Dentistry - Root canal sealing materials (ISO 6876:2012)

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 6876:2012 sisaldab Euroopa standardi EN ISO 6876:2012 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 6876:2012 consists of the English text of the European standard EN ISO 6876:2012.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 18.07.2012.	Date of Availability of the European standard is 18.07.2012.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 6876

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Supersedes EN ISO 6876:2002

English Version

Dentistry - Root canal sealing materials (ISO 6876:2012)

Médecine bucco-dentaire - Matériaux de scellement des canaux radiculaires (ISO 6876:2012)

Zahnheilkunde - Wurzelkanalfüllpaste (ISO 6876:2012)

This European Standard was approved by CEN on 16 June 2012.

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 CEN-CENELEC Management Centre 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 CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of 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 United Kingdom.

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

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Ref. No. EN ISO 6876:2012: E

Foreword

This document (EN ISO 6876:2012) 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 January 2013, and conflicting national standards shall be withdrawn at the latest by January 2013.

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 6876:2002.

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, the United Kingdom and Turkey.

Endorsement notice

The text of ISO 6876:2012 has been approved by CEN as a EN ISO 6876:2012 without any modification.

Introduction

Following the publication of the second edition of this International Standard (ISO 6876:2001), test houses reported difficulties with some of the test procedures. In an attempt to improve the test procedures, a planned programme of revision began in 2006. The following should be taken into account when using this International Standard.

— Verification for a claim of sterility is the responsibility of the manufacturer. This International Standard does not specify requirements or test methods for sterility and it is recommended that reference be made to any national requirements that may exist. When no national requirements exist, reference should be made to the United States, European or Japanese Pharmacopoeia.

— If a therapeutic effect is claimed, the purity and sterility of the constituents are expected to comply with the relevant pharmacopoeia applicable in the country in which the sealer is marketed, or with such national regulations as are applicable to purity and sterility of pharmaceutical products.

— Specific qualitative and quantitative test methods for demonstrating freedom from unacceptable biological risks are not included in this International Standard but it is recommended that, for the assessment of such biological risks, reference be made to ISO 10993-1 and ISO 7405.

Dentistry — Root canal sealing materials

1 Scope

This International Standard specifies requirements and test methods for root canal (endodontic) sealing materials which set with or without the assistance of moisture and are used for permanent obturation of the root canal with or without the aid of obturating points/cones. It only covers sealers intended for orthograde use i.e. a root filling placed from the coronal aspect of a tooth.

Specific qualitative and quantitative test methods for demonstrating freedom from unacceptable biological risks are not included in this International Standard but it is recommended that, for the assessment of such biological risks, reference be made to ISO 10993-1 and ISO 7405.

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 and film packets — Manufacturer specifications*

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

ISO 6873, *Dentistry — Gypsum products*

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
root canal sealing material
endodontic material intended to permanently seal the root canal filling material into the cavities previously occupied by the removed pulp

3.2
root canal filling material
endodontic material intended to permanently obturate the cavities previously occupied by the pulp

3.3
mixing time
that part of the working time required in order to obtain a satisfactory mix of the components

3.4
working time
period of time, measured from the start of mixing, during which it is possible to manipulate the root canal sealer without any adverse effect on its properties