



# SLOVENSKI STANDARD SIST EN ISO 18415:2017

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Nadomešča:  
SIST EN ISO 18415:2011

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**Kozmetika - Mikrobiologija - Ugotavljanje prisotnosti specifičnih in nespecifičnih mikroorganizmov (ISO 18415:2017)**

Cosmetics - Microbiology - Detection of specified and non-specified microorganisms (ISO 18415:2017)

Kosmetische Mittel - Mikrobiologie - Nachweis von spezifizierten und nichtspezifizierten Mikroorganismen (ISO 18415:2017)

Cosmétiques - Microbiologie - Détection des micro-organismes spécifiés et non spécifiés (ISO 18415:2017) <https://standards.iteh.ai/catalog/standards/sist/c0f7954d-1cc7-4309-afa6-ed470edb4297/sist-en-iso-18415-2017>

**Ta slovenski standard je istoveten z: EN ISO 18415:2017**

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07.100.40      Kozmetika - mikrobiologija      Cosmetics microbiology

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EUROPEAN STANDARD

EN ISO 18415

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English Version

## Cosmetics - Microbiology - Detection of specified and non-specified microorganisms (ISO 18415:2017)

Cosmétiques - Microbiologie - Détection des micro-organismes spécifiés et non spécifiés (ISO 18415:2017)

Kosmetische Mittel - Mikrobiologie - Nachweis von spezifizierten und nichtspezifizierten Mikroorganismen (ISO 18415:2017)

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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 CEN-CENELEC Management Centre has the same status as the official versions.

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**CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels**

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## European foreword

This document (EN ISO 18415:2017) has been prepared by Technical Committee ISO/TC 217 "Cosmetics" in collaboration with Technical Committee CEN/TC 392 "Cosmetics" the secretariat of which is held by AFNOR.

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of an identical text or by endorsement, at the latest by December 2017 and conflicting national standards shall be withdrawn at the latest by December 2017.

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INTERNATIONAL  
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2017-06

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**Cosmetics — Microbiology —  
Detection of specified and non-  
specified microorganisms**

*Cosmétiques — Microbiologie — Détection des micro-organismes  
spécifiés et non spécifiés*

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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](http://www.iso.org/directives)).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see [www.iso.org/patents](http://www.iso.org/patents)).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on 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 the following URL: [www.iso.org/iso/foreword.html](http://www.iso.org/iso/foreword.html).

This document was prepared by Technical Committee ISO/TC 217, *Cosmetics*.

This second edition cancels and replaces the first edition (ISO 18415:2007), of which it constitutes a minor revision with the following changes:

- in the Scope, “see ISO 29621” has been added and the reference has been added to the Bibliography;
- in the Scope, “used” has been changed to “substituted” and “validated” has been changed to “shown to be suitable”;
- in [3.8](#), the term “validated” has been changed to “demonstrated to be suitable”;
- in [Clause 4](#), the term “validated” has been changed to “demonstrated”;
- in [5.1](#), “specifications” has been changed to “instructions”;
- in [5.1](#), the phrase “are validated” has been changed to “have been demonstrated to be suitable”;
- in [5.2.1](#), [5.3.3.1](#), [11.3.1](#), [11.3.2](#), instances of the term “validation” and in the heading title of [11.3.3](#) have been changed to “suitability test”;
- in [11.3](#), the term “validation” in the heading title has been changed to “suitability”;
- in [11.3.3](#), instances of “validated” have been changed to “satisfactory”;
- in [Clause 12 f\)](#), the term “validation” has been changed to “demonstration of the suitability”.

## ISO 18415:2017(E)

### Introduction

Microbiological examinations of cosmetic products are carried out according to an appropriate microbiological risk analysis in order to ensure their quality and safety for consumers.

Microbiological risk analysis depends on several parameters such as:

- potential alteration of cosmetic products;
- pathogenicity of microorganisms;
- site of application of the cosmetic product (hair, skin, eyes, mucous membranes);
- type of user (adults, children including under 3 years).

For cosmetics and other topical products, the detection of skin pathogens such as *Staphylococcus aureus*, *Pseudomonas aeruginosa* and *Candida albicans* may be relevant because they can cause skin or eye infection. The detection of other kinds of microorganisms might be of interest since these microorganisms (including indicators of faecal contamination e.g. *Escherichia coli*) suggest hygienic failure during manufacturing process.

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