

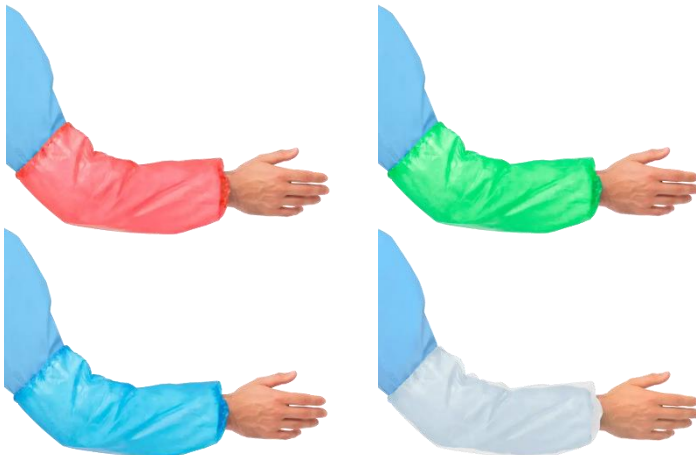
Presentation of the product

Packaging 2000 units

- **Content:** 20 bags of 100 units
- **Dimensions:** 420 x 340 x 290 mm

Bag of 100 units

- **Content:** 100 units
- **Dimensions:** 220 x 160 x 50 mm



Bag of 100 units

- | | |
|--|---|
| <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 |
|--|---|

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: 4.5 ± 0.2 g
- Thickness: 40 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 – DA02BC, White – DA02WC, Red – DA02RC, Green – DA02GC

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				
DA02WC	8437022212647	8437022212630	9,90	0,0414	30	5 x 6
DA02BC	8437022212265	8437022212586	9,90	0,0414	30	5 x 6
DA02RC	8436613860793	8436613860809	9,90	0,0414	30	5 x 6
DA02GC	8436613860816	8436613860823	9,90	0,0414	30	5 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

- 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

