SLOVENSKI STANDARD
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Dentistry - Dental root canal sealing materials (ISO 6876:1986)

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Zahnheilkunde - Zahnärztlicher Wurzelkanal - Versiegelungswerkstoffe (ISO 6876:1986)

Art dentaire - Produits dentaires pour le scellement des canaux radiculaires (ISO 6876:1986)

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This European Standard was accepted by CEN on 1989-12-20 and is identical to the ISO standard as referred to.
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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 CEN Central Secretariat has the same status as the official versions.

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CEN

European Committee for Standardization
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Europäisches Komitee für Normung

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Brief History

This draft European Standard has been taken over by CEN/TC 55 "Dental Products" from the work of the International Organization for Standardization (ISO).

The content of this draft European Standard is identical with the International Standard 6876 of ISO published in 1986.

The results of the Formal Vote being positive, the CEN Technical Board ratified this European Standard on 1989-12-20.

In accordance with the CEN/CENELEC Common Rules, the following countries are bound to implement this European Standard : Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

International Standard 6876

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION•МЕЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ ПО СТАНДАРТИЗАЦИИ•ORGANISATION INTERNATIONALE DE NORMALISATION

Dental root canal sealing materials

Produits dentaires pour le scellement des canaux radiculaires

First edition — 1986-12-01

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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.

Draft International Standards adopted by the technical committees are circulated to the member bodies for approval before their acceptance as International Standards by the ISO Council. They are approved in accordance with ISO procedures requiring at least 75 % approval by the member bodies voting.

International Standard ISO 6876 was prepared by Technical Committee ISO/TC 106, *Dentistry*.

Users should note that all International Standards undergo revision from time to time and that any reference made herein to any other International Standard implies its latest edition, unless otherwise stated.

Printed in Switzerland

Dental root canal sealing materials

1 Scope and field of application

This International Standard specifies requirements for materials used for permanent obturation of the root canal with or without the aid of obturating points. This International Standard only covers materials intended for orthograde (root filling inserted from coronal aspect) use.

2 References

ISO 3665, *Photography — Intra-oral dental radiographic film — Specification*.

ISO 3696, *Water for laboratory use — Specifications and test methods.* [1)]

ISO/TR 7405, *Biological evaluation of dental materials.*

3 Classification

The root canal sealing materials covered by this International Standard are classified into the following types :

Type 1 : Setting materials.

These are materials which set within 72 h of commencement of mixing.

Type 2 : Non-setting materials.

4 Requirements

4.1 Component

The component of the sealing material shall be free from extraneous matter.

The purity and sterility of the ingredients shall comply with the relevant pharmacopoeia applicable in the country in which the material is marketed, or with such national regulations as are applicable to purity and sterility of pharmaceutical products.

The ingredients shall, when used in accordance with the manufacturer's instructions, form a material which complies with the requirements of this International Standard.

4.2 Freedom from toxicity

The material shall not cause any irreversible damage when in contact with the oral tissues. Reference shall be made to ISO/TR 7405 which gives guidance on the biological evaluation of dental materials.

4.3 Flow

The flow of the material, when determined in accordance with 7.3, shall produce a disc with a diameter of not less than 20 mm.

4.4 Working time

The working time for type 1 materials having a working time of less than 30 min, when determined by the method given in 7.4, shall be within ± 10 % of the working time stated by the manufacturer [see 5e)].

4.5 Setting time

The setting time of type 1 materials, determined by the method given in 7.5, shall be within ± 10 % of the setting time stated by the manufacturer [see 5e)].

For materials having a setting time greater than 30 min for which the manufacturer quotes a range of times, the setting time measured shall be within the specified range.

4.6 Film thickness

The film thickness, for materials intended for use with obturating points, shall not be more than 50 µm, when tested in accordance with 7.6.

4.7 Radio-opacity

The material, when tested in accordance with 7.7, shall have a radio-opacity equivalent of not less than 3 mm of aluminium.

4.8 Solubility and disintegration

The solubility of the material, when determined in accordance with 7.8, shall not exceed 3 % by mass, nor shall the specimen show evidence of disintegration.

1) At present at the stage of draft.

5 Manufacturer's instructions

Instructions shall accompany each package and shall include the following:

a) instructions for use of the material, including, where applicable, the method of mixing and component mixing ratio;

b) the recommended method for sterilization, if possible or necessary;

c) principal components and active ingredients of material(s);

d) recommended conditions of storage;

e) the working time (if less than 30 min) and the setting time of the material — if the material is of the non-setting variety this should be stated; if a precise setting time cannot be determined but it exceeds 30 min, a range may be quoted;

f) indications for clinical use, including whether the material is manufactured for use with obturating points — if the material can cause staining of the tooth, this should be stated together with any precautions necessary to minimize this effect.

6 Sampling

The sample shall consist of one or more retail packages from the same batch, containing sufficient material to carry out the specified tests, plus an allowance for repeats, if necessary.

7 Test methods

7.1 Test conditions

Unless otherwise stated by the manufacturer, all tests shall be carried out at 23 ± 2 °C and at a relative humidity of (50 ± 5) %.

7.2 Preparation of material for testing

The material shall be manipulated in accordance with the manufacturer's instructions.

7.3 Flow

7.3.1 Apparatus

7.3.1.1 Two glass plates, having minimum dimensions of 30 mm × 30 mm, and approximately 5 mm thick.

7.3.1.2 Loading device, to apply a load of 2,5 kg.

7.3.1.3 Graduated glass delivery tube, designed to deliver 0,075 ± 0,005 ml of mixed material.

7.3.2 Procedure

Using the glass delivery tube (7.3.1.3), deposit 0,075 ml of the material, mixed in accordance with the manufacturer's instructions, onto one of the glass plates (7.3.1.1). After 180 ± 5 s from the start of mixing, place the other glass plate centrally on the material and carefully apply, by means of the loading device (7.3.1.2), the 2,5 kg load. After 10 min from the start of mixing, remove the load and measure the major and minor diameters of the disc. Record the mean of the major and minor diameters. If the diameters differ from each other by more than 1 mm, repeat the test.

7.3.3 Calculation and expression of results

Carry out three determinations, calculate the mean result and record it, to the nearest millimetre, as the flow value.

7.4 Working time

NOTE — This test applies only to type 1 materials having a working time of less than 30 min (see 4.4).

7.4.1 Apparatus

The apparatus specified in 7.3.1 shall be used.

7.4.2 Procedure

Using the glass delivery tube (7.3.1.3), deposit 0,075 ml of the material, mixed in accordance with the manufacturer's instructions, onto one of the glass plates (7.3.1.1). After 210 ± 5 s from the start of mixing, place the other glass plate centrally on the material and carefully apply, by means of the loading device (7.3.1.2), the 2,5 kg load. Apply the load for 7 min, then remove it and measure the major and minor diameters of the disc. Record the mean of the major and minor diameters.

Repeat the test with newly mixed material applying the load at increasing intervals of time after the start of mixing until the diameter has decreased by 10 % from the flow value (see 7.3.3).

7.4.3 Calculation and expression of results

Carry out three determinations, calculate the mean result and record it, to the nearest 30 s, as the working time of the material.

7.5 Setting time

NOTE — This test applies only to type 1 materials (see 4.5).

7.5.1 Apparatus

7.5.1.1 Cabinet, capable of being maintained at a temperature of 37 ± 1 °C and a relative humidity of not less than 95 %.

7.5.1.2 Gilmore-type metric indenter, having a mass of 100 ± 0,5 g and a flat end of diameter 2 ± 0,1 mm. The needle tip shall be cylindrical over a distance of at least 5 mm. The end of the needle shall be plane and at right angles to the longitudinal axis and shall be kept clean.

7.5.1.3 Stainless steel ring mould, having an internal diameter of 10 mm and a height of 2 mm.

7.5.1.4 Metal block, having minimum dimensions of 8 mm × 20 mm × 10 mm.

7.5.1.5 Flat glass plate, approximately 1 mm thick.

NOTE — A microscope slide is suitable.

7.5.2 Procedure

Place the mould (7.5.1.3) on the glass plate (7.5.1.5) and fill it to a level surface with material mixed in accordance with the manufacturer's instructions. After 120 ± 10 s from the start of mixing, place this assembly on the metal block (7.5.1.4) maintained at 37 ± 1 °C in the cabinet (7.5.1.1).

When the setting time stated by the manufacturer approaches, carefully lower the Gilmore-type needle (7.5.1.2) vertically onto the horizontal surface of the material. Repeat this operation until indentations cease to be visible and then record the time from the start of mixing.

7.5.3 Calculation and expression of results

Carry out three determinations, calculate the mean result and record it as the setting time.

7.6 Film thickness

7.6.1 Apparatus

7.6.1.1 Two optically flat circular glass plates, having a minimum uniform thickness of 5 mm and a contact surface area of approximately 200 mm^2.

7.6.1.2 Loading device, to apply a load of 15 kg.

7.6.1.3 Micrometer or **similar measuring instrument,** accurate to 1 µm.

7.6.2 Procedure

Measure the combined thickness of the two glass plates (7.6.1.1) in contact to an accuracy of 1 µm. Deposit a portion of material, mixed in accordance with the manufacturer's instructins, onto the centre of one of the glass plates. Place the other glass plate centrally on the material. After 180 ± 10 s from the start of mixing, carefully apply, by means of the loading device (7.6.1.2), a load of 15 kg vertically on the top plate. Ensure that the material completely fills the area between the glass plates. After 10 min from the start of mixing, measure the thickness of the two glass plates and the film of material using the micrometer (7.6.1.3).

7.6.3 Calculation and expression of results

Calculate the thickness of the film by determining the difference in the thickness of the plates with and without the material.

Carry out three determinations, calculate the mean result and record it, to the nearest 5 µm, as the film thickness.

7.7 Radio-opacity

7.7.1 Apparatus

7.7.1.1 Stainless steel ring mould, having an internal diameter of 10 mm and a height of 1 mm, together with covers, made of either plastic, paper or other radiolucent material.

7.7.1.2 Dental X-ray unit, capable of being operated at 65 kV.

7.7.1.3 Dental X-ray occlusal film of speed group D (as specified in ISO 3665), **developing solution** and **fixer.**

7.7.1.4 Aluminium step wedge, 50 mm × 20 mm, having a thickness range from 1 to 10 mm in steps of 1 mm, and made of at least 99,5 % pure aluminium.

7.7.1.5 Photographic densitometer.

7.7.2 Procedure

Place the material, mixed in accordance with manufacturer's instructions, in the mould (7.7.1.1) and press the covers on the top and bottom to make a specimen 1 mm thick. Position the specimen in the centre of the X-ray film (7.7.1.3) adjacent to the aluminium step wedge (7.7.1.4). If a cover is used, place an equivalent cover under the step wedge.

Irradiate the specimen, step wedge and film at a target film distance of approximately 300 mm for such a time that the exposed and processed film under the 1 mm thick section of the step wedge has a photographic density in the region of 1,5 to 2,5, including base and fog.

After developing, fixing and drying the exposed film, measure the photographic density of the radiographic image of the specimen, each of the steps of the step wedge and the totally exposed film, using the densitometer (7.7.1.5).

7.7.3 Expression of results

By comparison with the image of the step wedge, determine the thickness of aluminium equivalent to the specimen. Record this to the nearest 0,1 mm.

Carry out three determinations, calculate the mean result and record it as the radio-opacity value.