



SLOVENSKI STANDARD SIST EN ISO 14644-2:2001

01-junij-2001

Cleanrooms and associated controlled environments - Part 2: Specifications for testing and monitoring to prove continued compliance with ISO 14644-1 (ISO 14644-2:2000)

Cleanrooms and associated controlled environments - Part 2: Specifications for testing and monitoring to prove continued compliance with ISO 14644-1 (ISO 14644-2:2000)

Reinräume und zugehörige Reinraumbereiche - Teil 2: Festlegungen zur Prüfung und Überwachung zum Nachweis der fortlaufenden Übereinstimmung mit ISO 14644-1 (ISO 14644-2:2000)

Salles propres et environnements maîtrisés apparentés - Partie 2: Spécifications pour les essais et la surveillance en vue de démontrer le maintien de la conformité avec l'ISO 14644-1 (ISO 14644-2:2000)

Ta slovenski standard je istoveten z: EN ISO 14644-2:2000

ICS:

13.040.30 Kakovost zraka na delovnem mestu Workplace atmospheres

SIST EN ISO 14644-2:2001

en

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EUROPEAN STANDARD
NORME EUROPÉENNE
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EN ISO 14644-2

September 2000

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English version

Cleanrooms and associated controlled environments - Part 2:
Specifications for testing and monitoring to prove continued
compliance with ISO 14644-1 (ISO 14644-2:2000)

Salles propres et environnements maîtrisés apparentés -
Partie 2: Spécifications pour les essais et la surveillance en
vue de démontrer le maintien de la conformité avec l'ISO
14644-1 (ISO 14644-2:2000)

Reinräume und zugehörige Reinraumbereiche - Teil 2:
Festlegungen zur Prüfung und Überwachung zum
Nachweis der fortlaufenden Übereinstimmung mit ISO
14644-1 (ISO 14644-2:2000)

This European Standard was approved by CEN on 15 September 2000.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.



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

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EN ISO 14644-2:2000

Foreword

The text of the International Standard ISO 14644-2:2000 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 March 2001, and conflicting national standards shall be withdrawn at the latest by March 2001.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

NOTE FROM CEN/CS: The foreword is susceptible to be amended on reception of the German language version. The confirmed or amended foreword, and when appropriate, the normative annex ZA for the references to international publications with their relevant European publications will be circulated with the German version.

Endorsement notice

The text of the International Standard ISO 14644-2:2000 was approved by CEN as a European Standard without any modification.

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INTERNATIONAL STANDARD

ISO 14644-2

First edition
2000-09-15

Cleanrooms and associated controlled environments —

Part 2:

Specifications for testing and monitoring to prove continued compliance with ISO 14644-1

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Salles propres et environnements maîtrisés apparentés —

Partie 2: Spécifications pour les essais et la surveillance en vue de démontrer le maintien de la conformité avec l'ISO 14644-1

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ISO 14644-2:2000(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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this part of ISO 14644 may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 14644-2 was prepared by Technical Committee ISO/TC 209, *Cleanrooms and associated controlled environments*.

ISO 14644 consists of the following parts, under the general title *Cleanrooms and associated controlled environments*:

Part 1: Classification of air cleanliness

— *Part 2: Specifications for testing and monitoring to prove continued compliance with ISO 14644-1*

— *Part 3: Metrology and test methods*

— *Part 4: Design, construction and start-up*

— *Part 5: Operations*

— *Part 6: Terms and definitions*

— *Part 7: Separative enclosures (clean airhoods, gloveboxes, isolators, mini-environments)*

Users should note that the titles listed for parts 3 to 7 are working titles at the time of the release of part 2. In the event that one or more of these parts are deleted from the work programme, the remaining parts may be renumbered.

Annexes A and B of this part of ISO 14644 are for information only.

Introduction

This part of ISO 14644 provides a process to prove continued compliance with ISO 14644-1 and specifies minimum requirements for testing and monitoring. In any testing plan, consideration should also be given to the particular operational requirements, risk assessment of the installation, and its use.

Cleanrooms and associated controlled environments provide for the control of airborne particulate contamination to levels appropriate for accomplishing contamination-sensitive activities. Products and processes that benefit from the control of airborne contamination include aerospace, microelectronics, pharmaceuticals, medical devices, healthcare, food and others. Many factors besides airborne particulate cleanliness should be considered in the design, specification, operation and control of cleanrooms and other controlled environments.

In some circumstances, relevant regulatory agencies may impose supplementary policies or restrictions. In such situations, appropriate adaptations of the standard testing procedures may be required.

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