

## Mask for medical use, 3-ply CE-Marking (Type IIR) - ENI4683 Made in France

V 16.01.23



• Electrostatic filtering non-woven

• Without latex, silicone, PVC, GLASS FIBER

Nose bar (with shape memory)

· Manufacturing process guaranteeing the cleanliness of our products from the production line up to the packaging process



| Category                 | Non-sterile Class I Medical device<br>Single-use surgical mask (type IIR)  |  |  |
|--------------------------|--|--|--|
| Standard and legislation | EU Medical Devices Directive UE 2017/745 Complies with standard EN 14683:2019+AC:2019  |  |  |
| Description              | <ul> <li>Mask for medical use, non-sterile, for single use,</li> <li>Model: 1000 series Klap One</li> <li>Specifications:</li> <li>Adjustable shape memory nose clip.</li> <li>Dimensions: 175 X 95mm</li> <li>Bacterial filtration efficiency: see performance table</li> <li>Mask weight (+/- 10%): Type IIR: 2.95 gr</li> </ul>               |  |  |
| Composition              | <ul> <li>Inner and outer layers: polypropylene nonwovens spunbond.</li> <li>Intermediate layer: nonwovens meltblown in</li> <li>Nose clip: double steel and polypropylene ring</li> <li>Elastic: Polyamide mesh / spandex OR Polypropylene mesh / spandex</li> <li>French manufacturing lines – Controlled raw materials and products</li> </ul> |  |  |
| Materiovigilance         | The materials likely to come into contact with the wearer's skip do not present a risk   |  |  |

| Materiovigilance         | The materials likely to come into contact with the wearer's skin do not present a risk of irritation or harmful effects to health |
|--------------------------|---|
| Storage and preservation | Mask should be stored in a clean, dry, cool and well-ventilated place.  |

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Maximum storage period: 5 years in their original packaging

| Performances    | EN 14683:2019<br>Type   | Bacterial filtration<br>effectiveness (BFE) | Differential Pressure<br>(Pa/cm²) | Resistance to projections (kPa) | Cleanliness<br>microbial (cfu/g) |  |  |
|-----------------|---|---|-----------------------------------|---------------------------------|----------------------------------|--|--|
|                 | Type IIR  | ≥ 98 %                                      | < 60                              | ≥ 16                            | ≤ 30                             |  |  |
| Duration of use | 4 hours maximum (in one shift - continuous)   |   |                                   |                                 |                                  |  |  |
| Packaging       | Box of 50 units - 30 boxes in one cardboard box / carton - Packaging in bags available on request |   |                                   |                                 |                                  |  |  |
| Reference       | MAI602MBLA0I2   |   |                                   |                                 |                                  |  |  |