ICS 13.040.35 SLOVENSKÁ TECHNICKÁ NORMA Apríl 2017

STN	**Čisté priestory a príslušné riadené prostredie. Časť 14: Hodnotenie vhodnosti čistých priestorov pre zariadenia podľa koncentrácie častíc vo vzduchu (ISO 14644-14: 2016).**	**STN EN ISO 14644-14** 12 5301

Cleanrooms and associated controlled environments - Part 14: Assessment of suitability for use of equipment by airborne particle concentration (ISO 14644-14:2016)

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. 03/17

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EUROPÄISCHE NORM

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English Version

Cleanrooms and associated controlled environments - Part 14: Assessment of suitability for use of equipment by airborne particle concentration (ISO 14644-14:2016)

Salles propres et environnements maîtrisés apparentés - Partie 14: Évaluation de l'aptitude à l'emploi des équipements par la détermination de la concentration de particules en suspension dans l'air (ISO 14644-14:2016)

Reinräume und zugehörige Reinraumbereiche - Teil 14: Bewertung der Reinraumtauglichkeit von Geräten durch Partikelkonzentration in der Luft (ISO 14644-14:2016)

This European Standard was approved by CEN on 13 August 2016.

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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 14644-14:2016) 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of an identical text or by endorsement, at the latest by April 2017, and conflicting national standards shall be withdrawn at the latest by April 2017.

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

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Endorsement notice

The text of ISO 14644-14:2016 has been approved by CEN as EN ISO 14644-14:2016 without any modification.

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INTERNATIONAL STANDARD

ISO 14644-14

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Cleanrooms and associated controlled environments —

Part 14: Assessment of suitability for use of equipment by airborne particle concentration

Salles propres et environnements maîtrisés apparentés —

Partie 14: Évaluation de l'aptitude à l'emploi des équipements par la détermination de la concentration de particules en suspension dans l'air

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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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For an explanation on 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 the following URL: www.iso.org/iso/foreword.html.

The committee responsible for this document is ISO/TC 209, *Cleanrooms and associated controlled environments*.

A list of all part in the ISO 14644 series, published under the general title *Cleanrooms and associated controlled environments*, can be found on the ISO website.

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 and healthcare).

This part of ISO 14644 links the cleanroom classification of air cleanliness by particle concentration to the suitability of equipment for use in cleanrooms and associated controlled environments.

INTERNATIONAL STANDARD ISO 14644-14:2016(E)

Cleanrooms and associated controlled environments —

Part 14: Assessment of suitability for use of equipment by airborne particle concentration

1 Scope

This part of ISO 14644 specifies a methodology to assess the suitability of equipment (e.g. machinery, measuring equipment, process equipment, components and tools) for use in cleanrooms and associated controlled environments, with respect to airborne particle cleanliness as specified in ISO 14644-1. Particle sizes range from 0,1 µm to equal to or larger than 5 µm (given in ISO 14644-1).

NOTE Where regulatory agencies impose supplementary guidelines or restrictions, appropriate adaptation of the assessment methodology can be required.

The following items are not covered by this part of ISO 14644:

— assessment of suitability with respect to biocontamination;

— testing for suitability of decontamination agents and techniques;

— cleanability of equipment and materials;

— requirements on design of equipment and selection of materials;

— physical properties of materials (e.g. electrostatic, thermal properties);

— optimizing performance of equipment for specific process applications;

— selection and use of statistical methods for testing;

— protocols and requirements for local safety regulations.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 14644-1:2015, *Cleanrooms and associated controlled environments — Part 1: Classification of air cleanliness by particle concentration*