

ISO 14644-3 Guidelines

High-Efficiency Particulate Air (HEPA) filters are critical in maintaining cleanroom air quality by removing airborne contaminants. To ensure optimal performance, HEPA filter validation is essential. ISO 14644-3 outlines the testing methods required to verify filter efficiency and integrity in cleanroom environments.

Why HEPA filter validation matters

HEPA filters play a vital role in controlling airborne particulate levels in cleanrooms used for pharmaceutical, semiconductor, biotechnology, and aerospace industries. Proper validation ensures compliance with regulatory requirements and prevents contamination that could compromise product integrity.

ISO 14644-3: Key testing procedures

ISO 14644-3 defines methodologies for testing cleanroom environments, including HEPA filter validation. The primary tests include:

1. **Leak Testing** – Identifies any bypass or pinhole leaks in the filter media or housing. Conducted using an aerosol challenge such as DEHS or PAO. These tests are performed on installation to ensure the HEPA filters are fit for purpose. By using filters that are Individually tested to EN1822 standards you can help reduce the onsite failure rate
2. **Airflow Velocity and Uniformity Testing** – Measures the airflow distribution to ensure consistent air movement across the cleanroom.
3. **Particle Counting** – Assesses airborne particle concentrations before and after filtration to verify compliance with ISO 14644-1 classification. Depending on the ISO class cleanroom that you are

required to maintain will give a target particle concentration. The chart shows what the target concentration levels are per cleanroom

ISO Class	Maximum Number of Particles in Air					
	(Particles in each cubic meter = or > the specified size)					
	Particle size					
	> 0.1 μm	> 0.2 μm	> 0.3 μm	> 0.5 μm	> 1.0 μm	> 5.0 μm
ISO Class 1	10	2				
ISO Class 2	100	24	10	4		
ISO Class 3	1000	237	102	35	8	
ISO Class 4	10000	2370	1020	352	83	
ISO Class 5	100000	23700	10200	3520	832	29
ISO Class 6		237000	102000	35300	8320	293
ISO Class 7				352000	83200	2930
ISO Class 8				3520000	832000	29300
ISO Class 9				35200000	8320000	293000

4. Filter Integrity Testing – A filter integrity test ensures that the filter meets efficiency standards and that the difference in particles that enter the room through the filter, depending on the filter used only 0.1% (H13) or 0.01% (H14 filters) of the pre filtration particulate levels should enter the controlled environment. These tests are conducted periodically to ensure the integrity of the cleanrooms air quality is maintained

5. Pressure Drop Testing – A filter with a high pressure drop consumes more energy. A pressure drop test Evaluates resistance to airflow, ensuring filters operate within acceptable limits without excessive energy consumption.

Best practices for HEPA filter validation

To achieve reliable test results and maintain compliance with ISO 14644-3, consider these best practices:

- Perform testing under operational conditions to assess real-world performance.
- Use calibrated instruments and certified aerosol generators.
- Conduct regular maintenance and revalidation to detect filter degradation over time.
- Document all test results for regulatory audits and quality control.

Ensuring compliance and cleanroom efficiency

Regular HEPA filter validation not only ensures ISO compliance but also enhances cleanroom efficiency, reducing contamination risks. Implementing a structured validation schedule helps maintain high-performance filtration and extends the lifespan of cleanroom equipment.