



CLEAN STREAM TECHNOLOGIES

DISPOSABLE STERILE SURGICAL MASK

CLASS 1S (M) TYPE IIR

ARTG 336708. Pleat style with Ear Loops. Single use
PRODUCT CODE: CST-MASKST50

PURPOSE

The sterile mask is to be worn by medical personnel during surgical or other medical procedures, to prevent the transfer of airborne organisms while surgery is being performed, body fluids and particulate transfer.

REGULATORY INFORMATION

- Product CE marked as Directive 93 / 42 / EEC on Medical Device
- Class of device : 1S(M)TYPE IIR
- Product compliant with EN14683:2019 +AC:2019
- ARTG 336708

STORAGE INFORMATION

- Product should be stored in a cool, dry and well-ventilated area.
- Store below 30 degree Celsius

PACKAGING

- Shipping carton of 2000 masks.
- Shipping carton size : 525mm x 490mm x 565mm
- Gross weight : 12.5kg
- 50 masks (individually packed) per box and 40 boxes per shipping carton.

DIMENSIONS

Length / width :	17.5cm x 9.5cm
Length of Earloop :	20 cm
Length of Nose-piece :	10.5cm
Pleat Depth :	1.2cm x 3 folds

PROPERTIES

1	Bacterial Filtration Efficiency (BFE) Test	EN 14683:2019+AC:2019(E) Annex B	>99%
2	Respiratory Resistance Differential Pressure pa/cm ²	EN 14683:2019+AC:2019(E) Annex C	2.58 mm H ₂ O/cm ²
3	Synthetic Blood Penetration Test	ISO 22609:2004	>8CFU/g
4	Microbial Cleanliness Test	EN 14683:2019+AC:2019(E) Annex D	>99%
5	Particulate Filtration Efficiency	EN 14683:2019+AC:2019(E) Annex A	>30%

Suitable for theatre use



STERILISATION

- This is a sterile product.
- Method: 14 days Ethylene Oxide Sterilisation
- Sterilization temperature: 50 to 60°C
- Humidity: 30 to 80%
- Ethylene oxide concentration: 16kg / 20 cubic metre
- Exposure time: 4800 minutes; strong unfold time of 3 hours

SHELF LIFE

- 2 years from date of manufacture