



NSAI
Standards

Irish Standard
I.S. EN ISO 4049:2009

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

I.S. EN ISO 4049:2009

Incorporating amendments/corrigenda issued since publication:

<i>This document replaces:</i> EN ISO 4049:2000	<i>This document is based on:</i> EN ISO 4049:2009 EN ISO 4049:2000	<i>Published:</i> 1 October, 2009 2 November, 2000
This document was published under the authority of the NSAI and comes into effect on: 10 November, 2009		ICS number: 11.060.10
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I.S. EN ISO 4049:2009

EUROPEAN STANDARD

EN ISO 4049

NORME EUROPÉENNE

EUROPÄISCHE NORM

October 2009

ICS 11.060.10

Supersedes EN ISO 4049:2000

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)

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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of an identical text or by endorsement, at the latest by April 2010, and conflicting national standards shall be withdrawn at the latest by April 2010.

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I.S. EN ISO 4049:2009
**INTERNATIONAL
STANDARD**

**ISO
4049**

Fourth edition
2009-10-01

**Dentistry — Polymer-based restorative
materials**

Art dentaire — Produits de restauration à base de polymères



Reference number
ISO 4049:2009(E)

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Published in Switzerland

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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.

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.

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

This fourth edition cancels and replaces the third edition (ISO 4049:2000) which has been reviewed and essentially reconfirmed. Several minor changes have been made to clarify content. Changes have been made to the test method for radio-opacity (see 7.14) in order to simplify this test.

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

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