

Dentistry - Screening method for erosion potential of oral rinses on dental hard tissues (ISO 28888:2013)

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

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English Version

Dentistry - Screening method for erosion potential of oral rinses
on dental hard tissues (ISO 28888:2013)

Médecine bucco-dentaire - Méthode de criblage de
l'érosion potentielle des tissus durs dentaires due aux
rinçages oraux (ISO 28888:2013)

Zahnheilkunde - Screeningverfahren für das
Erosionspotential von Mundwässern auf Zahnhartgewebe
(ISO 28888:2013)

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Foreword

This document (EN ISO 28888:2013) 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of an identical text or by endorsement, at the latest by April 2014, and conflicting national standards shall be withdrawn at the latest by April 2014.

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Endorsement notice

The text of ISO 28888:2013 has been approved by CEN as EN ISO 28888:2013 without any modification.

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Introduction

This International Standard describes a screening method for assessing the erosion potential of dental hard tissues associated with the use of oral rinses.

The primary aim of this International Standard is to provide methodology for screening oral rinses for the potential for tooth erosion.

Oral rinses should not cause adverse reactions to the oral soft and hard tissues when used in accordance with the manufacturer's recommendation for frequency and duration of use.

The range of known side effects and biological hazards is wide and complex. The tissue interaction with a constituent material alone cannot be considered in isolation from the overall device design. Thus, in designing an oral rinse, the choice of the best material with respect to its tissue interaction might result in a less functional product, tissue interaction being only one of a number of characteristics to be considered in making that choice. Where a material is intended to interact with tissue in order to perform its function, the biological response to this interaction can be evaluated.

Dentistry — Screening method for erosion potential of oral rinses on dental hard tissues

1 Scope

This International Standard specifies a screening method for the erosion potential of non-fluoridated oral rinses on dental hard tissues.

The results of the screening method are intended for use in enamel and/or dentine erosion models.

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 78-2, *Chemistry — Layouts for standards — Part 2: Methods of chemical analysis*

ISO 1942, *Dentistry — Vocabulary*

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

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 78-2, ISO 1942 and the following apply.

3.1

dental erosion

progressive loss of calcified dental hard tissue by chemical processes that do not involve bacterial action

[SOURCE: ISO 1942:2009, 2.292]

4 Test method

4.1 General

The risk of enamel and dentine erosion due to oral rinses shall be assessed.

This method is intended to provide initial screening of potential for erosion for all non-fluoridated oral rinses.

In case a product fails the screening test, test methods that are more complex and close to clinical conditions shall be applied.

4.2 Maximum decrease in pH

The maximum allowable decrease in pH of this test method shall be 1,0.

Should a decrease of the pH greater than 1,0 be determined, then the oral rinse fails this screening test. In this case, test methods that are more complex and close to clinical conditions shall be performed in order to establish the erosive capacity of the oral rinse as specified in ISO 16408.