BS EN ISO 28399:2021

BSI Standards Publication

Dentistry – External tooth bleaching products

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National foreword

This British Standard is the UK implementation of EN ISO 28399:2021. It is identical to ISO 28399:2021. It supersedes BS EN ISO 28399:2020, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/106/7, Oral hygiene products.

A list of organizations represented on this committee can be obtained on request to its committee manager.

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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)

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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of an identical text or by endorsement, at the latest by October 2021, and conflicting national standards shall be withdrawn at the latest by October 2021.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.

This document supersedes EN ISO 28399:2020.

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 28399:2021 has been approved by CEN as EN ISO 28399:2021 without any modification.

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Document Sharing Hub

Full document details: BS EN ISO 28399:2021

Contents

Page

Foreword ... **iv**

Introduction ... **v**

1 Scope ... **1**

2 Normative references ... **1**

3 Terms and definitions ... **1**

4 Classification ... **2**
- 4.1 General ... 2
- 4.2 Products for professional application ... 2
- 4.3 Products for consumer application ... 2

5 Requirements ... **3**
- 5.1 Concentration of active ingredients for bleaching ... 3
- 5.2 Surface microhardness ... 3
- 5.3 Surface erosion ... 3

6 Measurements and test methods ... **3**
- 6.1 Preparation of tooth specimens ... 3
- 6.2 Preparation and application of tooth bleaching product ... 3
- 6.3 Surface microhardness ... 3

7 Packaging, marking and information to be supplied by the manufacturer ... **3**
- 7.1 General ... 3
- 7.2 Packaging ... 4
- 7.3 Marking and instructions for use ... 4

Annex A (informative) **Test method for the measurement of hydrogen peroxide concentration** ... **5**

Annex B (informative) **Light microscopy method for measuring erosion of enamel and dentine caused by external tooth bleaching products** ... **6**

Annex C (informative) **Test method for laboratory assessment of tooth bleaching efficacy** ... **19**

Bibliography ... **22**

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Document Sharing Hub

Full document details: BS EN ISO 28399:2021

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).

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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.

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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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Dentistry — External tooth bleaching products

1 Scope

This document specifies the 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 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/CIE 11664-1, *Colorimetry — Part 1: CIE standard colorimetric observers*

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

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

3 Terms and definitions

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

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

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— IEC Electropedia: available at http://www.electropedia.org/

3.1
bleaching
<natural teeth> removal of intrinsic or acquired discolorations of natural teeth, or changing their colour towards a lighter or whiter shade using chemicals, sometimes in combination with the application of auxiliary means

Note 1 to entry: Changing the colour of natural teeth towards a lighter or whiter shade is not limited to changing a discoloration.

Note 2 to entry: Auxiliary means for bleaching other than the application of external energy are also conceivable.

[SOURCE: ISO 1942:2009, 2.28, modified — Note 1 to entry and Note 2 to entry have been added.]

3.2
professional home use
<product> use prescribed by a professional and for use at home under the repeated supervision of the dentist

3.3
erosion
<tooth surface> progressive loss of calcified tissue by chemical processes that do not involve bacterial action

[SOURCE: ISO 1942:2009, 2.292, modified — the term has been modified, the admitted term has been deleted and a domain has been added.]

4 Classification

4.1 General

External tooth bleaching products can be classified for either:

a) professional application; or

b) consumer application.

NOTE External tooth bleaching products can be used alone or in conjunction with auxiliary means of application.

4.2 Products for professional application

These products are tooth bleaching products that are intended by the manufacturer to be applied only by dental professionals (in office tooth bleaching products).

4.3 Products for consumer application

These products are tooth bleaching products that are intended by the manufacturer to be applied by the consumer (for professional home use or for non-professional home use).

NOTE Such external bleaching products can be prescribed by a dental professional or directly available to consumers.

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