

Presentation of the product

Packaging 100 units

- **Content:** 100 bags of 1 unit
- **Dimensions:** 495 x 300 x 340 mm

Bag of 1 unit

- **Content:** 1 unit
- **Dimensions:** 285 x 230 x 10 mm



Bag of 1 unit

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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

Polypropylene visitor gown, featuring a collar and front Velcro fastening system. Lightweight garment manufactured from contamination-resistant material, equipped with four Velcro closures and designed without pockets. Lint-free construction. Fabric weight: 25 ± 2 g/m².

Manufactured in compliance with Regulation (EU) 2016/425 on Personal Protective Equipment (PPE). The polypropylene construction material provides resistance to localized liquid penetration and splash.

Shelf life: 3 years

Dimensions:

- Length: 110 ± 2 cm
- Width of chest: 65 ± 2 cm

Colors: White (DC04WE), Blue (DC04BE), Red (DC04RE), Green (DC04GE)

Clasification

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

Physical Properties

Composition and Features

Material used: Polypropylene (PP)

- 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				
DC04BE	8437017506928	8437014559682	6,5	0,0505	25	5 x 5
DC04WE	8437017506911	8437014559675	6,5	0,0505	25	5 x 5
DC04RE	8436613860830	8436613860847	6,5	0,0505	25	5 x 5
DC04GE	8437022212142	8437022212159	6,5	0,0505	25	5 x 5

Uses and applications

Its use is primarily recommended for visits to factories or cleanrooms, hospitals, and the agri-food sector. It is suitable for infection control, food contact environments, and protection against domestic or occupational dirt. The garment protects the wearer's clothing.

As a medical device, it provides protective functionality and can be used in healthcare environments by clinical staff and patients. It is a single-use, non-sterile product.

It is also highly suitable for artists and painters requiring protective clothing against potential spills of liquid products such as paint, or in situations where temporary protection is required to act as a protective barrier against splashes, including applications in research and veterinary fields.

Directives and Reference Standards

- Regulation (UE) 2016/425 Personal Protective Equipment
- Regulation (UE) 2017/745: Regulation on Medical Devices
- Regulation (CE) Nº1935/2004 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

