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## Dentistry — Oral care products — Oral rinses

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

**ISO 16408**

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**Third edition  
2025-06**

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This document was prepared by Technical Committee ISO/ TC 106, Dentistry, Subcommittee SC 7, Oral care products, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 55, Dentistry, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This third edition cancels and replaces the second edition (ISO 16408:2015), which has been technically revised. The main changes are as follows:

- [Clauses 1](#) and [3](#) were updated according to the ISO/IEC Directives, Part 2;
- [Clause 2](#) was 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 beyond the scope of this document;
- [subclause 5.1](#) was clarified as ISO 28888 contains a screening method for non-fluoridated oral rinses, and was also updated to include a reference for the critical pH of enamel erosion;
- [subclause 5.2](#) was updated to note the concentration of fluoride in mg/kg, to lower the maximum fluoride per container and to reference [7.4](#), which was added, 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, to add a note on acceptance criteria and to harmonize language with ISO 11609;
- [Clause 8 g\)](#) was updated to include the date of the test, the names of samples and deviations from procedure;
- [subclause 9.1](#) and [9.2](#) were updated for clarity;
- [subclause 9.2 e\)](#) was updated to note that the International Nomenclature for Cosmetic Ingredients is normally used for listing ingredients on the packaging;
- [subclause 9.2 g\)](#) was clarified regarding ethanol;

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- Annex A was removed as [7.4](#) and ISO 19448 are now referenced for the determination of fluoride;
- the Bibliography was reorganized according to the order that the references are mentioned in the document.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at [www.iso.org/members.html](http://www.iso.org/members.html).

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Oral rinses are used for oral hygiene purposes. They are intended to provide either health or cosmetic benefits or both.