

## PRODUCT SPECIFICATION

PRODUCT: BLACK POWDER FREE NITRILE GLOVE SENSITIVE

BRAND: SANYC

## I – PRODUCT

|                 |                              |
|-----------------|------------------------------|
| Ref. SANICEN    | N/A                          |
| Product         | DISPOSABLE GLOVE             |
| Composition     | NITRILE (LATEX FREE)         |
| Colour          | BLACK                        |
| 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       |
| XS   | 2,9 ±0,3   | ≥ 240       | 75 ±5      | 0,09 ±0,03     | 0,08 ±0,03 | 0,07 ±0,03 |
| S    | 3,0 ±0,3   | ≥ 240       | 85 ±5      | 0,09 ±0,03     | 0,08 ±0,03 | 0,07 ±0,03 |
| M    | 3,5 ±0,3   | ≥ 240       | 95 ±5      | 0,09 ±0,03     | 0,08 ±0,03 | 0,07 ±0,03 |
| L    | 3,8 ±0,3   | ≥ 240       | 105 ±5     | 0,09 ±0,03     | 0,08 ±0,03 | 0,07 ±0,03 |
| XL   | 4,1 ±0,3   | ≥ 240       | 115 ±5     | 0,09 ±0,03     | 0,08 ±0,03 | 0,07 ±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 |
|-----------|---------------|----------------|--------|-----------|------------|
| 5270 (XS) | 8431026052704 | 28431026052708 | 100    | 10        | 84         |
| 5271 (S)  | 8431026052711 | 28431026052715 | 100    | 10        | 84         |
| 5272 (M)  | 8431026052728 | 28431026052722 | 100    | 10        | 84         |
| 5273 (L)  | 8431026052735 | 28431026052739 | 100    | 10        | 84         |
| 5274 (XL) | 8431026052742 | 28431026052746 | 100    | 10        | 84         |

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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](mailto:qa@sanicen.com)

### Penetration and degradation resistance:

| According to EN ISO 374-1:2016/A1: 2018 (TYPE B)                                    |                       |     |                        |                    |      |      |
|-------------------------------------------------------------------------------------|-----------------------|-----|------------------------|--------------------|------|------|
|                                                                                     | PRODUCT               | COD | LEVEL<br>(Penetration) | Degradation<br>(%) |      |      |
|  | n-Heptane             | J   | 6                      | 47,11              |      |      |
|                                                                                     | Sodium hydroxide 40%  | K   | 6                      | -35,66             |      |      |
|                                                                                     | Hydrogen Peroxide 30% | P   | 2                      | -4,32              |      |      |
| Level                                                                               | 1                     | 2   | 3                      | 4                  | 5    | 6    |
| Time                                                                                | >10                   | >30 | >60                    | >120               | >240 | >480 |

### 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 all types of food 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                            |

### 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.