

SLOVENSKI STANDARD

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Nadomešča:

SIST EN ISO 20795-1:2008

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Zobozdravstvo - Osnovni polimeri - 1. del: Osnovni polimeri za proteze (ISO 20795-1:2013)

Dentistry - Base polymers - Part 1: Denture base polymers (ISO 20795-1:2013)

Zahnheilkunde - Kunststoffe - Teil 1: Prothesenkunststoffe (ISO 20795-1:2013)
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Médecine bucco-dentaire - Polymères de base - Partie 1: Polymères pour base de prothèses dentaires (ISO 20795-1:2013)

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11.060.10 Zobotehnični materiali Dental materials

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en

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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

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Supersedes EN ISO 20795-1:2008

English Version

Dentistry - Base polymers - Part 1: Denture base polymers (ISO 20795-1:2013)

Médecine bucco-dentaire - Polymères de base - Partie 1:
Polymères pour base de prothèses dentaires (ISO 20795-1:2013)

Zahnheilkunde - Kunststoffe - Teil 1: Prothesenkunststoffe
(ISO 20795-1:2013)

This European Standard was approved by CEN on 26 February 2013.

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, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

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

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Foreword

This document (EN ISO 20795-1:2013) 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 2013, and conflicting national standards shall be withdrawn at the latest by September 2013.

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.

This document supersedes EN ISO 20795-1:2008.

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, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

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The text of ISO 20795-1:2013 has been approved by CEN as EN ISO 20795-1:2013 without any modification.

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INTERNATIONAL STANDARD

ISO
20795-1

Second edition
2013-03-01

Dentistry — Base polymers — Part 1: Denture base polymers

*Médecine bucco-dentaire — Polymères de base —
Partie 1: Polymères pour base de prothèses dentaires*

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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.

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, *Prosthetic materials*.

This second edition cancels and replaces the first edition (ISO 20795-1:2008), of which it constitutes a minor revision. It also incorporates the Technical Corrigendum ISO 20795-1:2008/Cor 1:2009.

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

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

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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.

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

ISO 1942, *Dentistry — Vocabulary*

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

ISO 7491:2000, *Dental materials — Determination of colour stability*