

**Dentistry - Base polymers - Part 1: Denture base  
polymers**

## EESTI STANDARDI EESSÕNA

## NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 20795-1:2008 sisaldab Euroopa standardi EN ISO 20795-1:2008 ingliskeelset teksti.

Standard on kinnitatud Eesti Standardikeskuse 25.09.2008 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.

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This Estonian standard EVS-EN ISO 20795-1:2008 consists of the English text of the European standard EN ISO 20795-1:2008.

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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)

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## 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of an identical text or by endorsement, at the latest by February 2009, and conflicting national standards shall be withdrawn at the latest by February 2009.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.

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### Endorsement notice

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

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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.

# 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*

ISO 1942, *Dentistry — Vocabulary*

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

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

ISO 8601, *Data elements and interchange formats — Information interchange — Representation of dates and times*

ISO 22112:2005, *Dentistry — Artificial teeth for dental prostheses*

### 3 Terms and definitions

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

**3.1  
autopolymerizable materials**  
products having polymerization initiated by chemical means and not requiring application of temperatures above 65 °C to complete the polymerization

**3.2  
capsulated material**  
material consisting of two or more components supplied in a container that keeps them separated until the time they are mixed together and dispensed for use directly from the container

**3.3  
denture**  
artificial substitute for missing natural teeth and adjacent tissues, to also include any additions needed for optimum function

**3.4  
denture base**  
that part of a denture which rests on soft tissue foundations and to which artificial teeth are added

**3.5  
heat-polymerizable materials**  
products requiring application of temperatures above 65 °C to complete polymerization

**3.6  
immediate container**  
container that is in direct contact with the denture base materials

**3.7  
liquid**  
monomeric liquid to be mixed with polymeric particles to form a mouldable dough or fluid resin mixture used for forming denture bases

**3.8  
powder**  
polymeric particles to be mixed with monomeric liquid to form a mouldable dough or fluid resin mixture used for forming denture bases

**3.9  
outer packaging**  
labelled container or wrapping within which other containers are packed