

First edition
2023-10

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



Reference number
ISO 14644-18:2023(E)

© ISO 2023



COPYRIGHT PROTECTED DOCUMENT

© ISO 2023

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

This is a preview of ISO 14644-18:2023. [Click here to purchase the full version from the ANSI store.](#)

Contents

	Page
Foreword	v
Introduction	vi
1 Scope	1
2 Normative references	2
3 Terms and definitions	2
4 Description and cleanroom suitability properties of consumables	5
4.1 Types of consumables.....	5
4.2 Properties of consumables.....	5
4.2.1 General.....	5
4.2.2 Functional performance properties.....	5
4.2.3 Cleanliness attributes.....	6
4.2.4 Special properties.....	6
4.3 Intended use.....	6
4.4 Consumable use.....	7
4.4.1 Single-use.....	7
4.4.2 Multiple-use.....	7
5 Contaminant of concern	7
5.1 General.....	7
5.2 Emission of contaminants into the air.....	7
5.3 Surface contamination by contact transfer.....	7
5.4 Surface contamination via liquids.....	7
6 Cleanroom suitability assessment prerequisites	8
6.1 General.....	8
6.2 Considerations.....	8
6.3 Associated risks.....	8
6.4 Requirements, properties and cleanliness attributes.....	8
6.5 Sustainability.....	9
7 Customer requirements	9
7.1 General.....	9
7.2 Description and intended use.....	9
7.3 Requirements for consumable assessment.....	9
7.3.1 Functional performance properties.....	9
7.3.2 Cleanliness attributes.....	10
7.3.3 Special properties.....	10
8 Consumable properties as designed by the supplier	11
8.1 General.....	11
8.2 Description and designed use.....	11
8.3 Consumable properties and attributes.....	11
8.3.1 Functional performance properties.....	11
8.3.2 Cleanliness attributes.....	11
8.3.3 Special properties.....	12
8.4 Supplier quality documentation.....	12
9 Assessment	12
9.1 General.....	12
9.2 Initial comparison.....	13
9.3 Detailed comparison.....	13
9.4 Cleanroom suitability assessment.....	13
9.5 Implementation.....	13
10 Documentation	14
10.1 General.....	14

This is a preview of ISO 14644-18:2023. [Click here to purchase the full version from the ANSI store.](#)

10.2	Initial customer's documentation	14
10.3	Supplier documentation.....	14
10.4	Assessment documentation.....	15
Annex A	(informative) Personal and non-personal consumables	16
Annex B	(informative) Impact of consumables on cleanroom cleanliness levels	18
Annex C	(informative) Test methods.....	22
Annex D	(informative) Worked examples.....	29
Bibliography	37

This is a preview of ISO 14644-18:2023. [Click here to purchase the full version from the ANSI store.](#)

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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.