

Dentistry - Products for external tooth bleaching (ISO 28399:2011)

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 28399:2011 sisaldab Euroopa standardi EN ISO 28399:2011 ingliskeelset teksti.

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This Estonian standard EVS-EN ISO 28399:2011 consists of the English text of the European standard EN ISO 28399:2011.

This standard is ratified with the order of Estonian Centre for Standardisation dated 28.02.2011 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.

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English Version

Dentistry - Products for external tooth bleaching (ISO
28399:2011)

Médecine bucco-dentaire - Produits d'éclaircissement
dentaire, à usage externe (ISO 28399:2011)

Zahnheilkunde - Externe Zahnbleichmittel (ISO
28399:2011)

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Foreword

This document (EN ISO 28399:2011) 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of an identical text or by endorsement, at the latest by July 2011, and conflicting national standards shall be withdrawn at the latest by July 2011.

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Endorsement notice

The text of ISO 28399:2011 has been approved by CEN as a EN ISO 28399:2011 without any modification.

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Introduction

Products for external tooth bleaching are used in dentistry for changing the colour of natural teeth towards a lighter or whiter shade. They are applied in the oral cavity directly on the outer surfaces of teeth. This International Standard includes requirements and test methods for products intended for external bleaching of natural teeth by chemical means.

Dentistry — Products for external tooth bleaching

1 Scope

This International Standard specifies requirements and test methods for external tooth bleaching products. These products are intended for use in the oral cavity, either by professional application (in-office tooth bleaching products) or consumer application (professional or non-professional home use of tooth bleaching products), or both. It also specifies requirements for their packaging, labelling and instructions for use.

This International Standard is not applicable to tooth bleaching products:

- specified in ISO 11609;
- those intended to change colour perception of natural teeth by mechanical methods (e.g. stain removal) or using restorative approaches, such as veneers or crowns;
- auxiliary or supplementary materials (e.g. tray materials) and instruments or devices (e.g. lights) that are used in conjunction with the bleaching products.

This International Standard does not specify biological safety aspects of tooth bleaching products.

NOTE A tooth bleaching product can be evaluated for its biological safety using ISO 10993-1 and ISO 7405.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 1942:2009 *Dentistry — Vocabulary*

ISO 6344-1, *Coated abrasives — Grain size analysis — Part 1: Grain size distribution test*

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

3 Terms and definitions

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

3.1

bleaching

⟨natural teeth⟩ removal of intrinsic or acquired discolorations of natural teeth through the use of chemicals, sometimes in combination with the application of auxiliary means

NOTE Adapted from ISO 1942:2009, 2.28.