



SLOVENSKI STANDARD
SIST EN ISO 6874:2005

01-december-2005

BUXca Yý U.
SIST EN 26874:2000

Zobozdravstvo - Tesnilna sredstva na osnovi polimerov za otiske in razpoke (ISO 6874:2005)

Dentistry - Polymer-based pit and fissure sealants (ISO 6874:2005)

Zahnheilkunde - Kunststoffe zur Fissurenversiegelung (ISO 6874:2005)

Art dentaire - Produits dentaires a base de polymeres pour ccomblement des puits et fissures (ISO 6874:2005)

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Ta slovenski standard je istoveten z: EN ISO 6874:2005

ICS:

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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 6874

August 2005

ICS 11.060.10

Supersedes EN 26874:1992

English Version

Dentistry - Polymer-based pit and fissure sealants (ISO 6874:2005)

Art dentaire - Produits dentaires à base de polymères pour
ccomblement des puits et fissures (ISO 6874:2005)

Zahnheilkunde - Versiegelungskunststoffe für Grübchen
und Fissuren (ISO 6874:2005)

This European Standard was approved by CEN on 1 August 2005.

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, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

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

Management Centre: rue de Stassart, 36 B-1050 Brussels

EN ISO 6874:2005 (E)**Foreword**

This document (EN ISO 6874:2005) 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 February 2006, and conflicting national standards shall be withdrawn at the latest by February 2006.

This document supersedes EN 26874:1992.

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

Endorsement notice

The text of ISO 6874:2005 has been approved by CEN as EN ISO 6874:2005 without any modifications.

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INTERNATIONAL
STANDARD

ISO
6874

Second edition
2005-08-15

**Dentistry — Polymer-based pit and
fissure sealants**

*Art dentaire — Produits dentaires à base de polymères pour
comblement des puits et fissures*

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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.

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 6874 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 1, *Filling and restorative materials*.

This second edition cancels and replaces the first edition (ISO 6874:1988), and in comparison with the first edition the classification and the test for depth of cure have been aligned with ISO 4049:2000. It is intended to include sealant materials within the scope of ISO 4049 at its the next revision. The requirements and tests for uncured film thickness, sensitivity to ambient light and curing time for Type 2 sealants have been deleted from this edition of ISO 6874.

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ISO 6874:2005(E)**Introduction**

The efficacy of pit and fissure sealants for the prevention of dental caries is widely accepted. The polymer-based materials intended for this purpose and covered by this International Standard harden by a free-radical polymerization reaction that is either initiated by mixing components or by external energy, e.g. visible light.

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

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Dentistry — Polymer-based pit and fissure sealants

1 Scope

This International Standard specifies requirements and test methods for polymer-based materials intended for sealing pits and fissures in teeth.

This International Standard covers both self-cured and external-energy-activated materials.

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

3 Classification

For the purposes of this International Standard, polymer-based pit and fissure sealants are classified, according to the method of curing, 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 visible light (“external-energy-activated” materials).

4 Requirements

4.1 Biocompatibility

See ISO 7405 and ISO 10993-1 for guidance on biocompatibility.

4.2 Physical properties

4.2.1 Working time, Class 1 sealant

The working time for Class 1 sealants, determined in accordance with 6.4, shall not be less than 40 s.

4.2.2 Setting time, Class 1 sealant

The setting time for Class 1 sealants, determined in accordance with 6.5, shall not be greater than 5 min.