

Technical Data Sheet

C13600
C13700

SURGICAL CAPS
Medical Device Class I

FEATURES & BENEFITS

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

RECOMMENDED 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® – Surgical Caps
 Product type : Single use, non-sterile
 Material : 84 % Viscose + 16 % Polymer Binder
 Confection : Sewn
 Dimension : Circumference : 56 cm (± 2 cm)
 Height : 32 cm (± 2 cm)
 Unit weight : 7,2g ($\pm 10\%$)
 Manufacturing country : FRANCE 

Item	Color	
C13600		Blue
C13700		Green

MECHANICAL INFORMATION

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

Test	Standard	Laboratory		Average	Unit	Tolerance
Grammage	NF EN ISO 9073-1	Cetelor		40	g/m ²	$\pm 10\%$
Tensile strength	NF EN ISO 9073-3	Cetelor	Tensile strength SM:	55,4	N	$\pm 10\%$
			Tensile strength ST:	8,6	N	$\pm 10\%$

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 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 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 package 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	28 outercases (4 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