

Presentation of the product

Packaging 1000 Units

- **Content:** 10 boxes of 100 units
- **Dimensions:** 360 x 245 x 225 mm

Box of 100 units

- **Content:** 100 units
- **Dimensions:** 215 x 120 x 70 mm



Labeling

- Name and address of the manufacturing company
- Product name and commercial reference
- CE Marking
- Expiration
- Recommendations for use and precautions in different languages
- Pictograms
- Reference regulations
- Batch and barcode
- Size and Content

General specifications

Description: White latex gloves, lightly powdered with corn-starch. Very silky and soft, they offer greater comfort and extreme sensitivity to touch. Rolled Fist

Shelf life: 5 years

Clasification:

Medical Device **Class I**; Royal Decree 1591/2009, Regulation (EU) 2017/745.

Category III PPE; Regulation (EU) 2016/425

Sizes: Extra Small, Small, Medium, Large and extra large

Color: Natural




Physical Properties

Composition: Natural Rubber Latex, Sulfur, Rubber Accelerator, Zinc Oxide, Potassium Hydroxide, Polymer Coatings, Titanium Dioxide.

Features:



- Contains latex
- Ambidextrous
- Biodegradable
- Powder content máx: 10 mg / dm²

Property	Level/Result	Applied Standards
Medical Devices Regulation (EU) 2017/745		
Absence of holes	Pass	EN 455-1
Dimensions	Pass	EN 455-2
Force to break	Pass (average > 6 N)	
Biological safety requirements	Pass	EN 455-3
Individual Protection Equipment Regulation (EU) 2016/425		
Dexterity	5	EN 420
Resistance to the permeation of microorganisms		
Air leak test	Pass	EN 374-2
Water leak test	Pass	
Protection against bacteria and fungi	Pass	EN 374-5
Virus protection	Pass	 VIRUS
Resistance to chemical products permeation		
(T) Formaldehyde (37 %)	Level 3/ Permeation time > 60 min	
(K) Sodium hydroxide (40%)	Level 3/ Permeation time >60 min	

SX01
POWDERED LATEX GLOVE

DATA SHEET


(S) Acid fluorhídric

Level 3/ Permeation time >60 min

EN 374-1



KST

EN 16523-1:2015 +A1:2018

 Plastic materials intended to contact food Regulation 10/2011
 (Regulation 10/2011 (EU) 2016/1416)

Migration Test:

- Acetic acid 3%
- 10%, 20% and 50% ethanol
- Vegetable oil

Pass

EN 1186-7:2002


Sizes
Glove dimensions

Size	Length (mm)	Palm wide (mm) ± 5	Thickness Palm (mm) ±0.02	Weight (g) ± 0.3
XS	≥240	70	0.8	4.3
S	≥240	80	0.8	4.6
M	≥240	95	0.8	5.0
L	≥240	110	0.8	5.4
XL	≥240	≥110	0.8	5.9

Logistic sheet

REF - Size	Cod. EAN		Kg Packaging	Volume m ³	Boxes/ Pallet	Assembly/ Pallet (Boxes x heights)
	Interior Box	Exterior Box				
SX01BA – XS	8437014559392	8437014559439	4,75 KG	0,0201206	70	10 X 7
SX01BB – S	8437014559408	8437014559446	5,30 KG	0,0201206	70	10 X 7
SX01BC – M	8437014559415	8437014559453	5,80 KG	0,0201206	70	10 X 7
SX01BD – L	8437014559422	8437014559460	6,30 KG	0,0201206	70	10 X 7
SX01BE - XL	8437017506140	8437017506157	6,80 KG	0,0201206	70	10 X 7



Uses and applications

Exploration gloves in the **health** field, medical or dental use; its use is intended to protect the patient and the user against low biological and chemical risk, meets the requirements for the verification of microbiological safety and low chemical risk (EN374-1/2/4/5). It is recommended for tasks of short duration and with a high frequency of change.

They are widely used in **light industry** and in the **domestic sphere**. They can also be used in the **food industry** because these gloves comply with the requirements of EN 1186 and regulation 10/2011 regarding materials intended to come into contact with food.

Do not use for handling with organic solvents. This product contains natural rubber latex that can cause allergic reactions. DO NOT REUSE

Storage conditions

Keep stored in a cool and dry place. Avoid excess heat and protect from direct sunlight or fluorescent lighting.

Do not store these gloves with organic solvents since they can degrade them.

Ventilation is not necessary under normal storage conditions.



Reference Directives and Standards

- Royal Decree 1407/1992, referring to the Individual Protection Equipment, which transposes the European Directive 89/686/EEC.
- Regulation (EU) 2016/425, on personal protective equipment and repealing Council Directive 89/686/EEC
- EN 420; Protective gloves, general requirements and test methods.
- EN 374 / 1-2-4-5; Protective gloves against chemical products and microorganisms.
- ISO 13485:2003, Quality system for Medical Device manufacturing.



- EN 455 / 1-2-3-4; Medical protection gloves for single use.
- Royal Decree 1591/2009, by which Sanitary Products are regulated.
- Regulation (EU) 2017/745 on medical devices, amending Directive 2001/83 / EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385 / EEC and 93/42 / EEC (relevant text for the purposes of the EEA).
- Regulation EC/1935/2004, on materials and objects intended to come into contact with food.
- Regulation (EU) 2016/1416, which modifies and corrects Regulation (EU) No. 10/2011 on plastic materials and articles intended to come into contact with food
- Regulation 10/2011 (Regulation 2016/1416), on plastic materials and objects intended to come into contact with food. Relevant text for the purposes of the EEA.
- EN 1186-7; Test methods for global migration in simulators of aqueous foods using a bag.

Management system

Quality management system according to ISO 13485:2016.

Conformidad del Producto

