

ISO 14644 Cheat Sheet

Cleanroom classification at a glance — particle limits, applications, GMP grade map.

ISO Class	≥0.1 µm	≥0.2 µm	≥0.3 µm	≥0.5 µm	≥1.0 µm	≥5.0 µm
ISO 1	10	—	—	—	—	—
ISO 2	100	24	10	—	—	—
ISO 3	1,000	237	102	35	—	—
ISO 4	10,000	2,370	1,020	352	83	—
ISO 5	100,000	23,700	10,200	3,520	832	—
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

2. EU GMP GRADE ISO 14644 MAPPING

GMP Grade	At Rest (ISO)	In Operation (ISO)	Typical Use
A	ISO 5	ISO 5	Sterile filling, aseptic operations (LAF/RABS/Isolator)
B	ISO 5	ISO 7	Background to Grade A (aseptic preparation)
C	ISO 7	ISO 8	Less critical aseptic stages (preparation of solutions)
D	ISO 8	Not defined	Less critical stages (component handling)

3. QUICK DECISION MATRIX

- **Particle counter location:** Worst-case sampling: near critical operations, return air, personnel zones
- **Number of sample points:** min $\sqrt{\text{Area (m}^2\text{)}}$; for ISO 5: ≥5 points/area
- **Sample volume (ISO 5+):** ≥2 m³ at the critical particle threshold
- **Recovery test (Annex 1):** Cleanroom must recover from contamination event in ≤20 min (Grade B)
- **Pressure cascade (Annex 1):** +10 to +15 Pa minimum between adjacent grades; A→B not enforced if same enclosure
- **HEPA filter classes:** H13 (≥99.95% MPPS) for Grade C/D; H14 (≥99.995%) for Grade A/B

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