BS EN ISO 6874:2015

BSI Standards Publication

Dentistry — Polymer-based pit and fissure sealants

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National foreword

This British Standard is the UK implementation of EN ISO 6874:2015. It supersedes BS EN ISO 6874:2005 which is withdrawn.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.

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Dentistry - Polymer-based pit and fissure sealants (ISO 6874:2015)

Médecine bucco-dentaire - Produits dentaires à base de polymères pour comblement des puits et fissures (ISO 6874:2015)

Zahnheilkunde - Versiegelungskunststoffe für Grübchen und Fissuren (ISO 6874:2015)

This European Standard was approved by CEN on 10 July 2015.

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COMITÉ EUROPÉEN DE NORMALISATION
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European foreword

This document (EN ISO 6874:2015) 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of an identical text or by endorsement, at the latest by March 2016, and conflicting national standards shall be withdrawn at the latest by March 2016.

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 6874:2005.

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, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 6874:2015 has been approved by CEN as EN ISO 6874:2015 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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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 106, *Dentistry*, Subcommittee SC1, *Filling and restorative materials*.

This third edition cancels and replaces the second edition (ISO 6874:2005), of which it constitutes a minor revision.

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 polymerisation 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 but, when assessing possible biological hazards, reference can be made to ISO 10993 (all parts) and ISO 7405.

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-curing and external-energy-activated materials.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. 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 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 the Introduction for guidance on biocompatibility, ISO 7405 and ISO 10993-1.

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.

4.2.3 Depth of cure, Class 2 sealant

The depth of cure for Class 2 sealants, determined in accordance with 6.6, shall be not less than 1,5 mm. If the material is supplied in more than one shade, each shade shall comply with this requirement.