

Date: Mar. 14, 2022

## Product Technical Sheet

### Product Description

Product: Bouffant cap

Item No.: 404386

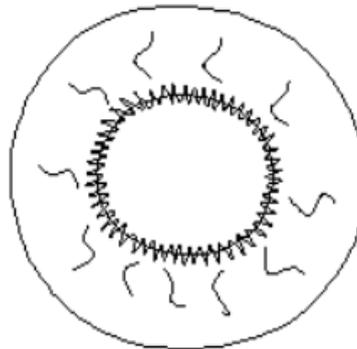
Colour: Blue

Material: PP

Thickness: 25g

Size: Please see below table

	cm	Tolerance
diameter	53	±1



Packing: 100pcs/bag, 1000pcs/ctn

Carton meas. : 50 x 27 x 27cm

### Suggested Sterilization

ETO: (pre-treatment cycle 16-72 hrs)  
(gas contact – 3 hrs/850 mg)  
(evaporation 48 hrs at 40°C)

### Suggested Storage:

Temperature : between -5°C and 40°C

Humidity : below 80%

Sunlight : not to expose to direct sunlight

Shelf-Life : 5 years

**Intended Use:** Used for general isolation in outpatient, ward, laboratory and other environments of medical institutions.

### Applicable Directive/Regulation:

Medical Device Regulation (EU) 2017/745.

**Applicable Standards:**

ISO 13485:2016  
ISO 10993-5:2009  
ISO 10993-10:2010

**Risk Analysis**

The raw material is approved to be safe to human health (refer to the manufacturer's safety data sheet).  
As for the product, no hazard is foreseeable to the safety and health of user.

**Instruction for Use:**

**Usage :**

1. Take it out from the package (box or polybag), then unfold it
2. Open it and put on the head.

**Cautions:**

1. This product is for single use. Do not re-use it.
2. This product is for protection of part of body, not for overall protection.
3. This product is for hygienic protection, not for any other personal protection against potential risk.
4. This product is non-sterile. It must be sterilized before being used as sterile wear.
5. Do not wear it directly without any clothes. It may cause skin uncomfortably when touching skin directly.
6. Do not wear it in the place where electrostatic prevention is requested. It is not anti-static treated.
7. Choose right size according to the user's stature and figure.