

TECHNICAL DATA SHEET

SAFE WEAR VITALS®



Bouffant Clip PP

Medical Device Classe I



FEATURES & BENEFITS

- Nonwoven spunbonded 100% polypropylene.
- Gluing and ultrasonic sealing.
- Elastic FREE of LATEX hemmed-in for the best comfort.
- Supple and very resistant nonwoven.
- Very breathable for better comfort.
- Extensible - suitable for all hair styles.

RECOMMENDED USE

- Can be used by nurse or for patient in operating room.
- Used in industrial environment and food industry.

PRODUCT DETAILS

Product name : Kolmi® - SAFEWEAR Vitals - Bouffant Cap
 Product type : Single use, non sterile
 Material : Polypropylene
 Size : Length : 44,5 cm (± 0,5cm)
 Width : 48 cm (± 1 cm)
 Unit weight : 2,4g (±10%)
 Manufacturing country : FRANCE

Item	Color
C12004	White
C12103	Blue
C12513A	Blue

MECHANICAL INFORMATION						
Measurements done by independent laboratories (measures are available upon request)						
TEST	STANDARD	LABORATORY		AVERAGE	UNIT	TOLERANCE
Grammage	ISO 9073-1	Cetelor		10	g/m ²	±10%
Tensile strength	ISO 9073-3	Cetelor	Tensile strength SM:	21,3	N	±10%
			Tensile strength ST:	8,4	N	±10%
Elongation	ISO 9073-3		Elongation SM:	36,8	%	±10%
			Elongation ST:	52,6	%	±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					INNER CASE SPECIFICATIONS		
ITEM	SIZE (mm)	GROSS WEIGHT (kg)	QTY / PALLET	BARCODE	SIZE (mm)	QTE / carton	BARCODE
C12004	295 x 260 x 190	0,9	108 cases (9 layers of 12 cases)	3 662 036 006 059	/	Dispenser box of 300 units	/
C12103	295 x 260 x 190	0,9	108 cases (9 layers of 12 cases)	3 662 036 006 066	/	Dispenser box of 300 units	/
C12513A	800 x 400 x 245	5,3	27 cases (9 layers of 3 cases)	3 662 036 006 080	/	12 polybag of 150 units	3 662 036 006 103