



**SLOVENSKI STANDARD**  
**oSIST prEN ISO 28399:2009**  
**01-julij-2009**

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**Zobobzdravstvo - Izdelki za zunanje beljenje zob (ISO/DIS 28399:2009)**

Dentistry - Products for external tooth bleaching (ISO/DIS 28399:2009)

Zahnheilkunde - Äußere Zahnbleichmittel (ISO/DIS 28399:2009)

Art dentaire - Produits d'éclaircissement dentaire (ISO/DIS 28399:2009)

**Ta slovenski standard je istoveten z: prEN ISO 28399**

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**ICS:**

97.170      Oprema za nego telesa      Body care equipment

**oSIST prEN ISO 28399:2009**

**en,fr,de**



EUROPEAN STANDARD  
NORME EUROPÉENNE  
EUROPÄISCHE NORM

**DRAFT**  
**prEN ISO 28399**

March 2009

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ICS 97.170

English Version

## Dentistry - Products for external tooth bleaching (ISO/DIS 28399:2009)

Art dentaire - Produits d'éclaircissement dentaire (ISO/DIS  
28399:2009)

This draft European Standard is submitted to CEN members for parallel enquiry. It has been drawn up by the Technical Committee CEN/TC 55.

If this draft becomes a European Standard, CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

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COMITÉ EUROPÉEN DE NORMALISATION  
EUROPÄISCHES KOMITEE FÜR NORMUNG

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<b>Contents</b>	<b>Page</b>
Foreword.....	<b>3</b>

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## Foreword

This document (prEN ISO 28399:2009) 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 document is currently submitted to the parallel Enquiry.

### Endorsement notice

The text of ISO/DIS 28399:2009 has been approved by CEN as a prEN ISO 28399:2009 without any modification.

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## DRAFT INTERNATIONAL STANDARD ISO/DIS 28399

ISO/TC 106/SC 7

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# Dentistry — Products for external tooth bleaching

*Art dentaire — Produits d'éclaircissement dentaire*

ICS 97.170

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### ISO/CEN PARALLEL PROCESSING

This draft has been developed within the International Organization for Standardization (ISO), and processed under the **ISO-lead** mode of collaboration as defined in the Vienna Agreement.

This draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel five-month enquiry.

Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month approval vote in ISO and formal vote in CEN.

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## Contents

	Page
Foreword.....	iv
Introduction.....	v
1 Scope .....	1
2 Normative references .....	1
3 Terms and definitions .....	1
3.1 Bleaching (of natural teeth).....	1
4 Classification.....	2
4.1 Professionally applied.....	2
4.2 Consumer applied .....	2
5 Requirements .....	2
5.1 Peroxide concentration .....	2
5.2 Surface microhardness .....	2
5.3 Surface erosion.....	2
6 Test methods.....	2
6.1 Preparation of tooth specimens.....	2
6.2 Preparation and application of Test samples.....	2
6.3 Surface microhardness .....	2
7 Packaging, marking and information to be supplied by the manufacturer .....	3
7.1 Packaging .....	3
7.2 Marking and instructions for use .....	3
Annex A (Normative).....	5
Test method for the measurement of hydrogen peroxide concentration.....	5
Annex B (Informative) .....	6
Test method for the measurement of erosion of enamel and dentine by products for external tooth bleaching .....	6
Annex C (Informative) .....	8
A method for laboratory assessment of tooth bleaching efficacy .....	8
Bibliography .....	10

## ISO/DIS 28399

**Foreword**

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 28339 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 7, *Oral care products*

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DRAFT

## Introduction

Products for external tooth bleaching are used in dentistry primarily for changing the colour of natural teeth towards lighter or whiter direction. They are applied in the oral cavity directly on the outer surfaces of teeth. This Standard includes requirements and test methods for products intended for external bleaching natural teeth by chemical means. A tooth bleaching product should be evaluated to determine its biological safety according to ISO 10993-1 and ISO 7405.

The efficacy of a bleaching product should be established by clinically relevant tooth colour change towards lighter or whiter direction using acceptable methods such as shade guides and/or electronic instruments; the methods should be described adequately and available for validation. In the case that clinical data on the efficacy of a tooth bleaching product is not available, users of this standard intending to assess the efficacy *in vitro* are advised to consider using a laboratory method as that given in Annex C (Informative).

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