



IS 18266 : 2023, Textiles — Medical Respirator — Specification

Workers, primarily those in the health care profession, involved in treating and caring for individuals injured or sick, can be exposed to risk of inhaling hazardous airborne particles such as dusts, fumes, vapors, infectious agents and aerosol/fluids (for example splashes, sprays). A medical respirator is a device designed to protect the wearer from inhaling harmful airborne particles, gases, or vapors.

The key aspects of medical respirators are **filtration efficiency, Comfort and Breathability, Fit and seal**, Durability and Use and protection against different hazard like

- **Particulate Protection:** Filters out particles, dust, allergens, and pathogens (like bacteria or viruses).
- **Chemical Protection:** Some respirators also offer protection against harmful gases and vapors

Indian Standard IS 18266, developed by the Bureau of Indian Standards (BIS), outlines the performance requirements and test methods of medical respirator intended to be worn by operating room personnel/staff during surgical procedures and other healthcare services such as patient care.

The important test like **Penetration of filter, Inward leakage, CO₂ content, Cleanliness-microbial** ensure the protection from inhaling harmful airborne particles, gases, or vapors. **Splash resistance** protects from biological liquids capable of transmitting disease.

Breathing resistance check for **ease of breathing** while wearing the medical respirator. Biocompatibility Evaluation ensure that respirator are **non-irritant** and non-sensitizer to skin and free from **cytotoxicity**. Flammability (resistance to flame) to avoid the fire hazard while storage and use. The head harness are to designed for good fit and ease of wear-removal.

Medical respirators have been categorized into two classes based on performance IN95 and IN99 based on degree of protection offered by them.

The markings requirement provide crucial information like **Class of medical respirator; Instruction for use; Disposability instructions** — for safe disposal of the product as per Biomedical Waste Rules 2016; features of flammability (if available); biocompatible product — cytotoxicity, irritation and skin sensitization and other requirement as per Medical Device Rules, 2017.