

PRODUCT SPECIFICATION
PRODUCT: BLUE POWDER FREE NITRILE GLOVE

BRAND: SANYC LITE

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 ±0,3 | ≥ 240 | 80 ±10 | 0,11 ±0,03 | 0,09 ±0,03 | 0,08 ±0,03 |
| M | 4,5 ±0,3 | ≥ 240 | 95 ±10 | 0,11 ±0,03 | 0,09 ±0,03 | 0,08 ±0,03 |
| L | 4,8 ±0,3 | ≥ 240 | 110 ±10 | 0,11 ±0,03 | 0,09 ±0,03 | 0,08 ±0,03 |
| XL | 5,1 ±0,3 | ≥ 240 | ≥110 | 0,11 ±0,03 | 0,09 ±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 |
|-----------|---------------|----------------|--------|-----------|------------|
| 5010 (S) | 8431026050106 | 28431026050100 | 100 | 10 | 54 |
| 5011 (M) | 8431026050113 | 28431026050117 | 100 | 10 | 54 |
| 5012 (L) | 8431026050120 | 28431026050124 | 100 | 10 | 54 |
| 5013 (XL) | 8431026050137 | 28431026050131 | 100 | 10 | 54 |

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 374-4:2019 | 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 (%) | |
| | Hydrogen peroxide 30% | P | 2 | 19,4 | |
| | Sodium hydroxide 40% | K | 6 | -52,7 | |
| | Formaldehyde 37% | T | 4 | 1,4 | |
| Level | 1 | 2 | 3 | 4 | 5 |
| Time | >10 | >30 | >60 | >120 | >240 |

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.) |

Labelling:

| Pictograms* on labelling | | | |
|---|---|---|---|
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  | | |

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

Food contact: Suitable for contact with all types of foods in accordance with 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 |