Description 说明

The following discussion is intended to help you differentiate standard versions and surgical versions of N95 particulate filtering facepiece respirators.
以下讨论可帮助您区分普通 N95 颗粒物防护口罩和医用 N95 颗粒物防护口罩。

NIOSH-Certified N95 Respirators NIOSH 认证的 N95 呼吸器

Particulate respirators are designed to help reduce the wearer's exposure to airborne particulate hazards. In the U.S., respirators are tested and certified by the U.S. National Institute of Occupational Safety and Health (NIOSH). NIOSH tests and certifies respirators based on their physical and performance characteristics, including filtration efficiency. For example, N95-rated filtering facepiece respirators have a filtration efficiency of at least 95% against non-oily particles when tested using the NIOSH criteria. The particles used to test the filtration are in a size range that is considered the most penetrating. Therefore, the test methods ensure that the filter media can filter particles of all sizes with at least 95% efficiency.
防颗粒物的呼吸器设计用于帮助降低佩戴者对空气中悬浮的颗粒状有害物质的暴露水平。在美国，呼吸器是由美国国家职业安全健康研究所（NIOSH）负责检测和认证的。NIOSH 根据呼吸器物理的和性能上的特点来进行检测和认证，包括过滤效率。例如 N95 级别的颗粒物防护口罩要在 NIOSH 规定的测试条件下，对非油性颗粒物应具备至少 95%的过滤效率，测试过滤效率所用的颗粒物属于最难过滤的粒度范围，因此，测试方法可确保过滤材料在过滤所有粒径的颗粒物时都具有至少 95%的效率。

FDA-Cleared Surgical Masks 美国药监局 FDA 批准的外科口罩

Surgical masks, in contrast, are designed to be worn by healthcare professionals during surgery and nursing, to help prevent contamination of the surgical field and/or the patient by capturing liquid droplets that are expelled by the wearer. Surgical masks are cleared for use as medical devices by the U.S. Food and Drug Administration (FDA), or equivalent agencies outside the U.S. That clearance is based on data and proposed claims provided by the manufacturer to the FDA for review, which the FDA evaluates and then "clears" for those products that meet the requirements. Because surgical masks are meant for use during surgeries, a key performance requirement is fluid resistance – the ability of masks to resist penetration by high-pressure streams of liquid, such as those that might result from a human artery being punctured during surgery[1].
对比来看，医用外科口罩是设计由专业的医护人员在手术和护理操作中佩戴，来帮助拦截佩戴者排出的飞沫，防止其对手术区域和/或患者的污染。医用外科口罩需得到美国食品药品监管局（FDA）或其他国家类似的机构的批准成为医疗器械。依据制造商向 FDA 提供的数据和所做的宣称，经过审查和评估后，对符合要求的产品做出“批准”。由于医用外科口罩专

门用来在给患者手术的时候佩戴，所以要具备一项关键的抗体液喷溅性能，对在类似外科手术中出现的动脉血管刺穿产生的高压流动液体要有阻隔性[1]。

Surgical N95 Respirators 医用 N95 防护口罩

Surgical respirators are both certified by NIOSH as an N95 respirator and also cleared by the FDA as a surgical mask. These products are frequently referred to as medical respirators, healthcare respirators, or surgical N95s.
医用的呼吸器既是获得 NIOSH N95 级认证的防护口罩，又是由 FDA 批准的医用外科口罩，这类产品也经常称作医用防护口罩或医用 N95 口罩。

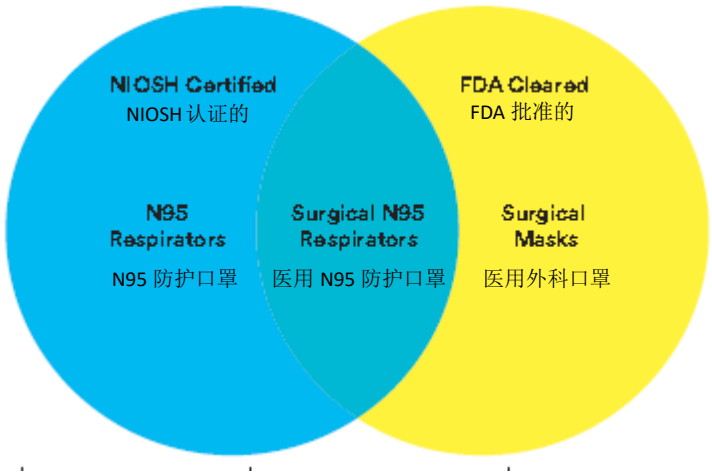
Comparing Standard N95s to Surgical N95s 对比普通 N95 和医用 N95 防护口罩

Putting this all together will help you differentiate between a standard NIOSH-certified N95 respirator and a surgical N95 respirator. While similar in appearance, the key difference is the fluid resistance and the resulting FDA clearance of surgical N95s. But when is that fluid resistance necessary?
把所有这些情况放在一起对比，可以帮助您区分普通的 NIOSH 认证的 N95 防护口罩和医用的 N95 防护口罩的差别，尽管它们外观相似，而分水岭就在于由 FDA 批准的医用 N95 要具备对液体的阻隔性能。那么什么时候这种对液体阻隔的性能才是必要的呢？

Many tasks performed by healthcare workers – such as patient intake and non-emergency patient evaluation – pose little to no risk of generating high-pressure streams of liquid and are not conducted in a sterile field. For workers performing such tasks, a primary potential hazard to consider is airborne viruses and bacteria, such as those generated by coughs and sneezes, which are effectively filtered by an N95 respirator.
医护人员从事的许多工作——如接诊和非急救性的诊疗——基本上不存在或很少存在高压体液喷溅的风险，也不需要在无菌区域内操作。对他们而言，所考虑的一个主要潜在风险是患者咳嗽、打喷嚏所造成的空气中悬浮的病毒和细菌，对这类危害，一个普通的 N95 防护口罩就可以有效过滤。

1. ASTM F1862 is a standard test method for resistance of medical facemasks to penetration by synthetic blood. This test is required because during certain medical procedures, a blood vessel may occasionally be punctured, resulting in a high-velocity stream of blood impacting a protective medical facemask. The test procedure specifies that a mask or respirator is conditioned in a high-humidity environment to simulate human use and is placed on a test holder. Synthetic blood (2cc) is shot horizontally at the mask at a distance of 30 cm (12 inches). Surgical masks and respirators are tested on a pass/fail basis at three velocities corresponding to the range of human blood pressure (80, 120, and 160 mmHg). The inside of the mask is then inspected to see if any synthetic blood has penetrated to the inside of the facemask. Fluid resistance according to this test method is when the device passes at any level.
注1. ASTM F1862 是测试医用口罩抗合成血穿透性能的标准测试方法。做这个测试的必要性在于，在某些医疗操作中，血管会不小心被刺穿，造成高速的血流会喷射到防护用的医用口罩上。测试条件中规定，医用外科口罩或医用防护口罩先要在一个高湿度的环境下进行预处理，用以模拟人佩戴使用的条件，然后把口罩固定在一个测试支架上，在距离口罩 30cm 的位置，将 2ml 合成血液体以水平方向喷射向口罩。判断医用外科口罩或医用防护口罩是否合格是以血压范围（80、120、160mmHg）所对应的液体喷射速度来决定的，要求口罩内侧不应有合成血透过来。满足其中任一喷射速度下的测试即可视为通过抗体液喷溅测试。

Therefore, if a healthcare facility is prioritizing respirator use – due to, for example, limited supply during a health emergency – they may want to consider prioritizing use of surgical N95 respirators for those healthcare workers requiring respiratory protection while performing surgery or other tasks that may expose them to high pressure streams of bodily fluid or conducting work in a sterile field. For other workers who will not be performing such surgical procedures or do not need to maintain a sterile field, a standard non-surgical N95 (or equivalent) respirator can be worn to help reduce those workers' exposure to patient-generated airborne viruses and bacteria.
所以，如果一个医疗机构出现了例如卫生突发事件期间的供应紧张问题，可以考虑对医用 N95 的使用做优先级判断。可以考虑让那些需要呼吸防护的，而且要做手术或在其他存在高压体液喷溅或在无菌区域内操作的医护人员来优先使用。其他不会参与手术操作的或不需要在无菌区域内操作的人员，可以使用普通的非医用的 N95（或级别相当的）防护口罩，来帮助他们降低对患者产生的存在病毒和细菌的气溶胶的暴露水平。



Function 功能	Help reduce particles inhaled by wearer 帮助佩戴者减少吸入颗粒物	Help reduce particles both inhaled and expelled by wearer (plus fluid resistance) 同时帮助降低佩戴者吸入的和排出的颗粒物（外加抗体液喷溅）	Help reduce particles expelled by wearer into environment (plus fluid resistance) 帮助降低佩戴者排出的颗粒物（外加抗体液喷溅）
Application 应用	Can be used for respiratory protection when wearer might be exposed to particulate hazards 当佩戴者面临有害的颗粒物的暴露时，能提供呼吸防护	Meant to be used during surgery and nursing tasks during which both of these are true: 当外科手术和护理中同时满足以下两点时专用： • Wearer requires respiratory protection ...and...佩戴者需要呼吸防护，并且 • Expelled particulates must be contained or fluid resistance is required 必须拦截佩戴者排出的颗粒物或需要抗体液喷溅	Can be used during surgery and nursing tasks to help protect patient, and/or when fluid resistance may be required 在外科手术和护理中能帮助保护患者，和/或需要抗体液喷溅时

The following chart demonstrates some key similarities and differences between three respirator

models. The 8210 is an N95 respirator, while the 1860 and 1870+ are both surgical N95 respirators.
在下面的图表中对三种型号的呼吸器的一些关键相似点和差别进行了对比示范，其中 8210 是一个 N95 防护口罩，而 1860 和 1970+都是医用 N95 防护口罩。

			
	N95 防护口罩 3M 型号 8210	医用 N95 防护口罩 3M 型号 1860	医用 N95 防护口罩 3M 型号 1870+
设计帮助佩戴者防护空气中悬浮的颗粒物（如粉尘、雾、烟、纤维和生物气溶胶，如病毒和细菌）	✓	✓	✓
防护口罩设计与佩戴者脸部能够实现紧密贴合	✓	✓	✓
满足 NIOSH 42CFR84 标准对 N95 级别的要求，对非油性的固态和液态颗粒物的过滤效率至少 95%	✓	✓	✓
获得 FDA 批准作为医用外科口罩销售	✗	✓	✓
抗体液喷溅——满足 ASTM 测试方法标准 F1862“医用口罩抗合成血穿透”确定的抗不同压力水平的合成血 [a]	✗	✓ 120 mmHg	✓ 160 mmHg

a. ASTM F1862 is a standard test method for resistance of medical facemasks to penetration by synthetic blood. This test is required because during certain medical procedures, a blood vessel may occasionally be punctured, resulting in a high-velocity stream of blood impacting a protective medical facemask. The test procedure specifies that a mask or respirator is conditioned in a high-humidity environment to simulate human use and is placed on a test holder. Synthetic blood (2cc) is shot horizontally at the mask at a distance of 30 cm (12 inches). Surgical masks and respirators are tested on a pass/fail basis at three velocities corresponding to the range of human blood pressure (80, 120, and 160 mmHg). The inside of the mask is then inspected to see if any synthetic blood has penetrated to the inside of the facemask. Fluid resistance according to this test method is when the device passes at any level.

ASTM F1862 是测试医用口罩抗合成血穿透性能的标准测试方法。做这个测试的必要性在于，在某些医疗操作中，血管会不小心被刺穿，造成高速的血流会喷射到防护用的医用口罩上。测试条件中规定，医用外科口罩或医用防护口罩先要在一个高湿度的环境下进行预处理，用以模拟人佩戴使用的条件，然后把口罩固定在一个测试支架上，在距离口罩 30cm 的位置，将 2ml 合成血液体以水平方向喷射向口罩。判断医用外科口罩或医用防护口罩是否合格是以血压范围（80、120、160mmHg）所对应的液体喷射速度来决定的，要求口罩内侧不应有合成血透过来。满足其中任一喷射速度下的测试即可视为通过抗体液喷溅测试。

For a list of 3M medical facemasks and surgical respirators, see this 3M Masks and Respirators Brochure.

欲了解 3M 医用口罩和医用防护口罩产品名录，见 3M 口罩和呼吸器产品手册。

Personal Safety Division
3M Center, Building 235-2W-70
St. Paul, MN 55144-1000

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