



BSI Standards Publication

<http://www.china-gauges.com/>

# Dentistry — Chairside denture base relining materials

---

Part 1: Hard type materials

## National foreword

This British Standard is the UK implementation of EN ISO 23401-1:2023. It is identical to ISO 23401-1:2023.

The UK participation in its preparation was entrusted to Technical Committee CH/106/2, Prosthodontic materials.

A list of organizations represented on this committee can be obtained on request to its committee manager.

### Contractual and legal considerations

This publication has been prepared in good faith, however no representation, warranty, assurance or undertaking (express or implied) is or will be made, and no responsibility or liability is or will be accepted by BSI in relation to the adequacy, accuracy, completeness or reasonableness of this publication. All and any such responsibility and liability is expressly disclaimed to the full extent permitted by the law.

This publication is provided as is, and is to be used at the recipient's own risk.

The recipient is advised to consider seeking professional guidance with respect to its use of this publication.

This publication is not intended to constitute a contract. Users are responsible for its correct application.

© The British Standards Institution 2023  
Published by BSI Standards Limited 2023

ISBN 978 0 539 14692 9

ICS 11.060.10

**Compliance with a British Standard cannot confer immunity from legal obligations.**

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 31 March 2023.

### Amendments/corrigenda issued since publication

Date	Text affected
------	---------------

---

EUROPEAN STANDARD

**EN ISO 23401-1**

NORME EUROPÉENNE

EUROPÄISCHE NORM

March 2023

ICS 11.060.10

English Version

## Dentistry - Chairside denture base relining materials - Part 1: Hard type materials (ISO 23401-1:2023)

Médecine bucco-dentaire - Matériaux de rebasage pour  
base de prothèses dentaires - Partie 1: Matériaux durs  
(ISO 23401-1:2023)

Zahnheilkunde - Unterfütterungswerkstoffe am  
Behandlungsstuhl - Teil 1: Harte Werkstoffe (ISO  
23401-1:2023)

This European Standard was approved by CEN on 9 March 2023.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and United Kingdom.



EUROPEAN COMMITTEE FOR STANDARDIZATION  
COMITÉ EUROPÉEN DE NORMALISATION  
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

## European foreword

This document (EN ISO 23401-1:2023) has been prepared by Technical Committee ISO/TC 106 "Dentistry" in collaboration with Technical Committee CEN/TC 55 "Dentistry" the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by September 2023, and conflicting national standards shall be withdrawn at the latest by September 2023.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

Any feedback and questions on this document should be directed to the users' national standards body/national committee. A complete listing of these bodies can be found on the CEN website.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

## Endorsement notice

The text of ISO 23401-1:2023 has been approved by CEN as EN ISO 23401-1:2023 without any modification.

# Contents

Page

<b>Foreword</b> .....	iv
<b>Introduction</b> .....	v
<b>1 Scope</b> .....	1
<b>2 Normative references</b> .....	1
<b>3 Terms and definitions</b> .....	1
<b>4 Classification</b> .....	2
4.1 Types.....	2
4.2 Classes.....	2
<b>5 Requirements</b> .....	2
5.1 Appearance.....	2
5.1.1 Liquid.....	2
5.1.2 Powder, paste and sheet.....	2
5.2 Consistency.....	2
5.3 Peak temperature.....	3
5.4 Porosity and defects.....	3
5.5 Surface finish.....	3
5.6 Water sorption.....	3
5.7 Water solubility.....	3
5.8 Knoop hardness.....	3
<b>6 Test methods</b> .....	3
6.1 Sampling.....	3
6.2 Preparation of test specimens.....	3
6.3 Conditions for testing.....	3
6.4 Visual inspection.....	4
6.4.1 Appearance.....	4
6.4.2 Porosity and defects.....	4
6.4.3 Surface finish.....	4
6.5 Consistency.....	4
6.5.1 Apparatus.....	4
6.5.2 Procedure.....	5
6.6 Peak temperature.....	5
6.6.1 Apparatus.....	5
6.6.2 Procedure.....	5
6.7 Water sorption and solubility.....	6
6.7.1 Materials.....	6
6.7.2 Apparatus.....	6
6.7.3 Preparation of test specimens.....	8
6.7.4 Procedure.....	8
6.7.5 Calculation and expression of results.....	9
6.8 Knoop hardness.....	9
6.8.1 Apparatus.....	9
6.8.2 Preparation of test specimens.....	10
6.8.3 Procedure.....	10
<b>7 Requirement for packaging, marking and instructions supplied by the manufacturer</b> .....	10
7.1 Packaging.....	10
7.2 Marking and manufacturer's instructions for use.....	10
<b>Bibliography</b> .....	12

## 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.

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](http://www.iso.org/directives)).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see [www.iso.org/patents](http://www.iso.org/patents)).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see [www.iso.org/iso/foreword.html](http://www.iso.org/iso/foreword.html).

This document was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 2, *Prosthetic 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).

A list of all parts in the ISO 23401 series can be found on the ISO website.

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](http://www.iso.org/members.html).

## Introduction

The purpose of denture base relining materials is to improve the fit of dentures to the oral mucosa. The materials can relin the denture the same day. Thus, they can be a useful material for the general denture patients and especially for bedridden patients who may have no access to dental surgery.

Requirements and test methods for the soft type materials are defined in detail by ISO 10139-1 and ISO 10139-2, but it is extremely difficult to incorporate the hard type materials in these International Standards of soft lining materials because of the differences in the main components, curing mechanisms and physical properties.

Also, chairside denture base relining materials and denture base materials covered by ISO 20795-1 and ISO 20795-2 differ in terms of polymerization method and required properties. As chairside denture base relining materials are partially or even mainly handled intraorally, properties such as consistency and exothermicity during intra-oral polymerization are quite important.

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

<http://www.china-gauges.com/>



# Dentistry — Chairside denture base relining materials

## Part 1: Hard type materials

### 1 Scope

This document specifies the requirements for acrylic hard type materials used as chairside denture base relining materials and the test methods to determine compliance with these requirements. This document also specifies requirements for packaging and marking the products and for the instructions for use to be supplied by the manufacturer.

Dentures which are relined by chairside denture base relining materials specified by this document are limited to those of acrylic.

This document is not applicable to either denture base relining materials that are for laboratory use or soft lining materials.

NOTE 1 Acrylic hard type materials contain acrylic and methacrylic monomers such as acrylic acid esters and substituted (meth)acrylic acid esters and their polymers.

NOTE 2 Acrylic dentures are made of polymers such as poly (acrylic acid esters), poly (substituted acrylic acid esters) and rubber-modified poly (methacrylic acid esters).

### 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 3696:1987, *Water for analytical laboratory use — Specification and test methods*

ISO 4545-1, *Metallic materials — Knoop hardness test — Part 1: Test method*

ISO 6344-3, *Coated abrasives — Determination and designation of grain size distribution — Part 3: Microgrit sizes P240 to P5000*

ISO 8601-1, *Date and time — Representations for information interchange — Part 1: Basic rules*

ISO 20795-1, *Dentistry — Base polymers — Part 1: Denture base polymers*

### 3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942, ISO 20795-1 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 chairside denture base relining

denture base relining where the relining material is moulded and partially or completely polymerized intraorally

### 3.2 peak temperature

maximum temperature during polymerization

## 4 Classification

### 4.1 Types

The chairside denture base relining materials are classified into the following types in accordance with their methods of polymerization.

- Type 1: materials whose setting is affected by mixing initiator(s) and activator(s) (“self-curing” materials);
- Type 2: materials whose setting is affected by the application of light from an external source (“light-curing” materials);
- Type 3: materials whose setting is affected by mixing initiator(s) and activator(s) and also by the application of light from an external source (“dual-curing” materials).

### 4.2 Classes

The chairside denture base relining materials are classified into the following classes in accordance with material form.

- Class 1: powder and liquid;
- Class 2: paste;
- Class 3: sheet.

## 5 Requirements

### 5.1 Appearance

#### 5.1.1 Liquid

The liquid shall be homogeneous when tested in accordance with [6.4.1](#). The liquid shall be free of deposits or sediment.

#### 5.1.2 Powder, paste and sheet

The powder, paste and sheet shall not contain extraneous materials when tested in accordance with [6.4.1](#). Separation of liquid (e.g. monomer) shall not be observed in the paste or sheet when tested in accordance with [6.4](#).

### 5.2 Consistency

The diameter of the compressed mixture of Class 1 or Class 2 materials shall be from 30 mm to 60 mm when tested in accordance with [6.5](#).

### 5.3 Peak temperature

The peak temperature of the Type 1 and Type 3 materials shall not be more than 60 °C when tested in accordance with [6.6](#).

### 5.4 Porosity and defects

The cured chairside denture base relining materials shall not have porosity or defects that can be easily identified when tested in accordance with [6.4.2](#).

### 5.5 Surface finish

The cured chairside denture base relining materials shall have a glossy surface when tested in accordance with [6.4.3](#).

### 5.6 Water sorption

The water sorption shall not be more than 32 µg/mm<sup>3</sup> when the cured chairside denture base relining material is tested in accordance with [6.7](#).

### 5.7 Water solubility

The water solubility shall not be more than 8,0 µg/mm<sup>3</sup> when the cured chairside denture base relining material is tested in accordance with [6.7](#).

### 5.8 Knoop hardness

The Knoop hardness of the cured chairside denture base relining materials shall not be less than 7 HK 0,1 /20 (load / dwell time) when tested in accordance with [6.8](#).

## 6 Test methods

### 6.1 Sampling

The test sample shall consist of a retail package, or packages, from the same batch and enough amount of the material to carry out the specified tests with an allowance for any repeat tests (approximately 60 ml).

### 6.2 Preparation of test specimens

Prepare the test specimens in accordance with the manufacturer's instructions for use. For Class 1 materials, vibration may be applied for 15 s or less to remove porosity immediately after mixing, if necessary.

### 6.3 Conditions for testing

Unless specified otherwise by the manufacturer or in this document, prepare and test all specimens at a temperature of (23 ± 2) °C and a relative humidity of (50 ± 20) %. Leave the chairside denture base relining material and test apparatus at a temperature of (23 ± 2) °C for 2 h or longer before testing, unless specified otherwise.

Leave the accessories used for fabrication of the test specimens under the same conditions for 30 min or longer before use.

## 6.4 Visual inspection

### 6.4.1 Appearance

Visually inspect the test sample of the liquid, powder, paste or sheet without magnification to determine compliance with the requirements (5.1.1 and 5.1.2).

### 6.4.2 Porosity and defects

Visually inspect the test specimen prepared in accordance with 6.7.3 without magnification to determine compliance with the requirements (5.4).

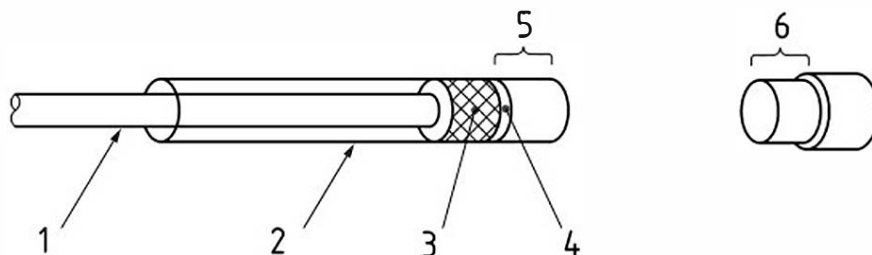
### 6.4.3 Surface finish

Visually inspect the test specimen prepared in accordance with 6.8.2 to determine compliance with the requirements (5.5).

## 6.5 Consistency

### 6.5.1 Apparatus

6.5.1.1 **Sampling instrument**, capable of measuring and collecting 0,5 ml of uncured material in a mixture of an appropriate amount (e.g. Figure 1).



#### Key

- 1 plunger
- 2 plastic (polyethylene or polypropylene) or glass tube
- 3 rubber plug
- 4 plastic (polyethylene or polypropylene) film
- 5 (0,5 ± 0,05) ml volume
- 6 plug gauge of (0,5 ± 0,05) ml volume

Figure 1 — Apparatus for measuring consistency

6.5.1.2 **Unplasticized sheets (polyester, polyethylene, or polypropylene)**, having a thickness of (50 ± 25) μm.

6.5.1.3 **Glass plate**, with dimensions of approximately 70 mm × 70 mm and a thickness of 1 mm.

6.5.1.4 **Plate for pressure**, with dimensions of approximately 70 mm × 70 mm and made of glass or metal.

6.5.1.5 **Weight**, with a mass of 750 g including the plate for pressure.

## 6.5.2 Procedure

Prepare enough amount of material using the method specified by the manufacturer, collect  $(0,5 \pm 0,05)$  ml using the sampling instrument (6.5.1.1) and place it on the central part of the lower glass plate (6.5.1.3) covered with an unplasticized sheet (6.5.1.2).

After 2 min from the start of mixing, gently place another unplasticized sheet on the plate for pressure (6.5.1.4) on top of the sample, then place the weight (6.5.1.5) centrally on the plate for a total mass of 750 g and apply for 5 min.

After removing the weight, measure the diameter values of the obtained disc-like sample in four directions at intervals of approximately  $45^\circ$  and calculate the mean of these values and make it the sample diameter.

Perform this test three times. When the consistency of at least two specimens fulfil the requirement (5.2), the material complies.

## 6.6 Peak temperature

### 6.6.1 Apparatus

**6.6.1.1 Unplasticized sheet (polyester, polyethylene, or polypropylene)**, having a thickness of  $(50 \pm 25)$   $\mu\text{m}$ .

**6.6.1.2 Two glass plates**, with dimensions of approximately 100 mm  $\times$  80 mm  $\times$  6 mm.

**6.6.1.3 Temperature measuring equipment**, using a calibrated thermocouple and potentiometer for monitoring the temperature.

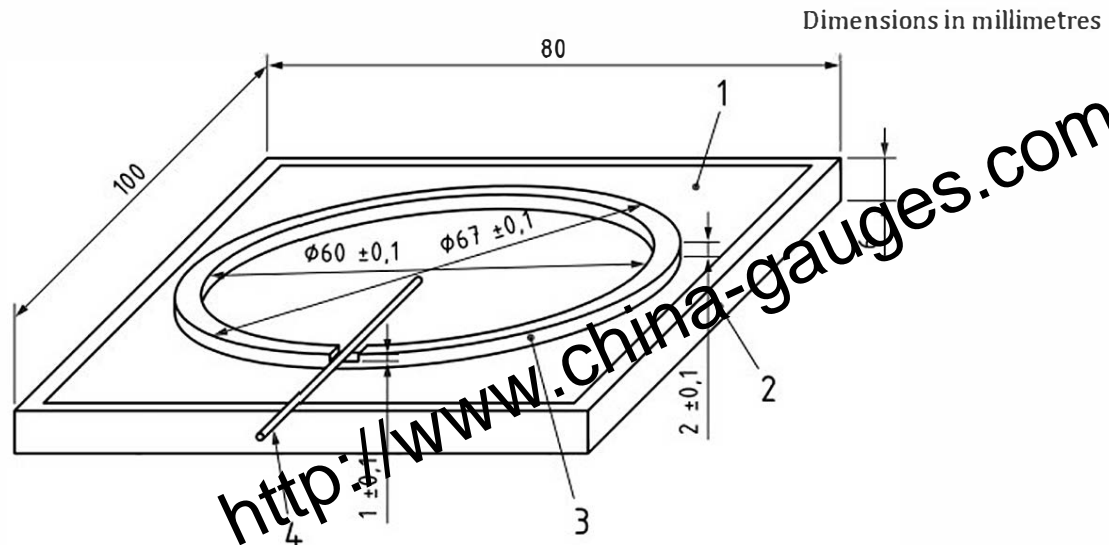
**6.6.1.4 Circular stainless steel ring**, with a notch in which a thermocouple can be placed, with an inner diameter of  $(60 \pm 0,1)$  mm, an outer diameter of  $(67 \pm 0,1)$  mm, a height of  $(2 \pm 0,1)$  mm, and a notch depth of  $(1 \pm 0,1)$  mm.

**6.6.1.5 Thermocouple**, consist of wires 0,1 mm to 1,0 mm in diameter, made of a material (e.g. copper/ copper-nickel alloy) capable of registering temperature changes in a specimen of setting material to an accuracy of 0,1  $^\circ\text{C}$ .

### 6.6.2 Procedure

Place one of the glass plates (6.6.1.2) in an oven at  $(37 \pm 2)$   $^\circ\text{C}$  at least 2 h before the start of testing.

Place the unplasticized sheet (6.6.1.1) on the first glass plate (6.6.1.2) that has been kept at  $(23 \pm 2)$   $^\circ\text{C}$  and place the ring (6.6.1.4) in the centre of it. Place the thermocouple (6.6.1.3) so that it is positioned in the centre of the ring (see Figure 2).



#### Key

- 1 unplasticized sheet
- 2 glass plate
- 3 circular stainless steel ring
- 4 thermocouple

**Figure 2 — Apparatus for measuring the peak temperature**

Prepare the material using the method specified by the manufacturer and place the material into the ring at a temperature of  $(23 \pm 2) ^\circ\text{C}$ , while applying vibration as necessary. Cover the ring with the unplasticized sheet and the second glass plate that has been kept at  $(37 \pm 2) ^\circ\text{C}$ . Remove excess resin that has overflowed outside the ring.

**NOTE** The mixing time of Class 1 material is the middle time recommended by the manufacturer.

Insert and maintain this assembly (material, glass plates, unplasticized sheets, ring and thermocouple) at a temperature of  $(37 \pm 2) ^\circ\text{C}$  within 1 min to 1,5 min after the start of mixing the material. Thereafter measure the temperature from 2 min after the start of mixing the material, until 2 min after the peak temperature is reached, and record the peak temperature to an accuracy of 0,5 °C.

The process of insertion of the assembly into the oven should be done within 10 s, and temperature in the open oven should be at least 30 °C.

Perform this test three times. When the peak temperature in at least two measurements fulfil the requirement (5.3), the material complies.

## 6.7 Water sorption and solubility

### 6.7.1 Materials

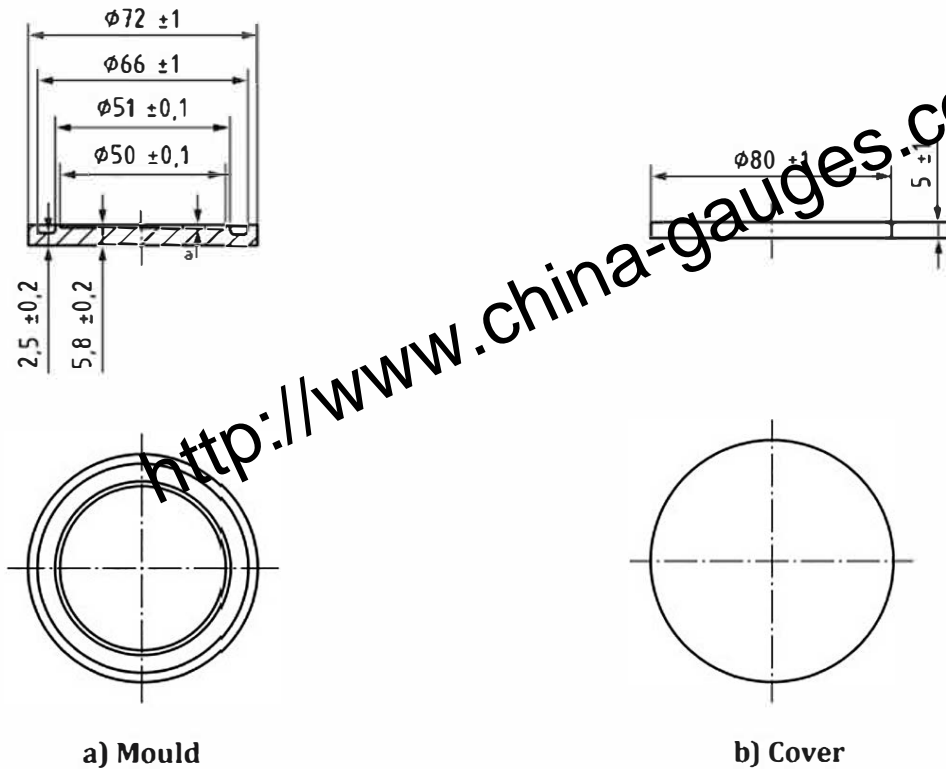
**6.7.1.1 Silica gel**, freshly dried in accordance with manufacturer's instructions for use or for  $(300 \pm 10)$  min at  $(130 \pm 5) ^\circ\text{C}$ .

**6.7.1.2 Water**, complying with grade 2 of ISO 3696:1987.

### 6.7.2 Apparatus

**6.7.2.1 Circular stainless steel mould and cover**, having the dimensions shown in [Figure 3](#).

Dimensions in millimetres



<sup>a</sup> Mould depth ( $0,5 \pm 0,1$ ) mm to form specimen.

**Figure 3 — Stainless steel mould and cover for specimen preparation for water sorption and solubility**

**6.7.2.2 Circular stainless steel ring**, with an inner diameter of ( $50 \pm 0,1$ ) mm and thickness of ( $0,5 \pm 0,1$ ) mm, and glass plates [\[6.6.1.2\]](#).

**6.7.2.3 Unplasticized sheet (polyester, polyethylene, or polypropylene)**, having a thickness of ( $50 \pm 25$ )  $\mu\text{m}$ .

**6.7.2.4 Micrometer or dial caliper**, accurate to 0,01 mm and fitted with parallel anvils.

**6.7.2.5 Rack**, to keep the specimens parallel and separated.

**6.7.2.6 Two desiccators**.

**6.7.2.7 Oven**, maintained at ( $37 \pm 1$ ) °C.

**6.7.2.8 Polymer-coated tweezers**.

**6.7.2.9 Towel**, clean and dry.

**6.7.2.10 Analytical balance**, accurate to 0,1 mg.

### 6.7.3 Preparation of test specimens

Prepare the material in accordance with the instructions for use specified by the manufacturer. Use either the mould and cover (6.7.2.1) or the steel ring (6.7.2.2) to prepare the specimen. Place the material immediately into the mould (6.7.2.1) or ring (6.7.2.2) with the unplasticized sheets (6.7.2.3) and glass plate to a slight excess, avoiding air inclusions. Place an unplasticized sheet onto the material in the mould or ring and cover this with cover or glass plate. Retain the unplasticized sheets during the processing cycle.

- For Type 1 materials: Polymerize the Type 1 material at  $(37 \pm 2)^\circ\text{C}$  for the curing time specified by the manufacturer.
- For Type 2 and Type 3 materials: Polymerize the Type 2 or Type 3 material by the method specified by the manufacturer and the instructions for use regarding the use of the external energy source(s).

Check with a micrometer or dial caliper (6.7.2.4) to ensure that each specimen has a diameter of  $(50 \pm 1)$  mm and a thickness of  $(0,5 \pm 0,1)$  mm and that the top and bottom surfaces are flat.

Make five specimens.

### 6.7.4 Procedure

#### 6.7.4.1 Conditioned specimens

Place the specimens in the rack (6.7.2.5) inside one of the desiccators (6.7.2.6) containing freshly dried silica gel (6.7.1.1). Store the desiccator in the oven (6.7.2.7) at  $(37 \pm 1)^\circ\text{C}$  for  $(23 \pm 1)$  h and then remove the desiccator from the oven.

Transfer the specimens kept in the rack directly to the second desiccator which has been supplied with freshly dried silica gel. Keep the second desiccator at  $(23 \pm 2)^\circ\text{C}$ . After  $(60 \pm 10)$  min in the second desiccator, the specimens are ready for weighing.

Use an analytical balance (6.7.2.10) to weigh the specimen to an accuracy of 0,1 mg. Keep the desiccators sealed except for the shortest possible period required for removing and replacing specimens. After all the specimens have been weighed, replace the silica gel in the first desiccator with freshly dried gel and place the first desiccator with the rack with the specimens in the oven.

Repeat the cycle described until a constant mass,  $m_1$ , to be called the "conditioned mass", is reached, i.e. until the loss in mass of each specimen is not more than 0,2 mg between successive weighing.

After final drying, take three measurements of the diameter with micrometer or dial caliper (6.7.2.4), at the angle of  $120^\circ$  to each other, to an accuracy of 0,01 mm and calculate the mean diameter. Measure the thickness of the specimen with a micrometer or dial caliper (6.7.2.4) to an accuracy of 0,01 mm at the centre of the specimen and at four equally spaced points on the circumference. Calculate the area, in square millimetres, from the mean diameter and then, using the mean thickness, calculate the volume,  $V$ , in cubic millimetres.

#### 6.7.4.2 Wet specimens

Immerse the conditioned specimen in 100 ml water (6.7.1.2) at  $(37 \pm 1)^\circ\text{C}$  for 7 d. After this time, remove the discs from the water with polymer-coated tweezers (6.7.2.8), wipe with a clean, dry towel (6.7.2.9) until free from visible moisture, wave in the air for  $(15 \pm 1)$  s and weigh  $(60 \pm 10)$  s after removal from the water to an accuracy of 0,1 mg. Record the mass as  $m_2$ .

#### 6.7.4.3 Reconditioned specimens

After this weighing, recondition the specimens to constant mass in the desiccator as described in 6.7.4.1. Record the mass of the "reconditioned" specimens as  $m_3$ .



It is essential that the same conditions be applied as for the first drying process, using the same number of specimens and the freshly dried silica gel in the desiccators.

## 6.7.5 Calculation and expression of results

### 6.7.5.1 Water sorption

Calculate the value for the water sorption,  $W_{sp}$ , for each of the five specimens, expressed in micrograms per cubic millimetre ( $\mu\text{g}/\text{mm}^3$ ), using the [Formula \(1\)](#):

$$W_{sp} = (m_2 - m_3) / V \quad (1)$$

where

$m_2$  is the mass of the specimen, in micrograms ( $\mu\text{g}$ ), after immersion in water;

$m_3$  is the reconditioned mass of the specimen, in micrograms ( $\mu\text{g}$ );

$V$  is the volume of the specimen, in cubic millimetres ( $\text{mm}^3$ ).

Round off the values calculated for water sorption to the nearest micrograms per cubic millimetre ( $\mu\text{g}/\text{mm}^3$ ).

### 6.7.5.2 Water solubility

Calculate the value for the water solubility,  $W_{sl}$ , for each of the five specimens, expressed in micrograms per cubic millimetre ( $\mu\text{g}/\text{mm}^3$ ), using the [Formula \(2\)](#):

$$W_{sl} = (m_1 - m_3) / V \quad (2)$$

where

$m_1$  is the conditioned mass of the specimen, in micrograms ( $\mu\text{g}$ );

$m_3$  is the reconditioned mass of the specimen, in micrograms ( $\mu\text{g}$ );

$V$  is the volume of the specimen, in cubic millimetres ( $\text{mm}^3$ ).

Round off the values calculated for water sorption to the nearest  $0,1 \mu\text{g}/\text{mm}^3$ .

### 6.7.5.3 Conformity evaluation

Calculate the water sorption and the water solubility for five specimens respectively.

When the water sorption or the water solubility of at least four specimens fulfil the requirement ([5.6](#) or [5.7](#)), the material complies.

## 6.8 Knoop hardness

### 6.8.1 Apparatus

**6.8.1.1 Circular stainless steel ring**, with an inner diameter of  $(30 \pm 2)$  mm and thickness of  $(1,5 \pm 0,2)$  mm.

**6.8.1.2 Abrasive paper**, P600 in accordance with ISO 6344-3.

**6.8.1.3 Abrasive paper**, between P1200 and P1500 in accordance with ISO 6344-3.

## 6.8.2 Preparation of test specimens

Prepare three test specimens using the ring (6.8.1.1) and the procedure of 6.7.3. Polish the surfaces of the test specimens with the abrasive paper (P600) (6.8.1.2) and then with abrasive paper (between P1200 and P1500) (6.8.1.3), and then, smooth the surface using 0,3 µm alumina powder. Store the specimens dark at room temperature.

## 6.8.3 Procedure

Perform the test (24 ± 3) h after the preparation of the test specimens. Measure the Knoop hardness at 10 points for each test specimen using 0,1 kg load and 20 s dwell time in accordance with ISO 4545-1. Calculate the mean value for the 10 measurement values for each of three test specimens.

The indentation points should be equally spread out on the test surface and should not be close to the circumference of the specimen.

Test three specimens.

When the Knoop hardness of at least two specimens fulfil the requirement (5.8), the material complies.

## 7 Requirement for packaging, marking and instructions supplied by the manufacturer

### 7.1 Packaging

The components shall be supplied in sealed containers made of materials that shall neither contaminate, nor permit contamination of the contents. The immediate containers shall be packaged so as to prevent damage or leakage during transit and storage.

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

### 7.2 Marking and manufacturer's instructions for use

The outer packages and the immediate containers or wrappings of the components shall be clearly marked with the information given in Table 1.

If the size of the immediate container or package is too small to fit the required information, reference shall be made on the outer package to a leaflet inside where the additional information shall be provided.

Instructions for use shall accompany each package and, shall at a minimum include the information given in Table 1.

**Table 1 — Requirements for marking and manufacturer's instruction**

Requirement		Outer package and immediate containers	Manufacturer's instruction
1	The trade name of the product	M	M
2	The manufacturer's name or trademark and address, or those of the agent in the country of sale	M	M
3	The Type and Class of material, as determined in accordance with 4.1 and 4.2	M	M
4	The colour of the material (if the material has multiple colours)	M	M
<b>Key</b>			
M : mandatory			
/ : no relevance for this combination of container/markings/instructions or that requirement would be impracticable or impossible or that the information can be informative but optional			

Table 1 (continued)

Requirement		Outer package and immediate containers	Manufacturer's instruction
5	The net content of the components expressed in grams or millilitres	M	M
6	The lot number (batch code)	/	/
7	The expiry date beyond which the material might not exhibit its required properties (year, month) shall be expressed in accordance with ISO 8601-1	M	/
8	The recommended conditions of storage	M	M
9	Any hazard warnings, where appropriate, for allergic, toxic, hazardous, inflammable or irritating characteristics and flash point of liquid	M	M
10	The indications for use	/	M
11	The contraindications, side-effects and interactions with other substances, if appropriate	/	M
12	The instructions for preparing the patient's oral tissues, if applicable	/	M
13	The instructions of how to prepare the surface of the denture base to be lined	/	M
14	The instructions of how to adhere to the denture base	/	M
15	The procedure for mixing or preparing the material (including the information on the mixing ratio, mixing time for the material of Class 1)	/	M
16	The procedure for application to the denture base	/	M
17	All details of the application procedure, trimming procedure, curing procedure, time, temperature, cooling, and any need for specialized equipment, where applicable (including the information on the recommended curing machine and curing condition for the Type 2 material)	/	M
18	The instructions for finishing and polishing	/	M
19	Information on the care of the lined denture by the patient and recommendations for cleaning, including reference to any method or material that would be inappropriate for cleaning the relining	/	M
20	Information on the infection control of the lined denture by the dentist or dental technician in order to minimize the possibility of cross-infection; include reference to any method or material that would be inappropriate	/	M
21	Any information on environmental conditions that may adversely affect the material, such as temperature, humidity or ambient light, and the disposal of waste, if precautions are necessary	/	M
22	Date of edition of the manufacturer's instructions	/	M
<b>Key</b>			
M : mandatory			
/ : no relevance for this combination of container/markings/instructions or that requirement would be impracticable or impossible or that the information can be informative but optional			

## Bibliography

- [1] ISO 7405, *Dentistry — Evaluation of biocompatibility of medical devices used in dentistry*
- [2] ISO 10139-1, *Dentistry — Soft lining materials for removable dentures — Part 1: Materials for short-term use*
- [3] ISO 10139-2, *Dentistry — Soft lining materials for removable dentures — Part 2: Materials for long-term use*
- [4] ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*
- [5] ISO 20795-2, *Dentistry — Base polymers — Part 2: Orthodontic base polymers*

<http://www.china-gauges.com/>

<http://www.china-gauges.com/>

# British Standards Institution (BSI)

BSI is the national body responsible for preparing British Standards and other standards-related publications, information and services.

BSI is incorporated by Royal Charter. British Standards and other standardization products are published by BSI Standards Limited.

## About us

We bring together business, industry, government, consumers, innovators and others to shape their combined experience and expertise into standards-based solutions.

The knowledge embodied in our standards has been carefully assembled in a dependable format and refined through our open consultation process. Organizations of all sizes and across all sectors choose standards to help them achieve their goals.

## Information on standards

We can provide you with the knowledge that your organization needs to succeed. Find out more about British Standards by visiting our website at [bsigroup.com/standards](http://bsigroup.com/standards) or contacting our Customer Services team or Knowledge Centre.

## Buying standards

You can buy and download PDF versions of BSI publications, including British and adopted European and international standards, through our website at [bsigroup.com/shop](http://bsigroup.com/shop), where hard copies can also be purchased.

If you need international and foreign standards from other Standards Development Organizations, hard copies can be ordered from our Customer Services team.

## Copyright in BSI publications

All the content in BSI publications, including British Standards, is the property of and copyrighted by BSI or some person or entity that owns copyright in the information used (such as the international standardization bodies) and has formally licensed such information to BSI for commercial publication and use.

Save for the provisions below, you may not transfer, share or disseminate any portion of the standard to any other person. You may not adapt, distribute, commercially exploit or publicly display the standard or any portion thereof in any manner whatsoever without BSI's prior written consent.

## Storing and using standards

Standards purchased in soft copy format:

- A British Standard purchased in soft copy format is licensed to a sole named user for personal or internal company use only.
- The standard may be stored on more than one device provided that it is accessible by the sole named user only and that only one copy is accessed at any one time.
- A single paper copy may be printed for personal or internal company use only.

Standards purchased in hard copy format:

- A British Standard purchased in hard copy format is for personal or internal company use only.
- It may not be further reproduced – in any format – to create an additional copy. This includes scanning of the document.

If you need more than one copy of the document, or if you wish to share the document on an internal network, you can save money by choosing a subscription product (see 'Subscriptions').

## Reproducing extracts

For permission to reproduce content from BSI publications contact the BSI Copyright and Licensing team.

## Subscriptions

Our range of subscription services are designed to make using standards easier for you. For further information on our subscription products go to [bsigroup.com/subscriptions](http://bsigroup.com/subscriptions).

With **British Standards Online (BSOL)** you'll have instant access to over 55,000 British and adopted European and international standards from your desktop. It's available 24/7 and is refreshed daily so you'll always be up to date.

You can keep in touch with standards developments and receive substantial discounts on the purchase price of standards, both in single copy and subscription format, by becoming a **BSI Subscribing Member**.

**PLUS** is an updating service exclusive to BSI Subscribing Members. You will automatically receive the latest hard copy of your standards when they're revised or replaced.

To find out more about becoming a BSI Subscribing Member and the benefits of membership, please visit [bsigroup.com/shop](http://bsigroup.com/shop).

With a **Multi-User Network Licence (MUNL)** you are able to host standards publications on your intranet. Licences can cover as few or as many users as you wish. With updates supplied as soon as they're available, you can be sure your documentation is current. For further information, email [cservices@bsigroup.com](mailto:cservices@bsigroup.com).

## Revisions

Our British Standards and other publications are updated by amendment or revision.

We continually improve the quality of our products and services to benefit your business. If you find an inaccuracy or ambiguity within a British Standard or other BSI publication please inform the Knowledge Centre.

## Useful Contacts

### Customer Services

**Tel:** +44 345 086 9001

**Email:** [cservices@bsigroup.com](mailto:cservices@bsigroup.com)

### Subscriptions

**Tel:** +44 345 086 9001

**Email:** [subscriptions@bsigroup.com](mailto:subscriptions@bsigroup.com)

### Knowledge Centre

**Tel:** +44 20 8996 7004

**Email:** [knowledgecentre@bsigroup.com](mailto:knowledgecentre@bsigroup.com)

### Copyright & Licensing

**Tel:** +44 20 8996 7070

**Email:** [copyright@bsigroup.com](mailto:copyright@bsigroup.com)

## BSI Group Headquarters

389 Chiswick High Road London W4 4AL UK