Kolmi®

# Technical Data Sheet

Medicom

## C13600 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)<br>Height : 32 cm (± 2 cm) |
| Unit weight : | 7,2g (±10%) |
| Manufacturing country : | FRANCE |

| Item | Color |
|---|---|
| C13600 | Blue |

**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/m² | ±10% |
| Tensile strength | NF EN ISO 9073-3 | Cetelor | Tensile strength SM: | 55,4 | N | ±10% |
| | | | Tensile strength ST: | 8,6 | N | ±10% |

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## 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

CE MD Medical Device 


*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 |