

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

## EESTI STANDARDI EESSÕNA

## NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 28399:2020 sisaldab Euroopa standardi EN ISO 28399:2020 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 28399:2020 consists of the English text of the European standard EN ISO 28399:2020.
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.
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Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

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English Version

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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This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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EUROPÄISCHES KOMITEE FÜR NORMUNG

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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of an identical text or by endorsement, at the latest by September 2020, and conflicting national standards shall be withdrawn at the latest by September 2020.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.

This document supersedes EN ISO 28399:2011.

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.

## Endorsement notice

The text of ISO 28399:2020 has been approved by CEN as EN ISO 28399:2020 without any modification.

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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](http://www.iso.org/directives)).

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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.

# Dentistry — External tooth bleaching products

## 1 Scope

This document 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 manufacturer's instructions for use.

This document is not applicable to tooth bleaching products:

- specified in ISO 11609;
- 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 document does not specify biological safety aspects of tooth bleaching products.

NOTE Maximum concentration of a bleaching agent for professional or non-professional use is subject to each country's regulatory body.

## 2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 1042, *Laboratory glassware — One-mark volumetric flasks*

ISO 1942, *Dentistry — Vocabulary*

ISO 3696, *Water for analytical laboratory use — Specification and test methods*

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

ISO 7405, *Dentistry — Evaluation of biocompatibility of medical devices used in dentistry*

ISO 8601-1, *Date and time — Representations for information interchange — Part 1: Basic rules*

ISO 8601-2, *Date and time — Representations for information interchange — Part 2: Extensions*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 11664-1:2007, *Colorimetry — Part 1: CIE standard colorimetric observers*

ISO 11664-2:2007, *Colorimetry — Part 2: CIE standard illuminants*

ANSI/ADA Specification No. 41: *Recommended Standard Practices for Biological Evaluation of Dental Materials*