

TECHNICAL DATA SHEET

SAFE WEAR VITALS®

SURGICAL CAPS

MEDICAL DEVICE CLASSE I



FEATURES & BENEFITS

- Very extensible aerated nonwoven
- Very aesthetic and covering cap
- Can be used by nurse, surgeon or for patient in operating room

WAY TO USE :

1. To be aesthetic, seams can be returned.
2. Adjust the cap by rolling up nonwoven from the bottom.

PRODUCT DETAILS

Product name: KOLMI - SafeWear Vitals – Surgical caps
Product type: Single use, non sterile
Material: 84 % Viscose + 16 % Polymer Binder
Confection: Sewn
Color: Blue / Green
Dimensions: Circumference : 56 cm (± 2 cm)
Height : 32 cm (± 2 cm)
Weight: 7,2 g (± 10%)
Packaging: Dispenser box of 100 units
Origin: France ■ ■

Item	Color
C13600	■ Blue
C13700	■ Green

MECHANICAL INFORMATION						
Measurements done by independent laboratories (measures are available upon request)						
TEST	STANDARD	LABORATORY		AVERAGE	UNIT	TOLERANCE
Grammage	ISO 9073-1	Cetelor		40	g/m ²	±10%
Tensile strength	ISO 9073-3	Cetelor	Tensile strength SM:	55,4	N	±10%
			Tensile strength ST:	8,6	N	±10%
Elongation	ISO 9073-3		Elongation SM:	10,5	%	±10%
			Elongation ST:	71,1	%	±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)	QTY / carton	BARCODE
C13600	575 x 225 x 370	4,6	35 outercases (5 layers of 7 cases)	3 662 036 001 108	200 x 108 x 350	5 dispenser boxes of 100 units	3 662 036 000 088
C13700				3 662 036 001 115			3 662 036 000 095