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

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 28888:2013 sisaldab Euroopa standardi EN ISO 28888:2013 inglisekeelset teksti.	This Estonian standard EVS-EN ISO 28888:2013 consists of the English text of the European standard EN ISO 28888:2013.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 02.10.2013.	Date of Availability of the European standard is 02.10.2013.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

ICS 97.170

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 28888

October 2013

ICS 97.170

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)

This European Standard was approved by CEN on 31 August 2013.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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

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of an identical text or by endorsement, at the latest by April 2014, and conflicting national standards shall be withdrawn at the latest by April 2014.

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.

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

Contents

Page

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.