

Using Legacy AeroTrak Portable Particle Counters for EU GMP Annex 1:2022 Classifications



Application Note CC-132 (US)

Introduction

The TSI AeroTrak™+ Portable Particle Counter A100 Series was introduced in 2023 with many new features to make taking airborne particle counts easier for a wide variety of applications. One of these was built-in functionality to assure that classification testing meets the requirements of the update to Annex 1 of the EU GMPs that was released in 2022. This includes automated checks against the maximum particle limits, minimum sample volumes/times, and minimum number of samples. It also includes the ability to generate reports that will provide a pass/fail result based on these requirements. This ensures easy compliance to this globally followed regulatory document. This is certainly beneficial for users who have the ability to replace their existing counters with new AeroTrak+ Portable Particle Counter A100 Series, however, that may not be possible for all users. Fortunately, existing legacy AeroTrak Portable Particle Counters are capable of providing the same functionality in most cases. The reason for this is the fact that one of the changes to Annex 1 involves aligning it with ISO 14644-1.



Alignment of Annex 1 and ISO 14644-1

The 2008 version of Annex 1 stated that classification should be performed in accordance with ISO 14644-1. Despite this declaration, it had several limits that did not align with those in the version of ISO 14644-1 that was effective at the time. A summary of these differences can be seen in Table 1. The update to ISO 14644-1 in 2015 resulted in even more differences. Most significantly, limits for $\geq 5 \mu\text{m}$ particles were removed for ISO 5 for the stated reason that, "Sampling and statistical limitations for particles in low concentrations make classification inappropriate." Therefore, testing per ISO 14644-1 may not comply with Annex 1 and so AeroTrak Portable Particle Counters provided the option to select which set of classification requirements, Annex 1 or ISO 14644-1, testing was to be performed against.

Table 1
2008 EU GMP Annex 1 Classification Limits

Grade	Maximum Limits for Total Particle $\geq 0.5 \mu\text{m}/\text{m}^3$ (ISO Class)		Maximum Limits for Total Particle $\geq 5 \mu\text{m}/\text{m}^3$ (ISO Class)	
	At Rest	In Operation	At Rest	In Operation
A	3 520 (ISO 5)	3 520 (ISO 5)	20 (1999 - ISO 4.8 2015 – Not specified)	20 (1999 - ISO 4.8 2015 – Not specified)
B	3 520 (ISO 5)	352 000 (ISO 7)	29 (1999 - ISO 5 2015 – Not specified)	2 900 (~ISO 7*)
C	352 000 (ISO 7)	3 520 000 (ISO 8)	2 900 (~ISO 7*)	29 000 (~ISO 8*)
D	3 520 000 (ISO 8)	Not Predetermined	29 000 (~ISO 8*)	Not Predetermined

*Actual ISO limits for Class 7 and Class 8 are 2 930 and 29 300, however, the 2008 version of Annex 1 stated these limits as equivalent to ISO 7 and ISO 8.

The update to Annex 1 in 2022 rectified this misalignment, see Table 2. The concentration limits are now identical to what is stated for all ISO classes, including ISO Class 7 and 8. In addition, limits for $\geq 5 \mu\text{m}$ particles have been removed for Grade A (at rest and in operation) and Grade B (at rest), making them equivalent to ISO 5. With this complete alignment, compliance to Annex 1 can be achieved by selecting ISO 14644-1:2015 and the appropriate Class for the room grade and status during zone configuration.

Table 2
2022 EU GMP Annex 1 Classification Limits

Grade	Maximum Limits for Total Particle $\geq 0.5 \mu\text{m}/\text{m}^3$		Maximum Limits for Total Particle $\geq 5 \mu\text{m}/\text{m}^3$	
	At Rest	In Operation	At Rest	In Operation
A	3 520 (ISO 5)	3 520 (ISO 5)	Not Specified	Not Specified
B	3 520 (ISO 5)	352 000 (ISO 7)	Not Specified	2 930 (ISO 7)
C	352 000 (ISO 7)	3 520 000 (ISO 8)	2 930 (ISO 7)	29 300 (ISO 8)
D	3 520 000 (ISO 8)	Not Predetermined	29 300 (ISO 8)	Not Predetermined

A possible complication to this approach is that users may want to classify for $\geq 5 \mu\text{m}$ particles for Grade A (at rest and in operation) and Grade B (at rest) areas. The likeliest reason for this is because Annex 1 continues to specify limits for monitoring these areas. It may therefore be logical to classify to the monitoring limits to avoid monitoring excursions. The stated limit for monitoring these areas is 29. This is equal to the ISO 5 classification limit from the 1999 version of ISO 14644-1. If these areas are to be classified against this limit, the best solution would be to select ISO 14644-1:1999 and a Class of 5 during zone configuration. This will assure that the particle counts are assessed against the proper limit and that the minimum sample volume is met. However, since the method for determining the minimum number of sampling locations changed with the 2015 version of ISO 14644-1, this requirement may not be properly assessed. This is because once a cleanroom has an area of $> 6 \text{ m}^2$, the 2015 version requires a higher number of sampling locations than the 1999 version did. Therefore, the number of sampling locations will need to be manually reviewed to assure compliance.

Conclusion

Annex 1 has long referenced ISO 14644-1 for cleanroom classification. Despite this, there were several differences in the defined limits between the two documents. The update to Annex 1 in 2022 removed these differences to achieve complete alignment. The result of this is that Annex 1 compliant classification testing can be achieved by selecting the appropriate ISO Class when using legacy AeroTrak Portable Particle Counters.



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