

**Cleanrooms and associated controlled environments -
Part 9: Classification of surface cleanliness by particle
concentration (ISO 14644-9:2012)**

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NATIONAL FOREWORD

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English Version

Cleanrooms and associated controlled environments - Part 9:
Classification of surface cleanliness by particle concentration
(ISO 14644-9:2012)

Salles propres et environnements maîtrisés apparentés -
Partie 9: Classification de la propreté des surfaces par la
concentration de particules (ISO 14644-9:2012)

Reinräume und zugehörige Reinraumbereiche - Teil 9:
Klassifizierung der partikulären Oberflächenreinheit (ISO
14644-9:2012)

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

Management Centre: Avenue Marnix 17, B-1000 Brussels

Foreword

This document (EN ISO 14644-9:2012) 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of an identical text or by endorsement, at the latest by February 2013, and conflicting national standards shall be withdrawn at the latest by February 2013.

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 14644-9:2012 has been approved by CEN as a EN ISO 14644-9:2012 without any modification.

Contents

Page

Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Abbreviated terms	2
5 Classification system	3
5.1 ISO-SCP classification format	3
5.2 Designation	6
5.3 General information on surface cleanliness by particle concentration	6
6 Demonstration of compliance	6
6.1 Principle	6
6.2 Testing	6
6.3 Test report	7
Annex A (informative) Surface characteristics	9
Annex B (informative) Descriptor for specific particle size ranges	12
Annex C (informative) Parameters influencing the SCP classification	15
Annex D (informative) Measurement methods for determining surface cleanliness by particle concentration	17
Bibliography	25

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 and ISO 14698-1 and ISO 14698-2 (biological contamination) deal exclusively with airborne particle and chemical contamination. Many factors, besides the classification 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 part of ISO 14644 provides a classification for the determination and designation of surface cleanliness levels based on particle concentrations. This part of ISO 14644 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.

Cleanrooms and associated controlled environments —

Part 9:

Classification of surface cleanliness by particle concentration

1 Scope

This part of ISO 14644 establishes the classification of cleanliness levels on solid surfaces by particle concentration 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 part of ISO 14644 applies to all solid surfaces in cleanrooms and associated controlled environments, such as walls, ceilings, floors, working environments, tools, equipment and products. The classification of surface cleanliness by particle concentration (SCP) is limited to particles between 0,05 μm and 500 μm .

The following issues are not considered in this part of ISO 14644:

- 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 classification and testing;
- other characteristics of particles, such as electrostatic charge, ionic charges, microbiological state, etc.

2 Normative references

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

ISO 14644-6:2007, *Cleanrooms and associated controlled environments — Part 6: Vocabulary*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 14644-6:2007 and the following apply.

3.1

descriptor for specific particle size ranges

differential descriptor that expresses SCP level within specific particle size ranges