

Presentation of the product

Packaging 2000 units

- **Content:** 20 bags of 100 units
- **Dimensions:** 360 x 320 x 360 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 white, blue, red, or green, hand-sealed.

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.

- 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

Colors:

Blue – DF01BB, White – DF01WB, Red – DF01RB, Green – DF01GB

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				
DF01BB	8437001000418	8437001000319	6,50	0,0414	24	6 x 4
DF01WB	8436613860625	8436613860632	6,50	0,0414	24	6 x 4
DF01RB	8437017506645	8437017506652	6,50	0,0414	24	6 x 4
DF01GB	8437017506669	8437017506676	6,50	0,0414	24	6 x 4

Uses and applications

In the healthcare sector, they provide protective shoe covers for work in clean and food-related environments, for laboratory use, and in general for all activities in which protection against environmental contamination is required, as well as a minimal barrier against splashes.

They are also used in the food, electronics, and cleaning industries because PE does not contain latex, which reduces the risk of skin irritation due to allergic reactions. Although they are not designed to be in direct contact with the skin, they offer acceptable comfort and ease of use.

In the food sector, these shoe covers comply with the regulations regarding plastic materials intended to come into contact with food, although they are not designed to be in 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

