



SLOVENSKI STANDARD
SIST EN ISO 28399:2021

01-julij-2021

Nadomešča:
SIST EN ISO 28399:2020

Zobozdravstvo - Proizvodi za zunanje beljenje zob (ISO 28399:2021)

Dentistry - External tooth bleaching products (ISO 28399:2021)

Zahnheilkunde - Äußere Zahnbleichmittel (ISO 28399:2021)

Médecine bucco-dentaire - Produits d'éclaircissement dentaire par voie externe (ISO 28399:2021)

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Ta slovenski standard je istoveten z: EN ISO 28399:2021

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ICS:

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71.100.70	Kozmetika. Toaletni pripomočki	Cosmetics. Toiletries

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EUROPEAN STANDARD

EN ISO 28399

NORME EUROPÉENNE

EUROPÄISCHE NORM

April 2021

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Supersedes EN ISO 28399:2020

English Version

Dentistry - External tooth bleaching products (ISO 28399:2021)

Médecine bucco-dentaire - Produits d'éclaircissement dentaire par voie externe (ISO 28399:2021)

Zahnheilkunde - Äußere Zahnbleichmittel (ISO 28399:2021)

This European Standard was approved by CEN on 21 February 2021.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
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CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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European foreword

This document (EN ISO 28399:2021) 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of an identical text or by endorsement, at the latest by October 2021, and conflicting national standards shall be withdrawn at the latest by October 2021.

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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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, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

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INTERNATIONAL
STANDARD

ISO
28399

Third edition
2021-03

**Dentistry — External tooth bleaching
products**

*Médecine bucco-dentaire — Produits d'éclaircissement dentaire par
voie externe*

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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).

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).

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.

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 third edition cancels and replaces the second edition (ISO 28399:2020), which has been editorially revised. The changes compared to the previous edition are as follows:

- “TEM” has been removed from “TEM grid” throughout this third edition;
- [B.10.2.6](#) EXAMPLE has been rewritten;
- “[B.9 A\)](#)” has been replaced with “[B.9](#)”;
- “See [Figure B.9 B](#)” has been removed;
- “In [Figure B.9 C](#), the value is 51,916 3 (i.e. 51,9 µm)” has been removed and [Figure B.9, k](#)), “number of ” has been replaced with “width in”;
- In [C.3.3.3](#), “ ΔE_{ab}^* ” has been added in the space between two commas.

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.

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.

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

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