

Dentistry - Polymer-based restorative materials

This document is a preview generated by EVS

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 4049:2009 sisaldab Euroopa standardi EN ISO 4049:2009 ingliskeelset teksti.

Standard on kinnitatud Eesti Standardikeskuse 31.12.2009 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.

Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 01.10.2009.

Standard on kättesaadav Eesti standardiorganisatsioonist.

This Estonian standard EVS-EN ISO 4049:2009 consists of the English text of the European standard EN ISO 4049:2009.

This standard is ratified with the order of Estonian Centre for Standardisation dated 31.12.2009 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.

Date of Availability of the European standard text 01.10.2009.

The standard is available from Estonian standardisation organisation.

ICS 11.060.10

Standardite reprodutseerimis- ja levitamiseõigus kuulub Eesti Standardikeskusele

Andmete paljundamine, taastekitamine, kopeerimine, salvestamine elektroonilisse süsteemi või edastamine ükskõik millises vormis või millisel teel on keelatud ilma Eesti Standardikeskuse poolt antud kirjaliku loata.

Kui Teil on küsimusi standardite autorikaitse kohta, palun võtke ühendust Eesti Standardikeskusega:
Aru 10 Tallinn 10317 Eesti; www.evs.ee; Telefon: 605 5050; E-post: info@evs.ee

Right to reproduce and distribute Estonian Standards belongs to the Estonian Centre for Standardisation

No part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying, without permission in writing from Estonian Centre for Standardisation.

If you have any questions about standards copyright, please contact Estonian Centre for Standardisation:
Aru str 10 Tallinn 10317 Estonia; www.evs.ee; Phone: +372 605 5050; E-mail: info@evs.ee

English Version

Dentistry - Polymer-based restorative materials (ISO 4049:2009)

Art dentaire - Produits de restauration à base de polymères
(ISO 4049:2009)

Zahnheilkunde - Polymerbasierende
Restaurationsmaterialien (ISO 4049:2009)

This European Standard was approved by CEN on 24 September 2009.

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 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 Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, 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

Foreword

This document (EN ISO 4049:2009) 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 April 2010, and conflicting national standards shall be withdrawn at the latest by April 2010.

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.

This document supersedes EN ISO 4049:2000.

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, 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 4049:2009 has been approved by CEN as a EN ISO 4049:2009 without any modification.

Contents

Page

| | |
|--|----|
| Foreword | iv |
| Introduction | v |
| 1 Scope | 1 |
| 2 Normative references | 1 |
| 3 Terms and definitions | 1 |
| 4 Classification | 2 |
| 5 Requirements | 2 |
| 5.1 Biocompatibility | 2 |
| 5.2 Physical and chemical properties | 2 |
| 5.3 Shade, restorative materials | 4 |
| 5.4 Colour stability after irradiation and water sorption | 4 |
| 5.5 Radio-opacity | 4 |
| 6 Sampling | 5 |
| 7 Test methods | 5 |
| 7.1 General reagent — Water | 5 |
| 7.2 Test conditions | 6 |
| 7.3 Inspection | 6 |
| 7.4 Preparation of test specimens | 6 |
| 7.5 Measurement of film thickness of luting materials | 6 |
| 7.6 Working time, Class 1 and Class 3 restorative materials, excluding luting materials | 9 |
| 7.7 Working time, Class 1 and Class 3 luting materials | 11 |
| 7.8 Setting time, Class 1 and Class 3 materials | 11 |
| 7.9 Sensitivity to ambient light, Class 2 materials | 13 |
| 7.10 Depth of cure, Class 2 materials | 14 |
| 7.11 Flexural strength | 15 |
| 7.12 Water sorption and solubility | 18 |
| 7.13 Shade and colour stability after irradiation and water sorption | 21 |
| 7.14 Radio-opacity | 22 |
| 8 Packaging, marking and instructions and information to be supplied by the manufacturer | 25 |
| 8.1 Packaging | 25 |
| 8.2 Marking | 25 |
| 8.3 Manufacturer's instructions and information for the user | 27 |
| Bibliography | 28 |

Introduction

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

Dentistry — Polymer-based restorative materials

1 Scope

This International Standard specifies requirements for dental polymer-based restorative materials supplied in a form suitable for mechanical mixing, hand-mixing, or intra-oral and extra-oral external energy activation, and intended for use primarily for the direct or indirect restoration of cavities in the teeth and for luting.

The polymer-based luting materials covered by this International Standard are intended for use in the cementation or fixation of restorations and appliances such as inlays, onlays, veneers, crowns and bridges. This International Standard does not cover those polymer-based luting materials that have an adhesive component within the structure of the material.

This International Standard does not cover materials intended to prevent caries (see ISO 6874) or those used for veneering metal sub-frames (see ISO 10477).

2 Normative references

The following referenced documents are indispensable for the application 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 1942, *Dentistry — Vocabulary*

ISO 3665, *Photography — Intra-oral dental radiographic film — Specification*

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

ISO 7491, *Dental materials — Determination of colour stability*

ISO 8601, *Data elements and interchange formats — Information interchange — Representation of dates and times*

3 Terms and definitions

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

3.1

opaque luting material

intensely pigmented polymer-based luting material intended to mask underlying materials and tooth structure

3.2

opaque

shade of an intensely pigmented polymer-based restorative material