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## Dentistry — Duplicating material

*Art dentaire — Produits pour duplication*

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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.

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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 14356 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 2, *Prosthetic materials*.

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# Dentistry — Duplicating material

## 1 Scope

This International Standard specifies 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 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 (all parts), *Dental vocabulary*

ISO 6873, *Dental gypsum products*

ISO 7490, *Dental gypsum-bonded casting investments*

ISO 9694, *Dental phosphate-bonded casting investments*

ISO 11245, *Dental restorations — Phosphate-bonded refractory die materials*

ISO 11246, *Dental ethyl silicate bonded casting investments*

## 3 Terms and definitions

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

### 3.1

#### **block out**

to flow or mould waxes and/or materials such as cements, clays and polymeric materials into undercut areas on a master model, and then shape them so as to leave only those undercuts that are essential to the subsequent steps in producing a prosthesis that will fit and function optimally

**NOTE** A blocked-out master model may also include other surface modifications needed relative to construction of a prosthesis.

### 3.2

#### **double boiler**

container system, usually in three parts, 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

### 3.3

#### **duplicating material**

elastic material used to make flexible negative copy impressions or moulds of objects (models or casts) into which a mix of a refractory investment, or another mixture intended for a similar purpose, can be poured to produce a positive copy of the original object

### 3.4

#### **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

### 3.5

#### **reversible duplicating material**

material which can be recycled for more than one use by changing it, by means of heating, from an elastic gel state to a pourable consistency, and then returning it to the gel state by cooling

### 3.6

#### **duplicating process**

⟨for making metal and ceramic objects⟩ method for making positive copies of master models from a negative mould

NOTE 1 The process is carried out according to the following steps:

- master model is blocked out,
- duplicating material is poured around blocked-out master model and allowed to gel or set,
- master model is separated from the duplicating material, leaving a flexible mould having surfaces that constitute a negative copy of the surfaces of the master model,
- an investment mixture is poured into the mould to form a refractory model on which polymeric or wax patterns, or both, can be laid down to form the shapes desired in metal or ceramic castings or on which slurries of porcelain can be applied for forming desired shapes.

NOTE 2 Gypsum product mixtures or other mixtures may be poured into the moulds to form copies of master models needed for other purposes.

### 3.7

#### **effective setting time**

⟨for materials setting at or near oral or room temperature⟩ 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

### 3.8

#### **functional life**

⟨reversible duplicating material⟩ 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

### 3.9

#### **gelation**

⟨agar duplicating material⟩ 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

### 3.10

#### **immediate container**

packaging component having internal surfaces in direct contact with the material contained

**NOTE** An immediate container may be a 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.

### 3.11

#### **initial 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 a test procedure, conducted at a specified temperature, indicates that the mixture has begun to set at a relatively rapid rate, thus indicating that the effective setting time will be reached at some predictable time thereafter

**NOTE** 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.

### 3.12

#### **investment**

⟨casting⟩ powdered refractory material 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

### 3.13

#### **master model definitive cast**

⟨fixed and removable denture construction⟩ positive copy of the hard and/or soft tissues of a dental arch, usually made by pouring a gypsum product slurry into an impression made of a dental arch

### 3.14

#### **melt**

⟨agar reversible duplicating material⟩ change a material, by heating, from a gel state to a pourable fluid state

### 3.15

#### **outer package**

wrapping or carton which is used to cover one or more immediate or primary containers in preparation for retail marketing and which may be required by law or International Standard to bear specified labelling information

### 3.16

#### **pouring temperature**

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

### 3.17

#### **primary container**

retail marketing packaging component which may or may not be covered by an outer package and which may be required by law or International Standard to bear specified labelling information

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

**NOTE** A primary container may also be an immediate container, and vice versa.

**3.18**

**refractory**

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

**3.19**

**slurry**

⟨ceramic, gypsum or refractory investment⟩ mixture, consisting of a powder and water, or a powder and another liquid, having a consistency that will allow 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

**3.20**

**storage**

holding of a material in an immediate container in a protected environment before the container is opened for the first use, and between subsequent openings of the container

**3.21**

**store**, verb

⟨melted agar reversible duplicating material⟩ to hold a material at the temperature specified in the manufacturer's instructions for keeping it at pouring consistency

## **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, it is necessary to review Clauses 9, 10 and 11 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 copy line b scribed on the test block (Figure 1), 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 gypsum if applicable)

When tested according to 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 copy line c for the full length of the distance between lines  $d_1$  and  $d_2$  (Figure 1).

## 5.7 Elastic recovery

When tested according to 8.4, the elastic recovery shall be at least 96,50 %.

## 5.8 Tear strength

When tested according to 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 may 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 International Standard, all specimen preparation and testing shall be conducted under ambient laboratory conditions of  $(23 \pm 2) ^\circ\text{C}$  and  $(50 \pm 10) \%$  relative humidity. Unless otherwise specified in this International Standard, 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 compliance with the specifications stated for them in this International Standard, 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  $\pm 1$  s over a 30 s period.

### 7.3.2 Preparation of Type 1 materials

Use the double-boiler method 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, providing 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 International Standard, 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 comply with the related requirement, the material passes. If none complies, the material fails. If only one specimen complies, make three additional specimens. If all three of the additional specimens comply, 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 comply with the related requirement, the material passes. If only one or two specimens comply, the material fails. If only three specimens comply, make a series of five additional specimens. If all five of the second series of specimens comply, the material passes; otherwise the material fails.

## 7.5 Expression of test results

Report the number of specimens tested, the number complying 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** (3.2) having a component that will accommodate 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 having 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 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 according to 8.1.2 with the maximum temperature stated in the manufacturer's instructions [11 c) 2)]. Then record whether this temperature complies 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 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 so as 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 (8.2.1.1, 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 (3 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 will be 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)], down along an internal surface of the ring mould so that the material will first enter the lines a, b and c 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 completion of 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 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 compliance 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 may 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 gypsum if applicable)

### 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 compliance 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 Slit mould** (see Figure 2), 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 will be closed during 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 will be 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 compliance with the "setting time" requirement specified in the related International Standard listed in Clause 2 of this International Standard. Product batches which do not comply with the related requirement shall not be used in the compatibility test.

NOTE The "setting time tests" described in the International Standards listed in Clause 2 are not for determining "final" or "effective" setting times. Instead they are for determining "initial setting time" as that term is defined in 3.11 of this International Standard.

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 for forming the investment or gypsum specimen to the ratio specified in the instructions provided by the manufacturer of the investment or gypsum, according to the requirements of the related International Standard [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 examination of the duplicating material specimen (8.3.1.1) for compliance with the detail reproduction requirement (5.5).

- Seat the specimen, lined surface down, in the recess of the slit mould so as 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 mixture, via mechanical vibration, down 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.

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 compliance 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 (see Figure 3)

**8.4.1.2 Polymeric ring flask** (see Figure 4, Key item 9), such as a segment of plumbing pipe, having 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 4).

**8.4.1.4 Specimen top-surface-forming plate**, a flat polymeric plate approximately 25 mm × 25 mm and 6 mm thick (see Figure 4).

**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 5).

**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**, having 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, as may be 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 6.

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 application of an initial force of  $(0,6 \pm 0,1)$  N onto the specimen. The stop on the test instrument shall be set to limit compression of the specimen to  $(4 \pm 0,1)$  mm.

#### **8.4.4 Specimen preparation — Type 1 materials (5 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 will be 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) down 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 a relatively large forceps, tongs or tweezers to grasp the rubber band encircling the mould (Figure 4, Key 8) so as to direct positioning the mould. 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 4.

Within 40 s after completion of 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 (5 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, down 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 may 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 [11 b) 4)].
- Within 40 s after completion of 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 of 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 ( $4 \pm 0,1$ ) 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 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 will be 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  $\pm 0,05$  %, using the equation:

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

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), and

$h_2$  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 7) having a depth that will provide for a specimen thickness of ( $4,5 \pm 0,5$ ) mm.

NOTE The specimen thickness may vary within the stated tolerance depending 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 having length/width dimensions approximating those for the mould cavity cover (see Figure 7), 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 (ASTM D624-98, Die C)** for cutting specimens to the dimensions specified in Figure 8.

NOTE A specimen-forming mould plate may be substituted for the ASTM Die C as an alternative method of shaping the specimens to the dimension specified in Figure 8.

**8.5.1.6 Specimen sheet support**, on which to place the specimen sheet for precision cut-out of the specimen without damage to 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. Thickness of the soft surface, which may consist of layers of waterproof paper, polymer or wax sheets, may vary depending upon 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  $\pm 0,01$  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 will provide support to the entire underside of the specimen (see Figure 8) 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 (5 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 will be approximately even with, but not above, the top of the mould cavity base (see Figure 7, 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 7, 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 (5 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 so as 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 (8.5.1.7) to measure the specimen thickness at a point just inside the 90° angle notch.
- Align the specimen and secure it in the instrument (8.5.1.8) for testing.

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.

- Experience seems to indicate that the optimum airline pressure, for use in pneumatic gripping of duplicating material specimens, is about 83 kPa (12 psi).
- Depending upon the type of grip surfacing, it may be necessary to cover the gripping surfaces with an adhesive-backed abrasive paper, about 240 grit (FEPA 280), in order to achieve effective gripping of the specimens.

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

### 8.5.3 Test procedure

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

### 8.5.4 Calculation of results

Calculate the tear strength using the following equation:

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

where

$T_s$  is the tear strength, in newtons per millimetre of specimen thickness;

$F$  is the force, in newtons, required to rupture the specimen;

$d$  is the specimen thickness, in millimetres.

### 8.5.5 Pass/fail determination and expression of results

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

## 8.6 Fungal growth resistance test — Type 1 agar materials only

### 8.6.1 Apparatus and materials

**8.6.1.1 Petri dishes**, each having 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 bread having no preservatives; for example, 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  $(95 \pm 5) \%$  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  $(30 \pm 5)$  min. Mark the dishes to indicate which is to contain the experimental specimen.

### 8.6.3 Test procedure

After completion of 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 7 days. Then examine the specimens for compliance 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 7-day incubation period, the material complies with the requirement stated in 5.9.

### 8.6.5 Expression of results

Report whether the material complies with the requirement.

## 9 Requirements for packaging

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

## 10 Requirements for labelling

Outer packages (3.15) for the duplicating materials shall be provided with labels giving the following information:

- trade or brand name of the product;
- 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;
- identification of the basic generic ingredient which, when mixed with other ingredients, provides for 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 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;
- g) any cautionary statements that may be necessary to avoid possible toxic or irritating effects that might be associated with use of the material;
- h) USE BEFORE date (expiry date), identified as such, beyond which the material may not 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.

## 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;
  - 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 is in compliance with requirements of the related International Standard listed in Clause 2;

- 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 is in compliance with requirements of ISO 6873 (see Clause 2).

c) Instructions for Type 1 materials only:

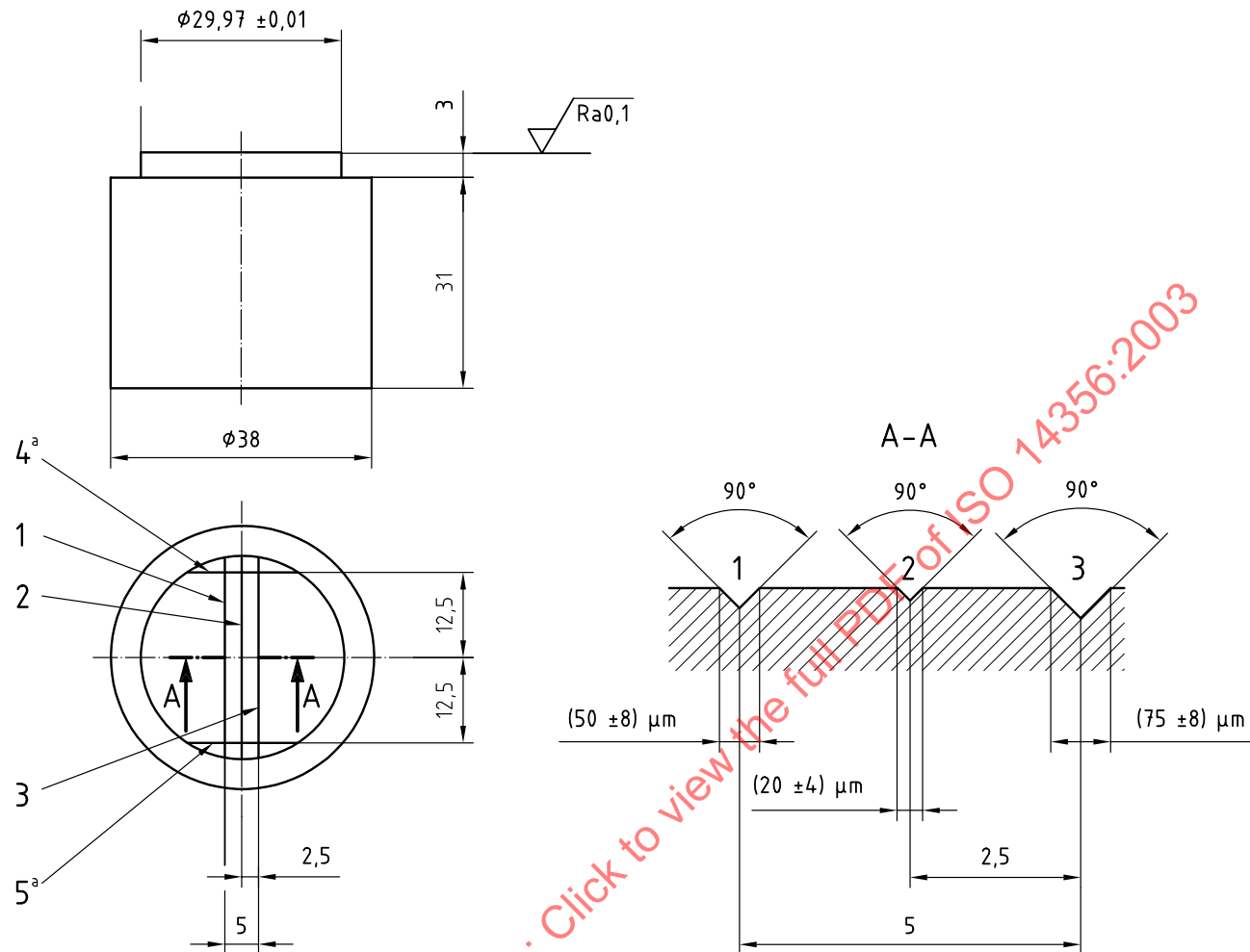
- 1) equipment recommended for the melting process;
- 2) maximum temperature recommended for the melting process;
- 3) method for maintaining the fluid duplicating material at the required pouring consistency, for example, if the material must be stirred continually or intermittently during prolonged 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 (3.8) 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 (3.7);
- 4) factors that can influence the time the mixed material will remain pourable (i.e. ageing of components, variations in room temperature, mixing rate, humidity, etc.).

Dimensions in millimetres, unless otherwise specified

Tolerances  $\pm 0,1$  mm unless otherwise specified for surface roughness  $\leq 3,2 \mu\text{m}$



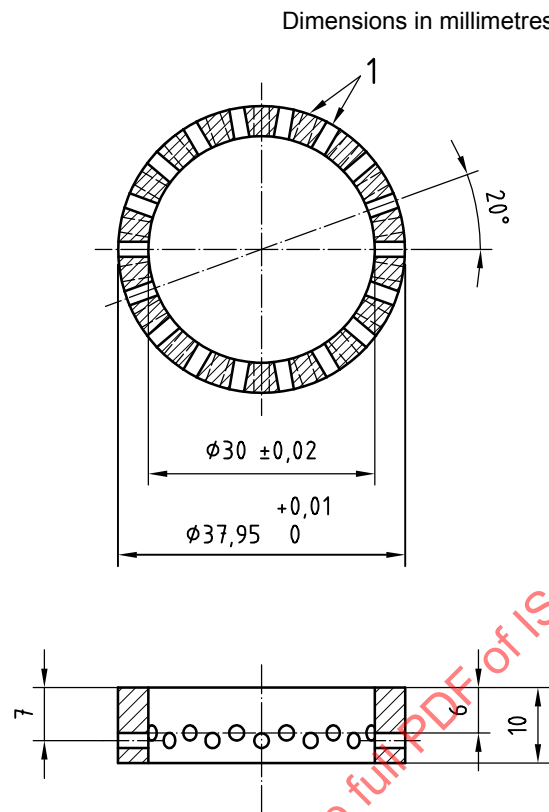
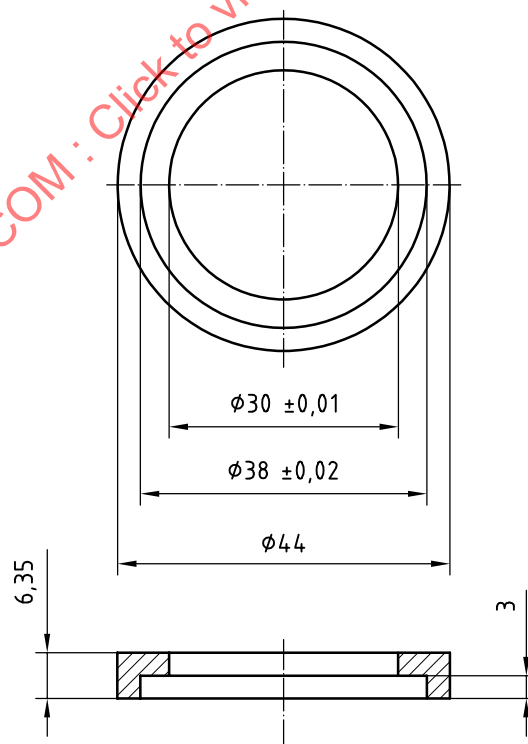
**Key**

- 1 line a
- 2 line b
- 3 line c
- 4 line  $d_1$
- 5 line  $d_2$

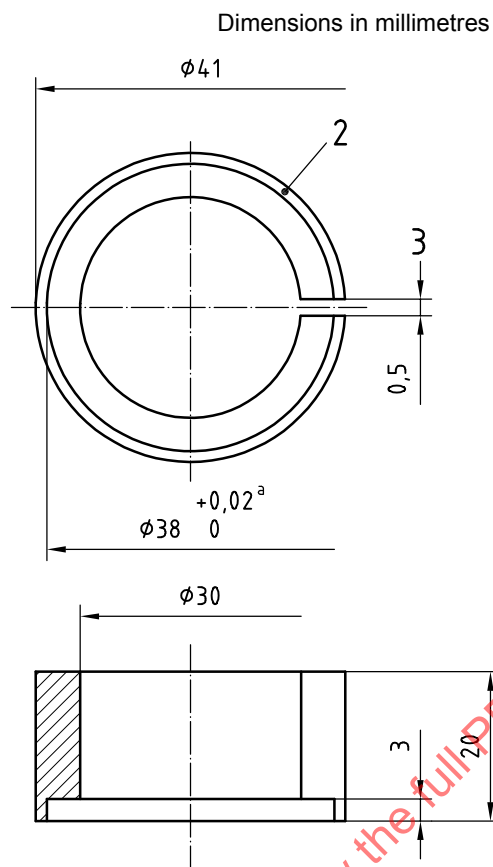
Material shall be cast or wrought austenitic stainless steel.

<sup>a</sup> Lines  $d_1$  and  $d_2$  shall be the same width as line c.

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

a) Ring mould<sup>b</sup>b) Ring mould retainer<sup>b</sup>

**Figure 2 — Accessories for detail reproduction test and test for compatibility with refractory investment and gypsum**



c) Slit mould<sup>c</sup>

**Key**

- 1  $\varnothing 2$  mm holes, with bell mouth, two rows of 18 holes each
- 2 rim of recess
- 3 width of slit before closing

<sup>a</sup> Internal diameter of the mould after the clamping mechanism closes the slit.

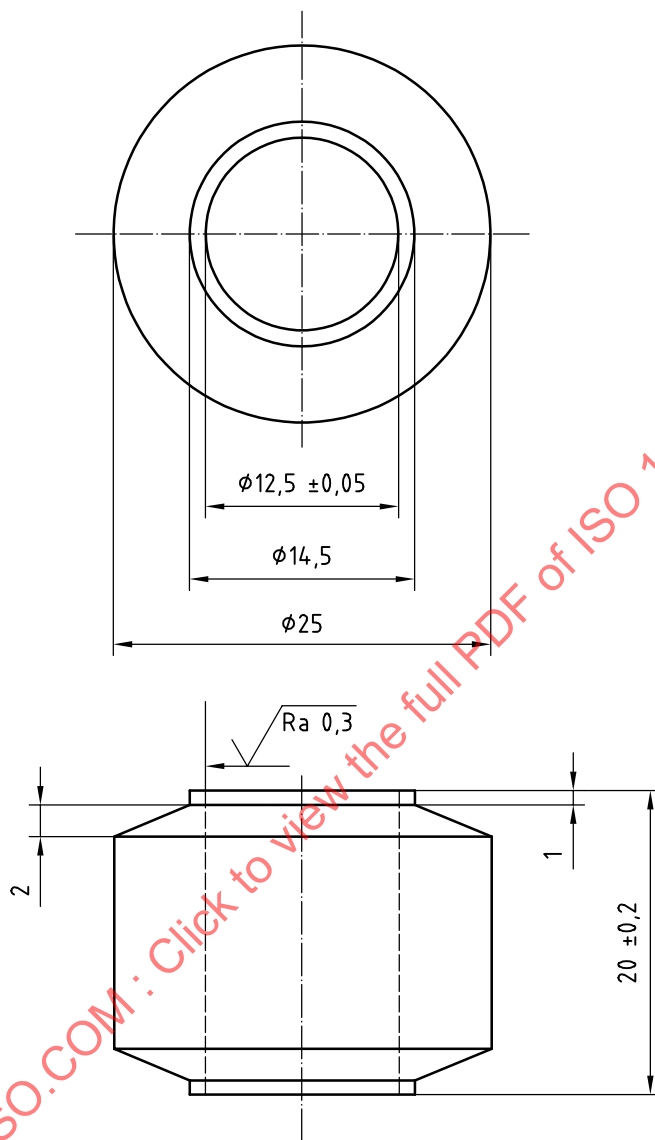
<sup>b</sup> Made of polymer, brass, or stainless steel.

<sup>c</sup> Made of brass (see Note in 8.3.1.3).

**Figure 2 (continued)**

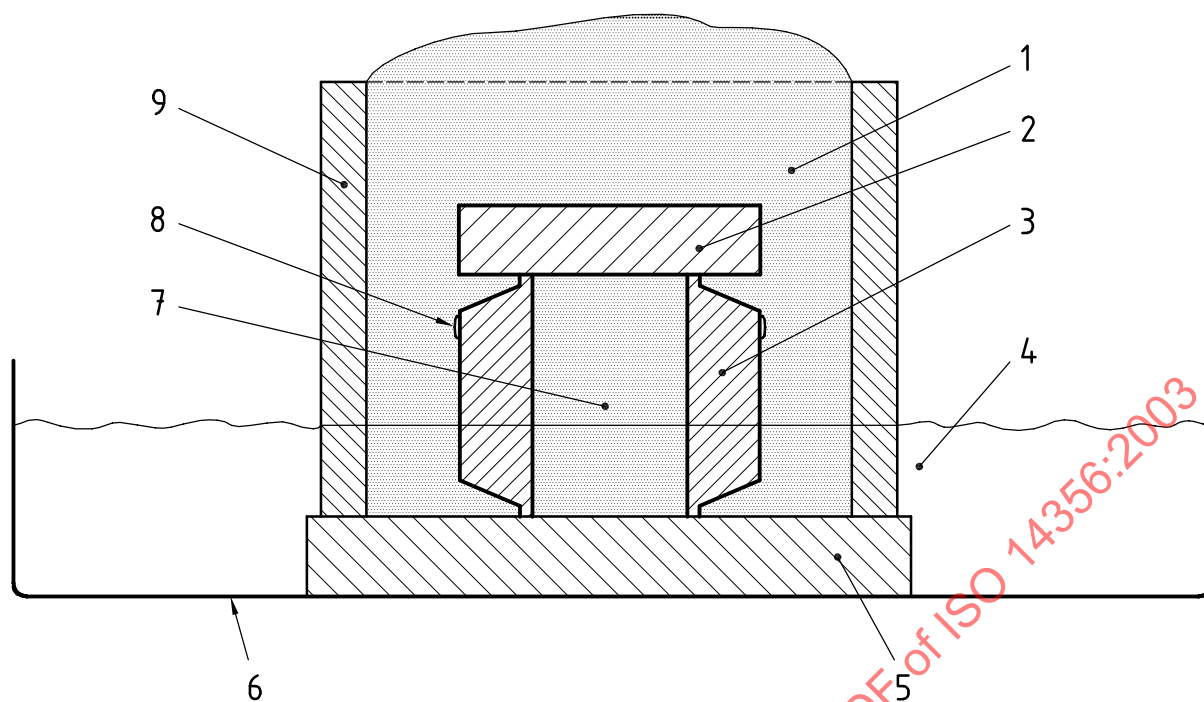


Dimensions in millimetres

Tolerances  $\pm 0,1$  mm unless otherwise specified, surface roughness  $\leq 3,2 \mu\text{m}$ 

Material shall be polymer.

**Figure 3 — Specimen-forming mould — Elastic recovery test, Type 1 materials**

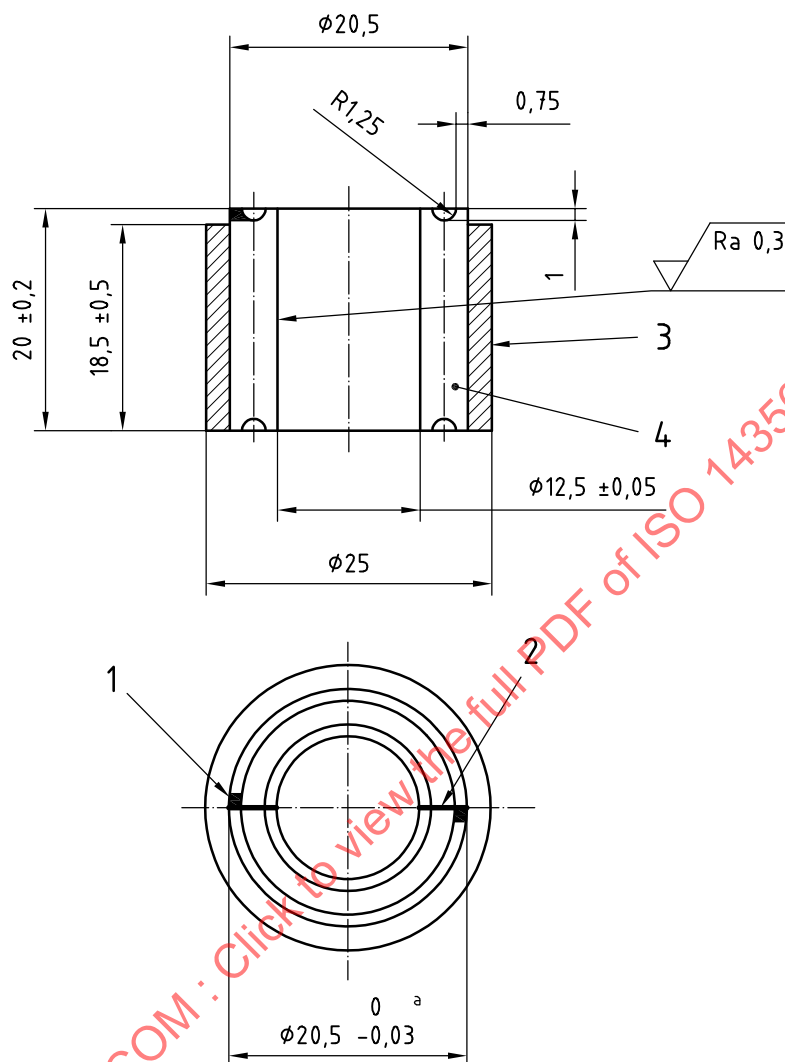


**Key**

- 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 4 — Specimen-forming assembly — Elastic recovery test, Type 1 materials**

Dimensions in millimetres

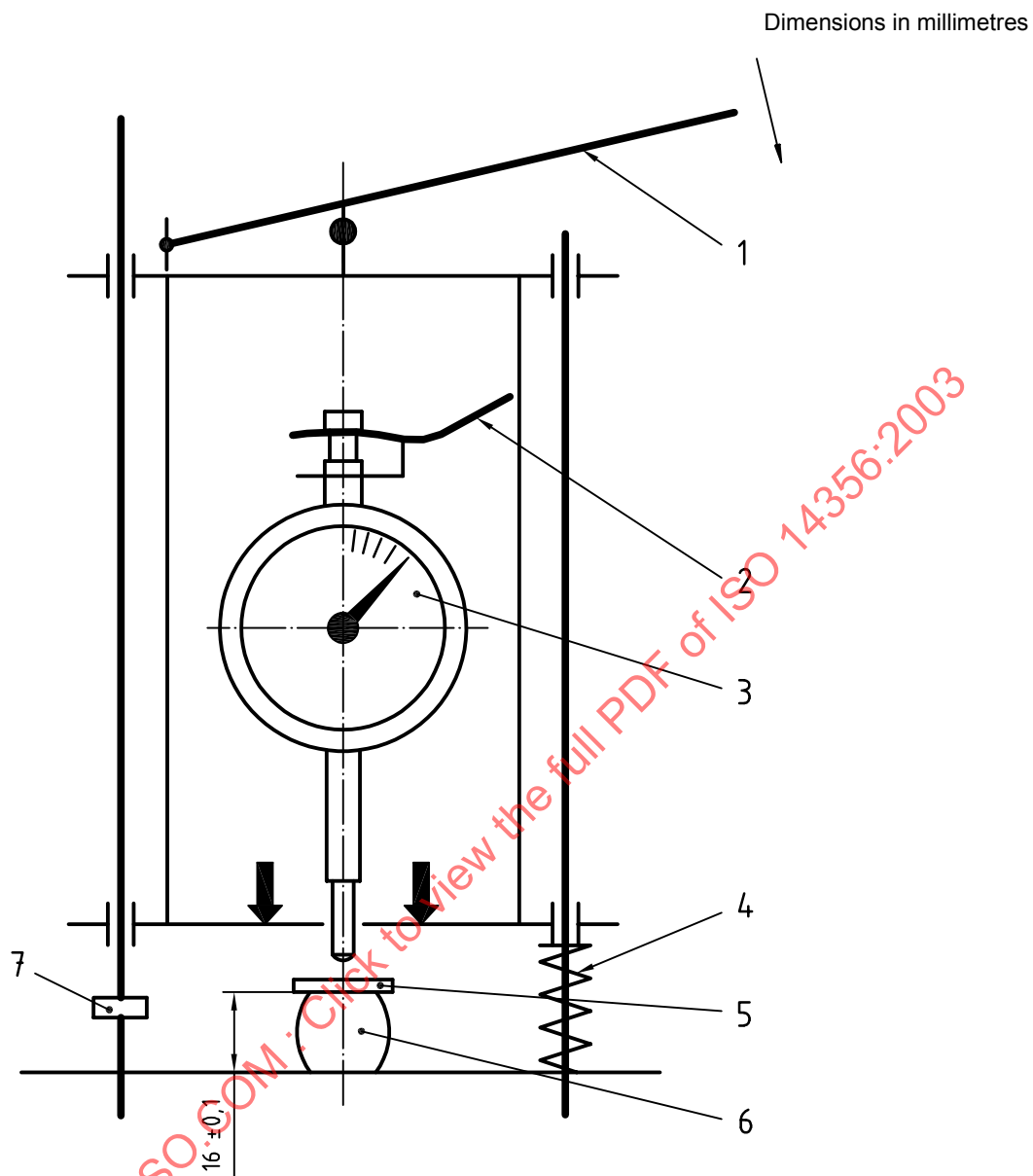
Surface roughness  $\leq 3,2 \mu\text{m}$  unless otherwise specified**Key**

- 1 cut-out,  $\approx 1,0 \text{ mm} \times 1,0 \text{ mm} \times 1,0 \text{ mm}$  in two places
- 2 split between mould halves
- 3 fixation ring
- 4 split mould, two halves, no bell mouth in bore

Components shall be made of anodized aluminium, brass or stainless steel.

<sup>a</sup> This is the outside diameter specified for the two split-mould halves (item 4) when they are assembled to fit within the fixation ring (3). For these components to be related as required for specimen formation, the inside diameter of the fixation ring shall be  $20,5 + \begin{smallmatrix} 0,03 \\ 0 \end{smallmatrix} \text{ mm}$ .

**Figure 5 — Split mould for forming specimens — Elastic recovery, Type 2 materials**



# Key

- 1 lever for compressing the specimen
- 2 control lever for dial indicator spindle position
- 3 dial indicator
- 4 spring
- 5 test plate
- 6 test specimen compressed ( $4 \pm 0,1$ ) mm
- 7 compression limit stop

Figure 6 — Elastic recovery test instrument