

H03602A

SAFEFEET® VITALS BLUE SHOECOVERS

Medical Device, Class I

FEATURES & BENEFITS

- Spunbonded non woven 100% polypropylene
- Assembly by gluing
- Elastic at the ankle
- Soft and resistant non woven fabric

Recommended use :

- Can be used for staff or patients in operating theatres and care units
- Can be used in industry and food processing on dry ground



PRODUCT DETAILS

Product name:	KOLMI - SafeFeet® Vitals shoe cover
Product type:	Single use, non stérile
Material :	Spunbonded non woven 100% polypropylene
Confection :	Gluing
Color :	Blue
Dimensions :	160 x 380 mm (± 5 mm) Standard model (Large)
Weight :	7 g (± 10%)
Packaging :	Dispenser box of 500 units
Origin :	France



Mechanical data

TEST	Standard			Average	Unit	Tolerance
Grammage	NF EN ISO 9073-1			38	g/m ²	± 10%
Tensile strenght	NF EN ISO 9073-3	Dry	MD	83,4	N	± 10%
		Dry	CD	61,8	N	± 10%
Elongation	NF EN ISO 9073-3	Dry	MD	53	%	± 10%
		Dry	CD	48,1	%	± 10%

Microbiological data (measurements made by the MICROSEPT laboratory)

Evaluation of the initial microbial contamination according ISO 11737:2018

CERTIFICATIONS & STANDARDS

Meet the requirements of Regulation (EU) 2017/745 on medical devices

Complies with the applicable harmonised standard EN ISO 14971.

Manufacturing site : ISO 9001 – ISO 13485

STORAGE

Product should be stored in clean, dry condition with in the temperature range 5°C and 40°C.

Shelf life of the product: 5 years

PRECAUTIONS FOR USE

The device should only be used on intact skin.

Their re-use or prolonged use can produce infection or cross-contamination.

After use, comply with the national regulations in force for the disposal of the device.

LOGISTICS



Outer case specifications

Item	Size Mm	Gross Weight Kg	QTY/ case
H03602A	400 x 400 x 370	4,1	500 pièces

Pallet specifications

QTY cases/ pallet
36 cases (6 layers of 6 cases)



EAN Code

Item	Outer case
H01038A	3 662 036 002 501

