Irish Standard
I.S. EN ISO 6876:2012

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

I.S. EN ISO 6876:2012

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EUROPEAN STANDARD

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EN ISO 6876

July 2012

ICS 11.060.10

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.

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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of an identical text or by endorsement, at the latest by January 2013, and conflicting national standards shall be withdrawn at the latest by January 2013.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.

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

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I.S. EN ISO 6876:2012

INTERNATIONAL STANDARD

ISO 6876

Third edition
2012-06-01

Dentistry — Root canal sealing materials

Médecine bucco-dentaire — Matériaux de scellement des canaux radiculaires

Reference number
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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 6876 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 1, *Filling and restorative materials*.

This third edition cancels and replaces the second edition (ISO 6876:2001), which has been technically revised. The main modifications are the following:

— the test procedures for flow, working time and solubility have been revised and a new limit value has been set;

— the test to determine dimensional change following setting has been removed.

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