International Standard

ISO 14356

Dentistry — Duplicating material

Médecine bucco-dentaire — Produits pour duplication

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

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Contents

Page

Foreword

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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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This document was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 2, *Prosthodontic materials,* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 55, *Dentistry,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 14356:2003), which has been technically revised.

The main changes are as follows:

— figures have been updated to be consistent with other impression material related standards;

— terminology, references and document format have been updated.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Dentistry — Duplicating material

1 Scope

This document specifies the requirements and tests for the duplicating materials used in dentistry which are primarily intended for forming flexible moulds needed to produce positive refractory investment copies of properly blocked-out master models.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 6873, *Dentistry — Gypsum products*

ISO 15912, *Dentistry — Refractory investment and die material*

ASTM D624-00, *Standard test method for tear strength of conventional vulcanized rubber and thermoplastic elastomers*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942 and the following apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
double boiler
container system in which the upper container fits into the lower container such that boiling water in the lower container heats the contents of the lid-covered upper container

3.2
non-reversible duplicating material
material which converts from a pourable consistency to a gel or rubber-like state and which thereafter cannot be returned to the pourable consistency for repeated use

3.3
effective setting time
time measured from the commencement of mixing components of a material together, or otherwise activating the chemistry involved, to the time at which the activated material has developed the properties (elasticity, hardness, etc.) that will permit it to be used with optimal effectiveness in a subsequent step or for its intended purpose

Note 1 to entry: This applies to materials setting at or near oral or room temperature.

3.4
functional life
number of times a material can be recycled for use, if handled and used according to the manufacturer's instructions, without loss of the properties required to ensure that the material is fit for the purpose intended

Note 1 to entry: This applies to reversible duplicating material.

3.5
gelation
transition of a material from a relatively fluid consistency to a gel state in which the material has developed the elastic properties needed for its intended purpose

Note 1 to entry: This applies to agar duplicating material.

3.6
immediate container
packaging component that has internal surfaces in direct contact with the material contained

Note 1 to entry: An immediate container can be an unlabelled container protected by more durable outer packaging, such as a can, carton or drum. If strong enough to protect its contents without outer packaging, an immediate container can serve as a primary container on which labelling may be required.

3.7
initial setting time
time measured from the commencement of mixing components of a material or otherwise activating the chemistry involved and ending at a time when results of a prescribed test, conducted at a specified temperature, show that the mixture has begun to set, thus indicating that the effective setting time is reached at some predictable time thereafter

Note 1 to entry: Initial setting times stated in the manufacturer's instructions are useful to test operators, users, and standards developers because:

— they can often be used for determining whether a product is of a quality suitable for testing or use. For example, if the initial setting time found by the test operator or user corresponds closely to that stated in the instructions, it can usually be assumed that the product is suitable for testing or use.

— they can be helpful in the development of standards for certain materials if there is a need for a standard to identify a reference point in time that can be used as a basis for specifying when certain subsequent procedures should begin.

[SOURCE: ISO 1942:2020, 3.3.1.31, modified — Note to entry added.]

3.8
investment
powdered *refractory* (3.13) containing a binder, to be mixed with a specified liquid to form a slurry that can be poured into a mould made of duplicating material where it is allowed to harden to form a heat-resistant positive copy of a master model, or which can be poured around patterns to form a heat-resistant mould used for forming ceramic or metal objects

Note 1 to entry: This applies to a casting material.

3.9
melt
change a material, by heating, from a gel state to a pourable fluid state

Note 1 to entry: This applies to agar hydrocolloid.

3.10
outer package
wrapping or carton, used to cover one or more *immediate containers* (3.6) or *primary containers* (3.12) in preparation for retail marketing

Note 1 to entry: Legislation or specific standards can apply.

[SOURCE: ISO 4823:2021, 3.8]

3.11
pouring temperature
temperature of the material designated in the manufacturer's instructions for pouring the material around an object to be duplicated

Note 1 to entry: This applies to duplicating material.

3.12
primary container
packaging component for retail marketing which can be covered by an *outer package* (3.10)

EXAMPLE Bottle, carton, drum, jar, tube, etc.

Note 1 to entry: A primary package can be required to bear specific labelling information by legislation or specific standard.

Note 2 to entry: A primary container may also be an *immediate container* (3.6), and vice versa.

3.13
refractory
material that retains its effective shape and composition when heated to the maximum temperature required for its use

3.14
slurry
mixture, consisting of a powder and water, or a powder and another liquid, that has a consistency that allows it to be poured around patterns or into moulds, or to be otherwise applied, and then be allowed or caused to harden so as to form a desired shape

Note 1 to entry: This applies to ceramic, gypsum or investment materials.

3.15
storage
holding of a material in an *immediate container* (3.6) in a protected environment before the container is opened for the first use, and between subsequent openings of the container

3.16
store, verb
⟨agar hydrocolloid⟩ to hold a material at the temperature specified in the manufacturer's instructions to keep it at pouring consistency

Note 1 to entry: This applies to agar hydrocolloid.

4 Classification by types

There are two types of duplicating material:

— Type 1: reversible duplicating materials;

— Type 2: non-reversible duplicating materials.

5 Material characteristics and properties — Requirements

5.1 General

In order to arrive at an objective evaluation of a duplicating material, Clauses 9, 10 and 11 shall be reviewed before any further steps in the evaluation are begun.

5.2 Melting temperature — Type 1 materials

When tested in accordance with 8.1, the melting temperature shall not exceed the maximum stated in the manufacturer's instructions [11 c) 2)].

5.3 Pouring temperature — Type 1 materials

The manufacturer's recommended maximum pouring temperature [11 c) 4)] shall not exceed 54 °C.

5.4 Component colours — Type 2 materials

Different components intended for use in the same mixture shall be supplied in contrasting colours in order to provide a means of determining when the components have been thoroughly mixed.

5.5 Detail reproduction

When tested according to 8.2, the duplicating material shall be in accordance with Figure 1, line b scribed on the test block, as a positive reproduction, for the full length of the distance between lines d_1 and d_2, both of which shall also be completely reproduced.

5.6 Compatibility with refractory investment and, if applicable, gypsum

When tested in accordance with 8.3, the duplicating materials shall impart a smooth surface to, and separate cleanly from, the investment or gypsum product poured against it. The investment and gypsum material poured against the lined surface of the duplicating material specimen shall be in accordance with Figure 1, line c for the full length of the distance between lines d_1 and d_2 (see Figure 1).

5.7 Elastic recovery

When tested in accordance with 8.4, the elastic recovery shall be at least 96,50 %.

5.8 Tear strength

When tested in accordance with 8.5, the tear resistance shall be at least 0,3 N/mm for Type 1 materials and at least 1,0 N/mm for Type 2 materials.

5.9 Resistance to fungal growth — Type 1 materials only

When tested in accordance with 8.6, the specimens shall exhibit no fungal growth.

6 Sampling

Samples of material to be tested shall be procured from a single manufacturing batch as packaged for retail marketing.

NOTE Amounts of approximately 7,5 l of Type 1 materials and 3,7 l of Type 2 materials are usually enough for conducting all of the tests and for the considerable practice that can be necessary for the test operator to become proficient in specimen preparation and testing.

7 Test methods — General

7.1 Laboratory conditions

Unless otherwise specified in this document, all specimen preparation and testing shall be conducted under ambient laboratory conditions of (23 ± 2) °C and (50 ± 10) % relative humidity. Unless otherwise specified in this document, all equipment and materials used in the tests shall be brought to ambient temperature before use in specimen preparation and testing procedures.

7.2 Verification of apparatus function

Examine all accessories, instruments and equipment before they are used in order to determine whether they are in acceptable working order. Perform whatever calibration steps are necessary to ensure that the items are in conformity with the specifications stated for them in this document, or in any related supporting standard.

7.3 Specimen preparation and testing

7.3.1 General

Unless otherwise specified, prepare and manipulate the materials to be used for forming the test specimens employing the equipment, and following the procedures, recommended in the manufacturer's instructions [see 11 b), 11 c) and 11 d)].

Time the schedules for specimen preparation and testing using a timing device such as a stopwatch accurate to ±1 s over a 30 s period.

7.3.2 Preparation of Type 1 materials

Use a double boiler for melting Type 1 materials. The amount of melted material prepared for testing purposes at any one time shall be approximately 700 ml. Melted material remaining after the preparation of one set of specimens may be used for forming other sets of specimens to be formed and tested on the same day, provided that the material can be kept at the recommended temperature and consistency for pouring without re-melting.

7.3.3 Preparation of Type 2 materials

For Type 2 materials, use mass/mass proportioning of the components to be mixed. A volume of approximately 20 ml shall be prepared for each specimen tested.

7.4 Pass/fail determinations

Unless otherwise specified in this document, the minimum number of specimens required for pass/fail determinations is either three or five, as indicated by an entry appearing beside the related specimen preparation or test procedure title.

Unless otherwise specified, the following rules apply:

— For a three-specimen minimum, make and test a series of three specimens initially. If at least two of the three specimens conform to the related requirement, the material passes. If none conforms, the material fails. If only one specimen conforms, make three additional specimens. If all three of the additional specimens conform, the material passes; otherwise the material fails.

— For a five-specimen minimum, make and test a series of five specimens initially. If at least four of the five specimens conform to the related requirement, the material passes. If only one or two specimens conform, the material fails. If only three specimens conform, make a series of five additional specimens. If all five of the second series of specimens conform, the material passes; otherwise the material fails.

7.5 Expression of test results

Report the number of specimens tested, the number conforming with the specified requirement, and whether the material passes or fails.

8 Specific specimen preparation and test procedures

8.1 Melting temperature test — Type 1 materials only

8.1.1 Apparatus

8.1.1.1 Ceramic, glass or stainless steel double boiler system which has a component that accommodates a volume of at least 700 ml of the melted duplicating material.

8.1.1.2 Temperature-measuring device, such as a calibrated 76 mm immersion thermometer which has graduations of 0,1 °C or equivalent.

8.1.1.3 Heat source, to provide the temperatures needed for the melting process.

8.1.2 Test procedure (one test)

Observe the rate of melting for the specified volume of material (7.3.2). When the material approaches the final stages of melting, use the device (8.1.1.2) to measure the temperature of the material periodically until the moment at which the entire volume is free of lumps and granules. Record the temperature for this occurrence.

8.1.3 Pass/fail determination

Compare the melting temperature recorded in accordance with 8.1.2 with the maximum temperature stated in the manufacturer's instructions [11 c) 2)]. Then record whether this temperature conforms with the requirement stated in 5.2.

8.2 Detail reproduction test

8.2.1 Apparatus and materials

8.2.1.1 Test block (see Figure 1).

8.2.1.2 Specimen forming ring mould and ring mould retainer (see Figure 2).

8.2.1.3 Putty-like material for covering external orifices of holes in the ring mould to prevent escape of the fluid duplicating material.

8.2.1.4 Flat glass or metal plate, approximately 50 mm × 50 mm and at least 3 mm thick**.**

8.2.1.5 Temperature-conditioning unit (oven, air cooler or water bath), capable of providing an environment in which the specimen forming assembly (see 8.2.1.1 and 8.2.2.2) can be conditioned to the temperature specified for the master cast [11 b) 3)] at the time duplicating material is poured against it.

8.2.1.6 Circulating water bath, (for Type 1 materials) set to the temperature specified in the instructions for cooling the poured duplicating assembly [11 b) 4)].

8.2.1.7 Microscope, capable of ×4 to ×12 magnification and low-angle illumination.

8.2.2 Specimen preparation (three specimens)

8.2.2.1 Initial preparation

Use a compatible and effective solution in an ultrasonic cleaner to clean the test block (8.2.1.1) prior to each specimen preparation. Then use the microscope (8.2.1.7) to inspect the lines scribed on the block surface to verify whether they have been cleared of contaminants.

Seat the ring mould (8.2.1.2) in the recess of the ring-mould retainer and use the putty-like material (8.2.1.3) to cover the exposed external orifices of the ring mould.

Seat the two assembled parts on the test block to form the specimen forming cavity.

For Type 1 materials, adjust the level of the water in the circulating water bath (8.2.1.6) so that it is approximately 5 mm below the bottom of the ring-mould retainer when the specimen forming assembly (8.2.1.1, 8.2.2.2) is placed for cooling.

Then condition this entire assembly, along with the flat plate (8.2.1.4), at the specified temperature (8.2.1.5) for at least 15 min.

8.2.2.2 Procedure for specimen formation

Immediately after removing the specimen-forming accessories from the temperature-conditioning environment, begin filling the mould cavity by introducing the fluid duplicating material, at the pouring temperature specified in [11 c) 4)], along an internal surface of the ring mould. Introduce the fluid so that the material first enters lines a, b and c (Figure 1) on one side of the test block surface and then flow evenly in the lines as it moves across to the opposite side of the mould cavity. Slightly overfill the mould cavity and then, with minimal pressure, push the flat plate down through the excess material and into contact with the top of the ring mould.

Air-cool the assemblies for Type 1 materials for 5 min and then transfer them to the water bath (8.2.1.6) for an additional 15 min cooling period. Allow assemblies for Type 2 materials to set for the time and at the temperature specified in the manufacturer's instructions [11 b) 4)].

Within 1 min after completing the effective setting or gelation process, separate the duplicating material/ring-mould assembly from the test block and flush it with distilled or deionized water. Use a gentle air stream to clear away the remaining surface moisture.

8.2.3 Test procedure

Immediately after clearing moisture from the specimen surface, use the microscope (8.2.1.7) to examine the specimen for conformity with the requirement specified in 5.5. Complete the examination within 3 min after separating the specimens from the forming assembly. Then, for Type 1 materials only, re-wet the lined surface of the specimen to keep it moist pending its use in the compatibility test (8.3).

NOTE Colour differences of the materials can make it necessary to use different light intensities or different colour filters, or both, when viewing specimens, in order to determine whether the required lines have been reproduced in surfaces of the duplicating material or to evaluate compatibility with investment or gypsum specimens.

8.2.4 Pass/fail determination and expression of results

Carry out the pass/fail determination and record results in accordance with 7.4 and 7.5

8.3 Test for compatibility with refractory investment and, if applicable, gypsum

8.3.1 Apparatus and materials

8.3.1.1 Detail reproduction test specimens, prepared according to 8.2.2 and found to be in conformity with 5.5 after examination according to 8.2.3.

8.3.1.2 Any mould-treating agent that may be recommended in the instructions for treating the duplicating material mould before an investment or gypsum product is poured into it.

8.3.1.3 Specimen forming slit mould (see Figure 3), with a clamping mechanism, such as worm gear hose clamp, for use in closing the slit.

Use of the slit mould requires the mould to be clamped so that the slit is closed during the formation of the investment or gypsum specimen. Later, the clamping force is released to allow the slit to open for easy removal of the specimen. The brass alloy of which the slit mould is made should therefore have a strain-at-elastic limit sufficiently high to permit closing and opening of the slit without significant permanent reduction in its width.

8.3.1.4 Mould-release agent, such as silicone grease, that is non-reactive with the slit mould (8.3.1.3) and the investment and gypsum products.

8.3.1.5 Refractory investment, in accordance with 11 b) 9).

8.3.1.6 Gypsum product, in accordance with 11 b) 10), if required.

8.3.1.7 Microscope, in accordance with 8.2.1.7.

8.3.2 Specimen preparation

8.3.2.1 General

Prepare three specimens for each different bonding category of investment (8.3.1.5) identified in the instructions and three specimens for a gypsum product (8.3.1.6), if such a product is identified in the instructions.

8.3.2.2 Initial preparation

Before using either the investment (8.3.1.5) or gypsum product (8.3.1.6) in the compatibility test, evaluate each product for conformity with the "setting time" requirement specified in ISO 15912 or ISO 6873. Product batches which do not conform to the related requirement shall not be used in the compatibility test.

NOTE The "setting time tests" described in ISO 15912 and ISO 6873 are not for determining "final" or "effective" setting times. Instead they are for determining "initial setting time" as defined in 3.7.

Treat the internal surfaces of the slit mould (8.3.1.3), including the slit surfaces, with a thin film of the mould-release agent (8.3.1.4) and use the clamping mechanism to close the slit in the mould.

Immediately before separating the duplicating material specimen from the specimen forming assembly, proportion the ingredients (powder and liquid) to be used to form the investment or gypsum specimen to the ratio specified in the instructions provided by the manufacturer of the investment or gypsum, in accordance with ISO 15912 or ISO 6873 [see 11 b) 9) or 11 b) 10)].

8.3.2.3 Procedure for specimen formation

Complete the following three steps within 5 min after completing the examination of the duplicating material specimen (8.3.1.1) for conformity with the detail reproduction requirement (5.5).

— Seat the specimen, lined surface down, in the recess of the slit mould to form the mould cavity into which the investment or gypsum material is to be poured.

— Invert the mould cavity assembly and begin mixing the proportioned ingredients.

— Introduce increments of the slurry, via mechanical vibration, into the slit mould along an internal surface, so as to first cover the ends of the raised lines (a, b, and c in Figure 1) on one side of the specimen surface,

and then be directed to gradually cover the lines to their opposite ends. Continue adding increments until the mould is slightly underfilled but not overfilled as a convex surface should be avoided.

At 45 min after the setting time (initial setting time) determined for the investment or gypsum (8.3.2.1), remove the clamping mechanism from the slit mould and separate the investment or gypsum specimen from the mould cavity assembly.

8.3.3 Test procedure

Use the microscope (8.3.1.7), with low-angle illumination, to examine the lined surface of the specimen for conformity with the requirement stated in 5.6 (see Note in 8.2.3).

8.3.4 Pass/fail determination and expression of results

Carry out the pass/fail determination and record results in accordance with 7.4 and 7.5.

8.4 Elastic recovery test

8.4.1 Apparatus — Type 1 materials

8.4.1.1 Specimen forming mould constructed with a polymeric material (see Figure 4).

8.4.1.2 Polymeric ring flask (see Figure 5, Key item 9), such as a segment of plumbing pipe, which has approximate dimensions of height 35 mm, inside diameter 38 mm and wall thickness 3,7 mm.

8.4.1.3 Glass baseplate, approximately 50 mm × 50 mm and 6 mm thick (see Figure 5, Key item 5).

8.4.1.4 Specimen top-surface-forming plate, a flat polymeric plate approximately 25 mm × 25 mm and 6 mm thick (see Figure 5, Key item 2).

8.4.1.5 Circulating water bath, in accordance with 8.2.1.6.

8.4.2 Apparatus — Type 2 materials

8.4.2.1 Split mould with fixation ring, for forming specimens (see Figure 6).

8.4.2.2 Two glass or metal plates, approximately 50 mm × 50 mm and at least 3 mm thick, to form the top and bottom surfaces of the specimens.

8.4.2.3 Polyethylene sheets, wrinkle free, approximately 50 mm × 50 mm and 0,035 mm thick (two per specimen).

8.4.2.4 Mould-release agent, such as silicone grease.

8.4.2.5 C-clamp, which has a minimum screw opening of 40 mm and a minimum throat depth of 30 mm.

8.4.3 Apparatus — Type 1 and Type 2 materials

8.4.3.1 Temperature-conditioning unit in accordance with 8.2.1.5, where applicable.

8.4.3.2 Glass or metal test plate, approximately 15 mm × 15 mm and 2 mm thick.

8.4.3.3 Test instrument, for example as shown in Figure 7.

The dial indicator shall be accurate to 0,01 mm and shall have a capacity for contributing, along with the mass of the test plate (8.4.3.2), to applying an initial force of (0,6 ± 0,1) N onto the specimen. The stop on the test instrument shall be set to limit compression of the specimen to (4 ± 0,1) mm.

8.4.4 Specimen preparation — Type 1 materials (five specimens)

8.4.4.1 Initial preparation

Adjust the level of the water in the circulating water bath (8.4.1.5) so that it is approximately 15 mm above the top of the baseplate (8.4.1.3) when the specimen forming assembly (8.4.4.2) is placed for cooling.

When the manufacturer's instructions specify warming or cooling the master cast before pouring the duplicating material around it, condition the specimen forming mould (8.4.1.1), the ring flask (8.4.1.2), and the specimen top-surface-forming plate (8.4.1.4) in the temperature-conditioning unit (8.4.3.1) for at least 15 min. Do not condition the glass baseplate (8.4.1.3).

8.4.4.2 Procedure for specimen formation

Complete the following five steps in rapid succession:

— Remove the specimen forming components from the temperature-conditioning unit and centre the ring flask on the baseplate.

— Pour the fluid material into the ring flask until the flask is slightly more than half full.

— Push the specimen forming mould (8.4.1.1) through the duplicating material so as to seat the bottom of the mould in contact with the centre of the baseplate, and so as to force the material up through and above the bore of the mould.

NOTE Seating the mould into contact with the baseplate can be made easier by using relatively large forceps, tongs or tweezers to grasp the rubber band encircling the mould (see Figure 5, Key item 8). The same instrument can be used for positioning the top surface forming plate as required for the step to follow.

— Push the specimen top-surface-forming plate (8.4.1.4) down through the material extruded above the mould until the plate is centred against the top surface of the mould.

— Pour additional material to cover the top-forming plate and to slightly overfill the ring flask (8.4.1.2)

Allow this specimen forming assembly to cool in air for 5 min and then immerse it to cool for 30 min in the circulating water bath (8.4.1.5) as shown in Figure 5.

Within 40 s after completing the specified cooling period, separate the specimen from the assembly, seat the specimen on the base of the test instrument (8.4.3.3) in preparation for testing, and centre the test plate (8.4.3.2) on top of the specimen.

8.4.5 Specimen preparation — Type 2 materials (five specimens)

8.4.5.1 Initial preparation

Cover one side of each glass or metal plate (8.4.2.2) with a polyethylene sheet (8.4.2.3).

Apply a thin film of mould-release agent (8.4.2.4) to all surfaces of the split mould and fixation ring (8.4.2.1).

Seat the fixation ring on one of the polyethylene-covered plates and, if there is a requirement for the temperature of the master model to be above or below room temperature, place this assembly, along with the two split halves, in the temperature-conditioning unit (8.4.3.1) to condition for at least 15 min at the specified temperature.

8.4.5.2 Procedure for specimen formation

Proportion and mix the components and then complete the following five steps in rapid succession.

— Pour the mixed material into the fixation ring until it is slightly more than half full.

— Press the two split halves of the mould, together, through the duplicating material until their bottom surfaces are in near contact with the polyethylene covered baseplate, and so as to force the material above the top surfaces of the split halves.

— Press the second polyethylene covered plate through the material extruded above the top surfaces and into near contact with the top of the split mould. Then use the C-clamp (8.4.2.5) to force the plates into contact with the top and bottom surfaces of the split mould.

NOTE If glass plates are used instead of metal plates, metal back-up plates can be used between the glass plates and the C-clamp parts to minimize scratching or breakage of the glass plates.

— Allow this assembly to set for the time/temperature cycle specified in the manufacturer's instructions for obtaining effective setting of the material [see 11 b) 4)].

— Within 40 s after completing the setting period specified in the manufacturer's instructions, separate the specimen and seat it for testing as for the Type 1 specimens.

8.4.6 Test procedure — Type 1 and Type 2 materials

Use the test instrument to conduct the test in accordance with the following time schedule, where t is the end of the time allowed for water-cooling Type 1 material specimens, or the time specified in the manufacturer's instructions for setting Type 2 materials [see 11 b) 4)].

— t + 45 s: Gently lower the dial indicator spindle contact point to rest on the test plate positioned on top of the specimen.

— t + 55 s: Read the dial indicator, lift the contact point from contact with the test plate, and record the dial indicator reading as h_1.

— t + 60 s: Deform the specimen (4 ± 0,1) mm (as limited by the stop on the test instrument) within 1 s. Release the deforming force slowly over a period of 5 s. Then lift and hold the contact point from contact with the test plate.

NOTE The possibility of lateral displacement of the specimen during application of the deforming force can be reduced by cementing a 600 grit (FEPA 1200) abrasive paper covering over the surfaces of the instrument base and the test plate that is in contact with the top and bottom surfaces of the specimen during the test.

— t + 170 s: Gently return the dial indicator contact point to rest on the test plate.

— t + 180 s: Record the dial indicator reading as h_2.

8.4.7 Calculation of results

Calculate the elastic recovery, K, for each specimen, expressed as a percentage, to the nearest ±0,05 %, using the formula:

$$K = 100 - \left[100 \left(\frac{h_1 - h_2}{h_0} \right) \right]$$

where

h_0 is the height of the mould;

h_1 is the dial indicator reading at t + 55 s (immediately before the specimen is deformed);

h_2 is the dial indicator reading at t + 180 s (115 s after the deforming force was removed from the specimen).

Discard values obtained for defective specimens.

NOTE Air inclusion defects in translucent specimens can often be discerned before testing. Such defects in opaque specimens can be detected, after testing, by sectioning the specimens axially into eight approximately equal size segments and then examining each segment for defects.

8.4.8 Pass/fail determinations and expression of results

Carry out the pass/fail determination and record results in accordance with 7.4 and 7.5.

8.5 Tear strength test

8.5.1 Apparatus and materials

8.5.1.1 Specimen sheet-forming mould (see Figure 8) which has a depth that provides for a specimen thickness of (4,5 ± 0,5) mm.

NOTE The specimen thickness is dependent upon the capacity of the specimen-gripping mechanism available for the test. Use of the optional method described in Annex A, for fitting tear-test specimens for gripping in the test instrument, allows accommodation of any specimen thickness within the specified tolerance.

8.5.1.2 Polyethylene sheet, wrinkle free, approximately 0,035 mm thick and which has length/width dimensions approximating those for the mould cavity cover (see Figure 8), one for each Type 2 specimen.

8.5.1.3 Temperature-conditioning unit, in accordance with 8.2.1.5, if applicable.

8.5.1.4 Circulating water bath, in accordance with 8.2.1.6, for cooling Type 1 material specimens.

8.5.1.5 Die, in accordance with ASTM D624-00:2020, Die C, for cutting specimens to the dimensions specified in Figure 9.

NOTE A specimen forming mould plate can be substituted for the ASTM D624-00:2020, Die C as an alternative method of shaping the specimens to the dimension specified in Figure 9.

8.5.1.6 Specimen sheet support, on which to place the specimen sheet for precision cut-out of the specimen without damage to the cutting edges of the die (8.5.1.5).

The top surface of the support should be flat, soft, and have length/width dimensions approximating those of the specimen sheet. The thickness of the soft surface, which may consist of layers of waterproof paper, polymer or wax sheets, may vary depending on the resistance to cutting exhibited by the soft surface and specimen sheet materials.

8.5.1.7 Instrument to measure specimen thickness, such as a dial indicator mounted on a conventional support stand.

The dial indicator shall be accurate to ±0,01 mm and shall be equipped with a circular, flat, broad-based contact point. The travel of the dial indicator spindle shall be regulated such that the force applied by the contact point during the thickness measurement does not exceed 22 kPa. The flat specimen support baseplate

on the dial indicator stand shall be dimensioned such that it provides support to the entire underside of the specimen (see Figure 9) during the measuring procedure.

8.5.1.8 Test instrument, capable of applying a tensile test load at a rate of 500 mm/min, and of applying a breaking load of at least 500 N.

8.5.2 Specimen preparation (five specimens)

8.5.2.1 Initial preparation

For Type 1 material specimens only: arrange for the water level in the circulating water bath (8.5.1.4) to be such that it is approximately even with, but not above, the top of the mould cavity base (see Figure 8, Key item 1).

For Type 2 material specimens only: adapt a polyethylene sheet (8.5.1.2) to the underside of the mould cavity cover (see Figure 8, Key item 5).

If the manufacturer's instructions specify warming or cooling of the master model, use the temperature-conditioning unit (8.5.1.3) to condition the specimen sheet-forming mould (8.5.1.1), including the cavity cover, to the required temperature for at least 30 min.

If the specimen is to be fitted for the optional gripping method described in Annex A, lay out all items needed for the fitting.

8.5.2.2 Specimen preparation steps (five specimens)

After completion of temperature conditioning of the mould cavity components (8.5.2.1), slightly overfill the mould cavity with fluid duplicating material and then press the mould cavity cover down through the excess material until it contacts the upper extremes of the cavity borders.

Air-cool the filled mould assemblies for Type 1 materials for 5 min, and then transfer them to the water bath (8.5.1.4) for 30 min to complete gelation of the specimen material. Allow assemblies for the Type 2 materials to set for the times and at the temperatures specified in the manufacturer's instructions [see 11 b) 4)].

Complete the following steps within 90 s after expiration of the time specified for gelation of the Type 1 materials or the time specified for effective setting of the Type 2 materials.

— Separate the specimen sheet from the assembly and place it on the soft-surfaced support (8.5.1.6) and use the die (8.5.1.5) to cut out the specimen shape.

It is very important to handle the specimen carefully during subsequent steps to avoid stressing the notched area of the specimen before the test load is applied.

NOTE If the mould plate (see Note to 8.5.1.5) is used as an alternative method for forming the specimen, the specimen is ready for subsequent steps as soon as it is separated from the mould.

— Use the instrument to measure the specimen thickness (8.5.1.7) at a point just inside the 90° angle notch.

— Align the specimen and secure it in the instrument for testing (8.5.1.8).

When fixation of the specimen in the instrument grips for testing is achieved through direct contact of the gripping surfaces with the end surfaces of the specimen, the following factors should be taken into account:

a) The optimum airline pressure for use in pneumatic gripping of duplicating material specimens is about 83 kPa (12 psi).

b) Depending on the type of grip surfacing, it can be necessary to cover the gripping surfaces with an adhesive-backed abrasive paper, about 240 grit (FEPA 280), in order to effectively grip the specimens.

Fitting the specimens for gripping as described in Annex A eliminates the need for such concerns.

8.5.3 Test procedure

Immediately after completing step d) in 8.5.2.2, apply the tensile test load at a speed of 500 mm/min until the specimen ruptures. Record the load at rupture.

8.5.4 Calculation of results

Calculate the tear strength using the following formula:

$$T_s = \frac{F}{d}$$

where

T_s is the tear strength of the specimen thickness, expressed in N/mm;

F is the force required to rupture the specimen, expressed in N;

d is the specimen thickness, expressed in mm.

8.5.5 Pass/fail determination and expression of results

Carry out the pass/fail determination and record the results in accordance with 7.4 and 7.5.

8.6 Fungal growth resistance test — Type 1 agar materials only

8.6.1 Apparatus and materials

8.6.1.1 Petri dishes, each of which has an inside diameter of approximately 60 mm and a depth of 15 mm (one for the test specimen and one for the control specimen).

8.6.1.2 Fungal culture, such as can be obtained from stale, preservative-free bread, e.g., fungal strains such as *Rhizopus nigricans*, *Aspergillus nidulans* and *Penicillium glaucum*.

8.6.1.3 Sterilized inoculating loop

8.6.1.4 Relative humidity chamber, capable of providing for a relative humidity of (95 ± 5) % at laboratory temperature (7.1).

8.6.2 Specimen preparation (1 test specimen and 1 control specimen)

Pour approximately 25 ml of the fluid duplicating material into each of the Petri dishes (8.6.1.1), cover the dishes and allow the material to cool at laboratory temperature for (30 ± 5) min. Mark the dishes to indicate which is to contain the experimental specimen.

8.6.3 Test procedure

After completing the cooling period, use the inoculating loop (8.6.1.3) and fungal culture (8.6.1.2) to inoculate the test specimen. Cover the specimens in both Petri dishes and store them in the relative humidity chamber (8.6.1.4) for seven days. Then examine the specimens for conformity with 5.9.

8.6.4 Pass/fail determination

If the test specimen and the control specimen exhibit no fungal growth after completion of the seven-day incubation period, the material conforms with the requirement stated in 5.9.

8.6.5 Expression of results

Report whether the material conforms with the requirement.

9 Requirements for packaging

No packaging requirements, other than those associated with labelling (see Clause 10) and instructions for use (see Clause 11), are specified in this document. However, manufacturers should supply the duplicating material in containers that protect it from contamination or loss of content.

10 Requirements for labelling

Outer packages for the duplicating materials shall be provided with labels giving the following information:

a) trade or brand name of the product;

b) name and address of the manufacturer, or the name and address of another company authorized by the manufacturer to distribute the material under a different trade name;

c) identification of the basic generic ingredient which, when mixed with other ingredients, provides elastic properties in the material (agar, polyether, silicone, etc.);

d) type description, to indicate clearly whether the material is reversible or non-reversible;

e) manufacturer's lot number (batch number);

NOTE ISO 15223-1 illustrates standardized symbols approved for use on label entries for lot numbers and serial numbers, recommended storage conditions, cautionary statements and USE BEFORE dates.

f) storage conditions required to prevent degradation of the material between the time it is manufactured and the time the immediate container is opened for first use of the material;

NOTE An immediate container can serve as a primary container.

g) any cautionary statements that can be necessary to avoid possible toxic or irritating effects that can be associated with use of the material;

h) USE BEFORE date (expiry date), identified as such, beyond which the material cannot exhibit its best properties. The date shall be expressed as a six-digit number; for example, 2001-09, where the first four digits indicate the year 2001, and the last two digits indicate the month of September;

i) net volume of material in each container;

j) all content within the outer container including accessories and instructions for use.

11 Instructions for use — Required information

Complete instructions for obtaining optimum performance of the material shall be furnished by the manufacturer with each package in which the material is prepared for retail marketing. The following information shall be provided:

a) product-identifying information:

1) trade or brand name of product;

2) generic nature of the material (agar, polyether, silicone, etc.);

b) instructions for use of both Type 1 and Type 2 materials:

1) storage conditions required after first opening of the immediate container, and between other openings thereafter, to minimize possibilities for degradation of the material or its components;

NOTE An immediate container can serve as a primary container.

2) type of duplicating material;

3) method and time for conditioning the master model to the temperature required before the duplicating material is poured around it;

4) method, temperature and time for air storage or water cooling, or both, required after pouring, to bring about optimum gelation or effective setting of the material;

5) method of separating the master model from the mould;

6) time lapse permitted between separation of the master model from the mould and pouring investment or gypsum materials into the mould;

7) any treatment of the mould required between the time of separation of the master model and the time of pouring the mould;

8) ambient environment in which the poured mould should be held while the investment or gypsum is setting;

9) identification, by brand name and bonding mechanism category, of at least one refractory investment product which the duplicating material manufacturer has found to be compatible with the duplicating material, and which meets the requirements of ISO 15912;

10) if the instructions indicate that the duplicating material is suitable for making moulds in which dental gypsum product models can be made, identification is required of at least one dental gypsum product, by brand name and type, which the duplicating material manufacturer has found to be compatible with the material; either one Type 3, one Type 4 or one Type 5, dental stone product which meets the requirements of ISO 6873.

c) instructions for Type 1 materials only:

1) equipment recommended for the melting process;

2) maximum temperature recommended for the melting process;

3) method for maintaining the fluid duplicating material at the required pouring consistency; for example, if the material requires continual or intermittent stirring during prolonged storing periods, that fact shall be stated;

4) pouring temperature range, maximum and minimum;

5) minimum temperature to be used in bringing about gelation of the material;

6) storage conditions and any other treatment required for the duplicating material between separation of the mould from a duplicated master model and commencement of required subsequent re-melting procedures;

7) procedures to be followed in order to obtain optimum functional life of the material.

d) instructions for Type 2 materials only:

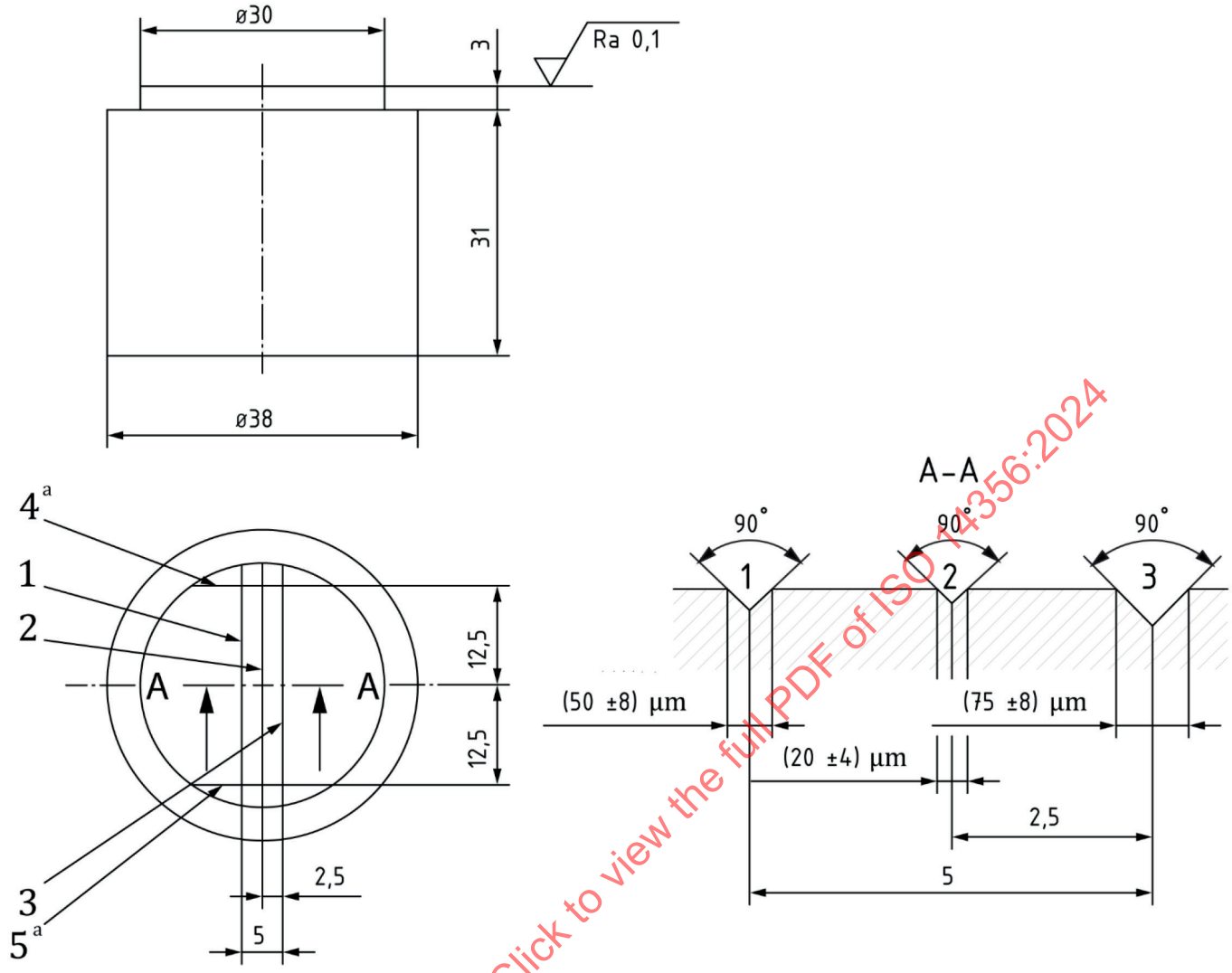
1) mass/mass proportioning for the components;

2) mixing method and time;

3) effective setting time;

4) factors that can influence the time the mixed material remains pourable (e.g. ageing of components, variations in room temperature, mixing rate, humidity).

e) date of latest edition/revision of the instructions for use.



Key

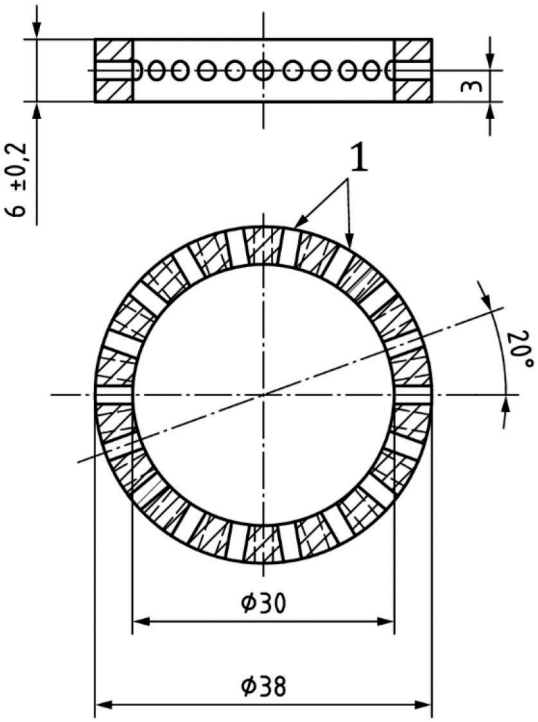
1 line a
2 line b
3 line c
4 line d_1
5 line d_2
[a] Has the same width as line c.

NOTE 1 Unless otherwise specified, dimensions are in millimetres.

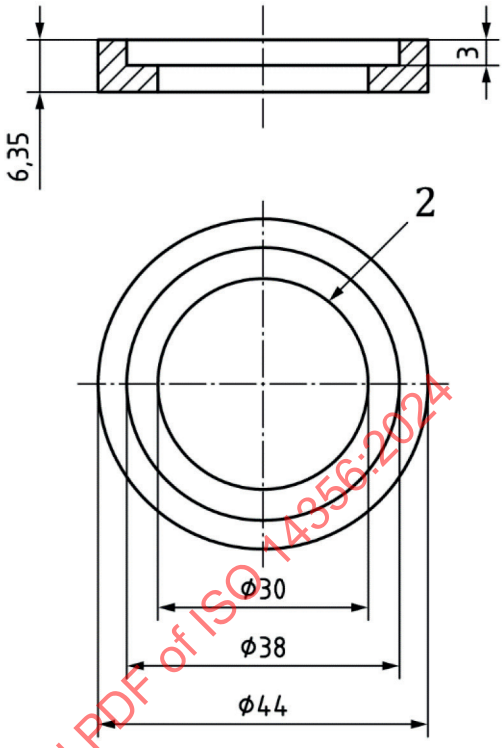
NOTE 2 Unless otherwise specified, tolerances are ±0,1 mm or 1° as appropriate; surface roughness is ≤ 3,2 µm; and material is cast or wrought austenitic stainless steel.

Figure 1 — Test block for detail reproduction test and tests for compatibility with refractory investment and gypsum

Dimensions in millimetres



a) Specimen forming ring mould [a,b]



b) Ring mould retainer [a,b]

Key

1 specimen material retention holes: 18 holes in a row with the holes with nominal diameters of 2 mm

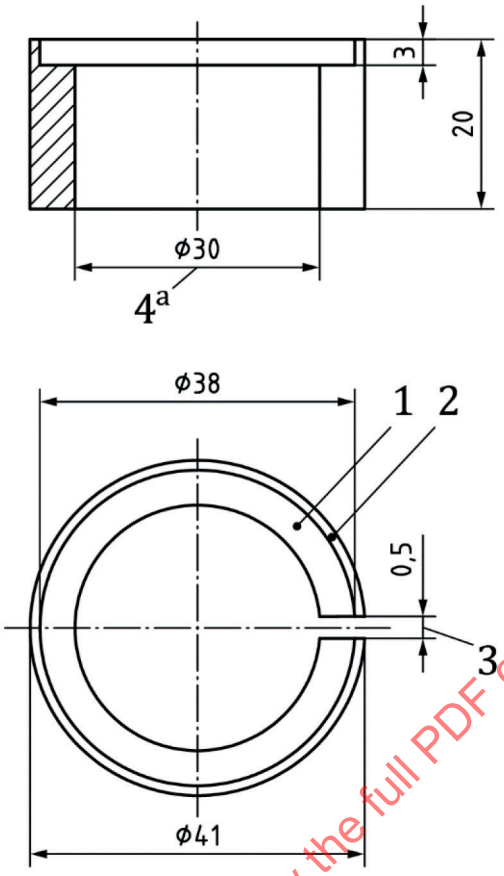
2 floor of the specimen forming ring mould retainer

[a] The specimen forming ring mould and retainer are made of anodized aluminium, brass or corrosion-resistant steel.

[b] The ring mould should fit in the ring mould retainer.

Figure 2 — Detail reproduction test — Specimen forming accessories

Dimensions in millimetres

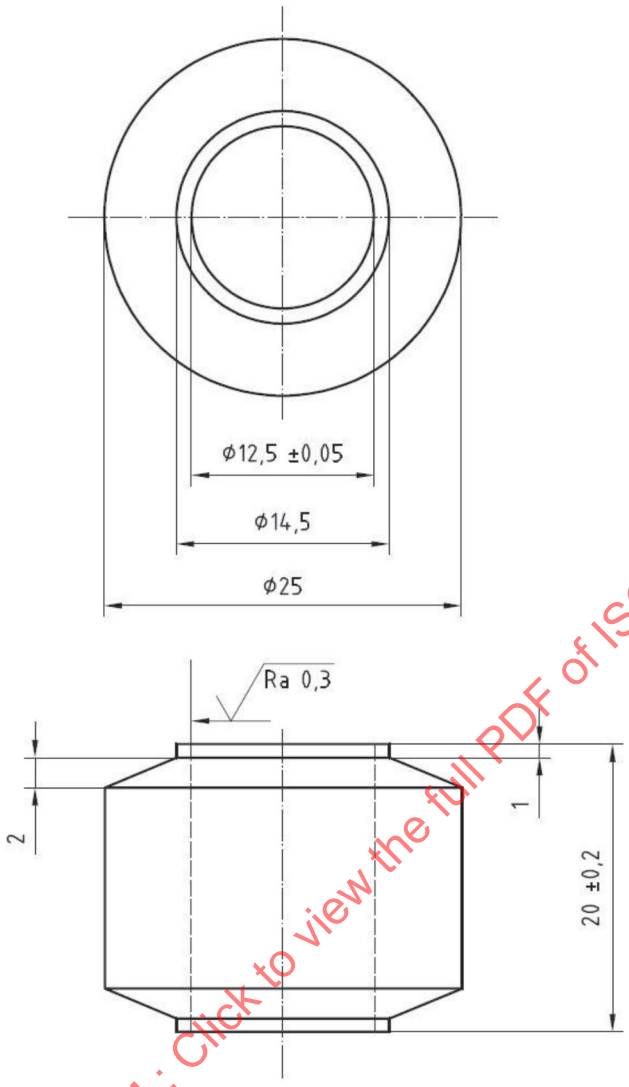


Key

1 floor of specimen forming assembly retaining recess
2 recess rim
3 width of slit in wall of mould before the slit has been closed
4 internal diameter of slit mould after the slit has been closed
a Specimen forming slit mould should fit in specimen forming ring mould [see Figure 2 a)].

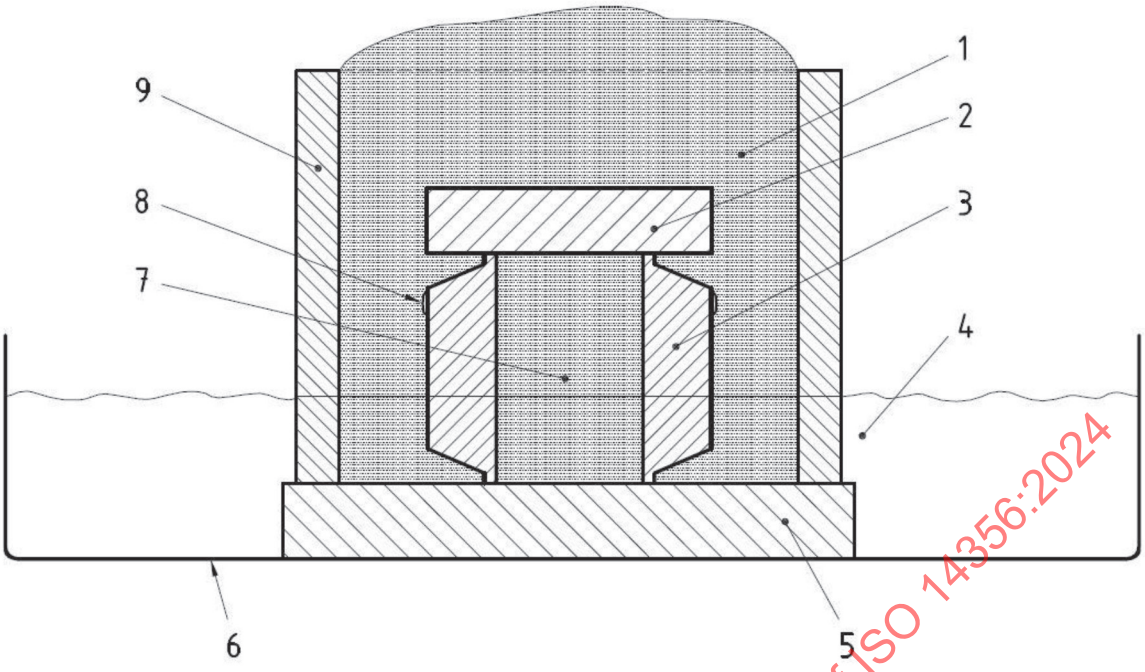
Figure 3 — Compatibility with gypsum test — Specimen forming slit mould

Dimensions in millimetres



NOTE Unless otherwise specified, tolerances are ±0,1 mm and surface roughness is ≤ 3,2 µm.

Figure 4 — Specimen forming mould — Elastic recovery test, Type 1 materials

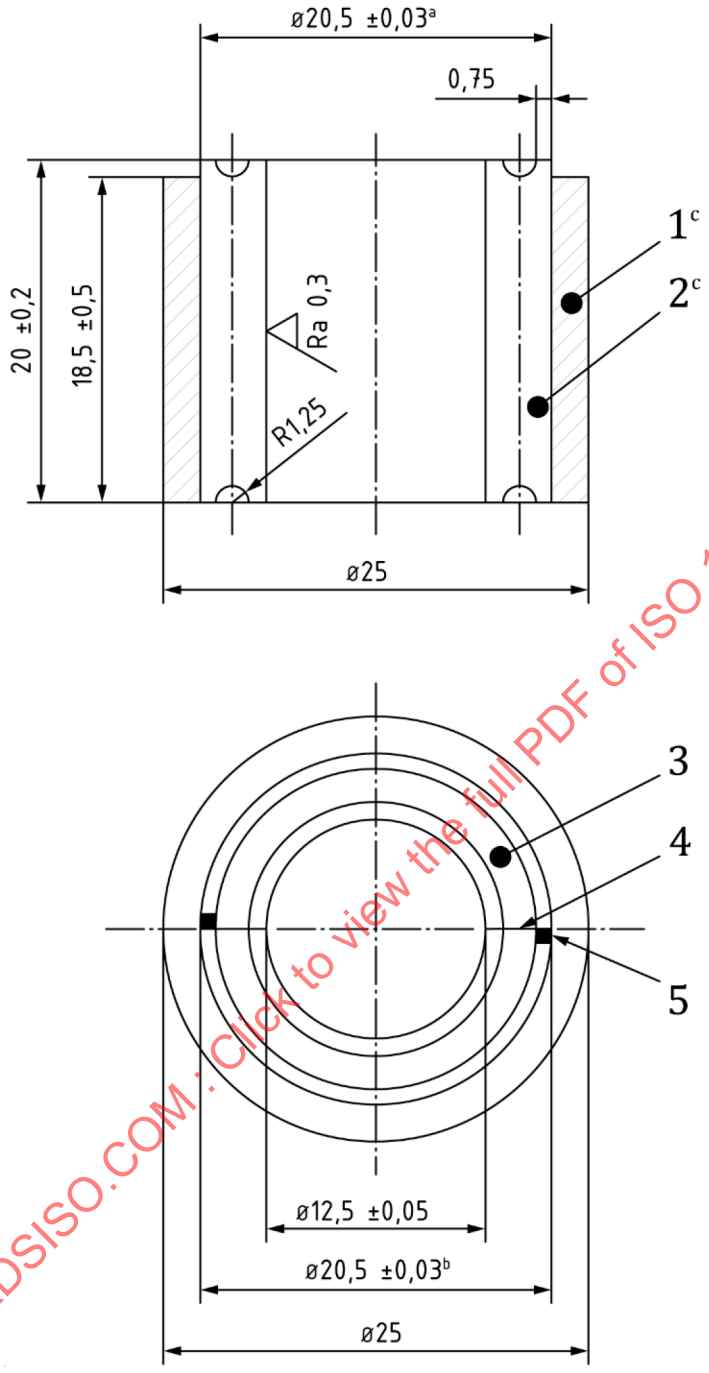


Key

1 agar duplicating material
2 top-surface-forming plate
3 specimen forming mould
4 cooling water
5 glass baseplate
6 cooling water container
7 specimen
8 rubber band (approximately 0,8 mm thick and 5 mm wide)
9 polymeric ring flask

Figure 5 — Specimen forming assembly — Elastic recovery test, Type 1 materials

Dimensions in millimetres



Key

1 fixation ring

2 split mould half, no bell mouth in bore of the assembly

3 grooved top and bottom surfaces of the split mould halves

4 split mould half interface

5 spillways (1 mm wide x 1 mm deep) cut through the external rims of the split mould halves adjacent to their interfacing end surfaces

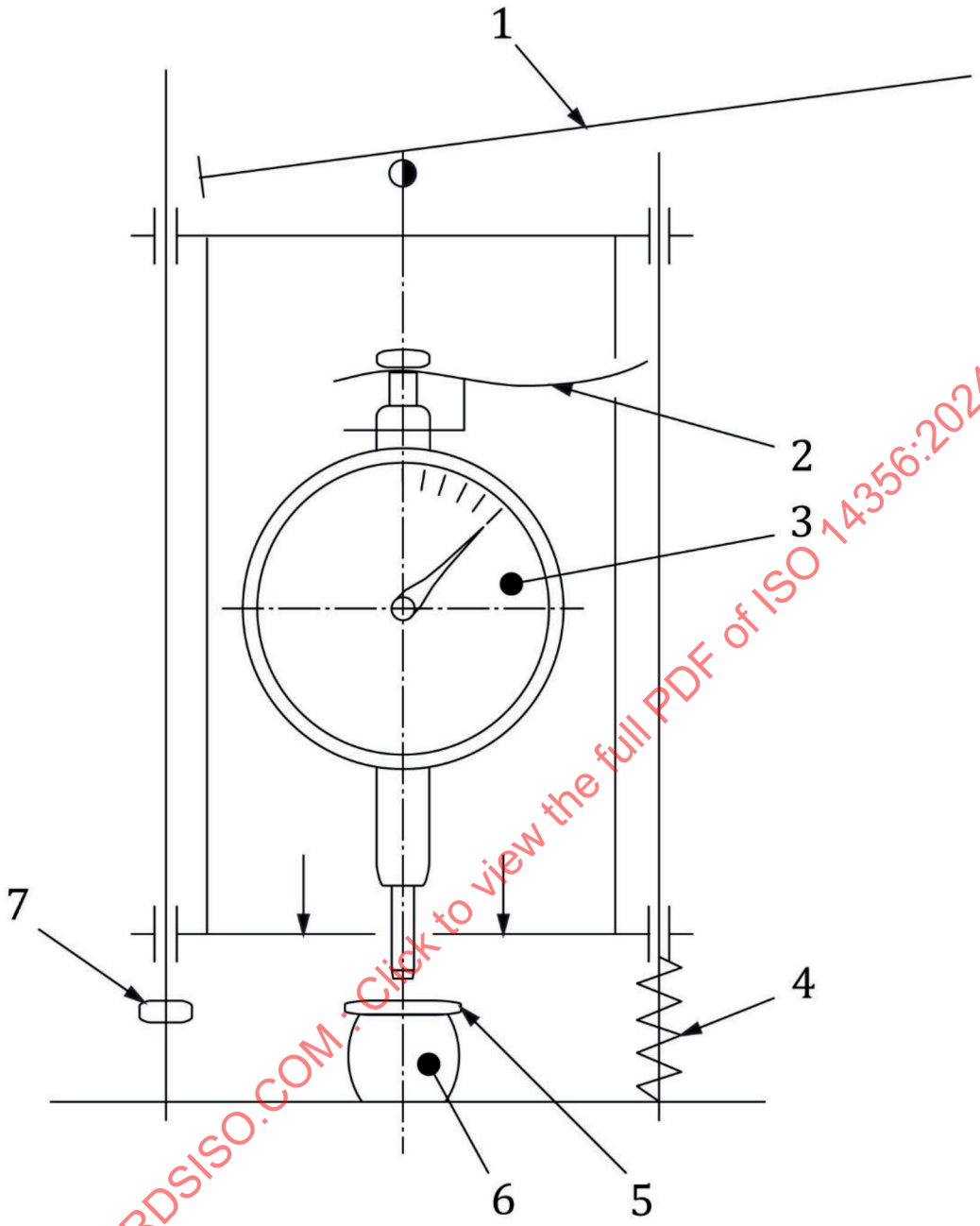
a Outside diameter of the split mould halves assembly.

b Inside diameter of the fixation ring.

c Corrosion-resistant steel.

Figure 6 — Elastic recovery test — Specimen forming split mould assembly, Type 2 materials

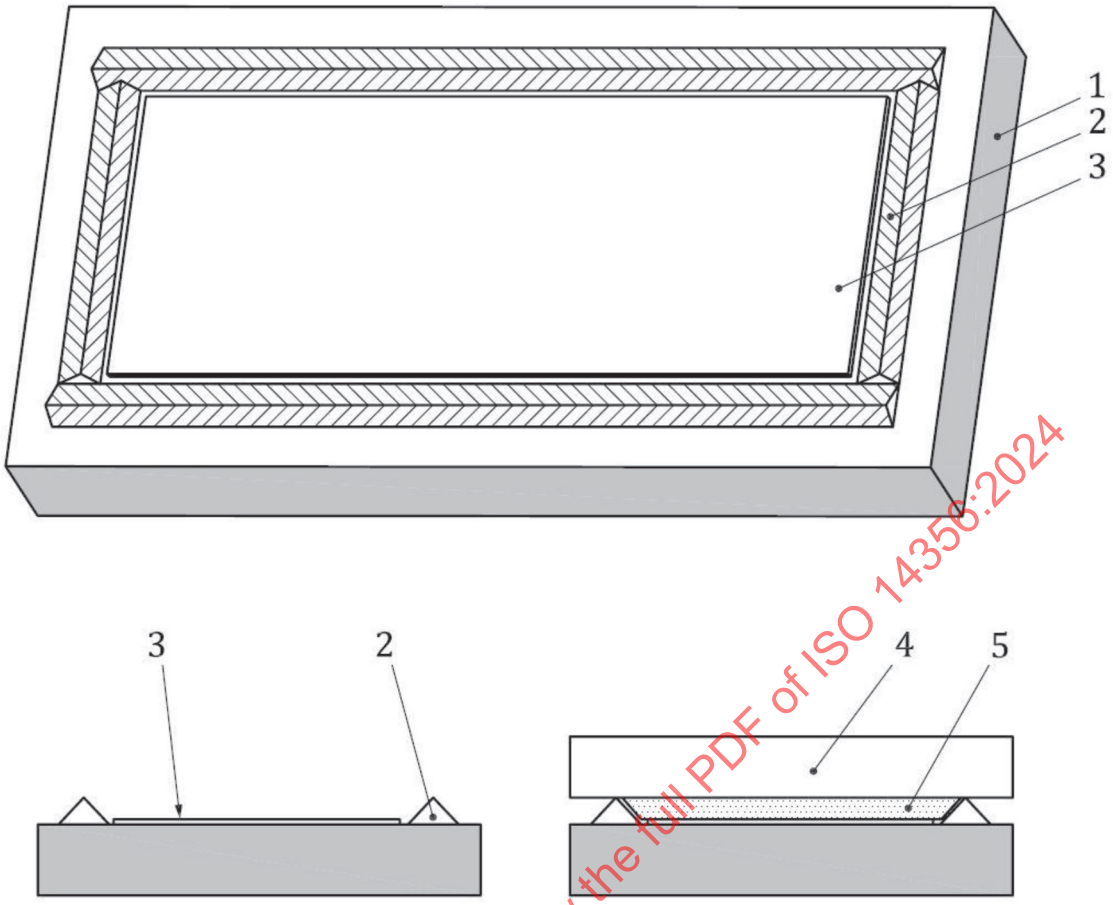
Dimensions in millimetres



Key

1 lever for activating the required compressive force
2 dial indicator spindle position control lever
3 dial indicator with divisions of 0,01 mm
4 spring (optional)
5 test plate
6 specimen compressed to limit
7 compressive force stop set to limit compression of the specimen to (4,0 ± 0,1) mm

Figure 7 — Elastic recovery test instrument



Key

1 mould cavity base[a]

2 mould cavity border[b]

3 mould cavity floor[c]

4 mould cavity cover[d]

5 specimen material

a For example, a glass dental cement mixing slab of approximate dimensions (154 × 75 × 12) mm; or thinner sheets of glass that have approximately the same length/width dimensions, which are cemented in layers to produce a base that has essentially the same dimensions.

b The mould cavity border consists of four triangular rod stock pieces with no undercuts, adjusted in height and cemented to the base so as to form a mould cavity (4,0 + 0,1) mm deep (see specimen thickness, Figure 9) and a mould cavity floor 120 mm long and 45 mm wide.

c The mould cavity floor is sometimes adjusted to height by a thin sheet wax or polymer sheet additions, in order to provide for the desired mould cavity depth.

d The mould cavity cover is a glass slab that has essentially the same dimensions as the mould cavity base.

Figure 8 — Tear test — Specimen sheet-forming mould