

## Presentation of the product

### Packaging 2000 units

- **Content:** 20 bags of 100 units
- **Dimensions:** 385 x 250 x 290 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"><li>• Name and address of the manufacturing company</li><li>• Name of the product in several languages</li><li>• Commercial reference and batch number</li><li>• Manufacturing and expiration dates</li><li>• Barcode (EAN) and UDI code</li></ul> | <ul style="list-style-type: none"><li>• Number of units</li><li>• Single use</li><li>• Storage conditions</li><li>• EC Marking</li><li>• Legislation and Reference</li><li>• Uses, applications, and warnings</li></ul> |
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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:  $40 \pm 2$  cm
- Width:  $20 \pm 2$  cm
- Weight:  $2.4 \pm 0.2$  g
- Thickness: 20  $\mu$ m (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 – DA03BC, White – DA03WC, Red – DA03RC, Green – DA03GC

## 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 <sup>3</sup> ) | Carton boxes/ Pallet | Assembly/ Pallet<br>(Carton boxes x layers) |
|-----------|---------------|---------------|------------------------|-------------------------------------|----------------------|---------------------------------------------|
|           | Interior bag  | Carton box    |                        |                                     |                      |                                             |
| DA03WC    | 8436613861134 | 8436613861141 | 5,50                   | 0,0279                              | 54                   | 9 x 6                                       |
| DA03BC    | 8437022212678 | 8437022212685 | 5,50                   | 0,0279                              | 54                   | 9 x 6                                       |
| DA03RC    | 8436613861158 | 8436613861165 | 5,50                   | 0,0279                              | 54                   | 9 x 6                                       |
| DA03GC    | 8436613861110 | 8436613861127 | 5,50                   | 0,0279                              | 54                   | 9 x 6                                       |

## 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

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- 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

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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

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Quality management system according to ISO 9001.

## Product conformity

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