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Micronclean Whitepaper

A Practical Framework for Assessing Non-Standard Cleanroom Items using EN ISO 14644-18

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Abstract

The control of particulate contamination in cleanrooms depends not only on environmental systems but also on the materials and equipment introduced into the space. While EN ISO 14644-18 provides a framework for assessing the particulate release from cleanroom consumables, its application to non-standard items remains inherently subjective and lacks clear guidance on interpretation.

This whitepaper proposes a best practice approach to implementing Annex B of EN ISO 14644-18 for the assessment of non-standard consumables (items such as trigger sprays, bulk containers, stationery, and cleaning hardware). A pragmatic test methodology was developed by Micronclean, based on use case simulation, to replicate realistic particulate generation mechanisms for consumables. This ensures that the particulate measured from these items is representative of their normal use.

A key outcome of this work is the development of a calculation tool that translates the raw particle count data acquired from a consumable into an estimate of cleanroom impact. By incorporating environmental parameters such as air change rate and room volume, the tool enables determination of item suitability for specific ISO cleanroom classifications. A secondary model based on typical cleanroom conditions was also developed to provide context for results generated using alternative test methods. Together, these approaches bridge the gap between standard guidance and practical decision making.

This work proposes a structured and reproducible interpretation framework for Annex B of EN ISO 14644-18, combining use-case simulation with quantitative modelling to enable defensible, risk-based decisions on cleanroom suitability for consumables.

Introduction

The control of particulate contamination is fundamental to the operation of cleanrooms across many pharmaceutical, biotechnology, and technology manufacturing sectors. While significant emphasis is placed on air handling systems and personnel controls, the contribution of materials and equipment introduced into the cleanroom is often less well characterised.

EN ISO 14644-18 represents an important step towards harmonising the assessment of particulate release from cleanroom consumables. However, many items used routinely within cleanrooms do not fall neatly within the categories addressed by standardised test methods. These so-called 'non-standard items' include equipment such as trigger sprays, reusable containers, stationery, and cleaning hardware. Despite their widespread use in cleanrooms, their particulate contribution is rarely quantified in a structured or comparable manner.

Annex B of EN ISO 14644-18 [1] provides a mechanism for addressing this gap by allowing the development of an in situ bespoke test method based on intended use (for those consumables without dedicated particulate test methods). However, this standard is broad and 'high level', lacking the detail required to perform the test practically and reproducibly. Furthermore, the standard does not explicitly address how particulate data should be interpreted in the context of cleanroom classification limits.

This paper proposes a structured approach to applying Annex B in a way that is both practical and defensible. It also introduces a calculation tool designed to translate particulate generation data into cleanroom impact, thereby enabling more informed decisions regarding suitability.

Background

Non-standard items present several challenges when attempting to assess their particulate generation. Unlike traditional consumables, such as wipes or garments, these items typically have complex geometries, incorporate multiple materials, and are often used in highly variable ways. For example, a trigger spray involves moving mechanical components and intermittent actuation, while a mop handle may experience repeated varying movements and contact events.

These characteristics mean that conventional test methods may either fail to capture relevant particle generation mechanisms or introduce conditions that are not representative of real use. Many established methods, such as tumbling or drum-based systems, are designed around flexible, lightweight materials (e.g. garments or wipes) and rely on bulk mechanical agitation to induce particle release. While effective for those product categories, these approaches do not reflect how non-standard items behave in a cleanroom environment.

Non-standard items often generate particles through highly specific and localised mechanisms, including friction at contact points, intermittent mechanical actuation and surface abrasion during handling. For example, a trigger spray may generate particles through repeated actuation of internal components, while a rigid container or mop handle may release particles through handling, surface contact, or impact events. These mechanisms are typically directional, transient, and dependent on user interaction, rather than the continuous and uniform agitation applied in many instrument based methods.

As a result, conventional methods may misrepresent particulate behaviour, leading to either underestimation or overestimation of particle generation. They may underestimate particle generation by failing to replicate critical stress points or modes of use, particularly where particle release is driven by specific mechanical interactions rather than general agitation. Alternatively, they may overestimate particle generation by subjecting items to excessive or non-representative mechanical forces, leading to particle release that would not occur under normal use conditions. As defined in EN ISO 14644-18, cleanroom suitability is the "ability of an item to maintain the critical control attributes or conditions of any clean zone when used as intended".

In addition to these fundamental limitations, practical constraints further restrict the applicability of standard instruments. Methods such as the Helmke drum have finite capacity and are not designed to accommodate larger or rigid items such as a 5L container or an isolator cleaning tool. Attempting to test such items may not only be impractical but may also risk damage to the equipment and/or consumable.

The non-standard consumable items selected for this study, including trigger sprays, 5L RFU containers, cleanroom stationery, and mop/isolator cleaning hardware, were chosen specifically because they exemplify these challenges. Each required careful consideration of how it is used in practice, in order to obtain meaningful particulate test results.

Annex B of EN ISO 14644-18 provides a flexible framework for the assessment of items that are not covered by any current standardised methods (i.e. Helmke drum IEST-RP-CC003.4 [2] for garments, or LPC IEST-RP-CC004.3 [3] for wipes). Annex B prescribes a loose procedure, that requires the user to interpret and implement based on the intended use of the item. Whilst this flexibility is essential for addressing a wide range of item types, it also places significant responsibility on the user to justify methodological choices. Without a structured approach, different users may develop markedly different test methods for similar items, limiting comparability and reproducibility.

In this study, Annex B was treated as a framework within which a consistent and repeatable methodology could be developed. Emphasis was placed on ensuring that test conditions were representative of real world use while maintaining sufficient control to allow meaningful comparison between items.

Methodology

The methodology developed in this study was based on the principle that particulate generation should be assessed under conditions that closely reflect actual use.

Set up:

- Within a cleanroom, a direct test zone of 1m^2 area centred below a unidirectional filter, with an 8m^2 clearance zone, is required (see figure 1).
- A fixed position particle counter, programmed to measure particles/m^3 (≥0.5µm) for 3 minutes, was used, with a sampling inlet approximately 20cm below the test item.
- The user of the consumable item should be dressed appropriately for the grade of cleanroom.

Method:

- A background particulate reading of the cleanroom should be taken.
- The user then steps into the direct test zone and conducts motions pretending to use the item being tested, but without the item present. This should be conducted for 3 minutes whilst another particulate reading is taken. This motion should be predetermined, controlled and precise.
- The user is then handed the consumable test item, and the same motions should be repeated whilst another particulate reading is taken.
- Each consumable should be tested at least in triplicate, with a new consumable being opened for each reading.

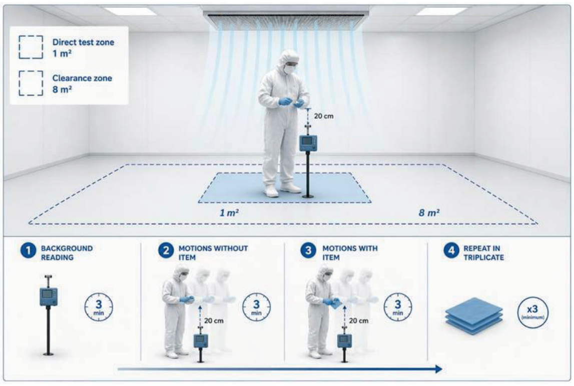

Figure 1: Micronclean proposed method for measuring non-standard consumable particulate release.

A test zone of 1m^2 was chosen so that there would be no airflow disruption or particulate contribution other than that contributed by the user and the consumable test item. Similarly, within the additional 8m^2 it is recommended that there are no personnel and only static equipment below the level of the particle counter.

The consistent distance between the items being tested and the particle counter, allowed differences in particle counts to be attributed primarily to the items themselves rather than variations in the test setup. 20cm was chosen as the optimum distance (close enough to allow maximum collection of particulate coming from the consumable, whilst far enough away that the consumable does not block the airflow to the particle counter).

Each item was subjected to a defined handling procedure designed to replicate its typical use. This procedure must also be predetermined, controlled and precise (so as to ensure accurate and repeatable particulate measurements). For trigger sprays, large containers, and pens Micronclean would propose that others adopt the following replicated movements:

- *Trigger Sprays:* Hold the trigger spray stationary 20cm above the particle counter with one hand. Depress the trigger handle normally every 3 seconds for the full 3 minutes.
- *Large Containers:* Holding the container upright in both hands, unscrew the cap and remove. Tilt the container 90° as if pouring liquid out, for 10s. Return the container upright and screw the cap back on. Hold the container stationary for 10s. Repeat cycle.
- *Cleanroom Pens:* Remove the pen cap/click the pen button. Mime the action of writing 'squiggling' the pen in the air 20cm above the particle counter, for 10s. Replace the cap/click the pen button. Hold the pen stationary vertically for 10s. Repeat the cycle.

The movements used to replicate the real use of each consumable will likely be the largest source of variation between cleanrooms, unless a standard set of movements is adopted by all.

It is important to note that any item that usually contained liquid was empty for the purpose of the test to prevent liquid droplets from providing false particulate readings.

Background particle levels were measured prior to testing, and multiple replicates were performed to assess variability. A background reading of the operator performing the motion of using each item, without the item present was also taken. This was then subtracted from the reading obtained from the operator using the consumable item, as this was seen as the particulate contributed by the operator and their movements, rather than the item. This also minimises the impact of operator variance across items. This approach assumes that operator derived and item derived particle sources are additive and independent. While this may not fully capture interaction effects, it provides a pragmatic and repeatable way to isolate item contribution.

Data Interpretation

The particulate readings recorded during the test cannot be used alone to determine the suitability of the given consumable for a specific ISO grade of cleanroom. Instead, information about the room in which the item is to be used is also required. These numbers then need to be compared to established particulate limits in order to assess suitability.

The conditions of the specific cleanroom are also important, as an item that generates a relatively high number of particles during a brief handling event may have a negligible impact in a cleanroom with a high air change rate. Conversely, an item that produces a lower but continuous level of particulate may contribute more significantly over time, particularly in environments with lower airflow.

EN ISO 14644-18 provides several different formulae to make this translation from measured data to cleanroom impact, which takes both environmental conditions and established particulate limits into account (see figure 2). However, this is complex and requires multiple inputs and assumptions by the user. As a result, there is a risk that decisions are made based on incomplete or misleading interpretations of test results.

$$C = \frac{S}{\varepsilon \cdot Q} \qquad \Delta C = \frac{2 \cdot S_{cons}}{Q}$$

$$S_{cons} = \frac{\Delta C \cdot Q}{2} \qquad S_{cons} = \frac{\Delta C_a \cdot Q_a}{2}$$

Figure 2: Some of the equations found in Annex B of EN ISO 14644-18 to help convert particulate data into cleanroom impact.

To address this limitation, Micronclean developed a user friendly calculation tool to convert measured particle counts into an estimate of their impact on cleanroom particle concentrations. The calculator is based on the principles and equations outlined in Annex B of EN ISO 14644-18.

The tool incorporates inputs from the measured particle counts, as well as environmental parameters such as clean air flow rate and ventilation effectiveness. Using these inputs, the calculator estimates the contribution of the item to steady state particle concentrations within the cleanroom. This output can then be compared directly with ISO classification limits [4], allowing a determination to be made of a consumable's suitability for a given environment (see figure 3).

EN ISO 14644 Annex B: In-room measurement of consumable particulate

Inputs	
Background particulate without the consumable (particles/m³)	196
Particulate with consumable present (particles/m³)	1229
Measured clean airflow for the cleanroom (m³/min)	13.3
Ventilation effectiveness ε (0.3–1.0; 0.5 default)	0.5

Selector	
ISO class (≥0.5 µm)	5
Is consumable Sterile?	Yes
Equivalent GMP Grade	A/B

Decision	
Suitable for selected ISO class?	YES

Calculations	
Change in particulate (particles/m³)	1033
Consumable particulate (particles/min)	6869
ISO limit (particles/m³)	3520
Allowable max particulate (particles/min)	22105

Figure 3: The Micronclean EN ISO 14644-18 Annex B Consumable Cleanroom Suitability Calculator.

Results

Following this method, Micronclean have tested their non-standard consumables to be able to provide customers with guidance on the suitable ISO grade. The results of this can be seen in table 1 below.

Product	Average Background Particulate Reading (particles/m³)	Average Product Particulate Reading (particles/m³)	Difference (particles/m³)	Suitable for ISO Grade	Equivalent GMP Grade
Trigger Spray	90	200	110	ISO 4	A/B
5L RFU	126	299	173	ISO 4	A/B
Ballpoint Pen	101	141	40	ISO 4	A/B
Marker Pen	62	137	75	ISO 4	A/B
IPA Resistant Pen	79	200	121	ISO 4	A/B
Munising Paper	114	161	47	ISO 4	A/B
Cleanroom Paper	196	1228	1032	ISO 5	C/D (non-sterile)
Mop Hardware	141	310	169	ISO 4	A/B (when sterilised before use)
Isolator Cleaning Tool	141	182	41	ISO 4	A/B (when sterilised before use)

Table 1: Results obtained using the methodology and calculator described.

Cleanroom paper exhibited higher particle generation than the other items tested, likely due to fibre shedding during handling. In contrast, rigid polymer-based items such as pens and trigger sprays demonstrated lower emission rates, consistent with reduced material fragmentation. Munising cleanroom paper showed lower particle generation than standard cleanroom paper due to the inclusion of plastic to seal fibres and minimise particulate generation.

Discussion

This approach represents a significant shift from just reporting particle counts of consumables to evaluating their practical impact in the area in which they will be used. It enables a practical and context driven assessment, supporting more informed decision making. It also fills gaps for non-standard cleanroom consumables, that were previously not tested, or tested using a method not suitable for them.

However, it is important to recognise the limitations of the approach. Manual agitation introduces some degree of variability, and the assumptions built into the calculator may not fully capture complex airflow dynamics within all cleanroom environments. As such, the method should be viewed as a tool to support, rather than replace, comprehensive contamination control strategies. This method should not be used to replace established test methods for standard cleanroom items, but instead to fill gaps for non-standard items that cannot currently be tested. When an established test method already exists for testing a particular type of consumable, such as LPC or Helmke drum testing, these methods should be used in preference to the Annex B method. The flowchart in figure 4 describes the decision-making flow to be used when selecting the correct method.

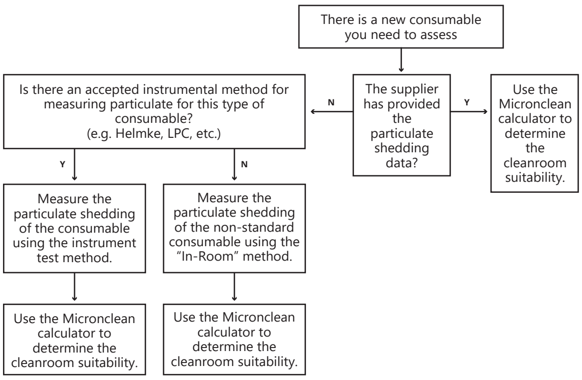

Figure 4: Decision making flowchart for determining the cleanroom suitability of consumables.

It is important to understand the particulate values obtained in the context of a cleanroom, regardless of which test method was used. Therefore, the Micronclean calculator was developed to also inform this. Using representative values for parameters such as air change rate and room volume, users can input particulate data from methods such as the Helmke drum or liquid particle counters and obtain an approximate indication of cleanroom impact and thus the suitable ISO grade for such consumables. This allows the same principles and level of analysis to be applied across all cleanroom consumables (see figures 4 and 5).

EN ISO 14644-18 Annex B: Separate Instrumental Consumable Particulate

Inputs	
Consumable particulate from separate instrumental test method (particles/min)	99880
Cleanroom/Isolator volume (m³)	75.0
Ventilation effectiveness ε (0.3–1.0; 0.5 default)	0.5

Selector	
Target ISO class	4
Is consumable Sterile?	Yes
Equivalent GMP Grade	A

Decision	
Suitable at Stated ISO at Low Air Change?	NO
Suitable at Stated ISO at High Air Change?	YES

Calculations	
ISO limit (particles/m³)	352
Air Change Low	600
Air Change High	1200
Air Flow Low (m³/min)	750
Air Flow High (m³/min)	1500
Typical background % contribution at rest	25
Background particulate without the consumable (particles/m3)	88
Change in particulate low (particles/m³)	266
Change in particulate high (particles/m³)	133
Change + Background Low	354
Change + Background High	221
Allowable Max Particulate low (particles/min)	99000
Allowable Max Particulate high (particles/min)	198000

Figure 5: The Micronclean EN ISO 14644-18 Annex B Consumable Cleanroom Suitability Calculator for consumables with provided instrumental particulate results.

Micronclean would propose that this methodology be adopted for the assessment of 'non-standard' cleanroom consumables and that universal usage simulation patterns for reproducible testing be adopted in practice. We hope that this study will allow for the cleanroom industry to adopt a consistent methodology according to the EN ISO 14644-18 framework and provide all cleanroom users with a quick and easy methodology for assessing new cleanroom consumables.

Conclusion

The methodology developed in this study demonstrates that Annex B of EN ISO 14644-18 can be applied in a structured and practical manner to assess non-standard items. By focusing on realistic use conditions and maintaining a consistent measurement setup, it is possible to generate data that is both meaningful and reproducible.

The introduction of the Micronclean cleanroom impact calculator addresses a key gap by providing a means of interpreting collected particulate data in context. This enables users to move beyond qualitative or relative assessments and towards quantitative, risk-based decision making.

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