



# SLOVENSKI STANDARD SIST EN ISO 28399:2020

01-maj-2020

Nadomešča:  
SIST EN ISO 28399:2011

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## Zobozdravstvo - Proizvodi za zunanje beljenje zob (ISO 28399:2020)

Dentistry - External tooth bleaching products (ISO 28399:2020)

Zahnheilkunde - Äußere Zahnbleichmittel (ISO 28399:2020)

Médecine bucco-dentaire - Produits d'éclaircissement dentaire, à usage externe (ISO 28399:2020)

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Ta slovenski standard je istoveten z: **EN ISO 28399:2020**  
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### **ICS:**

11.060.01	Zobozdravstvo na splošno	Dentistry in general
71.100.70	Kozmetika. Toaletni pripomočki	Cosmetics. Toiletries

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EUROPEAN STANDARD

EN ISO 28399

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## Dentistry - External tooth bleaching products (ISO 28399:2020)

Médecine bucco-dentaire - Produits d'éclaircissement dentaire, à usage externe (ISO 28399:2020)

Zahnheilkunde - Äußere Zahnbleichmittel (ISO 28399:2020)

This European Standard was approved by CEN on 2 March 2020.

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Contents	Page
European foreword.....	3

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## European foreword

This document (EN ISO 28399:2020) 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of an identical text or by endorsement, at the latest by September 2020, and conflicting national standards shall be withdrawn at the latest by September 2020.

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

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INTERNATIONAL  
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ISO  
28399

Second edition  
2020-03

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**Dentistry — External tooth bleaching  
products**

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# Contents

Page

<b>Foreword</b> .....	<b>iv</b>
<b>Introduction</b> .....	<b>v</b>
<b>1 Scope</b> .....	<b>1</b>
<b>2 Normative references</b> .....	<b>1</b>
<b>3 Terms and definitions</b> .....	<b>2</b>
<b>4 Classification</b> .....	<b>2</b>
4.1 General.....	2
4.2 Products for professional application.....	2
4.3 Products for consumer application.....	2
<b>5 Requirements</b> .....	<b>3</b>
5.1 Concentration of active ingredients for bleaching.....	3
5.2 Surface microhardness.....	3
5.3 Surface erosion.....	3
<b>6 Measurements and test methods</b> .....	<b>3</b>
6.1 Preparation of tooth specimens.....	3
6.2 Preparation and application of tooth bleaching product.....	3
6.3 Surface microhardness.....	3
<b>7 Packaging, marking and information to be supplied by the manufacturer</b> .....	<b>3</b>
7.1 General.....	3
7.2 Packaging.....	4
7.3 Marking and instructions for use.....	4
<b>Annex A (informative) Test method for the measurement of hydrogen peroxide concentration</b> .....	<b>5</b>
<b>Annex B (informative) Light microscopy method for measuring erosion of enamel and dentine caused by external tooth bleaching products</b> .....	<b>6</b>
<b>Annex C (informative) Test method for laboratory assessment of tooth bleaching efficacy</b> .....	<b>19</b>
<b>Bibliography</b> .....	<b>22</b>

## ISO 28399:2020(E)

### 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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see [www.iso.org/directives](http://www.iso.org/directives)).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see [www.iso.org/patents](http://www.iso.org/patents)).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see [www.iso.org/iso/foreword.html](http://www.iso.org/iso/foreword.html).

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 second edition cancels and replaces the first edition (ISO 28399:2011), which has been technically revised. The main changes compared to the previous edition are as follows:

- a light microscopy method is recommended as an example for the measurement of erosion of enamel and dentine caused by external tooth bleaching products;
- a visual assessment with shade guide has been revised.

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).

## Introduction

External tooth bleaching products 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 document includes requirements and test methods for products intended for external bleaching of natural teeth by chemical means.

Specific qualitative and quantitative requirements for freedom from biological hazard are not included in this document. It is recommended, that reference should be made to ISO 10993-1 and ISO 7405 when assessing possible biological or toxicological hazards.

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