VILAIR AAF CLEANROOM SYSTEMS

Ultra-clean environments for the biopharma industry

ISO cleanroom classifications

ISO standards for controlled environments

Adoption of ISO standards makes national standards such as AS 1386 redundant. The ISO standards shown below are complemented by ISO-14698, dealing with bio-contamination control and monitoring.

ISO-14644-1 Classification by Airborne Particles
ISO-14644-2 Monitoring for Compliance
ISO-14644-3 Measurement & Testing
ISO-14644-4 Design, Construction and Start-up
ISO-14644-5 Cleanroom Operations
ISO-14644-6 Terms, Definitions & Units
ISO-14644-7 Separative Enclosures
ISO-14644-8 Molecular Contamination

ISO air cleanliness classifications – Class limits (particles/m^3)

Classification number (N)	Maximum concentration limits (particles/m^3) for particles ≥ particle sizes shown					
	0.1 µm	0.2 µm	0.3 µm	0.5 µm	1 µm	5 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	1000000	237000	102000	35200	8320	293
ISO Class 7				352000	83200	2930
ISO Class 8				3520000	832000	29300
ISO Class 9				35200000	8320000	293000
Note: Uncertainties related to the measurement process require that data with no more than three (3) significant figures be used in determining the classification level.						

EU CGMP classifications

Grade	Maximum concentration limits (particles/m^3) for particles ≥ sizes shown			
	At rest (b)		In operation	
	≥ 0.5µm	≥ 5.0µm	≥ 0.5µm	≥ 5.0 µm
A	3500	0	3500	0
B (a)	3500	0	350000	2000
C (a)	350000	2000	3500000	20000
D (a)	3500000	20000	not defined (c)	not defined (c)

Notes:

(a) For B, C and D, the number of air changes should be related to the size of the room and the equipment and personnel present. The HVAC system should be provided with appropriate filters, e.g. HEPA for Grades A, B and C.

(b)The maximum permitted number of particles in the "at rest" condition correspond approximately to the US Federal Standard 209E & the ISO classifications as follows: Grades A and B ≈ Class 100, M 3.5, ISO 5; grade C ≈ Class 10 000, M 5.5, ISO 7 and Grade D ≈ Class 100 000, M 6.5, ISO 8.

(c) The requirement and classification limit for the area will depend on the nature of the operations carried out.

Cross-reference to AS 1386 and other standards

Standard	Classification					
ISO 14644-1	3	4	5	6	7	8
AS 1386	0.035	0.35	3.5	35	350	3,500
BS 5295	C	D	E/F	G/H	J	K
Federal Standard 209E	1	10	100	1,000	10,000	100,000
EU CGMP	-	-	A/B	-	C	D

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