

TECHNICAL DATA SHEET

SAFEwear VITALS®

PP Clip Clap - 15g/m²

MEDICAL DEVICE CLASSE I



FEATURES & BENEFITS

- 100% Polypropylene spunbonded nonwoven
- Bonding and ultrasound assembly
- LATEX-FREE synthetic elastic under the hem for better comfort.
- Soft and very resistant non-woven
- Very breathable for better comfort
- High stretch- can wrap around any hair type.

RECOMMENDED USE

- Can be used for nursing staff or for patients in the operating room and in the care departments
- Can also be used in a pharmaceutical, industrial, food industry environments

PRODUCT DETAILS

Product name : Kolmi® - SAFEWEAR Vitals – PP Clip Cap
Product type : Single use, non sterile
Material : Polypropylene
Size : Length : 44,5 cm (± 0,5cm)
Width : 48 cm (± 1 cm)
Unit weight : 3,4g (±10%)
Manufacturing country : FRANCE

Item	Color
C12001	White
C12101	Blue
C12201	Green

MECHANICAL INFORMATION						
Measurements done by independent laboratories (measures are available upon request)						
TEST	STANDARD	LABORATORY		AVERAGE	UNIT	TOLERANCE
Grammage	ISO 9073-1	Cetelor		15	g/m ²	±10%
Tensile strength	ISO 9073-3	Cetelor	Tensile strength SM:	34,1	N	±10%
			Tensile strength ST:	15,6	N	±10%
Elongation	ISO 9073-3		Elongation SM:	44,5	%	±10%
			Elongation ST:	51,6	%	±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, available upon request.

CERTIFICATIONS & STANDARDS

Meets the requirements of Regulation (EU) 2017/745 on medical devices.
 Manufacturing site : ISO 9001 and ISO 13485 certified.

PRECAUTIONS

The mask 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 CONDITIONS

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 packaged is damaged.

LOGISTICS INFORMATION

OUTER CASE SPECIFICATIONS				
ITEM	SIZE (mm)	GROSS WEIGHT (kg)	QTY / PALLET	BARCODE
C12001	295 x 260 x 190	0,9	108 outercases (9 x 12)	3 662 036 000 897
C12101				3 662 036 000 910
C12103				3 662 036 000 934