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Technical Bulletin

June 2020
EMEA Version 2

Healthcare filtering facepieces respirators and standard filtering facepieces respirator (FFP2 and FFP3) – Which to Consider?

Description

This is a general document that is not specific to any particular airborne contaminant, including viruses and bacteria, and that is intended for a sophisticated occupational audience.

The following information is intended to help you differentiate between standard versions and healthcare versions of FFP2 and FFP3 particulate filtering facepiece respirators based on European regulatory requirements.

Note: For information on Surgical N95 respirators please consult 3M Technical Bulletin - Surgical N95 vs. Standard N95 - Which to Consider? which offers a comparison of surgical and standard N95 filtering facepiece respirators based on U.S. regulatory requirements.

CEN certified standard respirators

Particulate respirators are designed to help reduce the wearer's exposure to airborne particulate hazards. Standard filtering facepiece respirators are certified to the Personal Protective Equipment Regulation (PPER) and are tested for compliance to EN149:2001.[1,2] Standard Filtering facepiece respirators are tested for filtration efficiency against a solid and liquid aerosol containing particles 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 80% efficiency. Additionally, these filtering facepiece respirators are tested for their ability to fit a panel of wearers and provide a total inward leakage (TIL) of no greater than 22%.

There are three classes of filtering facepiece respirators under PPPR:

- FFP1 – TIL no greater than 22%, filtration efficiency of at least 80%
- FFP2 – TIL no greater than 8%, filtration efficiency of at least 94%
- FFP3 – TIL no greater than 2%, filtration efficiency of at least 99%

CEN certified medical masks

The main intended use of medical masks is to help prevent contamination of the surgical field and/or the patient in a sterile environment by capturing liquid droplets that are expelled by the wearer, and additionally, in certain circumstances to protect the wearer against splashes of potentially contaminated liquids. Medical masks are also be intended to be worn by patients and other persons to reduce the risk of spread of infections, particularly in epidemic or pandemic situations. Medical masks are certified to the Medical Devices Regulation (MDR) and are tested for compliance to EN 14683.[3,4]

The fit of medical face masks that are held in place by ear loops positioned behind the wearer's ears varies considerably from those with tie bands around the head and a nose clip that can be shaped to the wearer's nose. Different classes of surgical masks are based on their bacterial filtration efficiency, their breathability and their resistance to liquid splash.

There are three types of medical masks:

- Type I medical face masks are used in order to reduce the risk of the spread of infections via the droplet route (either worn by patients and health care workers).
- Type II medical masks are principally intended for use by healthcare professionals in an operating room or other medical settings with similar requirements.
- Type IIR medical masks are principally intended for use by healthcare professionals in an operating room or other medical settings with similar requirements and where additionally splash resistance protection is required for example such as those that might result from a human artery being punctured during surgery.

CEN certified healthcare respirators

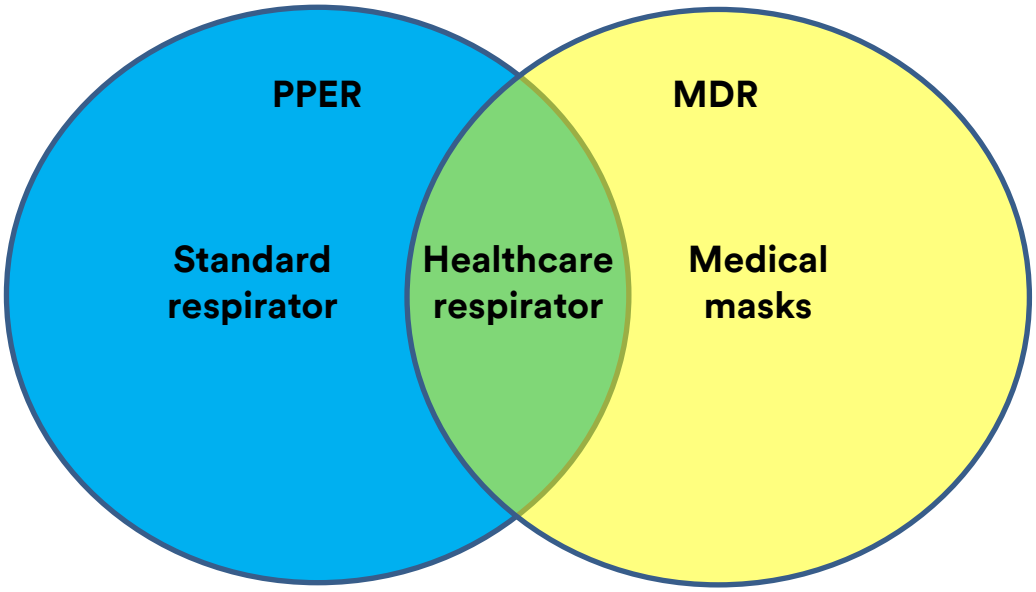
Some certified filtering facepiece respirators are designed to have the characteristics of both a certified respirator and a certified medical mask. In Europe, these products are tested to both EN 149:2001 (filtering facepieces) and EN 14683 (medical mask) standards and certified to both the Personal Protective Equipment Regulation and Medical Device Regulation.[1,2,3,4]

Comparing the differences

Putting this all together will help you differentiate between a CEN certified standard filtering facepiece respirator and a CEN certified healthcare filtering facepiece respirator. While similar in appearance, the key difference is the fluid resistance and the compliance with MDR.

But when is fluid resistance necessary?
Many tasks performed by healthcare workers – such as patient intake and non-emergency patient evaluation – pose little risk of generating high-pressure streams of liquid and are not considered surgical procedures. For workers performing such tasks, a primary potential hazard to consider is airborne droplet containing viruses and bacteria, such as those generated by coughs and sneezes, which can be effectively filtered by a properly selected and worn standard respirator.

Therefore, if a healthcare facility is prioritizing respirator use – due to, for example, limited supply during a health emergency – they may want to consider prioritising use of healthcare 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. For other healthcare workers who will not be performing such surgical procedures and do not, a standard filtering facepiece respirator can be worn to help reduce those workers' exposure to patient-generated airborne viruses and bacteria.



	Standard respirator	Healthcare respirator	Medical masks
Function	Help reduce particles inhaled by wearer	Help reduce particles both inhaled and expelled by wearer (plus fluid resistance)	Help reduce particles expelled by wearer into environment (plus fluid resistance)
Application	Can be used for respiratory protection when wearer might be exposed to particulate hazards	Meant to be used during surgery and other tasks during which both of these are true: • Wearer requires respiratory protection ...and... • Expelled particulates must be contained or fluid resistance is required	Can be used during surgery and other tasks to help protect patient, and/or when fluid resistance may be required

The following chart highlights some key similarities and differences between two FFP2 respirator models - the 3M Aura 1862+ healthcare respirator and the 3M Aura 9320+ standard respirator.

	3M Aura 1862+ Healthcare Respirator	3M Aura 9320+ Standard Respirator
Designed to help protect the wearer from exposure to airborne particles (e.g. Dust, mist, fumes, fibres, and bioaerosols, such viruses and bacteria)	✓	✓
Designed to fit tightly to the face and create a seal between the user's face and the respirator	✓	✓
Meets EN149 requirements for a minimum 94% filtration efficiency against solid and liquid aerosols	✓	✓
Certified under the MDR as a surgical mask	✓	✗
Not made with natural rubber latex	✓	✓
Fluid Resistant - Meets the requirements of EN14683 for splash resistance	✓ IIR	✗

For more details on 3M medical facemasks and surgical respirators, please refer to www.3m.com.

References

1. Personal Protective Equipment Regulation. Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32016R0425
2. EN 149:2001 +A1:2009 Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing, Marking. European Committee for Standardization, Brussels
3. Medical Devices Regulation. Regulation (EU) 2017/745 of the European Parliament and the Council of 5 April 2017 on medical devices https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32017R0745&from=EN
4. EN 14683:2019 Medical face masks - Requirements and test methods. European Committee for Standardization, Brussels

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