



NSAI
Standards

Irish Standard
I.S. EN ISO 28399:2011

Dentistry - Products for external tooth bleaching (ISO 28399:2011)

I.S. EN ISO 28399:2011

Incorporating amendments/corrigenda/National Annexes issued since publication:

The National Standards Authority of Ireland (NSAI) produces the following categories of formal documents:

I.S. xxx: Irish Standard – national specification based on the consensus of an expert panel and subject to public consultation.

S.R. xxx: Standard Recommendation - recommendation based on the consensus of an expert panel and subject to public consultation.

SWIFT xxx: A rapidly developed recommendatory document based on the consensus of the participants of an NSAI workshop.

This document replaces:

This document is based on:
EN ISO 28399:2011

Published:
27 January, 2011

This document was published
under the authority of the NSAI
and comes into effect on:
27 January, 2011

ICS number:
97.170

NSAI
1 Swift Square,
Northwood, Santry
Dublin 9

T +353 1 807 3800
F +353 1 807 3838
E standards@nsai.ie
W NSAI.ie

Sales:
T +353 1 857 6730
F +353 1 857 6729
W standards.ie

Údarás um Chaighdeáin Náisiúnta na hÉireann

I.S. EN ISO 28399:2011

EUROPEAN STANDARD

EN ISO 28399

NORME EUROPÉENNE

EUROPÄISCHE NORM

January 2011

ICS 97.170

English Version

Dentistry - Products for external tooth bleaching (ISO 28399:2011)

Médecine bucco-dentaire - Produits d'éclaircissement dentaire, à usage externe (ISO 28399:2011)

Zahnheilkunde - Externe Zahnbleichmittel (ISO 28399:2011)

This European Standard was approved by CEN on 11 September 2010.

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. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

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.

CEN members are the national standards bodies of 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, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.



EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: Avenue Marnix 17, B-1000 Brussels

Contents

Page

Foreword.....	3
----------------------	----------

Foreword

This document (EN ISO 28399:2011) 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 July 2011, and conflicting national standards shall be withdrawn at the latest by July 2011.

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

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, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of ISO 28399:2011 has been approved by CEN as a EN ISO 28399:2011 without any modification.

This page is intentionally left BLANK.

I.S. EN ISO 28399:2011
**INTERNATIONAL
STANDARD**

**ISO
28399**

First edition
2011-01-15

**Dentistry — Products for external tooth
bleaching**

*Médecine bucco-dentaire — Produits d'éclaircissement dentaire, à
usage externe*



Reference number
ISO 28399:2011(E)

© ISO 2011

PDF disclaimer

This PDF file may contain embedded typefaces. In accordance with Adobe's licensing policy, this file may be printed or viewed but shall not be edited unless the typefaces which are embedded are licensed to and installed on the computer performing the editing. In downloading this file, parties accept therein the responsibility of not infringing Adobe's licensing policy. The ISO Central Secretariat accepts no liability in this area.

Adobe is a trademark of Adobe Systems Incorporated.

Details of the software products used to create this PDF file can be found in the General Info relative to the file; the PDF-creation parameters were optimized for printing. Every care has been taken to ensure that the file is suitable for use by ISO member bodies. In the unlikely event that a problem relating to it is found, please inform the Central Secretariat at the address given below.



COPYRIGHT PROTECTED DOCUMENT

© ISO 2011

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

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.....	2
5.1 Concentration of active ingredients for bleaching	2
5.2 Surface microhardness.....	2
5.3 Surface erosion	2
6 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.....	3
7.3 Marking and instructions for use.....	3
Annex A (informative) Test method for the measurement of hydrogen peroxide concentration.....	5
Annex B (informative) Test method for the measurement of erosion of enamel and dentine caused by products for external tooth bleaching	6
Annex C (informative) Test method for laboratory assessment of tooth bleaching efficacy	10
Bibliography.....	13

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 28399 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 7, *Oral care products*.

Introduction

Products for external tooth bleaching 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 International Standard includes requirements and test methods for products intended for external bleaching of natural teeth by chemical means.

I.S. EN ISO 28399:2011

This is a free preview. Purchase the entire publication at the link below:

[Product Page](#)

-
- Looking for additional Standards? Visit Intertek Inform Infostore
 - Learn about LexConnect, All Jurisdictions, Standards referenced in Australian legislation
-