

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	60
5011 (M)	8431026050113	28431026050117	100	10	60
5012 (L)	8431026050120	28431026050124	100	10	60
5013 (XL)	8431026050137	28431026050131	100	10	60

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	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.)

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