

SLOVENSKI STANDARD

SIST EN ISO 20795-1:2008

01-november-2008

Zobozdravstvo - Osnovni polimeri - 1. del: Osnovni polimeri za proteze (ISO 20795-1:2008)

Dentistry - Base polymers - Part 1: Denture base polymers (ISO 20795-1:2008)

Zahnheilkunde - Kunststoffe - Teil 1: Prothesenkunststoffe (ISO 20795-1:2008)

Art dentaire - Polymères de base - Partie 1: Polymères pour base de prothèses dentaires (ISO 20795-1:2008)

Ta slovenski standard je istoveten z: EN ISO 20795-1:2008

<https://standards.iteh.ai/catalog/standards/sist/1bb1868f-d41e-4786-a0bf-cbb668ccf317/sist-en-iso-20795-1-2008>

ICS:

11.060.10 Z[à[c @ ã } ã æ ã ã Dental materials

SIST EN ISO 20795-1:2008 en

iTeh STANDARD PREVIEW
(standards.iteh.ai)

SIST EN ISO 20795-1:2008

<https://standards.iteh.ai/catalog/standards/sist/1bb18b8f-d41e-4786-a0bf-cbb668ccf317/sist-en-iso-20795-1-2008>

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 20795-1

August 2008

ICS 11.060.10

English Version

Dentistry - Base polymers - Part 1: Denture base polymers (ISO 20795-1:2008)

Art dentaire - Polymères de base - Partie 1: Polymères pour base de prothèses dentaires (ISO 20795-1:2008)

Zahnheilkunde - Kunststoffe - Teil 1: Prothesenkunststoffe (ISO 20795-1:2008)

This European Standard was approved by CEN on 18 July 2008.

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 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 Management Centre has the same status as the official versions.

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

[SIST EN ISO 20795-1:2008](https://standards.iteh.ai/catalog/standards/sist/1bb18b8f-d41e-4786-a0bf-cbb668ccf317/sist-en-iso-20795-1-2008)

<https://standards.iteh.ai/catalog/standards/sist/1bb18b8f-d41e-4786-a0bf-cbb668ccf317/sist-en-iso-20795-1-2008>



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

Management Centre: rue de Stassart, 36 B-1050 Brussels

Contents

Page

Foreword.....	3
---------------	---

iTeh STANDARD PREVIEW (standards.iteh.ai)

SIST EN ISO 20795-1:2008

<https://standards.iteh.ai/catalog/standards/sist/1bb18b8f-d41e-4786-a0bf-cbb668ccf317/sist-en-iso-20795-1-2008>

Foreword

This document (EN ISO 20795-1:2008) 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 February 2009, and conflicting national standards shall be withdrawn at the latest by February 2009.

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

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, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of ISO 20795-1:2008 has been approved by CEN as a EN ISO 20795-1:2008 without any modification.

iTeh STANDARD PREVIEW
(standards.iteh.ai)
SIST EN ISO 20795-1:2008
<https://standards.iteh.ai/catalog/standards/sist/1bb18b8f-d41e-4786-a0bf-cbb668ccf317/sist-en-iso-20795-1-2008>

iTeh STANDARD PREVIEW
(standards.iteh.ai)

SIST EN ISO 20795-1:2008

<https://standards.iteh.ai/catalog/standards/sist/1bb18b8f-d41e-4786-a0bf-cbb668ccf317/sist-en-iso-20795-1-2008>

INTERNATIONAL STANDARD

ISO
20795-1

First edition
2008-08-01

Dentistry — Base polymers — Part 1: Denture base polymers

Art dentaire — Polymères de base —

Partie 1: Polymères pour base de prothèses dentaires

iTeh STANDARD PREVIEW
(standards.iteh.ai)

[SIST EN ISO 20795-1:2008](https://standards.iteh.ai/catalog/standards/sist/1bb18b8f-d41e-4786-a0bf-cbb668ccf317/sist-en-iso-20795-1-2008)

<https://standards.iteh.ai/catalog/standards/sist/1bb18b8f-d41e-4786-a0bf-cbb668ccf317/sist-en-iso-20795-1-2008>



Reference number
ISO 20795-1:2008(E)

© ISO 2008

ISO 20795-1:2008(E)

PDF disclaimer

This PDF file may contain embedded typefaces. In accordance with Adobe's licensing policy, this file may be printed or viewed but shall not be edited unless the typefaces which are embedded are licensed to and installed on the computer performing the editing. In downloading this file, parties accept therein the responsibility of not infringing Adobe's licensing policy. The ISO Central Secretariat accepts no liability in this area.

Adobe is a trademark of Adobe Systems Incorporated.

Details of the software products used to create this PDF file can be found in the General Info relative to the file; the PDF-creation parameters were optimized for printing. Every care has been taken to ensure that the file is suitable for use by ISO member bodies. In the unlikely event that a problem relating to it is found, please inform the Central Secretariat at the address given below.

iTeh STANDARD PREVIEW (standards.iteh.ai)

[SIST EN ISO 20795-1:2008](https://standards.iteh.ai/catalog/standards/sist/1bb18b8f-d41e-4786-a0bf-cbb668ccf317/sist-en-iso-20795-1-2008)

<https://standards.iteh.ai/catalog/standards/sist/1bb18b8f-d41e-4786-a0bf-cbb668ccf317/sist-en-iso-20795-1-2008>

**COPYRIGHT PROTECTED DOCUMENT**

© ISO 2008

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

Contents

Page

Foreword.....	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions.....	2
4 Classification.....	3
5 Requirements	4
5.1 Unpolymerized material	4
5.2 Polymerized material	4
6 Sampling.....	6
7 Preparation of test specimens	7
7.1 Laboratory environment	7
7.2 Procedures	7
7.3 Special equipment	7
8 Test methods.....	7
8.1 Inspection for compliance determination.....	7
8.2 Packing plasticity.....	8
8.3 Colour	10
8.4 Colour stability	10
8.5 Polishability, translucency, freedom from porosity, ultimate flexural strength and flexural modulus	12
8.6 Fracture toughness with a modified bending test	17
8.7 Bonding to synthetic polymer teeth	22
8.8 Residual methyl methacrylate monomer.....	23
8.9 Water sorption and solubility	28
9 Requirements for labelling, marking, packaging and instructions supplied by the manufacturer	30
9.1 Packaging	30
9.2 Marking of outer packages and containers	30
9.3 Manufacturer's instructions	31
Annex A (normative) HPLC method for determination of MMA content	33
Bibliography	36

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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

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 20795-1 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 2, *Prosthodontic materials*.

This first edition cancels and replaces ISO 1567:1999 and Amendment 1:2003.

Significant differences between this first edition of ISO 20795-1 and the third edition of ISO 1567 and Amendment 1 lie with requirements and tests for materials with improved impact resistance.

ISO 20795 consists of the following parts, under the general title *Dentistry* — *Base polymers*:

- *Part 1: Denture base polymers*
- *Part 2: Orthodontic base polymers*

Introduction

Specific qualitative and quantitative requirements for freedom from biological hazard are not included in this part of ISO 20795, but it is recommended that in assessing possible biological or toxicological hazards, reference be made to ISO 10993-1 and ISO 7405.

iTeh STANDARD PREVIEW (standards.iteh.ai)

[SIST EN ISO 20795-1:2008](https://standards.iteh.ai/catalog/standards/sist/1bb18b8f-d41e-4786-a0bf-cbb668ccf317/sist-en-iso-20795-1-2008)

<https://standards.iteh.ai/catalog/standards/sist/1bb18b8f-d41e-4786-a0bf-cbb668ccf317/sist-en-iso-20795-1-2008>

iTeh STANDARD PREVIEW **(standards.iteh.ai)**

SIST EN ISO 20795-1:2008

[https://standards.iteh.ai/catalog/standards/sist/1bb18b8f-d41e-4786-a0bf-cbb668ccf317/sist-en-iso-2008](https://standards.iteh.ai/catalog/standards/sist/1bb18b8f-d41e-4786-a0bf-cbb668ccf317/sist-en-iso-20795-1-2008)

Dentistry — Base polymers —

Part 1: Denture base polymers

1 Scope

1.1 This part of ISO 20795 classifies denture base polymers and copolymers and specifies their requirements. It also specifies the test methods to be used in determining compliance with these requirements. It further specifies requirements with respect to packaging and marking the products and to the instructions to be supplied for use of these materials. Furthermore it applies to denture base polymers for which the manufacturer claims that the material has improved impact resistance. It also specifies the respective requirement and the test method to be used.

1.2 Although this part of ISO 20795 does not require manufacturers to declare details of the composition, attention is drawn to the fact that some national or international authorities require such details to be provided.

1.3 This part of ISO 20795 applies to denture base polymers such as those listed below:

- a) poly(acrylic acid esters);
- b) poly(substituted acrylic acid esters);
- c) poly(vinyl esters);
- d) polystyrene;
- e) rubber modified poly(methacrylic acid esters);
- f) polycarbonates;
- g) polysulfones;
- h) poly(dimethacrylic acid esters);
- i) polyacetals (polyoxymethylene);
- j) copolymers or mixtures of the polymers listed in a) to i).

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 463:2006, *Geometrical Product Specifications (GPS) — Dimensional measuring equipment — Design and metrological characteristics of mechanical dial gauges*