

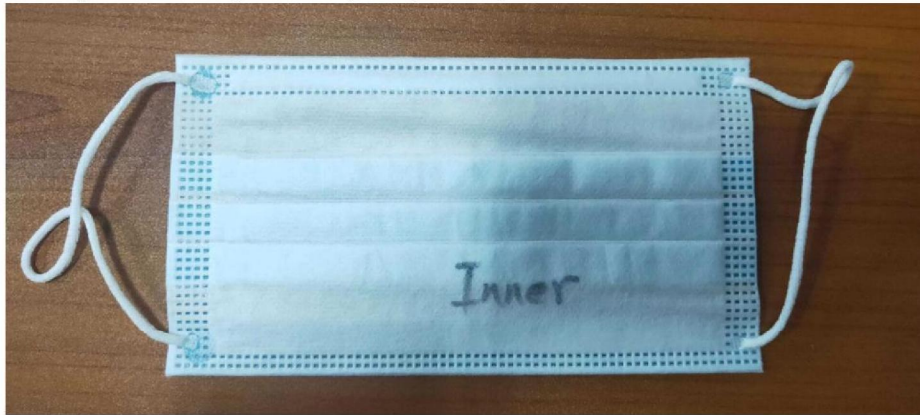
Specification 3 ply Face Mask Zogear

General documentation:

- ✓ Valid and verifiable EC certificate for non-woven face mask
- ✓ ISO 13485 certificate
- ✓ Test report against EN14683
- ✓ Declaration of Conformity

Visual Appearance:

- ✓ Size: 17.5 x 9.5cm (+/- 0.5 cm)
- ✓ Welding of the ear loop: on inside, always same position



- ✓ Ear loop size: 17.5 ±1cm
- ✓ Nose clip: plastic with a metal core. Fixation of nose clip such that it stays in position .
- ✓ Folding layers should be as per picture below





Quality: compliance to Type IIR according to EN14683 based on tests as described in this specific norm. Specifically

- ✓ Bacterial Filtration Efficiency: $\geq 98\%$
- ✓ Splash Resistance (ISO 22069): $\geq 120\text{mm Hg}$ (or 16.0 KPa)
- ✓ Differential Pressure: $< 60 \text{ Pa/cm}^2$ 通气阻力
- ✓ Microbial cleanliness (bioburden): $\leq 30 \text{ cfu/g}$
- ✓ Biocompatibility (EN ISO 10993): comply

Packaging: Three changes to current box.



Quality Certificate (inside box):

ZOGEAR 合格证

产品名称: 一次性使用医用口罩 (非灭菌)
 型号: P9001-3
 规格/尺寸: 3层, 耳带式, 17.5cm x 9.5cm (+0.5cm)
 执行标准: EN14683:2019 YY/T 0969-2013
 产品结构: 无纺布, 熔喷布, 耳带, 鼻架条
 产品成分: 80% 无纺布, 20% 熔喷布
 适用范围: 在一定程度上阻隔粉尘、花粉、飞沫、细菌的传播
 包装数量: 50pcs
 生产批号: Z0LM0401
 生产日期: 20200424
 有效期至: 20220423
 保质期: 二年
 检验结果: 合格品
 检验员: 01
 生产许可证号: 皖食药监械生产许20200058号
 产品注册证号: 皖械注准20202140113
 生产商: 天长市顺兴实业有限公司
 生产地址: 安徽省天长市经济开发区天康大道139号



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Release documentation: production inspection report, delivery note.