



ARTICLE

Designation: TYPE II MEDICAL MASK, ELASTIC, worn by the medical staff, it protects the patient from infectious agents. Reference : 300.00.17

REGULATORY COMPLIANCE

- This product is a medical device, which complies with the requirements of the European Directive 93/42/EEC.
- It bears the marking : **CE**
- It is manufactured under an EN ISO 13485: 2016 certified system.
- Its performance has been evaluated according to the criteria of the standard:

SPEC

EN 14683:2019

Bacterial Filtration Efficiency in vivo: BFE (%) : required $\geq 98\%$ / results : $\geq 99,6\%$

Breathability: Delta P (Pa/cm²) : required < 40 / results : 30,5

Microbial cleanliness (ufc/g) : required ≤ 30 / results : < 1

Filtration test carried out with bacteria calibrated to 3,0 μ m [± 0.3] / Pa = Pascal / cfu = colony-forming unit

Its biocompatibility has been assessed according to the criteria of the standard :

ISO 10993

Cytotoxicité +> required : Absence of cytotoxicity / results : Absence of cytotoxicity

Irritation => required : Non-irritating / results : Non-irritating

Sensitization => required : Topical and intradermal: non-sensitizing / results : Topical and intradermal: non-sensitizing

Composition & packaging: 1 Polypropylene layer + Meltblown filter + 1 Polypropylene layer, welded edges, 2 elastic ears, and a nose clip.

Colour: white inner side, blue outer side.

Approx. dimensions: Length 17.5cm, width 9.5cm.

Use-by date: 5 years after date of manufacture

Does not contain latex

Non-sterile product

Single use product

Keep out of direct sunlight.

Do not expose to moisture

Exposure temperature limit : +5 °C / +40 °C

Refer to the instructions on the side of the box.

PACKAGING

SUBPACKAGING

Quantity : 50 pieces Type: dispenser box

PALETTISATION

- 48 boxes

- Semi-heavy pallet: 80 x 120 cm

Packaging

Quantity: 1000 units (20 boxes of 50) Type: case

GENCOD	
CODE CARTON	3701102302500
CODE BOITE	3701102302517