

# 中华人民共和国医疗器械注册证

注册证编号：苏械注准 20202140740

注册人名称	扬州美德莱医疗用品有限公司
注册人住所	扬州市经济开发区金山路 108 号
生产地址	扬州市经济开发区金山路 108 号 扬州市开发区华发路 1 号
代理人名称	不适用
代理人住所	不适用
产品名称	医用防护口罩
型号、规格	挂耳式，按面罩外形为折叠式。根据口罩外形分为 I 型 9501 和 II 型 9501（95 表示颗粒物过滤效率要求为 95%，01 表示 GB19083-2010 中的过滤效率等级为 1 级），每个型号按尺寸的大小分为 S、M、L、XL 四种规格。
结构及组成	医用防护口罩由口罩体、鼻夹、口罩带组成。口罩体有四层：内层为聚丙烯纺粘无纺布、中间 2 层为熔喷无纺布、外层为聚丙烯纺粘无纺布，鼻夹由可弯折聚乙烯包裹双芯铝丝或铝制金属片材料制成，口罩带由氨纶弹性松紧织物制成或采用弹性无纺布制成。口罩为折叠式，根据口罩外形分为 I 型 9501 和 II 型 9501，每个型号按尺寸的大小分为 S、M、L、XL 四种规格。产品以无菌和非无菌两种状态提供，一次性使用，无菌提供产品经环氧乙烷灭菌，应无菌。
适用范围	适用于医疗工作环境下，过滤空气中的颗粒物、阻隔飞沫、血液、体液、分泌物等的自吸过滤。
附 件	产品技术要求
其他内容	
备 注	

审批部门：江苏省药品监督管理局

批准日期：2020 年 06 月 19 日

有效期至：2025 年 06 月 18 日

# Medical device registration Certificate of the People's Republic of China

Certificate No.: SFDA 20202140740

Registrant name	Yangzhou Medline Industry Co., Ltd.
Registrant address	No.108, Jinshan Road, Economic Development Zone, Yangzhou 225009, Jiangsu, China
Manufacturing address	No.108, Jinshan Road, Economic Development Zone, Yangzhou 225009, Jiangsu, China No.1, Huafa Road, Economic Development Zone, Yangzhou
Agent name	Not applicable
Agent address	Not applicable
Product name	Medical protective face mask
Specification & Model	Medical protective face mask is composed of mask body, nose clip and mask bands. The mask body has 4 layers: the inner layer is polypropylene spunbonded nonwoven fabric, the middle two layers are melt-blown nonwoven fabric, and the outer layer is polypropylene spunbonded nonwoven fabric. The nose clip is made of a double core aluminum wire wrapped in bent polyethylene or aluminum sheet, the mask belt is made of spandex elastic elastic fabric or non-woven elastic fabric. Mask itself is the folded type, and can be classified as I 9501 and II 9501 according to the mask shape. Each model can be divided into 4 specifications, S, M, L and XL based on the size. The product is available in both sterile and non-sterile states for single use only. Sterile medical protective masks shall be sterilized with ethylene oxide to be sterile.
Application range	Suitable for medical work environment, filter the particulate matter in the air, cut off droplets, blood, body fluids, secretions, etc.
Accessory	Product technical requirements
Other contents	
Remark	

Approved by: Jiangsu Drug Administration

Date of approval: 19<sup>th</sup>, June, 2020

Valid to: 18<sup>th</sup>, June, 2025