



NSAI
Standards

Irish Standard
I.S. EN ISO 16408:2015

Dentistry - Oral care products - Oral rinses (ISO 16408:2015)

I.S. EN ISO 16408:2015

Incorporating amendments/corrigenda/National Annexes issued since publication:

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I.S. xxx: Irish Standard — national specification based on the consensus of an expert panel and subject to public consultation.

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National Foreword

I.S. EN ISO 16408:2015 is the adopted Irish version of the European Document EN ISO 16408:2015, Dentistry - Oral care products - Oral rinses (ISO 16408:2015)

This document does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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In line with international standards practice the decimal point is shown as a comma (,) throughout this document.

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EUROPEAN STANDARD

EN ISO 16408

NORME EUROPÉENNE

EUROPÄISCHE NORM

September 2015

ICS 97.170

Supersedes EN ISO 16408:2004

English Version

Dentistry - Oral care products - Oral rinses (ISO 16408:2015)

Médecine bucco-dentaire - Produits de soins bucco-dentaire - Bains de bouche (ISO 16408:2015)

Zahnheilkunde - Mundhygieneprodukte - Mundspüllösungen und Mundwässer (ISO 16408:2015)

This European Standard was approved by CEN on 10 July 2015.

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European foreword

This document (EN ISO 16408:2015) has been prepared by Technical Committee ISO/TC 106 “Dentistry” in collaboration with Technical Committee CEN/TC 55 “Dentistry” the secretariat of which is held by DIN.

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of an identical text or by endorsement, at the latest by March 2016, and conflicting national standards shall be withdrawn at the latest by March 2016.

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.

This document supersedes EN ISO 16408:2004.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 16408:2015 has been approved by CEN as EN ISO 16408:2015 without any modification.

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INTERNATIONAL STANDARD

**ISO
16408**

Second edition
2015-08-15

Dentistry — Oral care products — Oral rinses

*Médecine bucco-dentaire — Produits de soins bucco-dentaire —
Bains de bouche*



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ISO 16408:2015(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.

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 WTO principles in the Technical Barriers to Trade (TBT) see the following URL: [Foreword - Supplementary information](#)

The committee responsible for this document is ISO/TC 106, *Dentistry*, Subcommittee SC 7, *Oral care products*.

This second edition cancels and replaces the first edition (ISO 16408:2004), which has been technically revised with the following changes:

- “heavy metals” has been replaced by the term *unintended heavy metals*, which has been defined in [3.3](#);
- reference to ISO 28888 and corresponding requirement in [5.1](#) were added;
- ambient storage conditions of real time test for determination of stability against ageing ([7.4.1](#)) was changed $(23 \pm 2) ^\circ\text{C}$ at $(60 \pm 15) \%$ relative humidity;
- the bibliography was updated by including latest ISO/TC 217 standards.

Introduction

Oral rinses are used for oral hygiene purposes intended to provide health and/or cosmetic benefits.

This International Standard specifies the chemical and physical properties of oral rinses. Common labelling aspects are also specified in order to enhance international understanding and trade.

Dentistry — Oral care products — Oral rinses

1 Scope

This International Standard specifies physical and chemical requirements and test methods for oral rinses. It also specifies the accompanying information such as the manufacturer's instructions for use, marking, and/or labelling requirements.

This International Standard is not applicable to other delivery systems (e.g. mouthsprays, foams, powders). It is not intended to describe regulatory aspects, e.g. methods of prescription.

This International Standard is not applicable to oral rinses available by prescription only.

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 1942, *Dentistry — Vocabulary*

ISO 3696, *Water for analytical laboratory use — Specification and test methods*

ISO 8601, *Data elements and interchange formats — Information interchange — Representation of dates and times*

ISO 28888, *Dentistry — Screening method for erosion potential of oral rinses on dental hard tissues*

INCI, *International Nomenclature for Cosmetic Ingredients*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942 and the following apply.

3.1

oral rinse

mouthrinse

mouthwash

liquid formulation used by the public for oral care purposes

[SOURCE: ISO 1942, 2009, 2.209]

3.2

mouthspray

liquid formulation in spray form for oral care purposes not requiring dilution with water

[SOURCE: ISO 1942, 2009, 2.185]

3.3

unintended heavy metals

heavy metal elements, which are detected in the analysis but not purposely included

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