

Technical Data Sheet

SAFE FEET® VITALS™

Universal Shoe Cover

Medical device Class I



FEATURES & BENEFITS

- Nonwoven spunbonded 100% polypropylene.
- Gluing sealing.
- Elastic free of latex at the ankle.
- Supple and very resistant nonwoven.

RECOMMENDED USE

- Can be used for staff or patients in operating theatres and care services.
- Used in industrial environment and food industry.

PRODUCT DETAILS

Product name : Shoe CoverPP Bleu SafeFeet® Vitals™
 Product type : Single use, non sterile
 Material : Nonwoven Polypropylene Spunbond
 Confection : Gluing
 Color : Blue
 Size : 190 mm x 380 mm (± 10%)
 Standard model (Large) + Extra high
 Unit weight : 7g (± 10%)
 Packaging : Dispenser box of 500 pcs
 Manufacturing country : FRANCE ■ ■

Item	Color
H03602A	■ Blue

MECHANICAL INFORMATION

Mesurements done by independent laboratories
 (measures are available upon request)

TEST	STANDARD	LABORATORY		AVERAGE	UNIT	TOLERANCE
Grammage	ISO 9073-1	Cetelor		38	g/m ²	±10%
Tensile strength	ISO 9073-3	Cetelor	Tensile stren. MD:	83,40	N	±10%
			Tensile stren. CD:	61,08	N	±10%
Elongation			Elongation MD:	53,04	%	±10%
			Elongation CD:	48,08	%	±10%

MICROBIOLOGICAL INFORMATION

Assessment of initial microbial contamination according to standards NF EN ISO 11737:2018 + A1: 2021.
Additional microbiological controls: ASR, E.coli, Staphylococci.

CERTIFICATIONS & STANDARDS

Meet the requirements of Regulation (EU) 2017/745 on medical devices.
Complies with applicable standards EN ISO 14971.
Manufacturing site : ISO 9001 – ISO 13485.

PRECAUTIONS

The product must be used on intact skin only.
The reuse or extended use may lead to infection or cross-contamination.
Please refer to your national legislation on the subject of disposal of this product once it has been used.

STORAGE

Normal conditions of conservation & storage : not to be exposed to moisture and sunlight, must be stored in a cool environment or at room temperature.
Shelf life of the product: 5 years.

MARKING ON PACKAGING



* Do not use if package is damaged

LOGISTICS INFORMATION

OUTER CASE SPECIFICATIONS				
ITEM	SIZE (mm)	GROSS WEIGHT (kg)	QTY / PALLET	BARCODE
H03602A	400 x 400 x 370	4,1	36 cases	3 662 036 002 501