



SLOVENSKI STANDARD SIST EN ISO 4049:2000

01-november-2000

BUXca Yý U

SIST EN 24049:2000

SIST EN 24049:2000/AC:2000

Dentistry - Polymer-based filling, restorative and luting materials (ISO 4049:2000)

Dentistry - Polymer-based filling, restorative and luting materials (ISO 4049:2000)

Zahnheilkunde - Füllungs-, restaurative und Befestigungskunststoffe (ISO 4049:2000)

Art dentaire - Produits d'obturation, de restauration et de scellement a base de polymeres (ISO 4049:2000)

[SIST EN ISO 4049:2000](https://standards.iteh.ai/catalog/standards/sist/c959031c-5179-46ca-ab9b-766ee90d39f8/sist-en-iso-4049-2000)

[https://standards.iteh.ai/catalog/standards/sist/c959031c-5179-46ca-ab9b-](https://standards.iteh.ai/catalog/standards/sist/c959031c-5179-46ca-ab9b-766ee90d39f8/sist-en-iso-4049-2000)

Ta slovenski standard je istoveten z: EN ISO 4049:2000

ICS:

11.060.10 Z[à [c @ ã } ã æ | ã ã Dental materials

SIST EN ISO 4049:2000

en

iTeh STANDARD PREVIEW
(standards.iteh.ai)

SIST EN ISO 4049:2000

<https://standards.iteh.ai/catalog/standards/sist/c959031c-5179-46ca-ab9b-766ee90d39f8/sist-en-iso-4049-2000>

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 4049

July 2000

ICS 11.060.10

Supersedes EN 24049:1993

English version

Dentistry - Polymer-based filling, restorative and luting materials (ISO 4049:2000)

Art dentaire - Produits d'obturation, de restauration et de scellement à base de polymères (ISO 4049:2000)

This European Standard was approved by CEN on 12 July 2000.

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 Central Secretariat 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 Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

iTeh STANDARD PREVIEW
(standards.itih.ai)

SIST EN ISO 4049:2000

<https://standards.itih.ai/catalog/standards/sist/c959031c-5179-46ca-ab9b-766ce90d39f8/sist-en-iso-4049-2000>



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

Central Secretariat: rue de Stassart, 36 B-1050 Brussels

Page 2
EN ISO 4049:2000

Foreword

The text of the International Standard ISO 4049:2000 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 supersedes EN 24049:1993.

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 January 2001, and conflicting national standards shall be withdrawn at the latest by January 2001.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

NOTE FROM CEN/CS: The foreword is susceptible to be amended on reception of the German language version. The confirmed or amended foreword, and when appropriate, the normative annex ZA for the references to international publications with their relevant European publications will be circulated with the German version.

Endorsement notice

The text of the International Standard ISO 4049:2000 was approved by CEN as a European Standard without any modification.

SIST EN ISO 4049:2000

<https://standards.iteh.ai/catalog/standards/sist/c959031c-5179-46ca-ab9b-766ce90d39f8/sist-en-iso-4049-2000>

INTERNATIONAL STANDARD

**ISO
4049**

Third edition
2000-07-15

Dentistry — Polymer-based filling, restorative and luting materials

*Art dentaire — Produits d'obturation, de restauration et de scellement à
base de polymères*

iTeh STANDARD PREVIEW
(standards.iteh.ai)

[SIST EN ISO 4049:2000](https://standards.iteh.ai/catalog/standards/sist/c959031c-5179-46ca-ab9b-766ee90d39f8/sist-en-iso-4049-2000)

<https://standards.iteh.ai/catalog/standards/sist/c959031c-5179-46ca-ab9b-766ee90d39f8/sist-en-iso-4049-2000>



Reference number
ISO 4049:2000(E)

© ISO 2000

ISO 4049:2000(E)

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.

iTeh STANDARD PREVIEW (standards.iteh.ai)

[SIST EN ISO 4049:2000](https://standards.iteh.ai/catalog/standards/sist/c959031c-5179-46ca-ab9b-766ee90d39f8/sist-en-iso-4049-2000)

<https://standards.iteh.ai/catalog/standards/sist/c959031c-5179-46ca-ab9b-766ee90d39f8/sist-en-iso-4049-2000>

© ISO 2000

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.ch
Web www.iso.ch

Printed in Switzerland

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, filling and 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 filling and restorative 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 information to be supplied by the manufacturer	24
8.1 Packaging	24
8.2 Marking	24
8.3 Manufacturer's instructions and information for the user	25
Bibliography.....	27

ISO 4049:2000(E)**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 3.

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 International Standard may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 4049 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 1, *Filling and restorative materials*.

This third edition cancels and replaces the second edition (ISO 4049:1988), which has been technically revised to include those polymer-based restorative materials (inlay/onlay materials) that are processed outside the mouth, in either the dental operator or laboratory. These have been added as Class 2, group 2 materials in a redesigned Classification (see clause 4). Materials that cure by both chemical means and external energy application (dual cure materials) have also been added to the Classification as Class 3 materials.

[SIST EN ISO 4049:2000](https://standards.iteh.ai/catalog/standards/sist/c959031c-5179-46ca-ab9b-766ce90d39f8/sist-en-iso-4049-2000)

<https://standards.iteh.ai/catalog/standards/sist/c959031c-5179-46ca-ab9b-766ce90d39f8/sist-en-iso-4049-2000>

Introduction

This International Standard now includes requirements for materials intended for the restoration of occlusal surfaces (type 1 materials). It does not cover materials intended to prevent caries (see ISO 6874) or those used for veneering metal sub-frames (see ISO 10477). The broad group of polymeric restorative materials that is covered by this standard is subject to rapid developments and during the drafting of this standard several new types of material have been marketed. These include “condensable” and “flowable” composites and “ormocers”. The manufacturers of such materials have the option of claiming compliance with this standard but it should be noted that the materials were not included in any collaborative testing during the preparation of this standard.

Also, this International Standard now includes requirements for polymer-based luting materials that are intended for cementing of restorations and appliances such as inlays, onlays, crowns and bridges. This has resulted in new tests and requirements for the working time and film thickness of luting materials.

In comparison with ISO 4049:1988, alterations have been made to the requirements for flexural properties (see 5.2.9) and water sorption (see 5.2.10). These requirements have been changed following collaborative testing and review of published data.

Changes have been made to the test methods for water sorption and solubility (see 7.12) and radio-opacity (see 7.14.) in order to clarify simplify and improve the accuracy of these tests.

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.

[SIST EN ISO 4049:2000](https://standards.iteh.ai/catalog/standards/sist/c959031c-5179-46ca-ab9b-766ee90d39f8/sist-en-iso-4049-2000)

<https://standards.iteh.ai/catalog/standards/sist/c959031c-5179-46ca-ab9b-766ee90d39f8/sist-en-iso-4049-2000>

iTeh STANDARD PREVIEW
(standards.iteh.ai)

SIST EN ISO 4049:2000

<https://standards.iteh.ai/catalog/standards/sist/c959031c-5179-46ca-ab9b-766ee90d39f8/sist-en-iso-4049-2000>

Dentistry — Polymer-based filling, restorative and luting materials

1 Scope

This International Standard specifies requirements for dental polymer-based filling and restorative materials and polymer-based luting 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.

The luting materials covered by this International Standard are intended for use in the cementing or fixation of restorations and appliances such as inlays, onlays, veneers, crowns and bridges.

This International Standard does not cover requirements for polymeric materials intended for veneering indirectly restoration metal sub-frames (see ISO 10477) and materials intended to prevent caries (see ISO 6874).

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 3665:1996, *Photography — Intra-oral dental radiographic film — Specification.*

ISO 3696:1987, *Water for analytical use — Specification and test methods.*

ISO 7491:1999, *Dental materials — Determination of colour stability of dental materials.*

ISO 8601:1988, *Data elements and interchange formats — Information interchange — Representation of dates and times.*

3 Terms and definitions

For the purposes of this International Standard, the following terms and definitions apply.

3.1

opaquer luting material

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

3.2

opaque

shade of a polymer-based restorative material intended to be less translucent than a non-opaque shade

ISO 4049:2000(E)

4 Classification

For the purposes of this International Standard, dental polymer-based restorative materials are categorized as one of the following types.

- a) **Type 1:** polymer-based filling and restorative materials claimed by the manufacturer as suitable for restorations involving occlusal surfaces;
- b) **Type 2:** all other polymer-based filling and restorative materials.

NOTE 1 It is not necessary to classify polymer-based luting materials into types.

The three classes of dental polymer-based filling, restorative and luting materials are as follows.

- **Class 1:** materials whose setting is effected by mixing an initiator and activator (“self-curing” materials).
- **Class 2:** materials whose setting is effected by the application of energy from an external source, such as blue light or heat (“external-energy-activated” materials). They are subdivided as follows:
 - 1) **Group 1:** materials whose use requires the energy to be applied intra-orally;
 - 2) **Group 2:** materials whose use requires the energy to be applied extra-orally. When fabricated, these materials will be luted into place.

Certain materials may be claimed by manufacturers to be both Group 1 and Group 2. In this event the material should fulfil the requirements for both groups.

NOTE 2 Class 2 luting materials will fall into Group 1 only.

- **Class 3:** materials that are cured by the application of external energy and also have a self-curing mechanism present [“dual cure” materials; see 8.3 e)].

5 Requirements

5.1 Biocompatibility

See the Introduction for guidance on biocompatibility. See ISO 7405 and ISO 10993-1 for further information.

5.2 Physical and chemical properties

5.2.1 General

If a filling and restorative material is supplied by the manufacturer in various shades, each shade, including opaque shades, shall be capable of satisfying all the requirements for sensitivity to ambient light (5.2.7), depth of cure (5.2.8), shade (5.3) and colour stability (5.4) appropriate to the material type and class. If the material is supplied such that it can be “tinted” or “blended” to the user’s specification, the material shall comply with the requirements both when used alone and when used with the maximum recommended proportion of tint or blender [see 8.3 d)].

Similarly, if the manufacturer supplies a luting material in various shades, each shade, including opaquer luting materials, shall be capable of satisfying all the requirements for depth of cure (5.2.8). Colour stability (5.4) of luting materials shall not be tested unless the manufacturer claims such a property.