SLOVENSKI STANDARD
SIST EN ISO 20795-2:2013

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Nadomešča:
SIST EN ISO 20795-2:2010

Zobozdravstvo - Osnovni polimeri - 2. del: Ortodontski osnovni polimeri (ISO 20795-2:2013)

Dentistry - Base polymers - Part 2: Orthodontic base polymers (ISO 20795-2:2013)

Zahnheilkunde - Kunststoffe - Teil 2: Kieferorthopädische Kunststoffe (ISO 20795-2:2013)

Médecine bucco-dentaire - Polymères de base - Partie 2: Polymères pour base orthodontique (ISO 20795-2:2013)

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ICS:

11.060.10	Zobotehnični materiali	Dental materials

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EUROPEAN STANDARD

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English Version

Dentistry - Base polymers - Part 2: Orthodontic base polymers (ISO 20795-2:2013)

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COMITÉ EUROPÉEN DE NORMALISATION
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Contents

Page

Foreword

This document (EN ISO 20795-2:2013) 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of an identical text or by endorsement, at the latest by September 2013, and conflicting national standards shall be withdrawn at the latest by September 2013.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.

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Endorsement notice

The text of ISO 20795-2:2013 has been approved by CEN as EN ISO 20795-2:2013 without any modification.

INTERNATIONAL STANDARD

ISO 20795-2

Second edition
2013-03-01

Dentistry — Base polymers —

Part 2: Orthodontic base polymers

Médecine bucco-dentaire — Polymères de base —

Partie 2: Polymères pour base orthodontique

Reference number
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Contents

Page

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.

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

This second edition cancels and replaces the first edition (ISO 20795-2:2010), which has been technically revised.

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

Polymeric materials based on methacrylates have been widely used in the construction of both active and passive removable orthodontic appliances for many years. These removable appliances are mainly used in the orthodontic treatment of children. The method of preparing the polymeric part of the orthodontic appliance has several potential problems. Depending on the polymerization process and polymer/monomer mixing ratio, the polymer part of the removable orthodontic appliance may be weaker than if conventional flasking and heat systems of polymerization were used. There may be a greater risk that an appliance will have more residual substances such as monomers than a conventional heat-cured denture base polymer. In addition, a high monomer content of the polymer/monomer mix may cause increased contraction on polymerization.

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 2:
Orthodontic base polymers

1 Scope

This part of ISO 20795 is applicable to orthodontic base polymers and copolymers used in the construction of both active and passive orthodontic appliances and specifies their requirements. It also specifies 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.

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, *Dentistry — Vocabulary*

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

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

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

ISO 20795-1:2008, *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 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
build up technique
spray on technique
gradual addition of increments of powder and liquid on the master cast until the desired shape is attained

3.3
immediate container
container that is in direct contact with the ⟨orthodontic⟩ base materials

3.4
light activated polymers
products having polymerization initiated by the application of energy from an external radiation source, such as visible light