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STN	**Čisté priestory a príslušné riadené prostredie Časť 9: Posudzovanie čistoty povrchu z hľadiska koncentrácie častíc (ISO 14644-9: 2022)**	**STN EN ISO 14644-9** 12 5301

Cleanrooms and associated controlled environments - Part 9: Assessment of surface cleanliness for particle concentration (ISO 14644-9:2022)

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 08/22

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English Version

Cleanrooms and associated controlled environments - Part 9: Assessment of surface cleanliness for particle concentration (ISO 14644-9:2022)

Salles propres et environnements maîtrisés apparentés - Partie 9: Évaluation de la propreté des surfaces en fonction de la concentration de particules (ISO 14644-9:2022)

Reinräume und zugehörige Reinraumbereiche - Teil 9: Klassifizierung der partikulären Oberflächenreinheit (ISO 14644-9:2022)

This European Standard was approved by CEN on 18 April 2022.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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Ref. No. EN ISO 14644-9:2022 E

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European foreword

This document (EN ISO 14644-9:2022) has been prepared by Technical Committee ISO/TC 209 "Cleanrooms and associated controlled environments" in collaboration with Technical Committee CEN/TC 243 “Cleanroom technology” the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by November 2022, and conflicting national standards shall be withdrawn at the latest by November 2022.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 14644-9:2012.

Any feedback and questions on this document should be directed to the users’ national standards body/national committee. A complete listing of these bodies can be found on the CEN website.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 14644-9:2022 has been approved by CEN as EN ISO 14644-9:2022 without any modification.

INTERNATIONAL STANDARD

ISO 14644-9

Second edition
2022-05

Cleanrooms and associated controlled environments —

Part 9: Assessment of surface cleanliness for particle concentration

Salles propres et environnements maîtrisés apparentés —

Partie 9: Évaluation de la propreté des surfaces en fonction de la concentration de particules

Reference number
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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 documents 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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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).

This second edition cancels and replaces the first edition (ISO 14644-9:2012), of which it constitutes a minor revision. The changes are as follows:

— "Class" (classification, classified) has been changed to grade or assessment where appropriate;

— ISO 14644-6 has been removed from the opening text of Clause 3 and, as a result, Clause 2;

— entry 3.8 removed from Clause 3;

— ISO 4287 and ISO 4288 replaced by ISO 21920-2 and ISO 21920-3, respectively;

— ISO 16232-2, ISO 16232-3, ISO 16232-4 and ISO 16232-5 replaced by ISO 16232;

— minor editorial changes.

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 provide for the control of contamination to levels appropriate for accomplishing contamination-sensitive activities. Products and processes that benefit from the control of contamination include those in such industries as aerospace, microelectronics, optics, nuclear and life sciences (pharmaceuticals, medical devices, food, healthcare).

ISO 14644-1 to ISO 14644-8, ISO 14698-1 and ISO 14698-2 deal exclusively with airborne particle and chemical contamination. Many factors, besides the assessment of surface cleanliness, should be considered in the design, specification, operation and control of cleanrooms and other controlled environments. These factors are covered in some detail in other parts of ISO 14644 and ISO 14698.

This document provides an analytical process for the determination and designation of surface cleanliness levels based on particle concentration. This document also lists some methods of testing, as well as procedure(s) for determining the concentration of particles on surfaces.

Where regulatory agencies impose supplementary guidelines or restrictions, appropriate adaptations of the testing procedures might be required.

NOTE When assessment of surface cleanliness by particle concentration (SCP) at critical control point(s) is used as an additional cleanliness attribute to classification of air cleanliness by airborne particle concentration in accordance with ISO 14644-1, then the space can be described as a cleanroom or clean-zone. If SCP is used alone, then the space is described as a controlled zone.

INTERNATIONAL STANDARD **ISO 14644-9:2022(E)**

Cleanrooms and associated controlled environments —

Part 9: Assessment of surface cleanliness for particle concentration

1 Scope

This document establishes a procedure for the assessment of particle cleanliness levels on solid surfaces in cleanrooms and associated controlled environment applications. Recommendations on testing and measuring methods, as well as information about surface characteristics, are given in Annexes A to D.

This document applies to all solid surfaces in cleanrooms and associated controlled environments, such as walls, ceilings, floors, working environments, tools, equipment and products. The procedure for the assessment of surface cleanliness by particle concentration (SCP) is limited to particles of between 0,05 µm and 500 µm.

The following issues are not considered in this document:

— requirements for the cleanliness and suitability of surfaces for specific processes;

— procedures for the cleaning of surfaces;

— material characteristics;

— references to interactive bonding forces or generation processes that are usually time-dependent and process-dependent;

— selection and use of statistical methods for assessment and testing;

— other characteristics of particles, such as electrostatic charge, ionic charges and microbiological state.

2 Normative references

There are no normative references in this document.