INTERNATIONAL STANDARD

**ISO 14644-18**

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# Cleanrooms and associated controlled environments —

## Part 18: Assessment of suitability of consumables

*Salles propres et environnements maîtrisés apparentés —*

*Partie 18: Évaluation de l'aptitude à l'emploi des consommables*



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# Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 209, *Cleanrooms and associated controlled environments*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 243, *Cleanroom technology*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

A list of all parts in the ISO 14644 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

# Introduction

Cleanrooms and associated controlled environments are used for the control of contamination to levels appropriate for performing contamination-sensitive activities.

Products and processes that benefit from the control of contamination include those in industries such as aerospace, microelectronics, optics, displays, nuclear, micro-mechanical devices, consumer goods, cosmetics and life sciences (e.g. pharmaceuticals, medical devices, food). Contamination control in the healthcare sector benefits the patients by enabling access to products free of potentially harmful particles.

Consumables are widely used during preparation and operations in cleanrooms, clean zones or controlled zones to maintain the air or surface cleanliness level in the cleanroom by shielding a contamination source or a vulnerable object or by removing contamination from a surface. For monitoring and testing purposes, consumables can be used for sampling contamination. Consumables need to be carefully selected and appropriately used in order to maintain cleanliness levels and mitigate risk for processes and products.

Consumables are used for a limited time only. They do not constitute a part of the final product.

This document addresses the suitability assessment of consumables for use in cleanrooms, clean zones or controlled zones in respect to contamination in air and on surfaces by:

— particles;

— chemicals;

— microorganisms.

Customers or users need to have the opportunity to assess a given consumable by matching their intended use requirements with the designed use data of the supplier. This can be supplemented by additional tests. This match of intended use and designed use is addressed as appropriate use.

Depending on the use case, an impact assessment to determine the kind and acceptable quantity of contamination from consumables can be derived by benchmarking the requirements with respect to emission of contaminants.

This document is written for suppliers (manufacturers of consumables or distributors) and customers (as users of consumables) to assess the cleanroom suitability of consumables.

The cleanroom suitability assessment always has to be accompanied with a description of use, technical data as required by the nature of the consumable and test results. A sole statement such as “suitable for cleanroom of classification ISO 5” is not foreseen, due to the variety and complexity of use cases and the likelihood that a cleanroom suitability assessment would not rely on test data relating solely to airborne particle emissions.

# Cleanrooms and associated controlled environments —

# Part 18:
# Assessment of suitability of consumables

## 1 Scope

This document gives guidance for assessing personal and non-personal consumables for their appropriate use in cleanrooms, clean zones or controlled zones, based on product and process requirements, cleanliness attributes and functional performance properties. The cleanliness attributes addressed are particles or chemicals in air or on surfaces. Biocontamination (viable particles, microorganisms or pyrogens) is considered as a special property of consumables. Identification of associated risks are considered.

This document complements cleanroom operation as outlined in ISO 14644-5.

This document gives guidance concerning:

— determination of cleanroom suitability of consumables in general;

— specification of requirements for an intended use of a consumable by the customer with respect to functional performance, cleanliness attributes and special properties;

— specification of properties for a designed use of a consumable by supplier;

— assessment of a consumable for an appropriate use;

— documentation.

Informative annexes are used to list examples for personal and non-personal consumables, verification methods for cleanliness attributes testing and the potential impact of consumables on a cleanroom.

Cleaning agents, disinfectants and lubricants are considered as consumables with respect to their packaging, as their packaging is likely to have cleanliness requirements in common with all consumables.

This document does not apply to:

— design details of consumables;

— testing of functional performance of materials, e.g. barrier properties of gloves, wear and slip resistance of flooring;

— health and safety requirements; legal requirements can apply in specific countries;

— cleanability;

— (raw) materials which are added within the production process as ingredients;

— performance or function testing;

— transport containers;

— process media such as gases or liquids;

— the functional performance of cleaning agents, disinfectants and lubricants.

## 2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 14644-1, *Cleanrooms and associated controlled environments — Part 1: Classification of air cleanliness by particle concentration*

ISO 14644-8:2022, *Cleanrooms and associated controlled environments — Part 8: Assessment of air cleanliness by chemical concentration (ACC)*

ISO 14644-9, *Cleanrooms and associated controlled environments — Part 9: Assessment of surface cleanliness for particle concentration*

ISO 14644-10:2022, *Cleanrooms and associated controlled environments — Part 10: Assessment of surface cleanliness for chemical contamination*

## 3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

**3.1**
**air cleanliness by chemical concentration**
**ACC**
quantity of chemical detected in the air, expressed in terms of an ISO-ACC level N, which represents the maximum allowable concentration of a given chemical species or a group of chemical species

Note 1 to entry: Units: $g/m^3$.

Note 2 to entry: This definition does not include macromolecules of biological origin, which are judged to be particles.

[SOURCE: ISO 14644-8:2022, 3.1.2, modified — Units moved to note to entry.]

**3.2**
**appropriate use**
application matching *designed use* (3.12) and *intended use* (3.13) within acceptable limits

Note 1 to entry: This use is typically stated by the customer of the *consumable* (3.9).

**3.3**
**chemical contamination**
non-particulate substances that can have a deleterious effect on the product, process or equipment

[SOURCE: ISO 14644-8:2022, 3.1.1]

**3.4**
**cleanliness**
condition not exceeding a specified level of *contamination* (3.10)

Note 1 to entry: In this document, *contamination* (3.10) refers to particles, chemicals or viables.

[SOURCE: ISO 14644-14:2016, 3.1, modified — Note to entry added.]

**3.5**
**cleanroom**
room within which the number concentration of airborne particles is controlled and classified, and which is designed, constructed and operated in a manner to control the introduction, generation and retention of particles inside the room

Note 1 to entry: The class of airborne particle concentration is specified.

Note 2 to entry: Levels of other cleanliness attributes, such as chemical, viable or nanoscale concentrations in the air, and also surface cleanliness in terms of particle, nanoscale, chemical and viable concentrations can also be specified and controlled.

Note 3 to entry: Other relevant physical parameters can also be controlled as required, e.g. temperature, humidity, pressure, vibration and electrostatic.

[SOURCE: ISO 14644-1:2015, 3.1.1]

**3.6**
**cleanroom suitability**
ability to maintain the critical control attributes or condition of any *clean zone* (3.7) when used as intended

[SOURCE: ISO 14644-14:2016, 3.3, modified — Note 1 to entry deleted.]

**3.7**
**clean zone**
defined space within which the number concentration of airborne particles is controlled and classified, and which is constructed and operated in a manner to control the introduction, generation and retention of contaminants inside the space

Note 1 to entry: The class of airborne particle concentration is specified.

Note 2 to entry: Levels of other cleanliness attributes, such as chemical, viable or nanoscale concentrations in the air, and also surface cleanliness in terms of particle, nanoscale, chemical and viable concentrations can also be specified and controlled.

Note 3 to entry: A clean zone can be a defined space within a *cleanroom* (3.5) or can be achieved by a separative device. Such a device can be located inside or outside a *cleanroom* (3.5).

Note 4 to entry: Other relevant physical parameters can also be controlled as required, e.g. temperature, humidity, pressure, vibration and electrostatic.

[SOURCE: ISO 14644-1:2015, 3.1.2]

**3.8**
**compatibility**
state of which at least two things are able to exist without adverse effect

Note 1 to entry: All types of *contamination* (3.10) emitted from the consumables under consideration that could have an impact on the quality of the product or process shall be taken into account.

**3.9**
**consumable**
item for use and disposal, if applicable, within *cleanrooms* (3.5) and controlled environments

**3.10**
**contamination**
unwanted matter in an undesirable location

[SOURCE: ISO 14644-13:2017, 3.4]

**3.11**
**controlled zone**
designated space in which the concentration of at least one contamination category (particles, chemical, biocontamination) in air and on surfaces is controlled and specified and which is constructed and used in a manner to minimize the introduction and impact of contamination

Note 1 to entry: Levels of cleanliness attributes such as chemical and viable concentrations in the air or cleanliness in terms of particle, chemical and viable concentrations on surfaces should be specified.

Note 2 to entry: Other relevant parameters may also be controlled as necessary, e.g. temperature, humidity and pressure, vibration and electrostatic.

Note 3 to entry: A controlled zone can be a defined space within a *cleanroom* (3.5) or may be achieved by a separative device. Such a device can be located inside or outside a *cleanroom* (3.5).

[SOURCE: ISO 14644-15:2017, 3.9, modified — deleted "by class(es)" in Note 1 to entry]

**3.12**
**designed use**
application as foreseen for a specified purpose and *shelf-life* (3.17)

Note 1 to entry: This is typically stated by the manufacturer or supplier of the *consumable* (3.9).

**3.13**
**intended use**
application in accordance with a specified purpose

Note 1 to entry: This is typically stated by a user, customer or third party of the *consumable* (3.9).

**3.14**
**material**
single substance or composite

Note 1 to entry: It can be necessary to provide material in a representative form to enable testing.

[SOURCE: ISO 14644-15:2017, 3.13]

**3.15**
**personal consumable**
*consumable* (3.9) that is worn by a person

**3.16**
**service life**
period of time or number of cycles a consumable is suitable for use

Note 1 to entry: Service life is dependent on *appropriate use* (3.2).

**3.17**
**shelf-life**
specified period of time from the date of manufacture of a product to its labelled expiration date

[SOURCE: ISO 18369-1:2017, 3.1.9.10]

**3.18**
**verification**
confirmation, through the provision of objective evidence, that specified requirements have been fulfilled

Note 1 to entry: The objective evidence needed for a verification can be the result of an inspection or of other forms of determination such as performing alternative calculations or reviewing documents.

Note 2 to entry: The activities carried out for verification are sometimes called a qualification process.

Note 3 to entry: The word “verified” is used to designate the corresponding status.

[SOURCE: ISO 9000:2015, 3.8.12]

# 4 Description and cleanroom suitability properties of consumables

## 4.1 Types of consumables

Consumables consist of 2 types:

a) Personal consumables: consumables worn by personnel, primarily to protect the product and process from contamination emitted by the wearers, see A.2. Personal consumables can also have a special function to protect the person wearing them. Fit, function and comfort are important aspects for personal consumables.

b) Non-personal consumables, see A.3.

In Annex A, examples of typical consumables are described.

## 4.2 Properties of consumables

### 4.2.1 General

Consumables are used operationally in a clean controlled environment to both maintain the cleanliness of this environment and facilitate the product realization process. However, due to their high use rate, and their proximity to the process and product, consumables can also pose a considerable risk of contamination with particles, chemicals or material of biological nature, such as microorganisms or pyrogens. Depending on the type, consumables can be either disposed of after a single use or reprocessed to the required quality for multiple use within a cleanroom.

In principle, consumables can be selected for three main properties:

a) functional performance properties;

b) cleanliness attributes;

c) special properties.

These properties and attributes can be generic or specific and apply to both types of consumables, personal or non-personal.

### 4.2.2 Functional performance properties

Functional properties are the starting point for consumable selection for use in a cleanroom, clean zone or controlled zone. All necessary functional performance properties for a consumable shall be considered. The following list can be used as an input for the consideration:

a) cleaning properties;

b) sorption;

c) physical properties;

d) chemical compatibility;

e) breathability, if applicable;

f) barrier protecting the cleanroom or controlled environment or process;

g) barrier protecting personnel;

h) application of liquids to surfaces;

i) surface protection;

j) abrasion resistance.

### 4.2.3 Cleanliness attributes

Cleanliness attributes address the contaminant of concern and how the implementation of a personal or non-personal consumable affects the overall cleanliness level when being used in a cleanroom or controlled environment. In order to be able to assess the cleanroom suitability of a consumable, it has to be specified which contaminants, such as particles, fibres, chemicals and microorganisms, are of interest. Therefore, the cleanliness attributes shall be captured at least by:

a) contaminant of concern (see Clause 5);

b) maximum concentration of contaminant(s) of concern at observed airflow conditions;

c) transfer of contamination (direct or indirect).

Biocontamination can be addressed as a special property, either as sterility or bioburden (number of contaminants and species). In addition, pyrogens can be assessed as applicable.

### 4.2.4 Special properties

Examples of special properties related to cleanroom suitability are:

a) antistatic or static dissipative properties;

b) supply chain management and logistics:

   1) quality management systems;

   2) batch or lot information or certification(s);

c) biocontamination sensitive processes:

   1) specific sterilization methods, packaging marking, etc.;

   2) material compatibility with sterilization processes;

   3) bioburden or sterility;

   4) pyrogens;

   5) cleaning or disinfecting consumables;

      i) particle filtration;

      ii) residue requirements;

d) appearance and texture (e.g. woven or non-woven);

e) dry or wet used;

f) recycling.

## 4.3 Intended use

The intended use shall be documented by the customer along with the consumable description. It shall take into consideration functional performance properties, cleanliness attributes and special properties, if applicable. A clear description of the intended use enables selection of the most suitable consumable(s)

for assessment. If known, reference should be made to the corresponding ISO classification of the controlled environment, including the cleanroom ventilation in which the consumable will be used.

### 4.4 Consumable use

#### 4.4.1 Single-use

Single-use consumables are designed to be used once and then disposed of. Regarding disposal, the consumable should be designed to be recyclable, wherever feasible. Single-use consumables are used at a discrete process stage or for a specified period and then discarded. A consumable is typically single-use.

#### 4.4.2 Multiple-use

Multiple-use consumables are designed to be used multiple times for a limited period of time and then disposed of. Regarding disposal, the consumable should be designed to be recyclable, wherever feasible. Multiple-use consumables are capable of being reprocessed and, when required, resterilized in order to be used again. When deciding for multiple-use, a full life cycle assessment can be applied to identify a good sustainable option.

The reprocessing shall ensure that the consumable continues to meet the functional, cleanliness and special requirements through periodic evaluation or testing. The number of reprocessing cycles that the consumable can undergo shall be specified and monitored. Ongoing conformity to requirements and reprocessing cycles shall be documented.

## 5 Contaminant of concern

### 5.1 General

A consumable can cause contamination by particles (including microorganisms), pyrogens or chemicals contamination by emission into the air of the controlled environment or onto a surface, either by contact transfer or deposition. Annex B provides methods that can be used to estimate the acceptable contamination from a consumable.

Contamination within a consumable or on its surface can be transferred into a liquid and by subsequent deposition can remain as a residue on a surface.

### 5.2 Emission of contaminants into the air

Particles as defined in ISO 14644-1 or larger particles as addressed in ISO 14644-17 can be emitted from the consumable by various mechanisms. Units and concentrations can be found in ISO 14644-1.

Chemical species as defined in ISO 14644-8 can be emitted from the consumable by various mechanisms. Examples of chemical species and concentrations can be found in ISO 14644-8.

### 5.3 Surface contamination by contact transfer

A consumable can transfer particles or chemicals onto surfaces in the cleanroom by contact. Units, chemical species and concentrations can be found in ISO 14644-9 and ISO 14644-10.

### 5.4 Surface contamination via liquids

Consumables can contaminate liquids with particles or chemicals. Contaminated liquids can create contaminated surfaces. Examples for chemicals can be found in ISO 14644-10.

# 6 Cleanroom suitability assessment prerequisites

## 6.1 General

This clause describes the steps and considerations that need to be taken by a customer and a supplier to facilitate a cleanroom suitability assessment of a consumable. Documented data gathered during this activity enables an effective comparison-based assessment. A consumable can then be selected on the basis of its cleanroom suitability for an intended use case.

This clause does not address the numerous formal risk and hazard quality assessment methods available. It is intended to highlight considerations that could negatively affect the cleanroom suitability assessment of a consumable, should they be ignored.

## 6.2 Considerations

The customer shall provide requirements of the consumable, taking into consideration 4.1 to 4.4 and Clause 5, together with an explanation of its intended use. Typical customer requirements for the consumable are described in Clause 7.

The supplier shall provide, upon request, a description and data for the designed use of the consumable, e.g. functional performance properties and cleanliness attributes. This information is usually made available in data sheets.

## 6.3 Associated risks

For any cleanroom suitability assessment, the user shall consider making a judgement regarding how critical the required consumable is to its cleanroom or controlled environment and product quality. This risk-based judgement can influence the depth of requirements gathering and the rigour of the assessment, plus the need for any subsequent verification activity, should the comparison-based assessment alone be judged to be insufficient. This judgement can be updated following the cleanroom suitability assessment, and prior to deployment of the consumable, as it can influence the scale of any final verification activity.

Separately, when mitigating personal safety hazards, the design of the personal protective equipment (PPE) consumable can present an associated contamination source. The selection of a consumable for its PPE function shall also include an evaluation of the potential for contamination with regard to its intended use. This evaluation can lead to measures to minimize the impact of this contamination source.

## 6.4 Requirements, properties and cleanliness attributes

For the intended use of a consumable, customers shall specify their requirements for:

a) functional performance properties;

b) cleanliness attributes;

c) special properties.

The specification shall follow Clause 7.

NOTE It is expected that the more critical a consumable is to the cleanroom or controlled environment, the more comprehensive the requirements and the related documentation.

Suppliers provide information on a consumable's properties as outlined in Clause 8 to allow a comparison between customer requirements and supplier data provided. Should additional data be required for the customer's cleanroom suitability assessment, the supplier can provide this data, if readily available. Alternatively, new data can be created by testing the consumable specifically.

The final assessment of cleanroom suitability (see Clause 9) is a comparison of information provided by the customer (Clause 7) and supplier (Clause 8).

### 6.5 Sustainability

Due to their high usage volumes and predominance of single-use, organizations involved within the creation, distribution and use of consumables shall address sustainability and thereby reduce their environmental impact.

a) Manufacturers should implement a formal environmental management programme that addresses impact mitigation ranging from energy and waste reduction to resource conservation generally and finally optimum materials selection and recycling.

b) Companies involved in the distribution of consumables should address waste and energy reductions via efficient logistics. Furthermore, they should enable material returns processes.

c) User companies should follow a formal environmental management programme. All users should segregate waste materials at source to enable either material repurposing or recycling. Recycling initiatives should also be enabled via the upstream supply chain (design for recyclability).

d) The sustainability of a consumable should be considered using a holistic approach. From production, reprocessing, use to final disposal or recycling.

## 7 Customer requirements

### 7.1 General

To enable the subsequent comparison assessment for cleanroom suitability of a consumable, gathering and documenting the customer (user) requirements is a key step. The content of this clause is intended to supplement existing selection and approval processes, which can exist, for example, as part of a customer quality management system.

### 7.2 Description and intended use

The customer shall describe the consumable for use within a cleanroom or controlled environment. Importantly, the intended use of the consumable shall also be documented so that potential suppliers can offer appropriate consumables and associated data for comparison.

### 7.3 Requirements for consumable assessment

#### 7.3.1 Functional performance properties

The following requirements (in no specific order) for functional performance properties shall be considered and the results shall be documented:

a) primary function, plus any secondary functions (should they exist);

b) materials for construction, important design and fabrication attributes;

c) relevant functional test methods and criteria if known, see Annex C;

d) single-use or multiple-use;

e) anticipated use cycles (e.g. using a wiper four folds);

f) expected service life;

g) shelf-life;

h) any additional performance attributes;

i) fit, function and comfort for personal consumables;

j) chemical compatibility requirements;

k) packaging regime.

Any additional specific requirements for functional performance properties shall also be documented.

### 7.3.2 Cleanliness attributes

The following requirements (in no specific order) for cleanliness attributes shall be considered and the results shall be documented:

a) destination cleanroom or controlled environment, with reference to International Standards;

b) contaminants of interest;

c) relevant cleanliness test methods, acceptance criteria and available test results, see Annex C;

d) judgement on criticality of the consumable to maintaining the customer's specified cleanliness levels;

e) primary packaging;

f) secondary packaging, if applicable;

Any additional specific requirements for cleanliness attributes shall also be documented.

### 7.3.3 Special properties

The following requirements (in no specific order) for special properties shall be considered and the results shall be documented:

a) sterility, including requirements for specific sterilization methods;

b) bioburden and species identification;

c) pyrogens;

d) regulatory-related requirements;

e) antistatic or static dissipative properties;

f) reprocessing requirements, if applicable;

g) personal protection function;

h) packaging material(s);

i) logistics;

j) lot identification or information;

k) required certificate(s);

l) supply chain information.

Any additional specific requirements for special properties shall also be documented.

# 8 Consumable properties as designed by the supplier

## 8.1 General

To facilitate the assessment for cleanroom suitability of a consumable, the supplier shall provide design and relevant application characteristics for the consumable.

NOTE Generic supplier information is usually provided in the form of data sheets.

## 8.2 Description and designed use

The supplier shall describe the consumable and its designed application(s) for use within a cleanroom or controlled environment.

## 8.3 Consumable properties and attributes

### 8.3.1 Functional performance properties

The following consumable functional performance properties (in no specific order) shall be considered:

a) designed functions;

b) materials of construction, important design and processing attributes;

c) performance properties and related test methods, see Annex C;

d) barrier properties, if applicable;

e) sizing and fit, if applicable;

f) use-cycle limitations;

g) expected service life;

h) shelf-life;

i) storage conditions;

j) chemical compatibility;

k) packaging.

Additional functional performance properties can exist for specific consumable designs and applications. If they are included for consideration, they shall also be documented.

### 8.3.2 Cleanliness attributes

The following consumable cleanliness attributes (in no specific order) shall be considered:

a) processing cleanroom or controlled environment, in accordance with ISO 14644-1, ISO 14644-8, ISO 14644-9, ISO 14644-10;

b) contaminants of interest,

c) relevant cleanliness test methods, acceptance criteria and available test results, see Annex C;

d) primary and secondary packaging information, if applicable.

NOTE For particles, the sizes can be of interest.

Additional cleanliness attributes can exist for specific consumable designs and applications. If they are included for consideration, they shall also be documented.

### 8.3.3 Special properties

The following consumable special properties (in no specific order) shall be considered.

a) sterilization methods and material compatibility to sterilization method;

b) bioburden and species identification;

c) pyrogens;

d) antistatic or static dissipative properties;

e) reprocessing information and associated logistics for multiple-use consumables;

f) personal protection functions or exclusions;

g) packaging material;

h) overall logistics;

i) lot identification or information;

j) required certificate(s);

k) supply chain information;

l) regulatory-related requirements.

Additional special properties can exist for specific consumable designs and applications, and if they are included for consideration, they shall also be documented.

## 8.4 Supplier quality documentation

Elements of the supplier's quality management system and related compliance adherence can form part of the customer's requirements with respect to a cleanroom suitability assessment. As an assessment progresses, supporting documentation from sub-suppliers can also be requested.

Following a successful assessment, supplier documentation can require updating. These updates can include:

a) operations and logistics documentation;

b) sub-supplier quality data and certifications;

c) testing results databases;

d) technical and application data sheets.

NOTE Operations can include manufacturing, total supply chain and quality control.

# 9 Assessment

## 9.1 General

The consumable assessment is primarily a comparison between documented customer requirements and supplier-provided data for a consumable, as outlined in Clause 7 and Clause 8.

An assessment can:

— be a straightforward comparison of customer requirements against published supplier data (see 9.2);

— be supplemented with the provision of additional data for functional performance properties, cleanliness attributes or special properties (see 9.3);

— include a verification step in order to show that the assessment based on submitted data is valid, and to quantify and mitigate any associated risks judged to exist with the consumable's appropriate use (see 6.3).

Comparison of supplier data using published data can be done if test methods are known. Sufficient test methodology shall be made available to allow reproducible test results.

NOTE The most valid comparisons can be obtained through side-by-side testing.

For worked examples see Annex D.

## 9.2 Initial comparison

Having identified and documented their requirements, along with a description of both the consumable and its intended use, the customer shall perform a comparison of their requirements against available design characteristics for the consumable. If no information or data gaps are identified, the customer may finalize the assessment at this stage and therefore select a consumable (see 9.4).

## 9.3 Detailed comparison

If comparison gaps have been identified, it can be impossible to select a consumable following an initial requirements comparison only. In this case, an assessment of additional supplier data is required. For example, this could be a results requirement for a specific cleanliness test. This additional data shall either be made available by the supplier upon request or, should it not exist, it can be created by testing of a consumable. This testing may be carried out by the supplier, customer or an independent third party.

## 9.4 Cleanroom suitability assessment

Consumables are considered suitable for a use case when an assessment has concluded that, when using the consumable appropriately, the cleanliness requirements or specifications for a process or product are not adversely affected.

Upon the completion of either an initial or detailed comparison, the customer may finalize the assessment for an intended use case and select a consumable.

It can be necessary for the selection of a consumable to compromise between functional performance properties, cleanliness attributes and special properties. Any compromise influencing the cleanroom suitability assessment shall be documented. Any previous analysis of associated risks shall be revisited.

A conclusion statement shall describe the consumable and its intended use, along with the requirements comparison data. Only the customer or third party may generate and document this conclusion.

## 9.5 Implementation

If a judgement on associated risks with the use of the consumable as intended rank sufficiently highly, then prior to full implementation the consumable shall be verified against its intended use. The verification process can vary between personal and non-personal consumables and intends to quantify whether any negative cleanliness impacts arise during appropriate use. Negative impacts could arise due to contamination emissions from the consumable or be related to the performance of a barrier function.

The findings of any previous assessment of associated risks should be taken into account.

The cleanroom suitability assessment statement can require subsequent updating.

# 10 Documentation

## 10.1 General

The documentation shall contain required information to give documented evidence for a final cleanroom suitability assessment. It starts from the customer's use case and specified intended use, includes the supplier's documentation for this or a similar use case (designed use) and ends with the documentation of the cleanroom suitability assessment by the customer or a third party.

## 10.2 Initial customer's documentation

The customer documentation shall include information and requirements which have been used to describe the use case (intended use) and how the cleanroom suitability assessment is related to the use case of a customer.

The documentation consists of, but is not limited to the following:

a) description of the consumable;

b) description of the intended use, including the location where the use occurs, e.g. on a tool, surface or product;

c) requirements for functional performance properties for the intended use;

d) requirements for cleanliness attributes for the intended use (see Clause 5);

e) requirements for special properties for the intended use;

f) requirement(s) for test results and related methods, if applicable;

g) reference to standards or guidelines to be applied;

h) customer's name;

i) person(s) stating the requirements;

j) date when the requirements were stated.

## 10.3 Supplier documentation

The supplier documentation shall include sufficient information to enable the two-stage assessment as outlined in 9.2 and 9.3.

The following information shall be provided:

a) description of the consumable;

b) description of the designed use case;

c) image of the consumable as it is;

d) image(s) of the consumable in its primary packaging and its secondary packaging, if applicable;

e) functional performance properties for the designed use case;

f) cleanliness attributes for the designed use case (see Clause 5);

g) technical data sheets, including material(s) of construction;

h) supplier, manufacturer and manufacturing site;

i) person(s) and function providing the information;

j) date when the information was stated.

### 10.4 Assessment documentation

The assessment documentation has to allow retracing to information provided by the supplier or customer and, if applicable, for any specific design or use case. It shall establish documented evidence for a consumable's cleanroom suitability when appropriately used.

The documentation consists of, but is not limited to the following:

a) description of the consumable;

b) image of the consumable as presented for its assessment;

c) image of the consumable in its primary packaging and its final packaging;

d) sample or lot number, including sample size used, of the consumable being used for the assessment;

e) involved parties (customer, supplier);

f) documentation which has been used for the assessment:

   1) provided by the customer;

   2) provided by the supplier;

   3) any additional testing, including test results and description;

g) supply chain assessment, if applicable;

h) manufacturing process assessment, if applicable;

i) gap analysis results and rationale for initial comparison-only conclusion or conclusion based on detailed comparison, as specified in 9.2 and 9.3;

j) description of the appropriate use;

k) conclusion of the assessment, including remaining risks associated with the appropriate use of the consumable;

l) name(s) of the person(s) performing the assessment;

m) organisation(s) of the person(s) performing the assessment;

n) date of the assessment.

# Annex A
(informative)

# Personal and non-personal consumables

## A.1 General

In this annex, examples of typical consumables are described. The consumables are divided into personal and non-personal consumables.

Personal consumables are worn by cleanroom personnel and typically fit different sizes of men and women. They fulfil a barrier function to shield the cleanroom or controlled environment or process from contamination emanating from the person. Some personal consumables are intended to protect the person from the environment or from materials associated with the process (chemical substances) that are used.

Non-personal consumables are used generally by a person to fulfil a specific function. These consumables can be mass-produced or dedicated products.

Each consumable has a set of functional performance properties, cleanliness attributes and special properties which can be set as requirements. In this document, the focus is on their impact on cleanliness attributes.

## A.2 Personal consumables

### A.2.1 Garments

Garments can be single-use or multiple-use. Garments are expected to meet the requirements after any decontamination processing. Garments have a barrier function and should cover the person as required. Their cleanroom suitability decreases after use since the person contaminates the garment. Multiple-use garments can degrade through wear and damage. Reprocessing cycles are therefore limited.

There are many tests on physical properties, durability and comfort of the garments. In respect of contamination, the barrier function and the cleanliness are important.

### A.2.2 Gloves

Cleanroom gloves are used to shield the cleanroom or controlled environment from skin particles, microorganisms and fingerprints. In some applications, gloves are used to protect the user from negative impacts of chemical or biological materials or extreme temperatures. Gloves are generally single-use. In some cases, gloves are multiple-use and can be reprocessed.

Gloves limit the sense of touch and precision manipulation. Therefore, the selection is an optimization of various requirements. Sometimes, two pairs of gloves are used. With respect to cleanroom suitability, the barrier function, cleanliness and integrity of the gloves are important.

### A.2.3 Face masks

A face mask shields the cleanroom or controlled environment from facial contamination, such as skin flakes, hair, saliva and aerosols. In some designs, a face mask contains a breathing filter to protect the user from harmful fumes or microbiological contamination. The material of the face mask can have an influence on the contamination. Face masks are generally single-use, but there are face masks which can be reprocessed.

### A.2.4 Covers

Head and beard covers create a barrier between a hairy skin and the cleanroom or controlled environment. The main function is to prevent hairs entering the cleanroom or controlled environment . Therefore, it is important that all the hairy parts of the skin, including beard, are fully covered. Head and beard covers are single-use.

Shoe covers create a barrier between a shoe and the cleanroom or controlled environment. The main function is to prevent sand, hairs, fibres and other particles entering the cleanroom or controlled environment. The strength of a shoe cover is important, since it can release many particles when it breaks during use. Shoe covers are single-use. Static dissipative shoe covers are available.

### A.2.5 Goggles

Goggles shield the cleanroom or controlled environment from facial contamination. These contain particles and microorganisms. Goggles can also be used to protect the eyes. Goggles are typically made from non-shedding material.

## A.3 Non-personal consumables

### A.3.1 Wipers

A wiper is a wiping material that can be used to clean a surface, to remove spilled liquid or to apply disinfectant. There are foam, non-woven, knitted and woven wipers. The application determines the material used. The material can also be a source of contamination. For critical applications, the finishing of the edges is important for reduction of the release of larger particles and fibres. Edges can be ultrasonic or laser cut and can be sealed. In some applications, the emission and extractability of chemicals should be considered. It should be noted that certain wiper materials leave residues on the cleaned surface which can emit contaminants afterwards.

### A.3.2 Swabs

A swab can be considered as a piece of wiping material on a stick or with a flexible support. A swab can be used either to clean a location with respect to the presence of particulate, microbiological or chemical contaminants or to take a surface sample. There are foam, non-woven and knitted swabs. The application determines the swab head material used. The material can also be a source of contamination. For critical applications, the finishing of the edges is important for reduction of the release of larger particles and fibres. In some applications, the emission and extractability of chemicals should be considered.

### A.3.3 Mops

A cleanroom mop is used to clean flat surfaces such as floors, walls and ceilings. For cleaning purposes, they are designed to have an efficient pick up of particles and fibres. For disinfection purposes, they have a capacity to release a variety of cleaning agents on the surface. Mops can be single-use or multiple-use and can be foam, knitted, non-woven or woven. They can have complex structures, especially when microfibres are used, and therefore present a challenge to effective reprocessing. When using mops, the potential re-release of particles and the extraction efficiency of chemicals are important aspects, especially following reprocessing.

### A.3.4 Others

There are many other consumables in a cleanroom, such as tapes, labels, note utensils (paper or pens), packing material and packaged consumables such as test media, e.g. agar plates, contact plates or witness plates.

# Annex B
(informative)

# Impact of consumables on cleanroom cleanliness levels

## B.1 General

Consumables can help to reach required cleanliness levels by posing a barrier function or by collecting surface contamination during cleaning. However, they can also contribute to contamination by excessive emission of unwanted contaminants in air and by contact transfer on surfaces. In this annex, the potential negative impact of consumables is addressed. The proposed formulae and calculation offer a simplified method to estimate the acceptable impact of consumables. With respect to air cleanliness, a separated approach to personal and non-personal consumables is proposed.

## B.2 Air cleanliness

### B.2.1 Air cleanliness by chemical concentration (ACC)

For impact of consumables on air cleanliness by chemical concentration (ACC), see ISO 14644-15.

### B.2.2 Air cleanliness by particle concentration (ACP)

The impact of consumables on the air cleanliness by particle concentration (ACP) is determined by:

— transfer of contaminants per total surface area of a consumable applied per $m^2$ cleanroom area;

— emission of contaminants per surface area of the consumable per time.

The contaminants considered are particle numbers (particles ≥ 0,5 µm and ≥ 5 µm as well as fibres with a length ≥ 100 µm) and mass of unwanted chemical species (in grams).

Time can be selected in seconds, minutes or hours. $S$ could also be seen as the maximum source strength used during the design of the cleanroom.

The achieved air cleanliness $C$ in a given cleanroom is determined by the total contamination source $S$ and the effective ventilation with clean air $\varepsilon \cdot Q$, as shown by Formula (B.1) for non-unidirectional air flow (see ISO 14644-4:2022, B.3.1):

$$C = \frac{S}{\varepsilon \cdot Q} \tag{B.1}$$

where

$C$ is the air cleanliness limit in contamination concentration, expressed in number of particles per $m^3$;

$S$ is the source strength during operation, expressed in number of particles per min;

$\varepsilon$ is the ventilation effectiveness;

$Q$ is the amount of clean supply air, expressed in $m^3$ per min.

NOTE The emission and dilution by air supply vary in time and position with respect to a consumable.

In a good non-unidirectional cleanroom, the ventilation effectiveness is $\varepsilon$ = 0,7. In a worst-case analysis, a ventilation effectiveness $\varepsilon$ = 0,5 can be used for the calculation. In an unidirectional air flow, the value of 0,5 is often too low compared to the real ventilation efficiency.

For worst-case evaluation, the change in air cleanliness by contamination from a consumable $S_{cons}$ and the effective ventilation with clean air $\varepsilon \cdot Q$, where $\varepsilon$ = 0,5, is given by Formula (B.2).

$$\Delta C = \frac{2 \cdot S_{cons}}{Q} \tag{B.2}$$

where

$\Delta C$ is the increase of the airborne particle concentration caused by the consumable, expressed in number of particles per $m^3$;

$S_{cons}$ is the source strength caused by the consumable, expressed in number of particles per min.

If the acceptable increase of the airborne particle concentration is known, the maximum emission of the consumable can be determined by Formula (B.3).

$$S_{cons} = \frac{\Delta C \cdot Q}{2} \tag{B.3}$$

The expected increase in airborne concentration is limited by the overall air cleanliness requirements.

To estimate the impact of a consumable, the state with and without the consumable can be compared. In most cases this is done locally. The ventilation efficiency can locally be smaller than the overall ventilation efficiency and be smaller than 0,5.

Formulae (B.1), (B.2) and (B.3) can be used for the location of interest by transferring them to an expression per $m^2$. Then the average local source strength and average local air supply is $S_a$ and $Q_a$ per $m^2$. These values can be multiplied with the area of interest.

The source strength of the consumable in the considered area is added to a state without the considered consumable. Then Formula (B.4) gives the local estimation:

$$S_{cons} = \frac{\Delta C_a \cdot Q_a}{2} \tag{B.4}$$

where

$S_{cons}$ is the source strength of the consumable, expressed in contamination per min per $m^2$;

$C_a$ is the air cleanliness limit at the considered location in contamination concentration, expressed in number of particles per $m^3$;

$Q_a$ is the amount of clean supply air, expressed in $m^3$ per min per $m^2$.

The expected increase in airborne concentration is limited by the local air cleanliness requirements.

The data to be used in the evaluation described in the following clause depends on the consumable to be considered.

## B.3 Personal consumables

Personal consumables consist of cleanroom clothing, face masks and gloves. The impact of cleanroom clothing is discussed in this subclause. To analyse the impact of other personal consumables, the state with and without these consumables is considered.

In the case of cleanroom clothing, the complete cleanroom and the number of persons can be considered. In this case the source strength without personnel is taken. This value can be determined by measuring the air cleanliness with running equipment but without personnel.

Then the acceptable increase in airborne particle concentration can be determined by Formula (B.5).

$$\Delta C = C - C_{\text{equip}} \tag{B.5}$$

where

$C$ is the air cleanliness limit at the considered location in contamination concentration, expressed in number of particles per $m^3$;

$C_{\text{equip}}$ is the achieved air cleanliness at the considered location with running equipment without personnel, expressed in number of particles per $m^3$;

The acceptable contribution by personnel $S_{\text{pers}}$ can be determined with Formula (B.6).

$S_{\text{pers}}$ is determined by the number of persons, their activity and their resulting emission, the efficiency of the barrier function of the cleanroom clothing and the emission by the cleanroom clothing, see Formula (B.6).

$$S_{\text{pers}} = N \cdot (P \cdot f + E) \tag{B.6}$$

where

$S_{\text{pers}}$ is the source strength;

$N$ is the number of persons;

$P$ is the average particle dispersion per person without cleanroom clothing, expressed in number of particles per min;

$f$ is the filter efficiency (ratio incoming and outgoing particles);

$E$ is the number of particles emitted per set of cleanroom clothing per min.

$(P \cdot f + E)$ can be obtained from a body box test. This analysis is not valid for larger particles that cannot be removed by airflow.

The filter efficiency and emission rate are parameters related to the garments. The average dispersion of a person can be estimated using published data.

Since the impact of personnel on air cleanliness is very high, the determination of the impact of personnel can be done when determining the required supply air volume rate in the design phase.

## B.4 Non-personal consumables

Since a non-personal consumable is used locally, Formula (B.7) can be used to determine the acceptable contribution by the considered consumable $S_{\text{cons}}$. The local air supply and the acceptable increase of the airborne concentration at the considered location can be determined.

When the emission data and used area of the consumables is known, then the contribution to the source strength is determined by Formula (B.7).

$$d = \frac{S_{\text{cons}}}{A_{\text{cons}}} \tag{B.7}$$

where

$d$ is the emission rate during intended use, expressed in contamination per min;

$A_{cons}$ is the used consumable area per $m^2$ cleanroom area.

## B.5 Surface cleanliness

Factors that influence the surface cleanliness are determined by:

— the total surface area of consumables applied per $m^2$ surface area;

— the inherent cleanliness of the consumable;

— the release of contaminants during contact;

— the transfer rate and the surface cleanliness of the consumable.

The contaminants considered are particle numbers (particles ≥ 0,5 µm and ≥ 5 µm as well as fibres with a length ≥ 100 µm) and mass of unwanted chemical species (in grams).

The impact on the surface cleanliness depends on the type of contact. If this is only a stationary contact then the contact area, the difference in surface cleanliness and the transfer efficiency determine the surface contamination.

The transfer efficiency for particles is somewhere between 2 % and 20 %, depending on the type of surfaces and the applied forces. In the worst-case analysis, 20 % may be used. If the transfer cannot be measured, 10 % may be applied as an initial estimate.

If friction causes release of contamination, 20 % of the released contamination to the surface cleanliness can be added. The supplier can reduce this contribution by supplying with a surface cleanliness equal to or better than SCP grade level 4 (surface cleanliness by particle concentration, see ISO 14644-9).

# Annex C
(informative)

# Test methods

## C.1 General

The test methods can be applied to measure the surface cleanliness of consumables and to measure the emission of particles or chemicals of a consumable in their intended use. For emission tests, various industry-specific and consumable-specific test methods are available. It is important that the test conditions reflect the intended use (e.g. by standardised mechanical or thermal agitation). At present, there are only a limited number of test methods available that are either specifically written for consumables or that can be applied for consumables to be used in cleanrooms.

It is up to the customer to check whether the test methods are correctly applied and the stated results can be adequately applied for the intended use case's cleanroom suitability assessment.

For the evaluation of attributes influencing the cleanliness levels, Table C.1 provides information on standards or guidelines in which test methodology or input for assessment are given, depending on the contaminant of concern. The table is not exhaustive. Test methods for functional performance properties and special properties are not addressed.

**Table C.1 — Common evaluation methods applicable for consumables for cleanliness attributes**

| Example of consumable | Description | Reference | Result | Comment |
|---|---|---|---|---|
| Garments<br>Head covers<br>Shoe covers | Test method for measuring the linting of nonwovens in the dry state | ISO 9073-10 | Particles or fibres per $m^3$ | Test modified for particle and fibre release by mechanical stress (modified Gelboflex test).<br>Test may be applied to other flexible fabrics, but can be inappropriate for non-personal consumables. |
| Garments<br>Head covers | Particle retention capacity or tightness (airborne particles) | VDI 3926 Blatt 1:2004, 1.2 | Mass (g) per filter membrane and particle concentration in an air volume (number of particles per $m^3$) | Method for evaluation of barrier function of textiles (function performance with influencing cleanliness levels). |
| Garments<br>Head covers | Standard test method for sizing and counting particulate contaminant in and on cleanroom garments | ASTM F51/F51M-20 | Particles or fibres per 0,1 $m^2$ of fabric | The test method for particulate sizing and numbers on garments is non-destructive and may be used to evaluate the contamination levels of fibres and particles on and in cleanroom garments. The test may be used for evaluating the cleanliness levels of new or cleaned garments. The test method includes vacuuming particles and fibres from the surface of a fabric. |

[a] Currently, there are no test methods for mops. It is possible to adapt wiper test methods for mops.

**Table C.1** *(continued)*

| Example of consumable | Description | Reference | Result | Comment |
|---|---|---|---|---|
| Garments<br>Head covers | Garment system considerations for cleanrooms and other controlled environments | IEST-RP-CC003.4:2011, B2.4 | Emissions in number of particles per min | The test chamber is designed to move air in a unilateral direction from the top to the bottom and the particles are sampled via the return air plenum. This test measures the release of particles to the smallest channel in the particle counter. Particle dispersion test (body box): this test uses a specified test chamber (1,22 m × 1,22 m × 2,44 m) to measure the particles dispersed by a person performing a set of simulated cleanroom actions. |
| | | IEST-RP-CC003.4, B2.5 | Emission in number of particles per min | The Helmke drum does not differentiate fibres from particles; it is used to measure particles smaller than 5,0 µm. Garment are graded as categories 1 to 3, based upon the number of particles released (0,3 µm or 0,5 µm)/min of tumbling.<br>Helmke drum: the test garment (typically size medium) is carefully placed in a specified size stainless-steel drum. The drum is rotated to cause the article to tumble. An aerosol particle counter is used to sample the air over the tumbling garments for a 10-minute sample.<br>The test may be used for evaluating the emission of new or reprocessed garments. |
| Gloves | Gloves and finger cots used in cleanrooms and other controlled environments | IEST-RP-CC005.4:2013, 16.2 to 16.4 | Particles or fibres per $m^2$ | Particle and fibres are extracted using water through orbital shaking. Enumeration counting small particles in liquid and fibres by optical microscopy. |
| | | IEST-RP-CC005.4:2013, Clause 17 | µg/g or µg/$cm^2$ | Extractable matter, inorganic and organic categories. Extracted by chosen solvent, at rest, at 22 °C ± 5 °C. Analysis by chosen analytical method. |
| | | IEST-RP-CC005.4:2013, 17.5 | µg/g or µg/$cm^2$ | For total non-volatile chemicals by extraction. Glove is extracted using specified solvent. Extractant dried at 110 °C ± 10 °C. |

[a] Currently, there are no test methods for mops. It is possible to adapt wiper test methods for mops.

**Table C.1** *(continued)*

| Example of consumable | Description | Reference | Result | Comment |
|---|---|---|---|---|
| Wipers[a] | Evaluating wiping materials used in cleanrooms and other controlled environments | IEST-RP-CC004.4:2019, 7.1.4 and 7.2.1 | Number of particles per 23 cm x 23 cm wiper | For particles 0,5 µm to 20 µm, 20 µm to 100 µm. Extracted by orbital shaking in a square container. Enumeration by counting in liquid. |
| | | IEST-RP-CC004.4:2019, 7.2.2 | Fibres per 23 cm x 23 cm wiper | For particles and fibres >100 µm, per wiper. Extract filtered. Enumeration by optical microscopy. |
| | | IEST-RP-CC004.4:2019, 8.1 | Mass per 23 cm x 23 cm wiper | For extractable matter. Extraction using a specified solvent. Extract is dried and weighed. |
| | | IEST-RP-CC004.4:2019, 8.2.2 | Ppm based on 23 cm x 23 cm wiper weight | For extractable or leachable ions. Extraction by water or other water-based solutions, e.g. acid-containing solutions depending on ion or metal. Quantification by ion chromatography. |
| Wipers[a] | Contamination during wiping and transfer of chemical residue | ECSS-Q-ST-70-05C:2019 Annex G | g or g/cm$^2$ | NVR measurement via contact: provides method to measure the contamination transfer of materials which can come into contact with hardware. |
| | | ECSS-Q-ST-70-05C:2019 Annex H | g or g/cm$^2$ | NVR measurement via immersion: provides method to measure the potential extractable contamination from materials with solvents. |
| Wipers[a] | Standard test method for size-differentiated counting of particles and fibres released from cleanroom wipers using optical and scanning electron microscopy | ASTM E2090-12(2020), 10.6 to 10.9, Clause 11 | Number of particles per m$^2$ | Provides a method for extracting particles and fibres (0,5 µm/m$^2$ to 5 µm/m$^2$, 5 µm/m$^2$ to 100 µm/m$^2$ and >100 µm fibres) in water. Wiper is extracted using a water solution through orbital shaking. The extract is filtered. The filter is placed on a scanning electron microscope (SEM) stub. Smaller particle size ranges are enumerated by SEM. |
| | | ASTM E2090-12(2020), 10.1 to 10.5, Clause 11 | Number of particles per m$^2$ | Particles and fibres > 100 µm/m$^2$ enumerated by optical microscopy. |
| Goggles<br>Shoes<br>Various | Cleanroom suitability assessment for use of equipment and materials by airborne chemical concentration | ISO 14644-15 | Specific emission rate of chemicals in g/(m$^2$·s) | Methods can be applied for consumables as well. |

[a] Currently, there are no test methods for mops. It is possible to adapt wiper test methods for mops.

**Table C.1** *(continued)*

| Example of consumable | Description | Reference | Result | Comment |
|---|---|---|---|---|
| Goggles<br>Shoes<br>Various | Surface cleanliness by surface chemical concentration | ISO 14644-10:2022, Annex D | g/m$^2$ | Method for measuring chemicals on surfaces that can be adapted for consumables. |
| Packaging materials | Flexible packaging materials for use in cleanrooms and other controlled environments | IEST-RP-CC032.1:2009, A1.2 | Number of particles per surface area of consumable | Provides test methods for particle release and microscopic analysis. |
| | | IEST-RP-CC032.1:2009, A1.1 | Number of particles per consumable tested (e.g. bags) | Provides test methods for particle release and quantitative analysis. |
| | | IEST-RP-CC032.1:2009 A4.2 | µg (mg. etc.) per unit area of consumable (e.g. per g or m$^2$) | Provides a method for collection and measurement of organic and inorganic extractable matter and non-volatile residues. |
| Various | Standard practice for sampling for particulate contamination by tape lift | ASTM E1216-11 (combined with ASTM F312-08) | Size distribution and quantity of particles, 5 µm and larger | Procedure for sampling surface to determine the presence of particulate contamination, 5 µm and larger. |
| Various | Compatibility of materials with the required cleanliness – particle emission | VDI 2083 Blatt 17:2013, 6.2 | Particles emission in number of particles per m$^3$ | Method for measuring particle emission of materials, that can be adapted for consumables. |
| Various | Compatibility of materials with the required cleanliness – chemical emission | VDI 2083 Blatt 17:2013, 6.3 | Emission of chemicals in g/m$^3$ | Method for measuring chemical emission of materials, that can be adapted for consumables. |

[a] Currently, there are no test methods for mops. It is possible to adapt wiper test methods for mops.

## C.2 Personal consumables

### C.2.1 Garments

In a body box, the particle emission of a person wearing a garment can be tested by using an airborne particle counter or a particle deposition monitor. The emitted microorganisms can be collected and enumerated after growth.

NOTE 1 The measured emission depends on the particle emission of the person inside the cleanroom garment. This can differ from person to person and from day to day.

NOTE 2 The body box measurement is influenced by the position of the particle counter(s) with respect to the body box and losses in sampling tubes, especially for particles ≥ 5 µm.

The Helmke drum tumble test is a method of measuring the particle release of a washed garment. The garment is tumbled in a rotating drum. The release of particles sized ≥ 0,3 µm and ≥ 0,5 µm is measured with an aerosol counter. See IEST-RP-CC003.4.

### C.2.2 Gloves

Next to the testing of the barrier function and surface cleanliness, the emission of chemicals is important in certain applications. See EN 455-2 and EN 455-3 and IEST-RP-CC005.4.

### C.2.3 Face masks

Face masks can be evaluated based on ASTM F2101 and ASTM F2299.

### C.2.4 Head covers

The same test methods as for single-use or multiple-use garments can be applied.

### C.2.5 Goggles

For goggles, see the applicable standards for personal protection.

### C.2.6 Shoes

There are no known standardized test procedures for shoes. For general test procedures, see ISO 14644-14 and ISO 14644-15.

### C.2.7 Shoe covers

See ISO 9073-10.

## C.3 Non-personal consumables

### C.3.1 Wipers

In some test methods, agitation is used to release the particles. Extraction is used to determine the release of chemicals and trace elements into liquids or onto surfaces.

IEST-RP-CC004.4 details a method for removing particles from a wiper for subsequent enumeration using a laser-based liquid particle counter (LPC) or optical microscopy. The technique involves immersing the wiper in deionized (DI) water and agitating using an orbital shaker.

### C.3.2 Swabs

In some test methods, agitation is used to release the particles. Extraction is used to determine the release of chemicals and trace elements into liquids or onto surfaces.

### C.3.3 Mops

The same methods as detailed for wipers can be used.

### C.3.4 Packaging materials

For the evaluation of packaging material, see Table C.1.

### C.3.5 Paper

For the evaluation of paper, see IEST-RP-CC020.2.

### C.3.6 Others

For hospital covers, standards concerning biocontamination are available. For many other non-personal consumables, there are no standardized measurement methods and therefore no data. In such cases, a self-test can be made with representative agitation, if applicable. The release of particles can be measured with a particle counter. Extraction methods can be used to determine the surface cleanliness and potential chemical release.

# Annex D
(informative)

# Worked examples

## D.1 Personal consumables

### D.1.1 General

This worked example uses the requirement for a multiple-use cleanroom garment system to illustrate the selection process for a personal consumable for a stated use case. The garment system used in this annex consists of 3 items: a hood, a coverall and a pair of boots. Although individual consumables can undergo some cleanroom suitability assessments, the impact of the garment system on air and surface cleanliness cannot be assessed for a single consumable. It is assumed the 3 items are constructed of the same medium in the same manner, with the exception of the footwear sole.

In order to make the worked examples concise, only some potential requirements and characteristics from each of the functional performance properties, cleanliness attributes and special properties were considered. Comfort has an impact on the emission of particles, fibres and microorganisms.

In the selection of the garment system, the ease of decontamination is also important. Decontamination is performed by laundry. Laundering can impact the structure and the efficiency of the barrier function. This impact depends on the medium and construction quality of the garment system. The chemicals used in the laundry process can impact both the decontamination effectiveness and chemical cleanliness requirements.

The following functional performance properties have an impact on the air cleanliness:

— barrier function, which is influenced by:
  — filtration efficiency or particle penetration of the fabric;
  — mean pore size;
  — particles retention capability;
  — quality of the construction;
  — fit which is related to size and design;
— comfort, which is related to:
  — air permeability;
  — water vapour transmission;
  — heat transmission;
— durability of the construction and fabric during laundry and use (wearing).

As special properties, the emission of microorganisms and the capability to be sterilised require consideration.

Important properties or parameters are used to compare customer requirements and supplier data and characteristics. Different suppliers publish different data. IEST-RP-CC003.4 and VDI 2083 Blatt 9.2 describe a number of tests for cleanroom clothing:

— particle penetration test (barrier function, filter efficiency in %);

— microbial penetration test (cfu filter efficiency in %);

— pore diameter test (µm);

— body box test (average number of particles ≥ 0,5 and 5 µm per person per min);

— Helmke drum test (number of particles ≥ 0,3 and 0,5 µm per $m^2$ per min in first 10 minutes);

— ASTM F51/F51M-20 surface cleanliness test (number of particles ≥ 5 µm or number of fibres per 0,1 $m^2$).

A test of the garment system for the intended use in the intended cleanroom accompanied with air cleanliness and particle deposition rate measurements would provide more verification data to determine the cleanroom suitability, if the customer assessment of associated risks reaches this conclusion.

### D.1.2 Outline of requirements

The intended use case cleanroom or controlled environment is ISO Class 6 for particles ≥ 5 µm in operation and less than 20 cfu/$m^3$. The number of people working in the cleanrooms is on average 60 per week and 12 per shift, 50 % male and 50 % female. The work is mostly standing and walking slowly at a dedicated location. The cleanroom temperature is 20 ± 2 °C. Garment systems are used daily (4 changes). No cleanroom undergarments are used.

To enable an effective supplier dialogue and subsequent selection of a consumable, the following customer preliminary activities are considered:

— specification of important requirements (Clause 4);

— contaminant of concern (Clause 5);

— cleanroom suitability assessment prerequisites (Clause 6);

— survey of available test methods and data;

— review and assessment of the contents of customer requirements (Clause 7) and supplier specifications (Clause 8).

The assembled and evaluated data can be used to assess the cleanroom suitability of the garment system for the intended cleanroom and activities. The final selection of the consumable is preceded by a comparison of customer requirements and supplier design characteristics and specifications.

Referring to the assessment, the customer documents requirements against the attributes. Subsequently following supplier(s) dialogue, the design characteristics of consumable(s) can be documented by the supplier.

In Clause 9, the assessment is described to enable an initial comparison.

### D.1.3 Cleanroom suitability assessment

#### D.1.3.1 General

For a complex personal consumable such as a garment system, it can be impossible to conclude a cleanroom suitability assessment based entirely on the comparison of customer requirements and supplier design characteristics. If a risk to acceptable cleanliness levels has been judged to be associated with the implementation of a garment system based on an initial data comparison only, the