



**SLOVENSKI STANDARD**  
**oSIST prEN ISO 16408:2024**  
**01-junij-2024**

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**Zobozdravstvo - Izdelki za ustno nego - Sredstva za izpiranje ust (ISO/DIS 16408:2024)**

Dentistry - Oral care products - Oral rinses (ISO/DIS 16408:2024)

Zahnheilkunde - Mundhygieneprodukte - Mundspüllösungen und Mundwässer (ISO/DIS 16408:2024)

Médecine bucco-dentaire - Produits de soins bucco-dentaire - Bains de bouche (ISO/DIS 16408:2024)

**Ta slovenski standard je istoveten z: prEN ISO 16408**

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**ICS:**

11.060.01	Zobozdravstvo na splošno	Dentistry in general
71.100.70	Kozmetika. Toaletni pripomočki	Cosmetics. Toiletries

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**en,fr,de**





# DRAFT International Standard

## ISO/DIS 16408

### Dentistry — Oral care products — Oral rinses

*Médecine bucco-dentaire — Produits d'hygiène bucco-dentaires  
— Bains de bouche*

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## ISO/DIS 16408:2024(en)

## Foreword

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This document was prepared by Technical Committee ISO/ TC 106, *Dentistry*, Subcommittee SC 7, *Oral care products*.

This third edition cancels and replaces the second edition (ISO 16408:2015), which has been technically revised with the following changes:

- Updates according to ISO/IEC Directives for [Clauses 1](#) and [3](#).
- [Clause 2](#) were updated to include the latest version of ISO 8601-1 and to include ISO 19448.
- [Clause 3](#) was updated to remove the definition of mouth spray as it is outside the scope of the document.
- [Subclause 5.1](#) was clarified as ISO 28888 contains a screening method for non-fluoridated oral rinses.
- [Subclause 5.2](#) was updated to lower the maximum fluoride per container and to reference new [subclause 7.4](#) and ISO 19448.
- [Subclause 5.3](#) was updated to include a reference to USP <233> Elemental Impurities Procedures.
- [Subclause 5.5](#) was updated to include references to USP <61>, USP <62>, and Ph.Eur. 2.6.12., include a note regarding acceptance criteria, and to harmonize language with ISO 11609.
- [Subclause 7.4](#) was added to include parts of removed Annex A.
- [Clause 8](#) g) date of the test was added.
- [Subclause 9.2](#) e) was updated to only include ingredients according to INCI.
- [Subclause 9.2](#) g) was clarified regarding ethanol.
- [Subclause 9.2](#) j) updated to include “and under adult supervision”.
- Annex A was removed as [subclause 7.4](#) and ISO 19448 are now referenced for the determination of fluoride.