

ISO 14644-1 : 2015 Cleanroom Classification

ISO 14644 is the international standard for cleanrooms and associated controlled environments.

Part 1 details the classification of air cleanliness by particle concentration.

This table details the air cleanliness classes by particle concentration within ISO 14644-1.

ISO Classification Number	Maximum allowable concentrations (particles/m ³) for particles equal to and greater than the considered sizes, shown below					
	≥0.1µm	≥0.2µm	≥0.3µm	≥0.5µm	≥1µm	≥5.0µm
ISO Class 1	10 ^b	d	d	d	d	e
ISO Class 2	100	24 ^b	10 ^b	d	d	e
ISO Class 3	1,000	237	102	35 ^b	d	e
ISO Class 4	10,000	2,370	1,020	352	83 ^b	e
ISO Class 5	100,000	23,700	10,200	3,520	832	d,e,f
ISO Class 6	1,000,000	237,000	102,000	35,200	8,320	293
ISO Class 7	c	c	c	352,000	83,200	2,930
ISO Class 8	c	c	c	3,520,000	832,000	29,300
ISO Class 9	c	c	c	35,200,000	8,320,000	293,000

Maximum permitted total particle concentration for classification by GMP grade

GMP Annex 1 details the maximum permitted particle concentrations for classification, for 'at rest' and 'in operation' states.

Clean room and clean air device classification, in relation to GMP Annex 1 (2015).

Grade	Maximum limits for total particle ≥0.5µm/m ³		Maximum limits for total particle ≥5.0µm/m ³	
	At rest	In operation	At rest	In operation
A	3,520	3,520	Not specified ^a	Not specified ^a
B	3,520	352,000	Not specified ^a	2,930
C	352,000	3,520,000	2,930	29,300
D	3,520,000	Not predetermined ^b	29,300	Not predetermined ^b

^a Classification including 5µm particles may be considered where indicated by the CCS or historical trends.

^b For grade D, in operation limits are not predetermined. The manufacturer should

establish in operation limits based on a risk assessment and routine data where applicable.

Comparison of Cleanroom Classifications

The 'at rest' limits for GMP, correspond with the limits for ISO classes.

This table below shows the ISO classes with the equivalent GMP grades. It also details the equivalent Federal Standard class.

Cleanroom Standard	Cleanroom Classification Guidelines					
	Class 3	Class 4	Class 5	Class 6	Class 7	Class 8
ISO 14644-1						
EU GMP (at rest)	-	-	A/B	-	C	D
Federal Standard 209E (replaced in 2001)	1	-10	100	1,000	10,000	100,000

The Federal Standard class was replaced by ISO 14644 in 2001.