

Presentation of the product

Packaging 2000 units

- **Content:** 20 bags of 100 units
- **Dimensions:** 400 x 260 x 300 mm

Bag of 100 units

- **Content:** 100 units
- **Dimensions:** 190 x 150 x 45 mm



Bag of 100 units

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| <ul style="list-style-type: none">• Name and address of the manufacturing company• Name of the product in several languages• Commercial reference and batch number• Manufacturing and expiration dates• Barcode (EAN) and UDI code | <ul style="list-style-type: none">• Number of units• Single use• Storage conditions• EC Marking• Legislation and Reference• Uses, applications, and warnings |
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General characteristics

Description

Polyethylene oversleeve, available in white, blue, red, or green, hand-sealed.

Soft surface, with elastic bands at both ends allowing a good fit with other protective elements. The construction material, polyethylene, provides impermeability against liquid penetration, while the rubber elastic facilitates placement and adjustment.

- Length: 40 ± 2 cm
- Width: 20 ± 2 cm
- Weight: 2.4 ± 0.2 g
- Thickness: 20 µm (microns)

Shelf life: 3 years

Clasification

- Class I Medical Device; Regulation (EU) 2017/745
- Category I PPE: Regulation (EU) 2016/425
- Suitable for contact with food

One size

Colors:

Blue – DA01BC, White – DA01WC, Red – DA01RC, Green – DA01GC

Physical Properties

Composition and Features

Material used: Polyethylene (PE)

- Ambidextrous
- Non-Sterile
- Protein-Free
- Latex-Free
- Powder-Free
- Tiuram-Free

Logistics Sheet

Reference	EAN code		Carton box weight (Kg)	Carton box volume (m ³)	Carton boxes/ Pallet	Assembly/ Pallet (Carton boxes x layers)
	Interior bag	Carton box				
DA01WC	8437001000487	8437001000388	5,50	0,0312	30	6 x 5
DA01BC	8437001000470	8437001000371	5,50	0,0312	30	6 x 5
DA01RC	8437017506560	8437017506577	5,50	0,0312	30	6 x 5
DA01GC	8436613860106	8436613860113	5,50	0,0312	30	6 x 5

Uses and applications

In the healthcare field, protective sleeves for conducting medical examinations, dentistry, clinical exams, diagnostic and therapeutic procedures, for laboratory use, and generally for any activity that requires a sleeve serving as a protective barrier, such as in veterinary practice.

They are also used in the food, electronics, and cleaning industries because the PE material is latex-free, reducing the risk of skin irritation from allergic reactions, while also providing comfort and ease of use.

Directives and Reference Standards

- Regulation (UE) 2016/425 Personal Protective Equipment
- Regulation (UE) 2017/745: Regulation on Medical Devices
- Regulation (CE) N°1935/2004 of the European Parliament and of the Council on materials and articles intended to come into contact with food
- Regulation (UE) 2020/1245, amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food
- ISO 9001:2015: Quality management systems
- ISO 13485:2016: Quality management systems for medical devices
- ISO 14001:2015: Environmental management systems

Storage conditions

Store in a cool, dry place, between 10 and 40 °C. Avoid excessive heat and protect from direct sunlight or fluorescent lighting, as well as from proximity to high-frequency equipment.



Management system

Quality management system according to ISO 9001.

Product conformity

