals. |
| EN 374-4:2013 | Determination of resistance to degradation by chemicals. |
| EN 374-5:2016 | Terminology and performance requirements for micro-organisms risks. |
| ISO 16604 | Determination of resistance of protective clothing materials to penetration by blood-borne pathogens. |
| **Food Contact** | **Info** |
| Reg. (UE) 10/2011 | Plastic materials and articles intended to come into contact with food. |
| Reg. (UE) 1935/2004 | Materials and articles intended to come into contact with food. |

If you need to delve deeper into the technical information provided here or require access to the corresponding declaration of conformity, please contact our Quality Department at qa@sanicen.com

**Penetration and degradation resistance:**

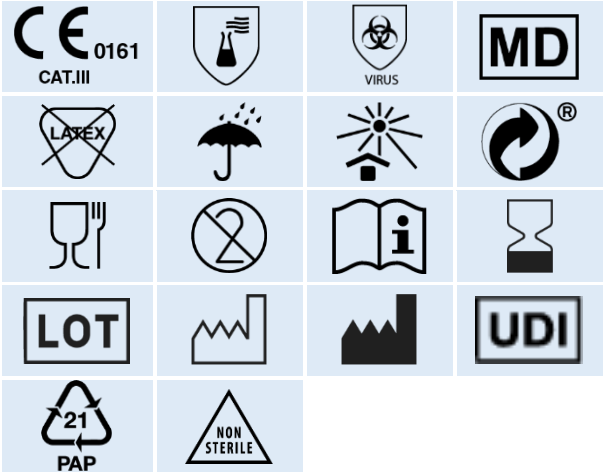
**According to EN ISO 374-1:2016/A1: 2018 (TYPE B)**

| PRODUCT | COD | LEVEL (Penetration) | Degradation (%) |
|---|---|---|---|
| n-Heptane | J | 3 | 17,28 |
| Sodium hydroxide 40% | K | 6 | -17,85 |
| Formaldehyde 37% | T | 3 | -18,34 |

| Level | 1 | 2 | 3 | 4 | 5 | 6 |
|---|---|---|---|---|---|---|
| Time | >10 | >30 | >60 | >120 | >240 | >480 |

**Labelling:**

**Pictograms* on labelling**




**The pictograms depicted here are for informational purposes. The product labeling may include specific technical information required by the standardization of the pictogram.*

**Additional information:**

| FEATURE | Before aging | After aging |
|---|---|---|
| Tensile strength (ASTM) | 14 MPa (min.) | 14 MPa (min.) |
| Ultimate elongation (ASTM) | 500% (min.) | 400% (min.) |
| Breaking force (EN 455-2) | 6 N (min.) | 6 N (min.) |

**Food contact:** Suitable for contact with alcoholic foods, aqueous, milk products and acid foods based on Regulation (EU) No 10/2011 of January 14, 2011, and its subsequent amendments.

| General labelling: |
|---|
| Product Name |
| Manufacturer name and address |
| Size and sizing chart |
| Lot number |
| Number of gloves inside the inner box |
| Production and expiry date |
| Use and storage instructions |
| EAN 13 |
| A.Q.L. 1,5 |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