

Medimask

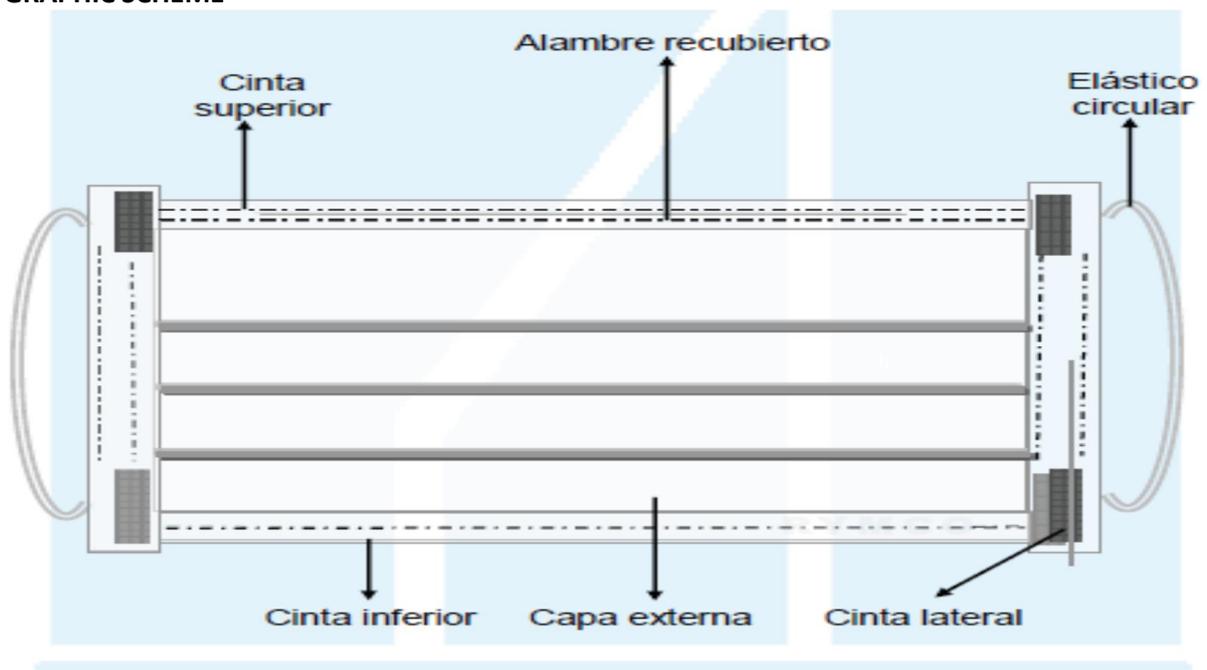
CE Number 93/42/EEC Medical Device Directive -Annex VII

CE Certification

Type IIR

EN Norm 14683

GRAPHIC SCHEME



DESCRIPTION OF THE DEVICE: Disposable facial mask, non-sterile, single use.

External layer: Made with non-woven cloth with a minimum weight of 13 g/m².

Middle layer – Filter: Made with a non-woven cloth filter with a minimum of 10 g/m².

(Bacteria

Filtration Efficiency of >98%).

Internal layer: Made with non-woven cloth with a minimum weight of 20 g/m².

Side bands: Made with non-woven cloth with a minimum weight of 20 g/m².

Covered wire: Made with wire covered with PE (polyethylene) plastic, 3.0 mm width, calibre of the wire:

0,5 mm

Circular elastic band: Made with Spandex and Polyester, does not irritate the skin.

Sealed with ultrasound

Dimensions of the Facial Mask:

Length of the mask: 172 mm - 178 mm

Width of the mask: 98 mm – 102 mm

Length of the wire: Minimum 95 mm

Length of the elastic band: 140 mm – 180 mm

Width of the side band: 8 mm – 12 mm

COMMERCIAL PRESENTATION

50 unidades / Foldable box

20 foldable boxes / Corrugated box

1000 units / Corrugated box

VISUAL INSPECTION

Absence of defects: The facial masks must be free from stains, foreign particles and strands. The facial masks must be free from holes and stains. In accordance with internal manufacturing norms.

PHYSICAL TESTS

Dimensions: length of the mask, width of the mask, length of the elastic band, length of the wire and width of the side band. In accordance with internal manufacturing norms.

Mechanical resistance: it determines the safety of the mask's joints when put under external tensile forces. In accordance with internal manufacturing norms.

BIOLOGICAL TESTS

Microbiological load determination for the product: Determine the number and type of microorganisms (microbiological load) present in the non-sterile face masks. In accordance with the BS EN 14683 Norm.