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BS EN ISO 3107:2011

BSI Standards Publication

Dentistry — Zinc oxide/eugenol cements and zinc oxide/non-eugenol cements (ISO 3107:2011)

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NORME EUROPÉENNE

EUROPÄISCHE NORM

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English Version

Dentistry - Zinc oxide/eugenol cements and zinc oxide/non-eugenol cements (ISO 3107:2011)

Médecine bucco-dentaire - Ciments dentaires à base d'oxyde de zinc-eugénol et à base d'oxyde de zinc sans eugénol (ISO 3107:2011)

Zahnheilkunde - Zinkoxid-Eugenolzemente und eugenolfreie Zinkoxidzemente (ISO 3107:2011)

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Foreword

The text of ISO 3107:2011 has been prepared by Technical Committee ISO/TC 106 "Dentistry" of the International Organization for Standardization (ISO) and has been taken over as EN ISO 3107:2011 by Technical Committee CEN/TC 55 “Dentistry” the secretariat of which is held by DIN.

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Foreword

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ISO 3107 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 1, *Filling and restorative materials*.

This fourth edition cancels and replaces the third edition (ISO 3107:2004), which has been technically revised. It also incorporates the Technical Corrigendum ISO 3107:2004/Cor.1:2006.

The main changes are that the

a) classification types have been consolidated into two,

b) compressive strength limit has been reduced to reflect materials in current use,

c) text on interpretation of compressive test results has been modified, and

d) lower setting time limit has been lowered to reflect materials in current use.

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Introduction

Specific qualitative and quantitative requirements for freedom from biological hazard are not included in this International Standard, but it is intended that in assessing possible biological or toxicological hazards, reference be made to ISO 10993-1 and ISO 7405.

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Dentistry — Zinc oxide/eugenol cements and zinc oxide/non-eugenol cements

1 Scope

This International Standard specifies requirements for non-water-based zinc oxide/eugenol cements suitable for use in restorative dentistry for temporary cementation, for bases and as temporary restorations.

This International Standard also specifies requirements for non-eugenol cements containing zinc oxide and aromatic oils suitable for temporary cementation.

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 2590, *General method for the determination of arsenic — Silver diethyldithiocarbamate photometric method*

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

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 apply.

4 Classification

For the purposes of this International Standard, the following classification for cements is used, based on their intended use:

a) type I: for temporary cementation;

b) type II: for bases and temporary restorations.

5 Requirements

5.1 Performance requirements

When tested in accordance with the appropriate test methods specified in Clause 7, type I and type II cements shall comply with the performance requirements specified in Table 1.

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Table 1 — Requirements

Type	Setting time at 37 °C		Compressive strength at 24 h		Film thickness	Acid-soluble arsenic mass fraction
	min		MPa		µm	mg/kg[a]
	min.	max.	min.	max.	max.	max.
Type I	1,5	10		35	25	2
Type II	1,5	10	5		N/A	2

N/A: not applicable

[a] mg/kg is the equivalent of ppm; ppm is a deprecated unit.

5.2 Biocompatibility

For guidance on biocompatibility, see ISO 10993-1 and ISO 7405.

6 Sampling

The test sample shall consist of packages prepared for retail sale from the same batch containing enough material to carry out the specified tasks plus an allowance for repeats. 50 g should be sufficient.

7 Test methods

7.1 Preparation of test specimens

Prepare the test material in accordance with the manufacturer's instructions (see 8.2).

7.1.1 Ambient conditions

Prepare and test all specimens at (23 ± 2) °C and a relative humidity of (50 ± 5) %. Before the start of mixing, condition the test samples and apparatus in these conditions for at least 1 h.

7.1.2 Procedure for mixing

Mix sufficient cement to ensure that the preparation of each specimen is completed from one mix. Prepare a fresh mix for each specimen.

7.2 Determination of setting time

7.2.1 Apparatus

7.2.1.1 **Cabinet**, capable of being maintained at a temperature of (37 ± 1) °C and a relative humidity of (95 ± 5) %.

7.2.1.2 **Indenter needle**

7.2.1.2.1 For type I materials, an indenter needle of mass (100 ± 0,5) g with a tip which is cylindrical for a distance of approximately 5 mm and has a flat end of diameter (2,0 ± 0,1) mm.

7.2.1.2.2 For type II materials, a similar indenter needle of mass (400 ± 5) g with a tip which is cylindrical for a distance of approximately 5 mm, and which has a flat end of diameter (1,0 ± 0,1) mm.

7.2.1.3 **Mould**, made of non-corrodible metal, consisting of a rectangular plate with a circular hole conforming to the dimensions given in Figure 1.

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Dimensions in millimetres

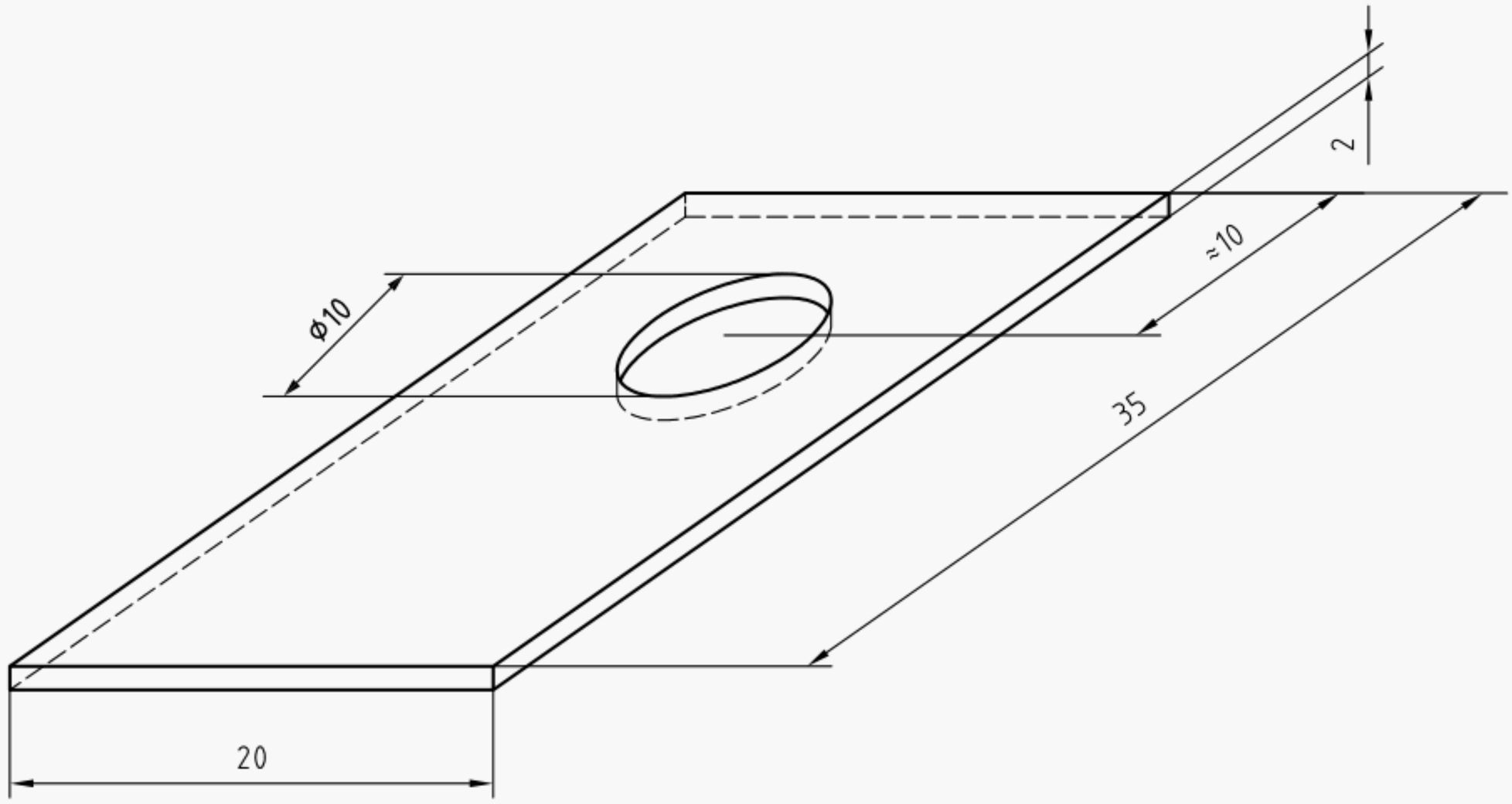

Figure 1 — Mould for use in determination of setting time

7.2.1.4 **Metal block**, of minimum dimensions 8 mm × 20 mm × 10 mm.

7.2.1.5 **Flat glass plate**, approximately 1 mm thick (for example, a microscopic slide).

7.2.2 Procedure

Condition the metal block (7.2.1.4) and indenter needle (7.2.1.2) in the cabinet (7.2.1.1) at (37 ± 1) °C.

Place the metal mould (7.2.1.3), conditioned at (23 ± 1) °C, on the flat glass plate (7.2.1.5) and fill to a level surface with the cement.

After (60 ± 10) s from the start of mixing for all cements, place the specimen, mould and glass plate on to the metal block.

30 s before the setting time given by the manufacturer, carefully lower the indenter needle vertically on to the surface of the cement. Make indentations at 15 s intervals with no superimposition of indentations until the setting time has been reached. Maintain the needle tip in a clean condition between indentations.

Record the setting time, to the nearest 15 s, as the period of time which elapses from the start of mixing to the time when the needle fails to penetrate completely the 2 mm depth of cement.

7.2.3 Treatment of results

The result shall either be one of the limit values or lie between the limits given in Table 1.

7.3 Determination of compressive strength

7.3.1 Apparatus

7.3.1.1 **Split moulds and plates**, for example as shown in Figure 2, suitable for the preparation of a cylindrical specimen with a height of 6 mm and a diameter of 4 mm, and made of a material that is neither attacked nor corroded by the cement, such as stainless steel.

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Dimensions in millimetres

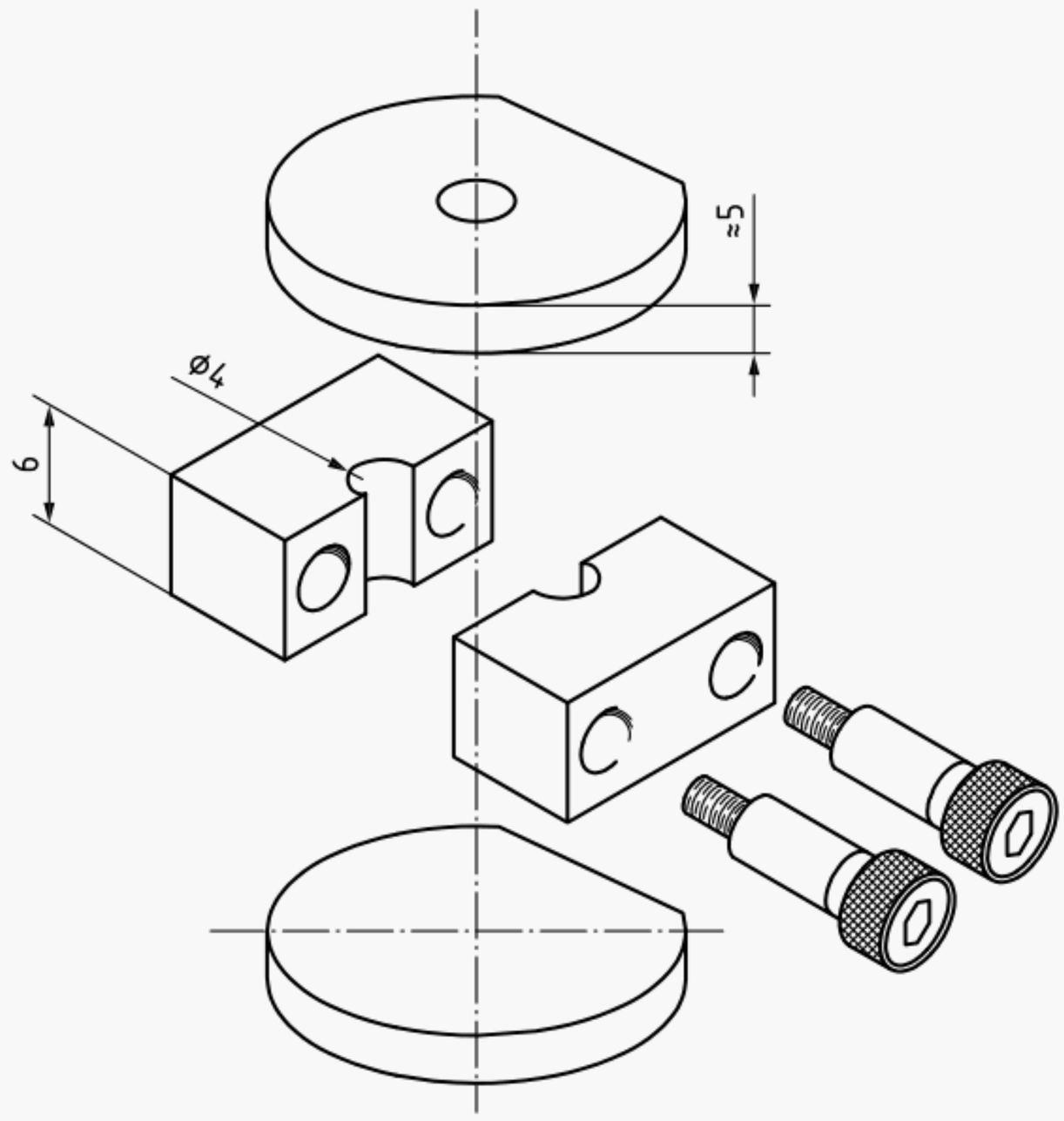

Figure 2 — Mould and plates for preparation of compressive strength test specimens

7.3.1.2 **Screw clamp**, of dimensions such that it can clamp the mould and plates together, such as is shown in Figure 3.

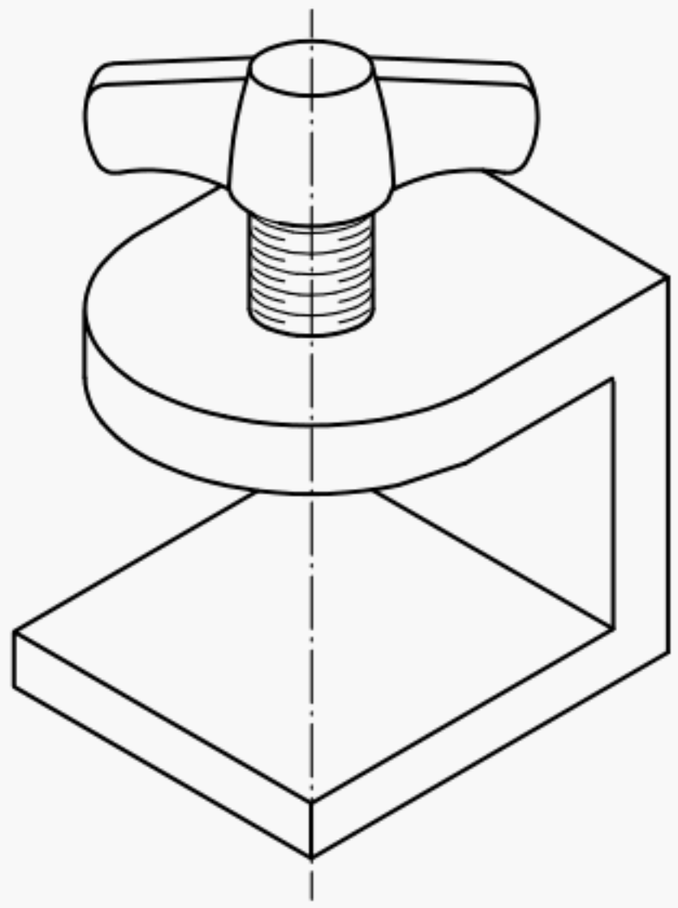

Figure 3 — Clamp for preparation of compressive strength test specimens

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7.3.1.3 **Cabinet**, as specified in 7.2.1.1.

7.3.1.4 **Micrometer or similar measuring device**, accurate to 1 µm.

7.3.1.5 **Mechanical tester**, capable of being operated at a cross-head speed of (0,75 ± 0,30) mm/min or at a loading rate of (50 ± 16) N/min.

7.3.2 Preparation of test specimens

Condition the moulds (7.3.1.1), screw clamps (7.3.1.2) and top and bottom plates (7.3.1.1) at (23 ± 1) °C.

After mixing in accordance with the manufacturer's instructions, pack the cement, to a slight excess, into the split moulds within 1 min of the completion of mixing. In order to consolidate the cement and to avoid trapping air, it is advisable to convey the largest convenient portions of mixed cement to the mould and apply to one side with a suitable instrument. Fill the mould to excess in this manner and then place the mould on the bottom plate and pack the cement, such that the excess is expressed.

To facilitate the removal of the hardened cement specimen, the internal surface of the mould may be evenly coated, prior to filling, with a 3 % solution of micro-crystalline or paraffin wax in pure toluene. Alternatively, a thin film of silicone grease or polytetrafluoroethylene (PTFE) dry film lubricant may be used.

Remove any extruded cement, place the top metal plate in position and squeeze together. Put the mould and plates in the clamp (7.3.1.2) and screw tightly together. Not later than 2 min after completion of mixing, transfer the whole assembly to the cabinet (7.3.1.3), maintained at (37 ± 1) °C.

One hour after completion of mixing, remove the plates, and prepare the surface of the ends of the specimen plane, at right angles to its long axis, using a small amount of 45 µm silicon carbide powder or similar abrasive, mixed with water (ISO 3696, grade 2) on a flat glass plate. Keep the specimen wet during preparation.

Alternatively, use an equivalent grade of abrasive coated paper and water (ISO 3696, grade 2). Keep the ends of the specimen flat by rotating the specimen one quarter turn every few strokes.

Remove the specimen from the mould immediately after surfacing and examine for air voids or chipped edges. Discard any specimens with these defects.

Immerse each specimen in distilled or deionized water (ISO 3696, grade 2) and maintain at (37 ± 1) °C for 24 h, after which condition in distilled or deionized water at (23 ± 1) °C for (15 ± 1) min prior to testing. Then, measure the diameter of the cylinder with the micrometer (7.3.1.4) to the nearest micrometre. Proceed immediately to testing. The testing procedure requires five specimens.

7.3.3 Procedure

Immediately after the end of the conditioning period, place the specimen with the flat ends between the platens of the mechanical testing apparatus (7.3.1.5) so that the load is applied in the long axis of the specimen. Use a cross head speed of (0,75 ± 0,30) mm/min or a loading rate of (50 ± 16) N/min until fracture. Record the maximum force applied when the specimen fractures.

Test five specimens.

Calculate the compressive strength, k , in megapascals, using the following equation:

$$k = 4F/\pi d^2$$

where

F is the maximum applied force, in newtons (N);

d is the measured mean diameter of the specimen, in millimetres (mm).

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7.3.4 Treatment of results

a) If at least four of the values are no less, or for type I materials for compressive strength no greater, than the limit specified in Table 1, the material is deemed to have complied with the requirement of 5.1.

b) If three or more of the values are less, or for type I materials for compressive strength are greater, than the limit specified in Table 1, the material is deemed to have failed without the need for further testing.

c) If only three of the values are no less, or for type I materials for compressive strength no greater, than the limit specified in Table 1, repeat the whole test. If any values are lower, or for type I for compressive strength greater, than the limit in Table 1, the material is deemed to have failed the test.

7.4 Determination of film thickness

7.4.1 Apparatus

7.4.1.1 Two glass plates, optically flat, square or circular, each having a contact surface area of (200 ± 25) mm^2. Each plate shall be of a uniform thickness of not less than 5 mm.

7.4.1.2 Loading device, of the type illustrated in Figure 4, or an equivalent means whereby a force of (150 ± 2) N may be generated vertically onto the specimen smoothly and without rotation via the upper glass plate. In Figure 4, the anvil that is attached to the bottom of the rod shall be horizontal and parallel to the base.

NOTE Each glass plate can be attached to the loading device by guides to prevent movement when the load is applied.

7.4.1.3 Micrometer or similar measuring device, accurate to 1 µm as in 7.3.1.4.

7.4.2 Procedure

Measure, with the micrometer or similar device, to an accuracy of 1 µm, the combined thickness of the two optically flat glass plates (7.4.1.1) stacked in contact (reading A). Remove the upper plate and place between 0,02 ml and 0,10 ml of the test material mixed in accordance with the manufacturer's instructions in the centre of the lower plate, and place this centrally below the loading device on its lower platen. Replace the second glass plate centrally onto the test specimen in the same orientation as in the original measurement.

At 10 s before the end of the working time specified by the manufacturer, carefully apply, by means of the loading device (7.4.1.2), a compressive force of 150 N vertically on the top plate and leave for at least 10 min. Ensure that the cement completely fills the space between the two glass plates.

Measure the thickness of the two glass plates and cement film (reading B).

Calculate the difference in thickness of the plates with and without the cement film (reading B – reading A), and record this as the thickness of the film to the nearest 1 µm. Carry out five determinations.

7.4.3 Treatment of results

a) If four or five of the results are equal to or lower than 25 µm (see Table 1), the material is deemed to have complied with the requirement of 5.1.

b) If three or more of the results are more than 25 µm, the material is deemed to have failed without the need for further testing.

c) If only three of the results are equal or lower than 25 µm, repeat the whole test. If any results are higher than 25 µm, the material is deemed to have failed the test.

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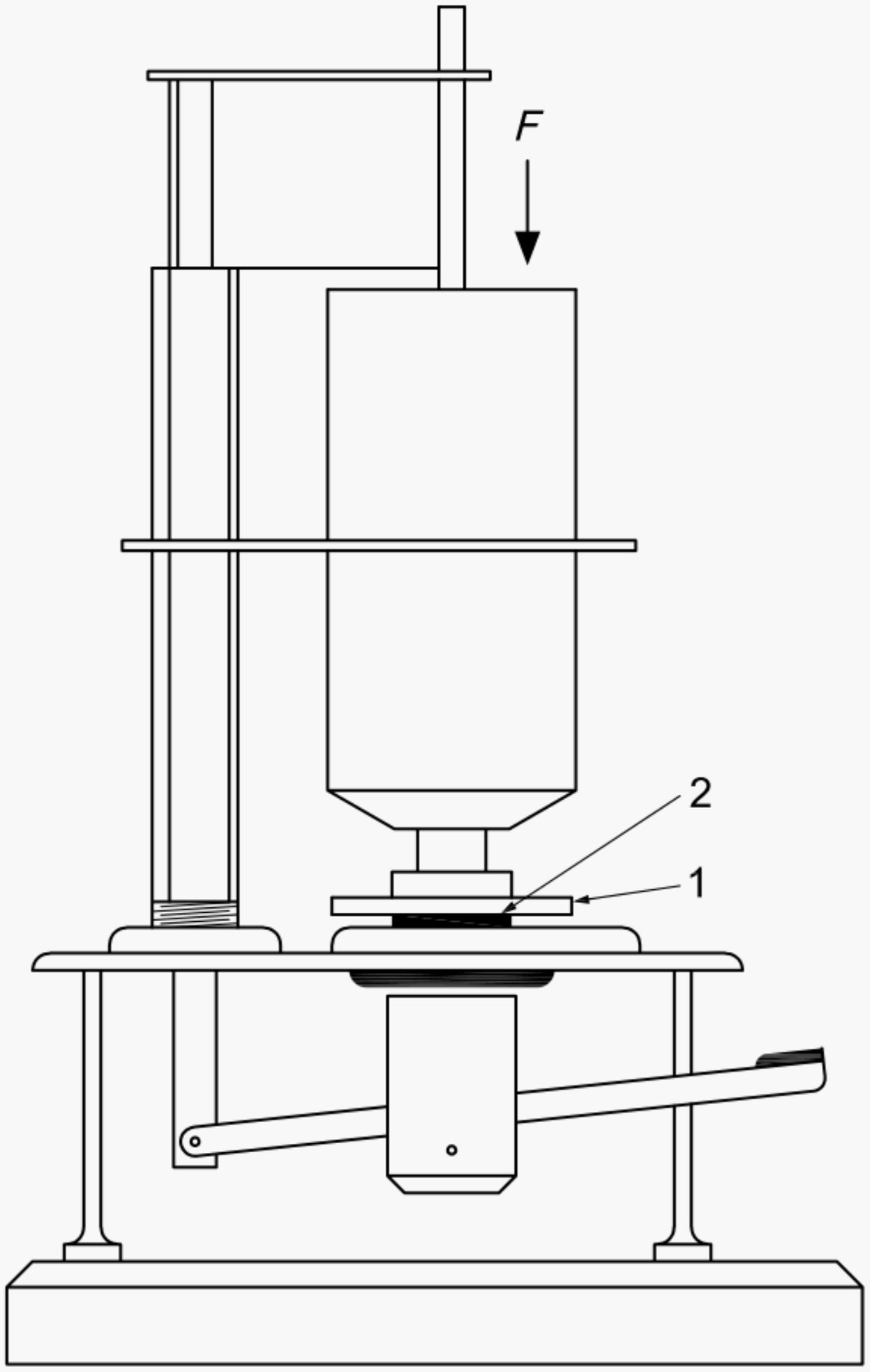

Key

1 glass plate
2 specimen
F load

Figure 4 — Loading device for film thickness test

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7.5 Determination of acid-soluble arsenic fraction

7.5.1 Preparation of test sample

Powder the set cement and sieve through a 75 µm (200 mesh) sieve. Disperse 2 g of the sieved powder in 30 ml of water (ISO 3696, grade 2) and add 10 ml of analytical grade hydrochloric acid, 36 % (mass fraction, ρ = 1,18 kg/m^3). Maintain the mixture at (37 ± 1) °C for 1 h, and filter.

7.5.2 Procedure

Determine the total arsenic fraction of the filtrate by the method described in ISO 2590 or any other analytical method of equivalent sensitivity.

7.5.3 Compliance

If the result is 2 mg/kg or less (see Table 1), the material is deemed to have passed the test.

8 Marking, labelling and packaging

8.1 Packaging

The components of the material shall be supplied in properly sealed containers, which adequately protect their contents and have no adverse effect on the quality of the product.

An outer pack may be used to present the individual containers as a single unit.

8.2 Marking and instructions for use

a) Information shall be clearly marked on the outermost packaging or containers (for multidose packs or capsules) as indicated in Table 2.

b) Instructions shall accompany each package of the material and shall include the information appropriate to the material (see Clause 5) and as indicated in Table 2.

c) Information additional to that specified in Table 2 may be supplied at the discretion of the manufacturer.

NOTE 1 Some information is indicated as mandatory (M), and other information as optional (/). Table 2 contains several optional references and serves as a guide to the manufacturer as to information which can be useful to users.

NOTE 2 Under item no. 11, manufacturers can choose to recommend specific functions for the material, such as sealing or durable temporary restoration.

If the compressive strength is quoted, it should be tested by 7.3.

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Table 2 — Requirements for marking and instructions for use

Item no.	Issue	Outermost pack	Outer pack of capsules	Capsule (single-dose), syringes or bottles	Manufacturer's instructions handbook
1	Name of the product	M	M	M	M
2	Identification or name of the manufacturer	M	M	/	M
3	Address of the manufacturer or the agent responsible for sale	M	/	/	M
4	URL	/	/	/	/
5	Information required by local/national legislation	M	M	/	M
6	Recommended conditions of storage	M	/	/	M
7	Manufacturer's batch number	M	M	/	/
8	Expiry date, expressed in accordance with ISO 8601, for the cement when stored under the manufacturer's recommended conditions	M	M	/	/
9	Shelf life under the recommended conditions of storage	/	/	/	/
10	Classification of the cement	M	/	/	M
11	Clinical application	/	/	/	M
12	Number of containers/capsules, for capsule or cartridge cements	M	M	/	/
13	Net volume in each container/capsule	/	M	/	M
14	Recommended ratio of components (e.g. powder/liquid) and instructions for use of any proportioning aids (scoops, etc.) and the proportions on a mass fraction basis to a precision of 0,1 g. (For hand-mixed materials only)	/	/	/	M
15	Rate of incorporation/mixing of the two components	/	/	/	M
16	Mixing time, if mixing required	/	/	/	M
17	Mixing condition (if appropriate, the condition and type of the mixing slab and spatula). For hand-mixed materials only	/	/	/	M
18	For encapsulated cements, the method of bringing about physical contact between the components, if required	/	/	/	M
19	Method, timing and type of mechanical mixing, if required	/	/	/	M
20	Setting time	/	/	/	M

/ indicates no relevance for this combination of container/marking/instructions or that such a requirement would be impracticable or that the information may be informative or optional.

M indicates that an item is mandatory.

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Bibliography

[1] ISO 7405, *Dentistry — Evaluation of biocompatibility of medical devices used in dentistry*

[2] ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

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