

Product:

LATEX POWDER-FREE GLOVE

Date: JULY 2016

Brand: "NEW MARK"

I - GENERAL

TYPE:	LATEX GLOVE, POWDER FREE, NON - STERILE		
CLASIFICATION:	PERSONAL PROTECTIVE EQUIPMENT PPE-CAT.III		
	MEDICAL DEVICE – TYPE I		
REF.	SIZE	EAN	DUN
127811	XP	8431026127815	28431026127819
127711	S	8431026127716	28431026127710
118411	M	8431026118417	28431026118411
128111	L	8431026128119	28431026128113

II – PICTURES



III – PRODUCT TECHNICAL DATA

- **Product classification**
PPE - Category III (European directive 89/686/CEE)
Medical device – class I ((European directive 93/42/CEE)
- **Recommended applications:** To prevent and to reduce contamination risks.
General cleaning and maintenance duties. These gloves are also suitable for food contact.
- **Material:** Natural rubber latex (Cis 1,4 Polyisoprene).
- **Chemical additives:**

The following chemical additives are used during manufacturing process.

Chemical name	Cas number	%	Application
Natural rubber latex	-	96.8	Latex compound
Titanium oxide	13463-67-7	0.4	Latex compound
Zinc oxide	1314-13-2	0.7	Chemical dispersion
Potassium Hydroxide	1310-58-3	1.0	Stabilizer
Sulfur	7704-34-9	0.7	Curing agent
(ZDBC), (ZDEC)	136-23-2, 14324-55-1	0.4	Acelerator

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There is no presence of the following chemical agents after the production process

Chemical test (µg/g)	Results
Tetrametiltiurano bisulfato (TMTD)	Not detectable
Mercaptobenzotiazol (MBT)	Not detectable
Mercaptobenzotiazol de Zinc (ZMBT)	Not detectable
Mercaptobenzimidazol de Zinc (ZMBI)	Not detectable
Dietilditiocarbamato de Zinc (ZDEC)	Not detectable
Dimetiltiocarbamato de Zinc (ZDMC)	Not detectable
Pentameten-diotiocarbamato de Zinc (ZPMC)	Not detectable
Dibutilditiocarbamato de Zinc (ZDBC)	Not detectable
Butil-Hidroxitolueno (BHT)	Not detectable
Butil-hidroxianisol (BHA)	Not detectable
Difenil Guanidina (DPG)	Not detectable
Difenil Tiourea (DPT)	Not detectable
Tetrasulfuro de Dipentametiltiuram (DPTT)	Not detectable
Dibencil ditiocarbamato de Zinc (ZBED)	Not detectable

• **Product features:**

Ambidextros
Powder-free
Beaded cuff
High sensibility
Elasticity and adaptability
Non-sterile product
Disposable. Single-use product
A.Q.L. 1.5

• **Color:** Natural

• **Powder content:** Powder free

• **Finishing:** Textured finishing outside and smooth chlorinated inside

• **Suitable to contact the following foodstuffs:** All aqueous, alcoholic and acidic foods (Simulant A,B,C and D1)

• **Information for people allergic to natural latex:** These gloves contain natural latex which may cause allergic reactions.

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• **Dimensions:**

ISO / EN	Size	Weight(+/- 0.03g)	Length (mm ± 5)	Width (mm ± 2)	Thickness (mm ± 0.03)		
					Fingertip	Palm	Cuff
EN-420	L	6.0g	240	105	0.14	0.10	0.08
EN-420	M	5.7g	240	94	0.14	0.10	0.08
EN-420	S	5.2g	240	84	0.14	0.10	0.08
EN-420	XS	4.9g	240	75	0.14	0.10	0.08

• **Physical properties:**

Feature	Before aging	After aging
Tensile strength (MPa)ASTM	16 MPa (min)	14 MPa (min)
Ultimate elongation (%) ASTM	550 % (min)	450 % (min)
Break force (N) EN-455-2	9.0 N (min)	6.0 N (min)

• **Conditions of use:** -20°C y 50°C

- **Storage conditions:** Store in dry and ventilated area. Avoid from direct sunlight. Temperature must be between -20°C and 50°C

- **Expiry date:** 5 years from manufactory date

• **Pictograms:**



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• **Packaging:**

Dispenser box: Carton box with 100 pieces
External carton with 10 dispenser boxes
Size indicator in both carton and dispenser box.

• **Cautions:**

Avoid direct contact with oil and organic solvents.
Verify glove integrity before using
Single use. Do not re-use
Wash and dry your hands before and after using

• **Labelling:**

Product name
Manufacturer address and name
Industrial register number
Size
Lot number
Content
Manufacture and expiry dates
Temperature and storage conditions
Pictograms:

- Protection against chemical and micro organisms
- CE Mark
- Single-use pictograms
- Food contact (fork and knife)

Barcode (EAN-13)
A.Q.L. 1.5

- **Logistic data sheet:** 10 dispenser boxes with 100 gloves each (10 x 100)

Ref	Size	EAN	DUN	Box/carton	Carton/layer	Layer/palet	Units/palet
127811	XS	8431026127815	28431026127819	10	10	7	700
127711	S	8431026127716	28431026127710	10	10	7	700
118411	M	8431026118417	28431026118411	10	10	7	700
128111	L	8431026128119	28431026128113	10	10	7	700

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IV – LEGAL REQUIREMENTS

- **Rules of application:**

These gloves comply with:

- UNE-EN 374- 1,2,3
- UNE-EN 455-1,2,3
- UNE-EN 388
- UNE-EN 420

- ISO 9001:2008 –CE CERTIFICATES

CE-CAT-III , According to European Directive 89/686/CEE .
Medical device – Class I (European directive 93/42/CEE)

- **Information:**

The information above is given with the aim of helping the user to choose the best PPE in each case.
However, if additional information is required, do not hesitate in contact our customer service department.
(PHONE: +34 925 784459, FAX: +34 925 784502, E-MAIL: info@sanicen.com)

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