

Presentation of the product

Packaging 2000 units

- **Content:** 20 bags of 100 units
- **Dimensions:** 630 x 330 x 205 mm

Bag of 100 units

- **Content:** 100 units
- **Dimensions:** 200 x 175 x 65 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 shoe covers, available in blue, machine made.

Textured surface, with elastic adjustment that allows a good adaptation to other protective elements. The material of construction, polyethylene, allows good resistance to liquid penetration and the rubber elastic makes it easy to put on and adjust. Waterproof.

Dimensions:

- Length: 41 ± 2 cm
- Width: 15 ± 2 cm
- Weight: 3.0 ± 0.3 g

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

Color: Blue

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				
DF03BB	8437022212692	8437022212708	6,50	0,0426	27	3 x 9

Uses and applications

In the sanitary field, protective shoe covers for work in clean sanitary and food environments, for laboratory use and in general for all activities where protection against contamination of the environment and a minimum protective barrier against splashes is required.

They are also used in the food, electronics and cleaning industries because PE contains neither latex nor chemical accelerators, thus reducing skin irritation problems due to allergic causes, although they are not designed to be in direct contact with the skin, and they also offer acceptable comfort and ease of application.

In the food area, these shoe covers comply with the requirements of regulation 2016/1416 for plastic materials intended to come into contact with food, although they are not designed to come into direct contact with food except accidentally.

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

