

MASKMD

3-PLY
MEDICAL FACE MASK
WITH EARLOOPS

COMMERICAL PROPOSAL | APRIL 2020



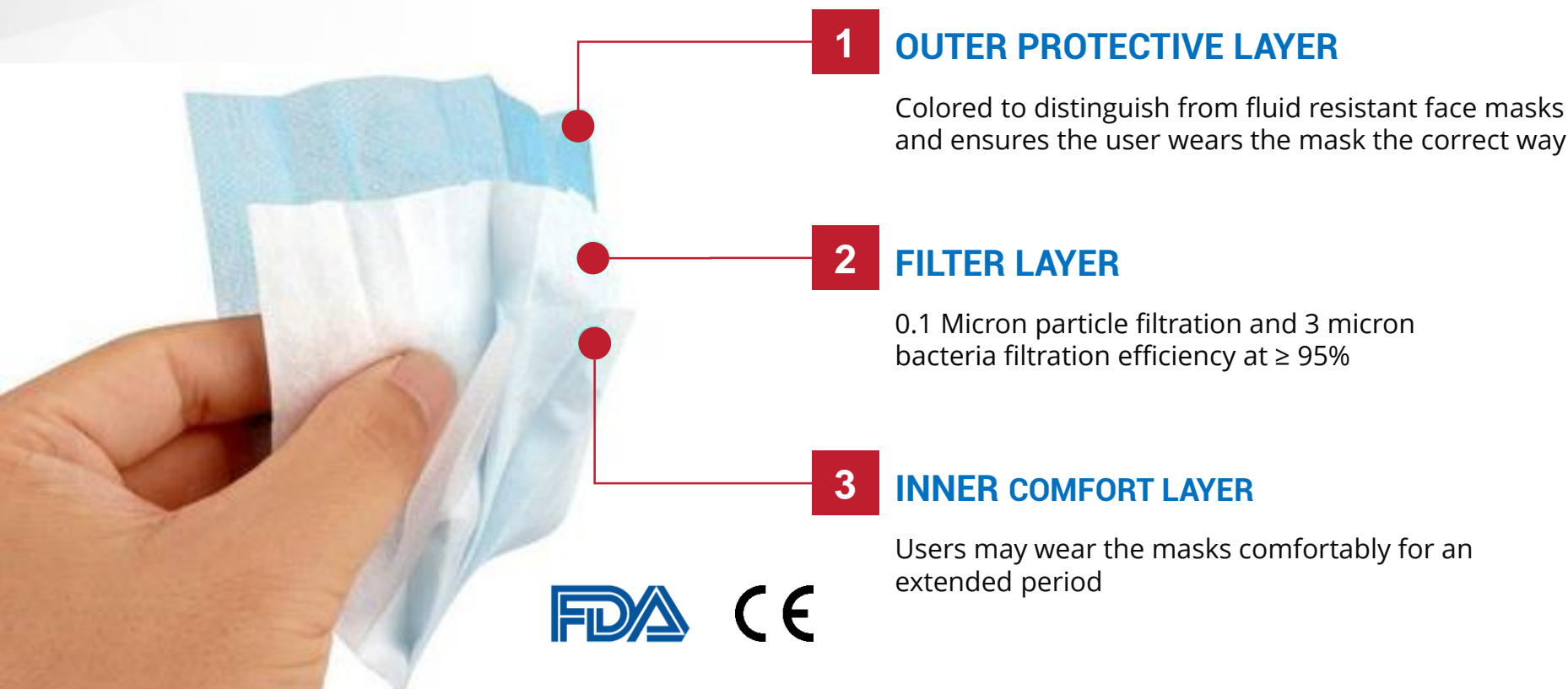
OVERVIEW

Our standard 3-ply face masks provide basic protection for medical staff. They are suitable for general patient care and procedures where there is no risk of exposure to blood and/or body fluids.

Our masks are fabricated using lightweight materials for maximum breathing comfort, with minimal risk of skin irritation and high level protection.



3-LAYER PROTECTION



SPECIFICATIONS

BFE $\geq 95\%$ AT 3 MICRONS | PFE $\geq 95\%$ AT 0.1 MICRONS

- **Product Type:** 3-Ply Disposable Medical Face Mask (Non-Sterile)
- **Quality Standard:** YY-T0969-2013 (Disposable Daily Mask) CE & FDA
- **Rating:** ASTM Level 1 - Meets EN 14683 Rating – Type II Standard
- **Protection Level:** 0.1 Micron particle filtration and 3 micron bacteria filtration efficiency at $\geq 95\%$
- **Filter Testing Subject Efficiency:** Bacterial aerosol MPS: 3um
- **Key Parameters:**
 - Low Fluid Resistance: 80mmHg
 - Filtration Efficiency: BFE $\geq 95\%$, PFE $\geq 95\%$ @ 0.1 Micron
 - Breathability – Delta P: $< 4.0\text{mm H}_2\text{O}/\text{cm}^2$
 - Flame Spread: Class 1
- **Filter layer:** Meltblown Fabric
- **Weight:** 3ply: 25 + 25 + 25 G/M2
- **Color:** Blue
- **Size:** One size for adult with earloops and adjustable nosepiece

PACKAGING

- **Quantity Per Box:** 50
- **Boxes Per Carton:** 40
- **Total Masks Per Carton:** 2000
- **Carton Size:** 52cm x 38cm x 34cm



CERTIFICATIONS

Review Report - 审查报告-검토 보고서-Rapport d'Evaluation

Form QAT_10-M04, version 00, effective since March 6th, 2020

CE Documentation Review

Holder: Sannuo Electronic Co., Ltd.
Floor 3, Block 1, Zhongyuan Industrial Park, No. 10, Shao'an Road, Qidong Avenue, Huashan Town, Huadu District, Guangzhou

Review goal: Verification of the presence of the Technical File regarding the Medical Devices Directive 93/42/EEC Annex I.

Product: Disposable Medical Masks (no sterile)

Model: Flat type 1, 10 cm * 9.5 cm

Classification: Class I (no sterile) (accordingly to the Manufacturer's declaration)

Review output: We attest that a Technical File in reference to the Directive 93/42/EEC is in place for the CE Marking process. Technical File identified with the no. TMDDMJ2003183551-AG170. The manufacturer is responsible for the CE Marking process, and not exempted to carry out all necessary compliance activities. This document has been issued on the basis of the regulation on ECM Voluntary Mark for the certification of products. RG01_ECM rev.3 available at: www.entecerma.it

Issuance date: 19 March 2020
Expiry date: 18 March 2025

Reviewer: Technical expert Amanda Payne
Approver: ECM Service Director Luca Bedonni

Ente Certificazione Macchine
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深圳市计量质量检测研究院
Shenzhen Academy of Metrology & Quality Inspection

MA A

检验报告
TEST REPORT

报告编号: WT204007418 (替代WT204000104报告)

第 1 页, 共 4 页

委托单位: [Redacted]
委托单位地址: [Redacted]
样品名称: 一次性使用医用口罩
型号/规格/等级: [Redacted]
检验类别: 送样检验
检验地点: 本实验基地

批准人: 滕万红 (副部长)
签发日期: 2020年03月03日 签名: 滕万红

深圳市计量质量检测研究院 Shenzhen Academy of Metrology & Quality Inspection info@szma.com.cn
电子邮局: szma@szma.com.cn 10012 注册代码: CN01 No. 1, 391611407001 & 391719061400
注册代码: 深圳前海深港现代服务业合作区桂湾片区111号 咨询电话: 0755-27528955 传真: 0755-27528707 邮编: 518131
Longhua Experimental Base: No. 155, Wukang North Road, Wukang Avenue, Longhua District, Shenzhen Tel: 0755-27528955

疫情防控急需第二类医疗器械应急备案信息表

备案编号: 粤深急械备 20200019 号

备案人名称	深圳市三诺电子有限公司
统一社会信用代码	91440300MA5D90101G
注册地址	深圳市宝安区燕罗街道塘下涌社区洋涌路 74 号二楼
生产地址	深圳市宝安区燕罗街道塘下涌社区洋涌路 74 号二楼、深圳市宝安区沙井街道新桥同富裕工业区恒明珠科技工业园 14 栋 14 楼一区 3 楼
产品名称	一次性使用医用口罩 (疫情应急产品)
型号/规格	长方形耳挂式
产品描述	由口罩体、鼻夹、口罩带组成。为非灭菌产品, 一次性使用。
预期用途	适用于覆盖使用者的口、鼻及下颌, 用于普通医疗环境中佩戴, 阻隔口腔和鼻腔呼出或喷出污染物。
备注	本备案仅在防控新冠肺炎疫情期间有效
备案单位 和日期	深圳市市场监督管理局 备案日期: 2020年2月22日

签单

BTK

Test Report

Page 1 of 3

Date: Mar. 13, 2020

Sample Name: Face Masks

Trade Name: N/A

Sample Model: PTMYKZ-01

Sample Received Date: 2020.02.12

Testing Period: 2020.02.12 to 2020.03.13

Test Requested: As specified by client, for compliance with Food and Drug Administration Regulations for determining the amount of total extractives from polypropylene articles intended for repeated use.

Test Method: Please refer to next page(s).

Test Result: Please refer to next page(s).

Signed for and on behalf of
Dexter Chan/ Approved Signatory

营业执照

统一社会信用代码: 91440300MA5D90101G
仅供口罩采购使用

名称: 深圳市三诺电子有限公司
类型: 有限责任公司 (外国法人独资)
住所: 深圳市宝安区燕罗街道塘下涌社区洋涌路74号二楼
法定代表人: 刘志坚
成立日期: 1996年07月05日

登记机关: 2016年05月13日

中华人民共和国国家市场监督管理总局