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

The European Standard EN ISO 14644-2:2000 has the status of a Swedish Standard. This document contains the official English version of EN ISO 14644-2:2000.

Swedish Standards corresponding to documents referred to in this Standard are listed in "Catalogue of Swedish Standards", issued by SIS. The Catalogue lists, with reference number and year of Swedish approval, International and European Standards approved as Swedish Standards as well as other Swedish Standards.

Renrum och tillhörande renhetskontrollerade miljöer – Del 2: Provning och övervakning för verifiering av fortsatt överensstämmelse med ISO 14644-1 (ISO 14644-2:2000)

Europastandarden EN ISO 14644-2:2000 gäller som svensk standard. Detta dokument innehåller den officiella engelska versionen av EN ISO 14644-2:2000.

Motsvarigheten och aktualiteten i svensk standard till de publikationer som omnämns i denna standard framgår av "Katalog över svensk standard", som ges ut av SIS. I katalogen redovisas internationella och europeiska standarder som fastställts som svenska standarder och övriga gällande svenska standarder.

ICS 13.040.30

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EN ISO 14644-2

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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.



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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.

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.