

# ISO 14644-18:2023, Assessment of suitability of (cleanroom) consumables

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## Introduction

In the 4th quarter of 2023, cleanroom standard ISO 14644-18 on the assessment of the suitability of consumables has been published. The document is prepared by ISO TC209 Working Group 11, that also developed the suitability assessment standards ISO 14644-14:17 and ISO 14644-15:2018. The aim of the document is to inform the customer on how to set requirements and the supplier on providing data that can be acquired by existing measurement methods and other relevant data of the considered consumable for use in the considered cleanroom, clean zone or controlled zone. It also informs on how to perform the assessment of that suitability. ISO 14644-18 complements cleanroom operations as outlined in ISO 14644-5.

## Consumables

A consumable is an item that is used for operations in a cleanroom. It can be disposed or reprocessed after use. A consumable has one or more functional properties, that are important for its use. Consumables are divided into personal and non-personal consumables.

Functional properties of personal consumables are there to protect the cleanroom from contamination by a person and sometimes to protect the person from potential harm by a process. Many personal consumables, such as cleanroom clothing, are person dependent because of its size and shape.

Most non-personal consumables are used for cleaning, such as wipes, swabs and mops. Other consumables are for example packaging materials and consumables for measurement.

In the standards an overview of personal and non-personal consumables is given and their function is described.

## Contaminants

In the standards, unwanted particles and chemical substance are treated as contaminants. In special cases micro-organisms can be a contaminant. Other than a sterility requirement of a consumable, this contaminant is not treated. Important are the surface cleanliness and the emission rate of contaminants during use.

In case of particles, the impact of the particle generation on the air cleanliness at the location of use must be considered. The air cleanliness can be expressed as the cumulative concentration of particles  $\geq$  a size of interest per  $\text{m}^3$  at a critical location (ISO 14644-2:2015), or as a class limit during operation (ISO 14644-1:2015), and the surface cleanliness in the cumulative concentration per  $\text{m}^2$  (ISO 14644-9:2022).

In case of chemical contamination, the impact of the emission of chemical substances on the air cleanliness at the location of use must be considered. The air cleanliness can be expressed as the mass in  $\text{g}/\text{m}^3$  at a critical location (ISO 14644-8:2022), and the surface cleanliness as the mass in  $\text{g}/\text{m}^2$  (ISO 14644-10:2022).

## Customer requirements

For the selection of consumables, the functional properties and the intended use are important. For example, for shielding products their barrier function, and for cleaning consumables, their cleaning efficiency are important. The consumable can be single use or multiple use.

For the cleanroom suitability, potential adverse effects on the cleanliness levels must be investigated. By performing an impact assessment of the vulnerable product or process, the required air cleanliness at the critical location can be determined. By investigating potential direct or indirect contacts with the product, the required surface cleanliness level of a consumable can be determined.

The emission of contaminants by consumables depends on the source strength (in amount/s) of the observed contaminant per  $\text{m}^2$  of consumable times the amount of consumables in  $\text{m}^2$  that are used in the time the critical product is exposed. By using the ventilation equation of ISO 14644-4:2022, the expected increase in airborne concentration is determined by the sources strength of the consumable  $S_{\text{consumable}}$  divided by the effective air supply  $\epsilon \cdot Q$ . Worst case the ventilation effectiveness  $\epsilon$  is  $\frac{1}{2}$ , so with the air supply volume rate  $Q$  the increase of the contaminant concentration  $\Delta C \leq 2 \cdot S_{\text{consumable}}/Q$ .

The impact of surface cleanliness depends on the number of contacts  $n$ , the surface cleanliness and contact area. In general  $\Delta C_s = n \cdot \eta \cdot C_{s\text{consumable}}$  where  $\eta$  is the transfer efficiency, which is in average 0,1 and maximum 0,2.

From the critical process, the maximum acceptable contribution by the applied consumable can be estimated. This information can be used to determine the maximum emission rate and surface cleanliness of the considered consumable.

The standard provides guidance on how to determine requirements. Limits can also be determined by monitoring and comparing the impact by different consumables.

Next to functional and suitability requirements, various potential special properties are listed.

## Consumable properties

The supplier has designed the functional and application properties of a consumable. For various types of consumables, several test methods for functional and cleanliness aspects are available. The supplier can use these measurement methods, to provide data of the considered consumable. The standard gives an overview of measurement methods per parameter per type of consumable.

If the consumer needs data, for which no standard measurement methods is available, the customer and supplier can agree on the applied measurement method.

Next to the properties of the consumable, the supplier has designed the packaging of the consumable and the suitability of the inner packaging should also be considered.

## Assessment

After analysis the product or process, a consumable can be assessed for its functional and other properties, emission limits and cleanliness levels. This work is input for the requirements of the consumable. In a table, requirements can be compared with data provided by the supplier.

To make a final decision, a list of criteria can be made to come to a final decision. Next to functionality and cleanliness, costs, packaging, delivery time etc. can be included.

## Conclusion

ISO 14644-18:2023 provides a structured approach to evaluate cleanroom consumables. Unfortunately no new measurement methods are introduced. Many available measurement methods are not up to date and not for all relevant parameters proper measurement methods are given.