BS EN ISO 4049:2019

BSI Standards Publication

Dentistry - Polymer-based restorative materials

bsi.

National foreword

This British Standard is the UK implementation of EN ISO 4049:2019. It is identical to ISO 4049:2019. It supersedes BS EN ISO 4049:2009, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/106/1, Dental restorative and orthodontic materials.

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

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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Compliance with a British Standard cannot confer immunity from legal obligations.

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EN ISO 4049

June 2019

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Supersedes EN ISO 4049:2009

English Version

Dentistry - Polymer-based restorative materials (ISO 4049:2019)

Médecine bucco-dentaire - Produits de restauration à base de polymères (ISO 4049:2019)

Zahnheilkunde - Polymerbasierende Restaurationswerkstoffe (ISO 4049:2019)

This European Standard was approved by CEN on 18 May 2019.

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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.

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

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

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European foreword

This document (EN ISO 4049:2019) 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of an identical text or by endorsement, at the latest by December 2019, and conflicting national standards shall be withdrawn at the latest by December 2019.

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 4049:2009.

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 4049:2019 has been approved by CEN as EN ISO 4049:2019 without any modification.

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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.

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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Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on 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 the following URL: www.iso.org/iso/foreword.html.

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

This fifth edition cancels and replaces the fourth edition (ISO 4049:2009), which has been technically revised. The main changes compared to the previous edition are as follows:

— the test for sensitivity to ambient light has been changed because a filter used in the current test was not available;

— the test for radio-opacity has been updated to refer to ISO 13116;

— luting materials no longer have to conform to the requirement for depth of cure;

— the manufacturer is now required to publish details of material composition, see Clause 8;

— several minor changes have been made to clarify content together with editorial changes.

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.

Introduction

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

INTERNATIONAL STANDARD **ISO 4049:2019**

Dentistry - Polymer-based restorative materials

1 Scope

This document 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 the teeth and for luting.

The polymer-based luting materials covered by this document are intended for use in the cementation or fixation of restorations and appliances such as inlays, onlays, veneers, crowns and bridges. This document does not cover those polymer-based luting materials that have an adhesive component within the structure of the material (see ISO/TS 16506).

The document does not cover polymer-based materials intended to prevent caries (see ISO 6874), core materials or those used for veneering metal sub-frames (see ISO 10477).

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 1942, *Dentistry — Vocabulary*

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

ISO 7491:2000, *Dental materials — Determination of colour stability*

ISO 8601-1:2019, *Date and time —Representations for information interchange Part — 1: Basic rules*

ISO 8601-2:2019, *Date and time —Representations for information interchange Part — 2: Extensions*

ISO 13116:2014, *Dentistry — Test method for determining radio-opacity of materials*

ISO 17304:2013, *Dentistry — Polymerization shrinkage: Method for determination of polymerization shrinkage of polymer-based 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

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

3.1
opaque
shade of an intensely pigmented polymer-based restorative material of low translucency

3.2
outer pack
form of packaging used to combine a number of single dose containers or capsules