



SLOVENSKI STANDARD SIST EN ISO 14644-9:2022

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Nadomešča:

SIST EN ISO 14644-9:2012

Čiste sobe in podobna nadzorovana okolja - 9. del: Ocenjevanje čistosti površine na osnovi koncentracije delcev (ISO 14644-9:2022)

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

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

Ta slovenski standard je istoveten z: EN ISO 14644-9:2022

ICS:

13.040.35	Brezprašni prostori in povezana nadzorovana okolja	Cleanrooms and associated controlled environments
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NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 14644-9

May 2022

ICS 13.040.35

Supersedes EN ISO 14644-9:2012

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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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of an identical text or by endorsement, at the latest by November 2022, and conflicting national standards shall be withdrawn at the latest by November 2022.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*

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ISO 14644-9:2022(E)

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.

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