

# Standards, Regulations and Recommendations

## Ventilation Filters

### Standards

Year	Reference	Type of test	Classification
1968	ASHRAE 52.2	ARRESTANCE EFFICIENCY	MERV 1 - 20
1980	EUROVENT 4/5	ARRESTANCE EFFICIENCY	EU1 to EU4 - EU5 to EU9
1982	AFNOR NF X 44.012	ARRESTANCE EFFICIENCY	
1993	CEN EN 779	ARRESTANCE EFFICIENCY	G1 to G4 - F5 to F9
2003	CEN EN 779:2002	ARRESTANCE EFFICIENCY	G1 to G4 - F5 to F9

### The new standard for general ventilation filters EN 779:2002

1. Measurement of filter efficiency using modern particle counting technique
2. The aerosol challenge is DEHS (the same as used with HEPA filters)
3. Classification based on a particle size of 0.4  $\mu\text{m}$
4. The test includes initiatives to determine the discharged efficiency of filters to better represent their performance in use. These are shown in Annexe A.

### Why a new standard?

Certain types of filter media rely on an electrostatic effect to achieve a high level of efficiency whilst promising a low pressure drop for a given air volume.

It is important that users are aware of filters that rely on this electrostatic effect and are also informed about the degradation in efficiency once the electrostatic effect dissipates.

This new test procedure describes in Annexe 'A' a mechanism that removes the electrostatic effect by treating the filter material with Isopropanol. This discharges the filter and enables the real efficiency to be determined. The average efficiency of the filters after discharge is recorded on the certificate.

Filters are classified based on their performance against particles of 0.4  $\mu\text{m}$ . Filters in Group F must achieve an average efficiency greater than 40%; below this they are included in Group G.

### ASHRAE 52.2/EN779/EN1822 Cross Reference Table

ASHRAE 52.2	EN779 / EN1822
MERV 1	EN779 : G1
MERV 2	EN779 : G2
MERV 3	EN779 : G2
MERV 4	EN779 : G2
MERV 5	EN779 : G3
MERV 6	EN779 : G3
MERV 7	EN779 : G4
MERV 8	EN779 : G4
MERV 9	EN779 : G4
MERV 10	EN779 : F5
MERV 11	EN779 : F6
MERV 12	EN779 : F6
MERV 13	EN779 : F7
MERV 14	EN779 : F8
MERV 15	EN779 : F9
MERV 16	EN1822 : E10
MERV 17	EN1822 : H13
MERV 18	EN1822 : H13

ASHRAE 52.2	EN779 / EN1822
MERV 19	EN1822 : H14
MERV 20	EN1822 : H14

### EN 779:2002 Classification

EN 779:2002 standard		Average arrestance Am (%)	Average efficiency Em (%)	EUROVENT 4/5 equivalent
Filter group	Filter class	Filter class limits		Filter class
Coarse (G)*	G2	65 ≤ Am < 80	-	EU 2
	G3	80 ≤ Am < 90	-	EU 3
	G4	90 ≤ Am	-	EU 4
Fine (F) **	F5	-	40 ≤ Em < 60	EU 5
	F6	-	60 ≤ Em < 80	EU 6
	F7	-	80 ≤ Em < 90	EU 7
	F8	-	90 ≤ Em < 95	EU 8
	F9	-	95 ≤ Em	EU 9

Initial efficiency (Ea): \* Ea < 20% ; \*\* Ea  $\geq$  20%

Final pressure drop: \* 250 Pa ; \*\* 450 Pa

### Very High Efficiency Filters

#### Standards

Year	Reference	Type of test	Classification
1956	MIL STD 282	DOP	0.3 $\mu\text{m}$ -
1972	AFNOR NF X 44.011	Uranine	0.15 $\mu\text{m}$ -
1976	EUROVENT 4/4	NaCl	0.65 $\mu\text{m}$ EU10 to EU14
1995	CEN EN 1822	MPPS	0.1 to 0.2 $\mu\text{m}$ HEPA: E10 to H14 ULPA: U15 to U17

### EN 1822:2009 Classification

Filter group	Filter class	Minimum efficiency (%)	Maximum penetration (%)	Minimum P.C.	Minimum efficiency (%)	Maximum penetration (%)	Minimum P.C.
EPA (E)	E10	85	15	6.7	-	-	-
	E11	95	5	20	-	-	-
	E12	99.5	0.5	200	-	-	-
HEPA (H)	H13	99.95	0.05	2,000	99.75	0.25	400
	H14	99.995	0.005	20,000	99.975	0.025	4,000
ULPA (U)	U15	99.9995	0.0005	200,000	99.9975	0.0025	40,000
	U16	99.99995	0.00005	2,000,000	99.99975	0.00025	400,000
	U17	99.999995	0.000005	20,000,000	99.99999	0.0001	1,000,000

EPA: Efficiency Particulate Air (filter)

HEPA: High Efficiency Particulate Air (filter)

ULPA: Ultra Low Penetration Air (filter)

P.C.: Purification Coefficient

# Standards, Regulations and Recommendations

## Classification as per Eurovent 4/4 recommendation, NaCl method

EUROVENT 4/4	Initial efficiency Ei (%)	Penetration Pi (%)
Filter class	Limits of filter classes	
EU 10	$95 \leq Ei < 99.9$	$5 \geq Pi > 0.1$
EU 11	$99.9 \leq Ei < 99.97$	$0.1 \geq Pi > 0.03$
EU 12	$99.97 \leq Ei < 99.99$	$0.03 \geq Pi > 0.01$
EU 13	$99.99 \leq Ei < 99.999$	$0.01 \geq Pi > 0.001$
EU 14	$99.999 \leq Ei$	$0.001 \geq Pi$

## Clean rooms

### Classification of different air qualities required for manufacture of sterile products

Maximum number of particles per m <sup>3</sup> of a size greater than or equal to					Max. nbr. of $\mu$ organisms per m <sup>3</sup> (active)
0.5 $\mu$ m	0.5 $\mu$ m	0.5 $\mu$ m	0.5 $\mu$ m		
inactive (b)		active			
A	3.500	0	3.500	0	< 1
B	3.500	0	350,000	2.000	10
C	350,000	2.000	3.500,000	20,000	100
D	3.500,000	20,000	not defined (c)	not defined (c)	200

## Pharmaceutical industry

Guide to good Manufacturing Practice (2002) (b) Corresponds approximately to the US Federal Standard 209 E and ISO as follows: classes A and B to class 100. M 3.5. ISO 5; class C to class 10,000. M 5.5. ISO 7; class D to class 100,000. M 6.5 ISO 8.

### Comparison of international classification standards

Nbr of part 0.5 µm/ m³ (approx.)	US Fed. Std 209 E 1992		EN ISO 14644- 1 1996	France AFNOR NF X 44.101 1981	European Union Pharma industry Guide GMP 1989	Nbr of part 0.1 µm/ m³ (approx.)
-	-	-	ISO 1	-	-	10
1	-	-	-	-	-	35
4	-	-	ISO 2	-	-	100
10	M 1	-	-	-	-	350
35	M 1.5	1	ISO 3	-	-	1,000
100	M 2	-	-	-	-	3,500
353	M 2.5	10	ISO 4	-	-	10,000
1,000	M 3	-	-	-	-	35,000
3,530	M 3.5	100	ISO 5	4,000	A and B	100,000
10,000	M 4	-	-	-	-	350,000
35,300	M 4.5	1,000	ISO 6	-	-	1,000,000
100,000	M 5	-	-	-	-	-
353,000	M 5.5	10,000	ISO 7	400,000	C	-
1,000,000	M 6	-	-	-	-	-
3,530,000	M 6.5	100,000	ISO 8	4,000,000	D	-
10,000,000	M 7	-	-	-	-	-
35,000,000	-	-	ISO 9	-	-	-

## Permissible particle levels in different classes of clean rooms and clean zones

ISO classification CD 14644-1 (1996)	Maximum permissible concentrations (particles/m <sup>3</sup> of air) of particles of a size greater than or equal to the size shown below					
	0.1 $\mu$ m	0.2 $\mu$ m	0.3 $\mu$ m	0.5 $\mu$ m	1 $\mu$ m	5 $\mu$ m
ISO 1	10	2				
ISO 2	100	24	10	4	x	-
ISO 3	1,000	237	102	35	8	-
ISO 4	10,000	2,370	1,020	352	83	-
ISO 5	100,000	23,700	10,200	3,520	832	29
ISO 6	1,000,000	237,000	102,000	35,200	8,320	293
ISO 7	-	-	-	352,000	83,200	2,930
ISO 8	-	-	-	3,520,000	832,000	29,300
ISO 9	-	-	-	35,200,000	8,320,000	293,000

$$C = 10N(0.1/D)2.08 \text{ part / m}^3$$

## US Fed Std 209 E (1992)

	Maximum permissible concentrations (particles/m <sup>3</sup> of air) of particles of a size greater than or equal to the size shown below					
	0.1 $\mu$ m	0.2 $\mu$ m	0.3 $\mu$ m	0.5 $\mu$ m	1 $\mu$ m	5 $\mu$ m
M 1	-	350	75.7	30.9	10.0	-
M 1.5	1	1,240	265	106	35.3	-
M 2	-	3,500	757	309	100	-
M 2.5	10	12,400	2,650	1,060	353	-
M 3	-	35,000	7,570	3,090	1,000	-
M 3.5	100	-	26,500	10,600	3,530	-
M 4	-	-	75,700	30,900	10,000	-
M 4.5	1000	-	-	-	35,300	247
M 5	-	-	-	-	100,000	618
M 5.5	10,000	-	-	-	353,000	2,470
M 6	-	-	-	-	1,000,000	6,180
M 6.5	100,000	-	-	-	3,530,000	24,700
M 7	-	-	-	-	10,000,000	61,800

$$\text{particles / m}^3 = 10M(0.5/d)^2 \cdot 2$$

$$\text{particles / ft}^3 = Nc(0.5/d)^2 \cdot 2$$

## Air-conditioning / Comfort

### Air quality of premises with non specific pollution

Regulatory aspect		Recommendations
Labour code / Circular of application of decrees 84/1093-1094 dated 7/12/1984		UNICLIMA Air-conditioning & Health guide (1993)
Fresh air	Labour code Art. R235.2.6 Minimum arrestance efficiency 90% (G4 according to EN 779:2002)	Air-conditioning system inlet: 85% opacimetric (F7 according to EN 779:2002) Air-conditioning system outlet: 90% opacimetric (F8 according to EN 779:2002)
Recycled air	Labour code Art. R232.5.4 Minimum opacimetric efficiency 50% (F5 according to EN 779:2002)	85% opacimetric (F7 according to EN 779:2002)