

# **Technical Data Sheet**

**Made In France** 

813600 813700

**Surgical Caps** Medical Device Class I

#### **FEATURES & BENEFITS**

- Airy and extensible non-woven
- · Very aesthetic and very covering cap
- Instructions for use:
  - 1. To be more aesthetic, turn the seams
  - 2. Adjust the height by turning the edge

#### **Recommendation:**

Can be used by nurses, surgeons or patients in the operating room



#### **TECHNICAL DESCRIPTION**

Product name: MEDICOM Surgical caps – Surgical caps

Product type: Single use, non sterile Material: 84% Viscose + 16% Ethylene

copolymer-vinyl acetate

Confection: Sewn

Color: Blue / Green

Dimensions: Circumference: 56 cm (± 2 cm)

Height: 32 cm (± 2 cm)

Unit weight: 7,2 g (± 10%)

Dispenser box of 100 units Packaging:

Origin: France

Item	Color	
813600	Blue	
813700	Green	

Marking on packaging:















Mechanical Information (Measurements done by Cetelor Laboratory)						
TEST	Standard		Average	Unit	Tolerance	
Grammage	ISO 9073-1		40	g/m²	± 10%	
Tonsilo strongth	ISO 9073-3	Dry ME	55,4	N	± 10%	
rensile strength	Tensile strength ISO 9073-3	Dry CD	: 8,6	N	± 10%	
Elongation ISO 9073-3	Dry ME	): 10,5	%	± 10%		
	150 90/3-3	Dry CD	: 71,1	%	± 10%	

## Manufacturing Microbiological Information (by ICARE Laboratory)

Bioburden evaluation meets the requirements of EN ISO 11737: 2018+A1 2021 Additional microbiological controls: ASR, E.coli, Staphylococcus.

#### **STANDARDS & CERTIFICATION**

Manufactured under ISO 13485 certified quality system.

In conformity with the relevant harmonized standard EN ISO 14971.

Complies with the requirements of Regulation (EU) 2017/745 relating to Medical Devices.

### **STORAGE CONDITIONS**

Normal conditions of conservation & storage: not to be exposed to moisture and sun, store in a cool environment or at room temperature.

Product life: 5 years.

#### **PRECAUTIONS**

The device should only be used on clean, intact skin.

Their re-use or prolonged use can produce infection or cross-contamination.

After use, comply with the national regulations in force for the disposal of the device.

#### **LOGISTICAL INFORMATION**



# Dispenser box specifications

Item	Size mm	Gross weight kg	QTY/ pallet	Size mm	QTY
813600 813700	575 x 225 x 370	4,6	35 cases (5 layers of 7 cases)	200 x 108 x 350	5 dispenser boxes of 100 pieces

#### **EAN Code**

Item	Outer case	Dispenser box
813600	3 662 036 015 198	3 662 036 015 204
813700	3 662 036 015 211	3 662 036 015 228



